Falconer S (Sandra)

From: Stock RG (Bob)
Sent: 26 September 2003 17:22
To: Minister for Health and Community Care
Cc: Deputy Minister for Health and Community Care; PS/HD Health; Freeman J (Jeane); Clark M (Matthew); Policy Unit Mailbox; Gordon IW (Ian); Macleod AK (Andrew); Keel A (Aileen); Marshall J (Jan); Miller CR (Colin) (LPS); Lodge T (Trevor); Falconer S (Sandra); Press Health
Subject: FW: Hepatitis C

19.9.03 letter to Exec.doc (15... Submission Sep 26 Public Enqui... Letter to HCCC re ST 'relevati...

Please find attached a 1 page submission with 7 page annex. The submission discusses briefing for Mr Chisholm's forthcoming meeting with Philip Dolan (Chairman of the Scottish Haemophilia Groups Forum) - the actual briefing is attached as the annexes - and a draft letter in response to the Health Committee, attached as a separate document.

BOB STOCK

GRO-C

Advice to Ministers — elephant trips

29

From: Bob Stock
Health Planning & Quality
26 September 2003

Minister for Health & Community Care

HEPATITIS C – PUBLIC ENQUIRY ISSUES ETC.

Purpose

1. To provide a response to the Convenor of the Health Committee's letter of 19 September.

2. To provide lines to take and briefing for Mr Chisholm's meeting with Philip Dolan, Chairman of the Scottish Haemophilia Groups Forum.

Priority

3. Routine – but reply to Convenor is required by 6 October latest, meeting with Dolan scheduled for 8 October.

Discussion

4. Lines to take for the Dolan meeting are at Annex A and associated background notes at Annex B. Highlighted text in bold italics is taken from the letter sent in by Dolan requesting the meeting. It is highly likely that Dolan will also allude to the recent 'revelations' in the Sunday Times and Scotland on Sunday and seek to link them to a call for a public enquiry.

5. A draft letter to the Health Committee convenor is attached as a separate document. The 'new' documentation referred to in the convenor's letter has been brought to the media by Carol Grayson, campaign co-ordinator of Haemophilia Action UK, as what appears to be a superficially alarming piece of evidence when viewed out of context. We know that Grayson holds many other documents and, whilst not discounting the possibility that there may be issues of genuine concern in some of them, there is potential for future unfounded 'revelations' on an ongoing basis.

6. The letter does not mention the issue of the Medicines and Healthcare products Regulatory Agency being outwith devolved powers. OSSE and Constitutional Policy advise that there may be difficulties sustaining this as an argument for not holding an enquiry and it might weaken the other arguments.

7. With that in mind, the reply to the convenor has been drafted as a lengthy, detailed letter that attempts to set out the context to the whole situation – rather than just responding to the specific request in the convenor's letter.

8. It is apparent that the Committee is poorly informed on this issue and our view is that past briefing provided by Committee clerks and parliamentary researchers has been inadequate. I have discussed this with Dr Keel and we feel that if we both made ourselves available to brief the Committee then this would offer the opportunity to provide accurate briefing. This might pre-empt any further counter productive diversions of this nature. The reply is drafted to include such an offer. The down side to making such an offer is that the Committee is very likely to insist that such briefing occurred in public session and this would then take on the aspect of a mini public enquiry in its own right.

Conclusion

Ministers are asked to note the attached briefing, consider the attached draft letter to the Committee and consider whether an offer of briefing by officials should be made.

BOB STOCK
Health Planning & Quality GRO-C 26 September 2003

SCGV0000256_077_0003

Copy List:	For Action	For Comments	For Information		
			Portfolio Interest	Constit Interest	General Awareness
Deputy Minister for Health & Community Care					X

PS/HD
Press Health
Jeane Freeman - Senior Special Adviser
Matthew Clark - Special Adviser
Policy Unit
Ian Gordon, Service Policy and Planning
Andrew MacLeod, Health Planning & Quality
Dr Aileen Keel, DCMO
Jan Marshall, OSSE
Colin Miller, Constitutional Policy
Trevor Lodge, Business Management

SCGV0000256_077_0004

ANNEX A

HEPATITIS C – PUBLIC ENQUIRY ISSUES ETC.

LINES TO TAKE FOR DOLAN MEETING

"explain how you have arrived at a package that is at variance from that recommended by your own Expert Group"

SIZE OF AWARDS cf EXPERT GROUP

Expert Group recommended £10k for everyone who contracted the virus, an additional £40k to those who developed 'chronic Hepatitis C', and awards based on common law damages for those progressing to cirrhosis, liver cancer or other similar conditions. Implementing these recommendations was costed at being between **£62m and £89m** (the £62m figure reflects 16% of those infected progressing to cirrhosis and the £89m figure reflects 60%). These figures are based on an estimated 4000 people being infected.

The figure of **£15m** quoted by the Executive is based on 580 people coming forward in the first 3 years of the scheme and 20% of those originally infected progressing to cirrhosis. On the basis of the same statistical report that was used to inform the Expert Group figures we would predict that 1165 eligible people are still alive and therefore another 585 persons might claim at some stage in addition to the 580 group. Using the same basis for calculations this would increase the £15m figure to £30m.

Not therefore valid to compare £15m with £89m – more appropriate to compare £30m with £62m.

The underlying principle behind the ex gratia payments announced is that they should go to people who are still alive and suffering. Have to weigh the issue of making a fair and reasonable payment to these people against all the other demands on the health budget. Lord Ross and the Expert Group were asked to ensure that any recommendations be consistent with efficient health service operation and represent a fair deal for all patients – but clearly they did not have access to information on other demands on the health budget to enable them to make that sort of judgement. [NB Dolan was a member of the Expert Group]

STATISTICAL BASIS UNDERPINNING AWARDS

Philip Dolan questions the validity of our estimate of 4000 people originally infected and 1165 still alive – he believes these to be over-estimates. He has previously quoted Professor David Goldberg of SCIEH as saying that the statistics (prepared by a DoH statistician) were suspect. I have checked this out with Goldberg – he says that some of the assumptions made in developing the statistics are questionable, but he was not prepared to say whether better assumptions would yield larger or smaller numbers.

SIZE OF AWARDS cf EIRE

[Dolan has consistently refused to acknowledge that the situation in Eire is not comparable with that in Scotland]

Payments made in the Republic followed on from a judicial inquiry (the Finlay Tribunal) which concluded that the contamination of the Irish blood supply should have been avoided, and was due to wrongful practices on the part of the Irish Blood Transfusion Service Board.

Those wrongful practices started when a blood from a patient with jaundice was used to manufacture blood products, and a catalogue of poor management following on from this meant that the entire Irish blood supply was jeopardised.

The size of the awards made in the Republic has to be viewed in that context – where the Transfusion Service has been shown to be negligent. And, much as you would expect in a scheme (called the Hepatitis C Compensation Tribunal) that is effectively making out of court settlements, there is no fixed tariff of awards. Each case is judged on its merits – there have been large awards (e.g. £3.1m) and modest awards too (e.g. £2000)

In contrast we do not acknowledge here in Scotland that there was any wrongful practice or negligence on the part of the Scottish National Blood Transfusion Service.

"concerned that relatives of those who have died were not included"

ELIGIBILITY

The eligibility date for the scheme is 29th August 2003. In the case of people whose situation on that date would have entitled them to payments, but who die before payment can be made, the payments will be made to their relatives.

[realise that might appear inconsistent with our policy of not paying the dependants of people who died before eligibility date for the scheme but the pragmatic thing to do is just live with that inconsistency.]

PAYMENTS TO 'DECEASED'

Have great sympathy for relatives and dependants of those who died before the eligibility date for the scheme, but have to consider the effects of the financial outlay on this scheme on ability to provide treatment for other patients. For that reason our scheme focuses on those who are currently suffering.

If 580 people come forward in the first three years then the cost to that the Health budget is likely to be over £15m – as much as can afford to divert away from other patient care. Those payments in the first three years would almost certainly cover all the haemophiliacs still alive and also some people infected via blood transfusions.

We know that isn't the end of the story. Our estimates indicate that another 580 people infected via transfusion might come forward in due course [SCIEH figures still rising]. And if we were to pay out in respect of people who have died then we are potentially looking at 4000 claimants and a bill of over £100m if everyone eligible claimed [NB Expert Group costs estimated on the basis that only 31% would claim].

"several hurdles such as liver biopsy that would be required to determine whether individual had 'chronic Hepatitis C' .... We have now demonstrated that such tests are not required"

MEDICAL TRIGGER

Although Expert Group's recommendations included awards linked to a diagnosis of 'chronic Hepatitis C' this is not a feature of our announced scheme. Making the second payment of £25k to this additional group would increase the cost of the scheme beyond what can be afforded.

However, recognise that using cirrhosis as the medical trigger is not ideal as excludes some people who are experiencing significant suffering whilst including others who are not suffering. And there could be problems with patients asking for biopsies where it would not be in their medical interests to provide them.

Will take a fresh look at that to see whether we can use a better medical trigger. This is a complex medical area and will be guided by the experts in this field. No guarantee that can

agree a better trigger – and adoption of any new trigger would have to take into account any cost implications for the scheme. [Happy to involve patient groups in these discussions at an appropriate stage]

DETAILS OF SCHEME

Don't envisage any major departure from the basic awards have previously announced. The basic requirement for people to be eligible will just be that they have contracted Hepatitis C as a result of having received blood or blood products from the NHS in Scotland before they were made 'Hepatitis C safe' – and that they have not cleared it spontaneously. [No requirement for eligibility that applicants have been registered with SCIEH – it is just that our prediction of £15m outgoings in the first 3 years was linked to the published SCIEH figures at the time of January announcement]

People who satisfy the basic eligibility criteria will receive £20,000. People who have progressed to a more serious stage of the illness (still considering the best way to define that) will receive a further £25,000. There will be no payments in respect of people who die before 29 August 2003 or to those who have cleared the virus.

All other scheme details yet to be decided. Have fairly advanced initial thoughts on all of these issues, but need to develop these to a stage where can be robustly incorporated into a scheme constitution. Will do that quickly – but until have done so would be counterproductive to make them public.

[Examples of scheme details to be finalised: UK Trust; use of Macfarlane; levels of evidence required; payments to people who have had liver transplants; co-infected with HIV; infected by virus being transmitted from someone themselves infected by NHS blood; adjustments for monies received form other litigation]

Officials are exploring possible benefits of a common administration scheme across all UK administrations but will not allow this to unduly delay the making of payments.

INVOLVEMENT OF PATIENT GROUPS

Will involve patient groups in discussions on scheme administration (and medical trigger at appropriate stage). [But not regarding basic scheme parameters]

WHEN PAYMENTS WILL START

People who satisfy the eligibility requirements for scheme as of 29 August will qualify for payments. When they receive those payments will depend on a number of factors.

Need to finalise details of scheme and how it will be administered. Anticipate making these payments through a charitable Trust. That will need to be established, detailed rules for its operation worked out and agreed and charitable status obtained. Payments to people who currently stand to lose social security benefits may best be delayed until social security legislation can be amended.

Once all details are finalised will make a high profile announcement advertising the scheme and making it quite clear what people need to do to apply. In meantime officials are taking details of people who contact the Department and will proactively contact them at the time of the announcement.

SOCIAL SECURITY

Now the devolved power issue had been resolved hopeful that social security payments won't be a problem for our scheme. However the social security issue can't be finally agreed until the key details of the schemes here and in the rest of the UK have been finalised.

Understand that the relevant social security legislation is routinely reviewed and amended twice yearly. Our working assumption is that any amendments to cover our scheme could come into effect next April. Will confirm the need for legislation and the timetable once the scheme has been finalised.

This won't, of course, prevent the scheme paying out to claimants who would be unaffected by social security benefit loss. It also won't prevent the scheme from processing applications in advance of the date when social security legislation is amended – so the actual payments can be made without delay after that date.

PUBLIC ENQUIRY

Lessons to be learned

Not convinced that there are any lessons to be learnt that have not already been learnt. Nowadays risk management and the precautionary principle are key issues for the Health service. And we are committed to better communication between clinicians and patients – especially on risk.

No consensus on seriousness of HCV infection

Acknowledge that some clinicians had serious worries about the seriousness of Hepatitis C infection as early as the mid 1970s (and in consequence about the use of commercial products). But many experts also took the view that it was a mild, non-progressive condition and the benefits outweighed any adverse consequences.

There was much debate in the medical press and between individuals as to whether non-A non-B hepatitis was a serious issue or not. Some 20 years later, and with the knowledge that hepatitis C may take 15 – 30 years to manifest itself in causing liver disease, it is not surprising that these discrepancies of opinion were present. This divergence of opinion continued until at least 1985 after which an increasing number of experts came to regard it as a serious disease with significant long term consequences. That view did not come to be universally held in the relevant medical and scientific communities until after 1989.

Link between HCV and clotting factor – public knowledge

Numerous published articles in eminent medical journals, such as the Lancet, in the 1970s and 1980s that record information, interest and controversy on this issue.
The link between treatment with blood clotting factor concentrates and HCV infection was regularly discussed at annual meetings of the Congress of the World Federation of Hemophilia (certainly as early as 1975). These meetings were organised by the World Federation of Hemophilia (WFH). The UK Haemophilia Society was a founder member of the WFH and will have seen the conference abstracts even if they did not attend.

Product information leaflets contained statements that the risk of transmitting hepatitis could not be excluded. This information was directly available to all clinicians involved in the treatment of haemophiliacs with these products and also to the substantial proportion of patients who were practising home therapy (40% in 1978).

Copies of published articles in medical journals (e.g. the Lancet) – demonstrating that the risk of HCV infection was widely and publicly acknowledged and that there was a wide range of opinion – were lodged in Parliament's Reference Centre in October 2000 as part of the documentation supporting the SE "Report on the Heat Treatment of Blood Products for Haemophiliacs in the 1980s".

Professional judgement

In the circumstances prevailing in 1982 (the date of the report 'revealed' by the Sunday Times and the Scotland on Sunday) the fact that commercial products carried a greater risk of infection would have been viewed against:

- the background of conflicting expert opinion on the seriousness of Hepatitis C infection,
- variations in the efficacy of different products in treating haemophilia in individual patients,
- variation in the not inconsiderable side effects,
- the fact that both commercial and NHS products were licensed by the Medicines Division of the Department of Health and Social Security (the predecessor of the Medicines Control Agency – now the Medicines and Healthcare Products Regulatory Agency), and
- the inability of the NHS to meet UK demand.

Not convinced that any officials or NHS staff acted wrongly in the light of the facts that were available to them at the time

Bob Stock
Health Planning & Quality
GRO-C

26 September 2003

ANNEX B

HEPATITIS C – PUBLIC ENQUIRY ISSUES ETC.

BACKGROUND NOTES FOR DOLAN MEETING

Situation in the Republic of Ireland

Finlay Tribunal

The payments in the Republic are originally linked to incidents involving the contamination of the Anti-D supply as detailed below (Anti-D is a manufactured blood product obtained from women at the end of their pregnancy). People who had received the contaminated Anti-D then went on to donate blood – thus potentially contaminating the whole blood supply.

Extract from the report of the 'Tribunal of Enquiry into the Blood Transfusion Service Board' [The Finlay Tribunal]:

- *The primary cause of the infection of Anti-D with Hepatitis C was the use of blood or plasma from Patient X (in 1976), a person undergoing therapeutic plasma exchange treatment who developed jaundice and hepatitis*
- *The use of this plasma was clearly in breach of BTSB's own standards for donor selection…..*
- *BTSB failed properly to react to reports made to them that recipients of the Anti-D made from the plasma of Patient X, had suffered jaundice or Hepatitis C.*
- *BTSB failed to properly investigate the possible existence of complaints by other recipients of Anti-D which were suspected of being contaminated.*
- *BTSB failed to recall the contaminated batches which had been issued and to prevent issue of any further batches made from plasma obtained from patient X.*
- *BTSB acted unethically in obtaining and using plasma from her without her consent*
- *A further cause of infection of Anti-D with Hepatitis C was the use of plasma from Donor Y (in 1989) who was undergoing a course of therapeutic plasma exchange and whose plasma was subsequently used, notwithstanding that it had been tested for Hepatitis C, and in four separate tests proved positive*

The main reasons why these wrongful acts were committed……..

These payments are made by the "Hepatitis C Compensation Tribunal" under the Hepatitis C Compensation Tribunal Act 1997. The Irish Health Minster amended this Act in 2001 to enable it to also pay Haemophiliacs who were infected with HIV and dependants of those deceased. [This decision was not driven by any tribunal verdict and might be viewed as a compassionate act. In one sense it brought Eire in line with the UK but the payment system piggybacked on the existing HCV regime and is therefore much more generous than Macfarlane]

The total expenditure by the Irish Hepatitis C Compensation Tribunal at 2001 was £354.2m in respect of 1477 awards (an average of £240k). Awards in 2001 ranged from £2,000 to £3.1m with the average award being £246k

Lindsay Tribunal

A further tribunal of inquiry completed its deliberations in 2002. This had been tasked with examining the infection of haemophiliacs with HIV and HCV. It took no view on compensation – since this had already been dealt with by the abovementioned amendment to the Hepatitis C Compensation Tribunal Act 1997. It endorsed the international view that the use of surrogate tests was a matter for individual countries but criticised BTSB for failing to act on its own analysis that they would have been effective in Eire. It drew a very helpful conclusion in relation to the lack of consensus on the seriousness of HCV infection as follows:

In the 'Report of the Tribunal of Inquiry into the Infection with HIV and Hepatitis C of Persons with Haemophilia and Related Matters' (September 2002) Judge Alison Lindsay concludes:

"The Tribunal has formed the view from this evidence that the consensus which existed in the late1970s and early 1980s that NANB hepatitis was relatively mild or benign did change as the results of studies became available showing the condition to have potentially serious consequences for some people infected by it. A number of experts came to regard it as a serious disease with significant long term consequences, especially and increasingly in the period after approximately1985. That view did not, however, come to be universally held in the relevant medical and scientific communities until after 1989."

Previous view of the Committee on holding a Public Enquiry

The Committee rejected a public enquiry in its own Hepatitis C report in October 2001. It said:

"we would be unwilling to advocate any new enquiry on this issue. In practice this would presumably involve hearing evidence as to memories or conversations between practitioners and patients 15 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 practical difficulties involved in any enquiry along these lines. A more fundamental objection is that such an investigation would again perpetuate the link between fault-finding and examining the case for providing practical assistance for Hepatitis C sufferers"

Public enquiry – other issues

In practice there would be little mileage in holding an enquiry here in Scotland because most of the documentation that would need to be reviewed relates to bodies based in England.

Role of the licensing authority

Both imported and NHS products were licensed by the Medicines Division of the Department of Health and Social Security (the predecessor of the Medicines Control Agency – now subsumed within the Medicines and Healthcare Products Regulatory Agency). Although this is a reserved area but we do not have a definitive view at this stage from OSSE on exactly what constraints would apply to an enquiry constituted with health care as its remit.

Constitutional policy advise that in political and constitutional terms, it would be setting an unwelcome and undesirable precedent for either the Executive or the Parliament to establish an enquiry which focused on the actions of a UK Government Department without securing

prior agreement from the UK Government, and if the Executive did so there is no guarantee that UK would co-operate with the inquiry. This is a weak argument to use for not holding an enquiry because it would be open to the Executive to seek such agreement – as was apparently done for the Holyrood enquiry. Until more definitive advice is available from OSSE it is advisable not to proactively mention the reserved nature of MHRA.

Sunday Times and Scotland on Sunday 'revelations'

The articles quote a report entitled "Haemophilia Centre Directors Hepatitis Working Party for Year 1980/81" (prepared by Dr Craske) – which appears to have been considered at a meeting of Haemophilia Directors in September 1982.

The report indicated that Haemophilia Directors were gathering data on which blood clotting factor products were linked to non-A non-B hepatitis infection. It concluded that there was a 4-20 times higher incidence associated with US commercial concentrate compared with NHS. A casual reading may also lead to the conclusion that it also showed some US commercial products carried a higher risk than others – but the opening remarks caution against such a conclusion.

Bob Stock
Health Planning & Quality
GRO-C

26 September 2003

SCOTTISH EXECUTIVE

Minister for Health & Community Care
Malcolm Chisholm MSP

St Andrew's House
Regent Road
Edinburgh EH1 3DG

Telephone: 0131-556 8400
scottish.ministers@scotland.gsi.gov.uk
http://www.scotland.gov.uk

Christine Grahame MSP
Convener
Health and Community Care Committee
Committee Chambers
The Scottish Parliament
Edinburgh EH99 1SP

«Date»

Hepatitis C issues in the 1970s and 1980s

Following receipt of your letter of 10 September my officials contacted Carol Grayson, campaign co-ordinator of Haemophilia Action UK. As a result, I have now seen a copy of the document cited in the recent Sunday Times and Scotland on Sunday articles and referred to in your letter of 19 September. The document in question is a report entitled "Haemophilia Directors' Hepatitis C Working Party Report for Year 1980-81" – which appears to have been considered at a meeting of Haemophilia Directors in September 1982.

The substantive point that has been raised with respect to this document is that it reveals that government officials were aware from as early as 1974 that treatment with blood clotting factor concentrates carried a risk of infection with what we now know as Hepatitis C.

Whilst there is no doubt that this document does confirm that haemophilia directors and the Department of Health and Social Security were aware of such a link, I am afraid that this does not constitute new evidence. I am aware of numerous published articles in eminent medical journals, such as the Lancet, in the 1970s and 1980s that record information, interest and controversy on this issue. When you read such material you become aware how important it is to consider the Haemophilia Directors' report in an appropriate context.

It is apparent that in the early 1970s Hepatitis C infection was largely regarded as benign, although there is no doubt there were some clinicians who strongly dissented from that view. As more information became available more clinicians began to voice concern – although not uncommonly the view was expressed that the benefits of the treatment outweighed the consequences of the resultant infection. Certainly up until 1985 at least there was no universal consensus that the Hepatitis C infection had serious consequences and many experts viewed it as a mild, non-progressive condition. This is recorded in the Scottish Executive's Report on Heat Treatment of Blood Products (October 2000) along with appropriate references.

INVESTOR IN PEOPLE
POSITIVE ABOUT DISABLED PEOPLE

From at least 1976, product information leaflets also contained statements that the risk of transmitting hepatitis could not be excluded. This information was directly available to all clinicians involved in the treatment of haemophiliacs with these products and also to the substantial proportion of patients who were practising home therapy (40% in 1978).

In making these observations, I should point out that I am not flying in the face of current wisdom on the issue. The Committee may wish to note the findings in the Irish Republic of Judge Alison Lindsay in the 'Report of the Tribunal of Inquiry into the Infection with HIV and Hepatitis C of Persons with Haemophilia and Related Matters' (September 2002). In it she concludes:

"The Tribunal has formed the view from this evidence that the consensus which existed in the late1970s and early 1980s that NANB hepatitis was relatively mild or benign did change as the results of studies became available showing the condition to have potentially serious consequences for some people infected by it. A number of experts came to regard it as a serious disease with significant long term consequences, especially and increasingly in the period after approximately1985. That view did not, however, come to be universally held in the relevant medical and scientific communities until after 1989."

The subsidiary point made with respect to the Haemophilia Directors' Report is that there was a greater risk of Hepatitis C infection from some concentrate products than from others and, in particular, a much greater risk from commercial products than from NHS products. With hindsight it is easy to jump to the conclusion that radical action should have been taken to stop the use of commercial products. However, in the actual circumstances prevailing in 1982, this information will have been viewed against the background of conflicting expert opinion on the seriousness of Hepatitis C infection, variations in the efficacy of different products in treating haemophilia in individual patients, variation in the not inconsiderable side effects, the fact that both commercial and NHS products were licensed by the Medicines Division of the DHSS (the predecessor of the Medicines Control Agency), and the inability of the NHS to meet UK demand.

Clearly even 'mild, non-progressive' infection should be avoided – all other things being equal – and concern about the unknown long term outcomes from Hepatitis C infection was a driver for the initiative for UK self sufficiency in blood products. I am pleased to say that the Scottish National Blood Transfusion Service was in the forefront in the efforts to produce adequate supplies of non-commercial product.

In your letter, you asked me to comment on whether or not I consider this 'new' evidence to be sufficient to hold a public inquiry. Taking account of all the issues I have listed above I do not see that the unearthing of this particular document changes the situation in any way that indicates it would be in anyone's interest to hold a public enquiry.

A copy of the Scottish Executive's Heat Treatment report was placed in the Parliament's Reference Centre at the time it was made public – together with the associated references (which include many contemporaneous articles in the medical press). We should be happy to provide the Committee with copies of these documents if that would be helpful. We also have copies of other documents that show that the link between treatment with clotting factor concentrates and hepatitis infection was available to organisations representing patient interests.

INVESTOR IN PEOPLE
POSITIVE ABOUT DISABLED PEOPLE

I note that the Committee decided at its 16 September meeting that it needed to receive private briefing from the Committee clerks before it could usefully consider the matter further. As I have indicated above there are a number of important documents that might assist the Committee which it does not appear to have seen. I would be happy to make my officials available to assist in any briefing if that would be helpful.

MALCOLM CHISHOLM

INVESTOR IN PEOPLE
POSITIVE ABOUT DISABLED PEOPLE

SCGV0000256_077_0015

The Scottish Parliament

Malcolm Chisholm MSP
Minister for Health and Community Care
St Andrews House
Regent Road
Edinburgh

19 September 2003

Dear Malcolm

Hepatitis C

The Health Committee at its meeting on 16 September 2003 again considered the matter of Hepatitis C and your proposals for financial assistance to those who have contracted the disease from infected blood or blood products provided by the NHS in Scotland.

The Committee understand that you have been presented with new documentation by the sufferers of Hepatitis C claiming that the danger of using infected blood products on haemophiliacs was known to government officials more than 20 years ago. Please confirm that you have received these documents. If you have received this information, can you give the Committee an indication of when you will be in a position to comment on whether or not you consider this evidence to be sufficient to hold a public inquiry?

The Committee is aware from your evidence on 9 September that you have indicated that the most obvious model to arrange payments to claimants in a Scottish context might be similar to the Macfarlane and Eileen Trusts. I would be obliged if you could inform the Committee of any decisions you take in this regard.

The Committee intends to hold a briefing for new members on the current position on Hepatitis C on 7 October 2003. It would be useful if the information requested in paragraph 2 could be available for this meeting.

Yours sincerely

Christine Grahame MSP
Convener

Health and Community Care Team Committee Chambers The Scottish Parliament Edinburgh EH99 1SP
0131 348 5224 peter.mcgrath@ GRO-C

3
Hep C scheme.

The Herald
Section: Main
4 October 2003
Page: 9

Article Size (cm2) 222.50
Circulation: 85,932
Scottish Circulation: n/a
Source: ABC Jan-Jun 2003

Tests for hepatitis infection 'were not foolproof'

Blood chief admits a 'very few' may have fallen victim

HELEN PUTTICK
HEALTH CORRESPONDENT

SCOTS could have been infected with hepatitis C through blood transfusions since screening was introduced, the head of Scotland's blood transfusion service said yesterday.

Angus Macmillan Douglas, service director, said that in a tiny number of cases the infection could have been incubated in blood supplied by donors but not shown up in "state-of-the-art" tests.

Dr Brian McClelland, a consultant with the organisation, also said they could not rule out the possibility that haemophiliacs had been infected with blood products imported by doctors since heat treatment to make the products safe had been used in Scotland.

He conceded that, while existing supplies of blood products were recalled when the new treatment was first developed in the 1980s, older stocks were not recalled from hospital stores as the procedure was improved and higher temperatures used.

"I think what was intended was they would continue to use whatever stocks they had and just flow in the new material," he said.

However, in an interview with The Herald following claims that Scots have caught hepatitis C from blood and blood products as late as 1995 – despite safeguards – he insisted that the Scottish National Blood Transfusion Service's own blood stocks at that time were "safe".

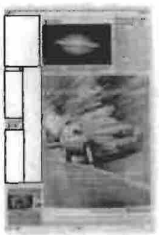
He said not recalling the blood products was a decision made with haemophilia directors, and all blood stocks were tested for hepatitis C when screening became possible in 1991.

The comments came as it emerged that Frank Maguire, the solicitor-advocate who last week revealed he had been approached by patients claiming they contracted hepatitis C from blood since the safeguards were launched, now has approximately 30 such cases on his books.

He said the patients involved had attended different hospitals across Scotland, and one of the new complainants dated infection from 1994. Mr Maguire said the comments made by the SNBTS made the need for a public inquiry even more pressing.

Mr Macmillan Douglas said: "We are confident that, so far as we know, there have been no transmissions of hepatitis C by the SNBTS products since testing was introduced in September 1991.

"There still could have been a very few transmissions because there is a so-called window period which is somewhere between 60 and 80 days, depending on the person, between the period of someone becoming infected with hepatitis C and the first type of test



The contents of the publications from which these extracts have been taken are copyright works and without prior permission or save as permitted by statute may not be copied or otherwise reproduced (even for internal purposes) or resold.

Ref: H20031004020

The Herald
Section: Main
4 October 2003
Page: 9

Article Size (cm2) 222.50
Circulation: 85,932
Scottish Circulation: n/a
Source: ABC Jan-Jun 2003

actually picking up that they had the disease.

"We have reduced that window period in the year 2000 to about 20 days by the introduction of a thing called nucleic acid testing (a DNA test), which tests for the disease rather than the antibody developed to fight it."

He accepted "a very few" people may have been infected this way through blood transfusions since testing began in September 1991, but said the chances were one in a million.

Dr McClelland, who has been with the blood transfusion service since 1977, volunteered a number of other scenarios "which could lead to a person turning up today saying I have got hepatitis C and I think I got it from blood".

He said some patients with haemophilia "may have received treatment with a blood product manufactured somewhere else that might even have been administered here".

While SNBTS aimed to supply sufficient blood clotting agents to meet the needs of Scottish patients during the late 1980s and early 1990s, he said the service had no control over which product doctors prescribed.

He also said hepatitis C, which is most commonly transmitted through intravenous drug use and more occasionally through sexual intercourse, could lay dormant for 20 years, so people might discover they were infected a long time after they had contracted the disease.

"There could well be some people who have discovered relatively recently that they had the infection and who in their minds have attributed it to transfusion," said Dr McClelland.

"If that is the case, that can be resolved."

He and Mr Macmillan Douglas urged such patients to approach the hospital where they were treated to find out which unit of blood had been used, as samples of all units have been kept since the mid-1980s and can be checked.

However, Mr Maguire said that such checks could be done as part of a public inquiry, adding: "I want an outsider to look at it."

The contents of the publications from which these extracts have been taken are copyright works and without prior permission or save as permitted by statute may not be copied or otherwise reproduced (even for internal purposes) or resold.

Ref: H20031004020