To: CMO

From: William Connon

Date: 4 December 2006

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CONTAMINATED BLOOD PRODUCTS and HEPATITIS C

Issue

MS(PH) and MS(R) have requested a meeting with you, (provisionally scheduled for the 13 December) to discuss the need for a Public Inquiry. The submission dated 24 July 2006 sets out the background (annexe A). The Haemophilia Society is pressing for a Public Inquiry into contaminated blood products in the 1970s and 1980s in relation to hepatitis C.

An alternative to holding a Public Inquiry would be to commission an independent review and commentary by a QC, which might head off further calls for an Inquiry. This was explored in the submission to SoS in July 2006. It would build on the internal review of all existing papers currently underway (see page 4). This internal review of all available papers is due to report at the end of January 2007.

There is no indication of fault and the Government have consistently said that a Public Inquiry would not significantly add anything to the debate. However, MS(PH) and MS(R) appear to have softened their approach and be more sympathetic to an Inquiry.

In response to the July submission SoS said, if MS(R) and MS(PH) really believe an independent commentary is worth it, and affordable, then she is content. However, she feels that it will fuel, not deflect, calls for a public enquiry - which we are right not to do.

A chronology of events is attached at Annexe B

Background

Although the focus is hepatitis C, HIV was an integral part of the events at the time and reference to HIV is included in this background note.

There have been long running calls for a Public Inquiry into the contamination of blood products with hepatitis C during the 1970s and 1980s. Haemophilia patient groups have pressed for higher levels of compensation, and believe an Inquiry could help achieve this by demonstrating the Department was culpable.

SoS advised in July that she considers an Inquiry would be a disproportionate measure and not justified under the circumstances; a view also expressed by the Scottish Health Minister, Andy Kerr.

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The Government accepts that haemophilia patients were infected with HIV and hepatitis C through contaminated blood products. One thousand, two hundred and forty three people with haemophilia were infected with HIV and around 4,000 – 5,000 (estimate) with hepatitis C before viral inactivation of blood products began in 1985.

In 1989, around 770 haemophilia patients who were infected with HIV through contaminated blood products, and 190 of their partners and close relatives took legal action against the Department, Welsh Office, the Medicines Licensing Authority and Committee on Safety of Medicines to claim compensation for damages, alleging negligence. The Government denied liability. In an out of court settlement the Department paid £44m in 1991 (administered through the Macfarlane Trust). Details of the Macfarlane and Eileen Trusts and Skipton Fund are included in Annex A.

In October 2000, the Hepatitis C litigation against the National Blood Authority (NBA) began. The litigation involved a group of people infected with hepatitis C through blood transfusion between 1 March 1988 and 1 September 1991. The action was taken under the Consumer Protection Action 1987 (CPA) which implemented the European Product Liability Directive 1985. All 117 claimants won damages.

The Department were not party to the hepatitis C litigation but through the process of non-party discovery, the Department agreed to release all documents it had for the period 1988 – 1991. On disclosure it was obvious that the papers were incomplete, a series of files recording the minutes and background papers of the Advisory Committee on the Virological Safety of Blood (ACVSB) between May 1989 and February 1992 were missing. Subsequent to this a request was made for the release of papers that were the subject of non-disclosure during the HIV litigation, these files were not found and were believed to be destroyed or mislaid. An internal audit review in April 2000 identified that the ACVSB files were marked for destruction and were destroyed between July 1994 and March 1998. A note on the destruction/loss of files is provided in Annex C.

The loss of documentation, identified in 2000, fuelled calls for a Public Inquiry into contamination of blood products. Lord Owen also stated that when he was Minister for Health he allocated special finance in order to increase the existing production of Factor VIII (the treatment for haemophilia patients). He claims that this policy was announced in Parliament but was not fulfilled by the Department of Health. The consequences were that plasma was imported from other counties such as USA. However, the serious risks of hepatitis C only become apparent after full characterisation of the virus in 1989 and this is not a problem unique to the UK.

Haemophilia patient groups have cited Ireland and Canada as paying significantly higher sums to those infected with post-transfusion hepatitis C, in both cases negligence was found. An extract of Lord Warner's answer to this question in the Lords Report for 25 March 2004 is provided in Annexe D.

In 2002, Yvette Cooper the then Health Minister asked officials to undertake an internal review of the surviving documents, roughly between 1973-1985 , to produce a chronology of events and an analysis of the key issues. The actual analysis was extended to 1991, the year that a test to screen blood donations for hepatitis C was introduced in the UK. Without this, it was considered difficult to answer any detailed accusations levelled against the Department

DHSC5069877_0002

by Lord Owen and others. The Department commissioned a report on 'Self-Sufficiency in Blood Products in England and Wales A Chronology from 1973 – 1991'. This was published in 2006.

Following publication of the 'Self-Sufficiency' report and further publicity surrounding the loss of documents relating to HIV and hepatitis C a firm of solicitors acting for claimants advised that they held documents relating to the HIV litigation. These were returned to the Department in May 2006.

A further internal review of documents was commissioned in June 2006 with the brief to review all available documents relating to the safety of blood products, specifically non-A non-B hepatitis for the period 1970 – 1985. This included the documents returned by the firm of solicitors. Progress on the current internal review is provided below, the draft summary from the review is provided at annexe E, and the final report will be complete in January 2007, the review has found no new evidence that identifies any culpability of the Department.

Public Inquiry

The benefit of a Public Inquiry is that it would ensure transparency, be viewed as an appropriate and independent response and reduce the risks of a judicial review. An Inquiry has the power to compel witnesses to give evidence or produce documents.

An Inquiry would significantly raise the profile and the cost would be significant. Examples of the costs of past inquiries include: Bloody Sunday, eight years so far at an estimated cost of over £120 million; Stephen Lawrence, two years, over £4 million; BRI, three years, over £14 million; Shipman, over four years, £21 million; Alder Hey, 14 months, £3.5 million; Victoria Climbe, two years, £3.8 million. We thin that Alder Hey is the most comparable in cost terms.

Independent Review

An independent review would, assuming a time requirement of five months, cost up to £150,000 (£20,000 - £30,000 per month) and support costs estimated at £46,000. It may be possible to appoint a retired QC at an estimated cost of £15,000 - £20,000 per month. . This is a budgetary guide, and any costs would need to be negotiated once the brief was finalised. An independent review would not be able to compel witnesses to give evidence. We have no current funding for any review.

Legal Advice

SOL has advised that "An alternate course of action to a Public Inquiry would be to put the relevant documents in the public domain so far as we are willing and can legally do so. This might involve an appropriate person reviewing all the documents which we make available and producing a "commentary" on them. This could be commissioned under the NHS Act 1977 as something incidental to the discharge of the Secretary of State's duty to continue to promote a comprehensive health service designed to secure improvement in the treatment of illness, and the duty to provide medical services and other services required for the treatment

of illness; because amongst other things it would be a way of passing information to the public about the treatment of illness. Of course the 1977 Act does not empower the Secretary of State to compel witnesses to give evidence or to produce documents therefore if the reviewer wanted to probe beyond the available documents, this may not be possible, and the reviewer's terms of reference should be drawn accordingly. Further, the more such a review takes on the nature of an Inquiry in substance (for example the reviewer taking on a more investigative role), the less appropriate it is likely to be to rely on the powers under the 1977 Act."

Commissioning a review of the documents, if that is as far as it goes, would be similar to the work undertaken by independent Counsel on the documents returned by a firm of solicitors, to catalogue and review them.

Internal Review

MS(PH) and MS(R) asked us to bring in a civil servant to undertake this review. Linda Page, a grade 6 civil servant started in July, and the review is expected to be completed with her report in January. The cost of this resource for the seven months will be about £54,000. The brief was to consider all documents available to the Department, to assess the approach to issues in relation to the safety of blood, specifically the inactivation of blood products for non-A non-B hepatitis (NANBH), later known as hepatitis C, during the period 1970 – 1985.

The review looks at all available documents relating to the subject during this time, including those held by the Scottish Executive. To identify where possible any documents previously thought destroyed or mislaid. To prepare and release in line with FOI the references to the report 'Self-Sufficiency in Blood Products in England and Wales A Chronology between 1974 – 1991' commissioned in 2002 and published in 2006 and those documents returned to the Department by a firm of solicitors. There are over 6,000 documents included in the review, these are identified as:

- Wellington House files. These have always been in the possession of DH and were located at Wellington House in 47 lever arch files.
- The unpublished references to the report 'Self-Sufficiency in Blood Products A Chronology from 1973 – 1991'. These were in Wellington House in two lever arch files.
- The documents 'returned by solicitors'. These files were returned to DH following press articles on lost documents and were in 11 lever arch files.
- Files recalled from DRO Nelson. A search at DRO Nelson identified ninety-two files of possible interest; these were scanned for content relating to NANB and ten files identified for further review. These files are now at Wellington House.
- Documents released by the Scottish Executive.

Progress

1. The first draft of the report has been completed; the final report is due at the end of January. Over 6,000 documents were read and NANBH (hepatitis C) was the subject, or primary subject, in just under 1.5% of these.

2. References to the 'Self-Sufficiency' report were released in line with FOI in August 2006, the documents returned by solicitors were released in November 2006. This represents 12.5% of the documents available.

3. Some documents previously thought destroyed or mislaid have been located. These are documents that were the subject of non-disclosure during the HIV litigation. No minutes of the Advisory Group on the Safety of Virology of Blood have been found.

4. The review of documents is 70% complete, there are a further 31 departmental files to be reviewed and the Scottish review to be considered.

One document has been located that required a detailed explanation on its release in line with FOI. An internal minute from Dr Diana Walford dated 15 September 1980 refers to Non-A Non-B hepatitis virus stating 'This form of hepatitis can be rapidly fatal (particularly when acquired by patients with pre-existing liver disease) or can lead to progressive liver damage. It can also result in a chronic carrier state, thus increasing the "pool" of these viruses in the community."

This comment was raised in a letter from the Haemophilia Society and the following response provided, "You have drawn attention to comments in the note from Dr Walford (dated 15 September 1980) about reports of fatal complications following the administration of Factor IX concentrates. She may have been referring to a report in the Lancet in March 1979. This reported three fatalities in jaundiced patients (who did not have haemophilia) subsequently shown to have severe cirrhosis due to either alcohol (2) or Wilsons disease (1), who were given Factor IX concentrate to correct clotting abnormalities prior to liver biopsy. The circumstances were thus rather different from those that might be expected in patients receiving factor concentrates for haemophilia, and the finding is not born out by our current knowledge of acute hepatitis C infection in patients without underlying liver disease. This report is included in the references in the paper from Craske (ref 26) recently released to you."

The draft summary of the report is provided in Annexe E.

Conclusions

The review will conclude that, on balance, taking account of the content of all available documentation relating to NANBH, that a careful and proper approach was taken to the issues of blood safety. With regard to a Public Inquiry, the Government has never agreed that any wrongful practices were employed, and does not consider that a Public Inquiry is justified.

The report will recommend the release of all the documents reviewed that have not already been released as part of this review. This includes documents that, at that time, fell within Classes which should not be disclosed in civil litigation on grounds of the public interest. These documents relate to the period in office of a previous administration, relate to policy formulation, submissions to Ministers and briefing notes, and draft replies to letters. By this action, all available documented evidence, available to the Department of Health, will be in the public domain. This will have resource implications, the documents will need to be prepared for release with the appropriate redactions and notifications. This work is estimated to take about ten weeks and cost up to £20,000.

We have not to date recommended an Inquiry for the following reasons:

- There is no evidence that any wrongful practices were employed. This is supported by the outcome on an internal review of all available documents
- Release of all available documents in line with FOI could provide much of the information sought by interested parties.
- Practice in terms of communication between health professionals and patients, and assessing and communicating the risks of medical treatment, has changed significantly since the 1980s when these infections occurred and important lessons have been learned.
- A Public Inquiry under the Inquiries Act is an expensive, time consuming and labour intensive undertaking; it is a disproportionate measure and cannot be justified.

Haemophilia patient groups will view the internal review with suspicion and it may not head off calls for a Public Inquiry. An independent review by a QC may have more standing with external parties although if this does not reveal any significant new information we strongly suspect such a review will equally be dismissed by campaigners.

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Head of Blood Policy
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GRO-C

ANNEXE A

SoS

From: Caroline Flint
Norman Warner

Date: 24 July 2006

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CONTAMINATED BLOOD PRODUCTS and HEPATITIS C

Issue
This note updates you on the issue of contaminated blood products and hepatitis C, and pressure for a Public Inquiry.

Significant parliamentary interest in this issue has been generated both in the House of Lords and in the Scottish Parliament, prompted by the concerns of patient groups.

Background
Following firstly HIV and secondly hepatitis C litigation procedures in the 1990s, we know that various relevant Department of Health papers were destroyed in error. Currently we do not know the full extent of what was destroyed nor the content of all available papers. We need to establish more information about those papers as soon as practicable, as the issue has attracted considerable interest via FoI requests and parliamentary questions.

The Macfarlane and Eileen Trusts were set up to provide financial aid for, respectively, haemophiliacs and others infected with HIV as a result of receiving contaminated blood products. More recently, in 2004, the Skipton Fund was established to provide ex gratia payments for those infected by hepatitis C.

The Haemophilia Society believes that there should be a Public Inquiry into the issue of contaminated blood products and hepatitis C, and that their case is supported by the fact that relevant papers are missing. They have lobbied extensively to that end.

Documents
Following an internal audit of events surrounding the loss of papers, officials are now analysing all the papers available, including over a thousand released in Scotland recently. They anticipate that this may take up to six months, but it is important it is undertaken to establish the facts and our position in relation to any Inquiry. We would propose to release these under FoI provisions.
Further, some files have recently been returned to the Department by Blackett, Hart and Pratt (Solicitors), and we have requested that high priority be given to examination of these by an independent Counsel following points made in a recent HoL starred question from Lord Jenkin. This is in hand.

Demand for a Public Inquiry
The requests for a Public Inquiry have become more vocal. Haemophilia patient groups have pressed for higher levels of compensation, and believe an Inquiry could help to achieve this by demonstrating the Department was culpable. They are supported by Lord Morris and others in the House of Lords. In addition, the Scottish Parliament Health Committee decided in April this year to call for a full judicial Inquiry.

We have received a copy of the response to the SP Health Committee from the Scottish Minister for Health. This firmly rejects the call for an Inquiry.

While an Inquiry would ensure transparency, and be viewed by interested parties as an appropriate and independent response, as well as minimise the risks of judicial review, it would on the other hand not only be costly and resource intensive to run but also significantly raise the profile of the issue and expectations of interested parties that cannot be met. Importantly, it would also set a precedent, especially for an issue where we do not consider the UK was at fault.

Officials have therefore on balance advised that an Inquiry would be disproportionate and not justified in the circumstances, in line with the views of the Scottish Minister.

As an alternative we have explored the possibility of commissioning an independent review and commentary on all the papers. With regard to the relevant statutory powers, this could be done under the NHS Act 1977, as something incidental to your duty as SoS to continue to promote a comprehensive health service designed to secure improvement in treatment of illness, and to provide services required for treatment, as it would amongst other things be a way of passing information to the public about these issues. It would provide additional reassurance and information to the public, and would build on the steps officials are already taking to review all the existing papers. It would however not provide powers to compel witnesses to give evidence or produce documents, and we would need to draw the terms of reference accordingly.

Conclusion

You are invited to note the current position, and the line we propose to take against the need for an Inquiry, and further, to consider the option of producing an independent commentary on the papers under the Act.

ANNEXE B

Chronology of Events

Date	Event
March 1973	DHSS Expert Group on the Treatment of Haemophilia recommends that the NHS should be self-sufficient in blood products as soon as possible
August 1974	Non-A Non-B Hepatitis (NANBH) first predicted by Prince et al
December 1974	Minister of State (David Owen) earmarks central funds of £0.5m, half of which is recurring, to increase the output of plasma from Regional Transfusion Centres to 275,000 donations annually for the preparation of Factor VIII and 100,000 donations for cryoprecipitate
Beginning of 1975	Expert Group on the Treatment of Haemophilia estimated that 275,000 donations of blood would be required to achieve self-sufficiency in Factor VIII.
May 1975	WHO resolution states that each country should be able to supply sufficient quantities of its own blood and blood products to meet clinical needs
August 975	Mannucci et al. reports 45% of patients with NANBH had raised ALT levels; Craske et al. links an outbreak of hepatitis (some NANBH) after intravenous injections of commercial Factor VIII concentrate.
April 1976	Department issues a press release re-affirming the aim of the UK to become self-sufficient in the supply of blood products by mid 1977.
June 1977	Factor VIII production target set in beginning of 1975 attained; however demand has increased
Early 1980	Blood products begin to be heat-treated; however, yield is very low and not shown subsequently to inactivate NANBH.
October 1980	Craske claims that NANBH is mild and often asymptomatic, but might cause chronic liver disease not associated with overt disease.
1982/1983	Studies published that indicate that NANBH is more serious than previously thought.
1983	Studies confirm that commercial and BPL concentrates carry equal risk of transmitting hepatitis.
1983	US patients with haemophilia contracted AIDS strengthening concerns over the safety of imported blood
May 1984	Trial issues of HT1 Factor VIII (60° C for 24 hours)
1985	Studies revealed almost 100% transmission of NANBH following treatment with unsterilised large donor pool clotting factor concentrate
1985	Hay et al. reported that progressive liver disease in patients with haemophilia was an understated problem
February 1985	First issues of heated (HT2) Factor VIII (70ºC for 24 hours}
July 1985	Trials of a new, high purity product, Factor 8Y, conducted
September 1985	BPL starts general issue of its new 8Y heat-treated Factor VIII
1886	Research identifies the need for retrospective NANBH studies, recognising that the disease might be quite mild but progression to severe symptomatology may be very protracted.
September 1988	UK was not self-sufficient in blood products due to errors in estimating both the amount of plasma stockpiled and the net yield for Factor VIII production at BPL and could not expect to be so for a couple of years.

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1989	Identification of hepatitis C.
1989	A series of studies provided evidence that the heat-treated product BPL 8Y introduced in 1985 appears to have prevented transmission of hepatitis C as well as HIV.
1989	Haemophiliac patients infected with HIV through contaminated blood products and partners and close relatives take legal action
1991	In response to the claim by haemophiliac patients, On the advice of the judge an out of court settlement by the Department paid £44m.
September 1991	Second generation hepatitis C virus screening assays become widely used in the screening of donor blood in the UK
1992	A retrospective hepatitis C study questioned whether hepatitis C virus infection was a disease in waiting and also confirmed that the acute infection was perceived in the 1970s as mild and that in 1980 analysis emphasised its relatively benign short-term prognosis.
1992	A study on long-term mortality after transfusion-associated NANBH concluded that there was no increase in mortality from all causes after transfusion-associated NANBH, although there was a small but statistically significant increase in the number of deaths related to liver disease.
1995	Look-back exercise started in UK to trace as many people as possible who had contracted hepatitis C through blood transfusions. Carried out between 1995 and 1997 and covered all donors who tested positive for the hepatitis C virus from the date of introduction of testing in 1991.and subsequent search for those every recipient of each donation to offer counselling and treatment where appropriate..
October 2000	Hepatitis C litigation against the National Blood Authority began. Action was taken under the Consumer Protection Act. All 117 claimants won damages. (Note the Government was not party to this litigation).
October 2000	Identified that files relating to the Advisory Committee on the Virological Safety of Blood between May 1989 and February 1992 were missing. Independent audit identified that they were destroyed in error.
[Oct} 2000	Subsequent to the identification of missing ACVSB files, a request for papers that were the subject of non disclosed during the HIV litigation were requested and found to be missing.
	Demands for a Public Inquiry in response to loss of documents. Lord Owen stated that as Minister for Health finance was allocated to increase the production of Factor VIII to attain self-sufficiency and that this policy was not fulfilled by the Department.
2002	Health Minister requested an internal review of all surviving documents between 1973 and 1991, the 'Self-Sufficiency in Blood Products in England and Wales A Chronology between 1973 – 1991'.
April 2006	The report 'Self-Sufficiency in Blood Products in England and Wales A Chronology between 1973 and 1991 published.
May 2006	Documents relating to the HIV litigation returned to Department by claimants solicitors, independent Counsel appointed to review documents.
June 2006	Appointment of civil servant to undertake an internal review of all available papers.

June 2006	Review by independent Counsel of documents returned by a firm of solicitors. SOL conclude that on balance, Counsel advised me that she thought the documents show a very careful and proper approach to the issues of blood safety by those involved.
July 2006	Submission to SoS setting out background to demands for a Public Inquiry and an alternative option of a review by an independent QC..
July 2006	Response of SoS, "if MS(R) and MS(PH) really believe an independent commentary is worth it, and affordable, then she is content. However she feels that it will fuel, not deflect, calls for a public enquiry – which we are absolutely right to do so".

Destroyed/Mislaid Files

1. This internal review of all available documents relating to the safety of blood products, specifically non-A non-B hepatitis was commissioned in June 2006 in response to the return, by a firm of solicitors, of photocopies of some of the documents that had been destroyed in error by the Department of Health.

2. There were two instances of documents relating to blood products being inadvertently destroyed or mislaid. In the first instance, large numbers of documents were retrieved and passed to solicitors for use in the HIV litigation in 1990. These were removed from their original files and arranged for trial by Counsel. The trial folders were returned to DH, but when a subsequent request for disclosure of documents was made, we were unable to retrieve some of the documents requested.

3. Some years later, between September 1994 and March 1998, a number of files documenting the work of the Advisory Committee on the Virological Safety of Blood were inadvertently destroyed. An internal audit report commissioned in February 2000, found that the files had been first marked for subsequent Branch review, then soon afterwards sent to the Departmental Records Office for destruction. The report concluded that the person who sent the files for destruction had probably been unaware of their importance, and offered a number of recommendations for improved induction and guidance.

4. The lack of documentation, including documents that were the subject of non-disclosure during the HIV litigation, generated demands for a Public Inquiry into the safety of blood products in relation to hepatitis C during the 1970s and early 1980s.

ANNEXE D

Comparison with Ireland/Canada

During a debate in the House of Lords on 25 March, the Parliamentary Under Secretary of State for Health, Lord Warner, made clear the Government's position on this issue. Official Report, Column 796 of the Lords Report for 25 March 2004.

Lord Warner's answer –

My Lords, I am grateful to the noble Earl for giving me the opportunity to clarify the issue. My understanding of the position in Ireland, which has been corroborated by officials in the Department of Health and Children in Dublin since my last utterances on the subject in the House, is that the Irish Government set up their hepatitis C compensation scheme following evidence of negligence by the Irish Blood Transfusion Service.

A judicial inquiry, the Finlay report, found that "wrongful acts were committed". It is important to stress that the blood services in the UK have not been found to be similarly at fault. Compensation is therefore being given in very different, specific circumstances in Ireland that do not apply in the UK. I do not believe that the Irish scheme creates any precedent for us.

The awards being made in Canada follow a class action brought against the Canadian Government. The compensation from the federal Government is limited to those infected between 1986 and 1990. Subsequent inquiries found that wrongful practices had been employed, and criminal charges were made against organisations including the Canadian Red Cross Society. Those conditions in Ireland and Canada do not apply in the UK.

D R A F T

Review of Documents Relating to the Safety of Blood Products, Specifically Non-A Non-B Hepatitis, 1970 - 1985

1. Summary (to date)

1.1. Documents relating to the safety of blood during the period 1970-1985 were identified, inventoried and a review undertaken to assess the knowledge of those involved of post-transfusion NANBH. Over 6,000 documents were read and NANBH was the subject, or primary subject, in XX% of these.

1.2. On balance, the documents show a careful and proper approach to the issues of blood safety. There are no significant challenges to the DH position that NANBH was initially thought to be a mild disease.

1.3. The introduction of clotting factor preparations in the 1960s significantly improved life expectancy. The introduction of home treatment in the 1970s, made possible by Factor VIII, dramatically improved the quality of life for haemophiliacs.

1.4. The push to self-sufficiency was initiated with the increased use of dried concentrates from large pools of donors and concern that commercial products ran a higher risk of transmitting hepatitis than NHS products. Based on the clinical knowledge at this time, the increased risk of clinical illness did not out weigh the advantages of using concentrates. In the mid 1970s came the recognition that, as well as hepatitis A and hepatitis B, there were other hepatitis agents which were not A or B (NANBH).

1.5. In the mid to late 1970s, most of the documents examined are primarily correspondence and notes of meetings and are focussed on self-sufficiency and the Medicines Division's inspection of the Blood Products Laboratory (BPL) and its subsequent development. Home treatment became established and there was a substantial increase in the total amount of Factor VIII used. A new type of hepatitis, NANBH, was recognised. The focus at this time is on epidemiological studies, although the risk of progression to chronic liver disease was recognised towards the end of the 1970s, NANBH was described as an acute illness that is clinically mild.

1.6. In the first half of the 1970s, commercial products had a higher risk of hepatitis and were more costly. It was this that provided the impetus to plan for the UK to be self-sufficient. However, in the mid to late 1970s the incidence of NANBH were recorded as being similar in commercial and NHS products. The need for research into NANBH and to devise a diagnostic test was recognised and promoted.

1.7. The tragedy of AIDS on the haemophiliac community dominates the latter part of the early to mid 1980s. In the 1980s published research into NANBH expanded, NANBH was thought now to be the main cause of chronic liver disease, although more than one agent was suspected. The severity of the chronic hepatitis remained unrecognised, with most patients in this group being symptom less, with no specific

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diagnostic tests available NANBH remained a disease diagnosed by exclusion; if hepatitis A and hepatitis B had been excluded, the hepatitis was diagnosed as NANBH.

1.8. Although progression to liver disease was not the rule, a study attributed only 0.4% of chronic liver disease after blood transfusion to NANBH agent, in the early to mid 1980s there was an emerging recognition that the long term clinical significance of the chronic (NANBH) condition had not yet been determined. The overall benefit of Factor VIII was considered to be of significant benefit to haemophiliacs and outweighed the clinical risks, as they were then perceived.

1.9. There is evidence of a growing concern during the early to mid 1980s that NANBH could lead to progressive liver disease and was an understated problem. However, the focus of discussion and research is primarily on epidemiology, with less coverage on the severity of any resulting conditions. It is at the end of this period, 1985 that the foundation for a resolution concerning the severity of NANBH was set in motion with the suggestion that it is not as benign as previously supposed, that progression from chronic mild NANBH to a more severe outcome of cirrhosis may be protracted and only identified with long-term studies. Research in 1986 identified the need for retrospective studies, recognising that the disease might be quite mild but progression to severe symptomatology may be very protracted. The maximum prospective evaluation for chronic NANBH at that time was 10 years.

1.10. It is post 1985, that longer duration follow-up studies were achievable, studies of less than 10 years having underestimated the importance of the disease. Long-term retrospective studies identified that there was a small but statistically significant increase in the number of deaths related to liver disease after transfusion-associated NANBH. Reflecting back in 1992, on earlier studies, confirm that the acute infection was perceived in the 1970s as mild and that in 1980 analysis emphasised its relatively benign short-term prognosis.

1.11. Heat treatment to inactivate the virus was sought from the early 1980s with a heat-treated product, BPL Factor 8, introduced in 1985 primarily to inactivate HIV. A series of studies in 1989 provided evidence that this product appears to have prevented transmission of hepatitis C and HIV. The hepatitis C virus was identified in 1989. It has since been shown to account for the majority of cases of post-transfusion NANBH. The second-generation hepatitis C virus screening assays became widely available and the screening of donor blood was introduced in the UK in September 1991.

1.12. The review concludes that, on balance, taking account of the content of all available documentation relating to NANBH, that a careful and proper approach was taken to the issues of blood safety. With regard to a Public Inquiry the Government does not accept that any wrongful practices were employed, and does not consider that a Public Inquiry is justified.

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1.13. The report recommends the release of all the documents reviewed, in line with FOI that have not already been released as part of this review. This includes documents that, at that time, fell within Classes which should not be disclosed in civil litigation on grounds of the public interest. These documents relate to the period in office of a previous administration, relate to policy formulation, Ministerial correspondence and submissions to Ministers and briefing notes, and draft replies to letters. By this action all available documented evidence, available to the Department of Health, will be in the public domain