FOI [illegible]

To: MS(PH), MS(R)

From: Linda Page

Date: [DATE]

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CONTAMINATED BLOOD PRODUCTS and HEPATITIS C

1. Issue

1.1. As agreed with you previously, we have undertaken an internal review of all existing papers (see page 4). The report of the internal review is attached.

1.2. The documents reviewed provide no new information that challenges the DH position relating to the infection of haemophiliacs with NANBH during 1970-1985. The information reviewed supports the advice in the 1970s and early 1980s that NANBH was a mild disease, a view widely shared at this time.

1.3. A submission by you to SoS dated 24 July 2006 sets out the background in relation to a public inquiry and the option of appointing independent counsel (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.

1.4. SoS said that she did not want a Public Inquiry, however, 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 she feels we should continue to resist.

1.5. A chronology of events is attached at Annexe B

2. Background

2.1. 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.

2.2. 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 a Public Inquiry could help achieve this by demonstrating the Department was culpable.

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

2.4. 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.

2.5. 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. The Department established the Macfarlane Trust with £44m to administer payments to haemophiliacs with HIV in 1991 Details of the Macfarlane and Eileen Trusts and Skipton Fund are included in Annex A.

2.6. 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 Act 1987 (CPA) which implemented the European Product Liability Directive 1985. All 117 claimants won damages.

2.7. 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.

2.8. 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.

2.9. 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 C.

2.10. 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 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.

2.11. 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.

2.12. A further internal review of documents was commissioned in June 2006 with the brief to review all documents available to the Department 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. The report on the internal review is now completed and a copy attached. A summary of the findings is provided in the attached report, the review has found no new evidence that identifies any culpability by the Department.

3. Public Inquiry

3.1. 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. A Public Inquiry has the power to compel witnesses to give evidence or produce documents.

3.2. A Public 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.

4. Independent Review

4.1. 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.

4.2. Legal Advice

SOL has advised that an alternate to a Public Inquiry would be to put as many of the relevant documents as possible in the public domain. 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 a Public 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.

5. Internal Review

5.1. You 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 was completed in February 2007. The cost of this review is about £58,000. The brief was to examine all documents available to the Department, to assess the approach 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.

5.2. The review looks at all documents available to the Department 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.

5.3. Over 6,000 documents were read and NANBH (hepatitis C) was the subject, or primary subject, in 2.2% of these.

5.4. 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% of the documents available, an inventory of the documents was provided with the release, not a review.

5.5. 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.

5.6. One document has been located that required a detailed explanation on its release in August 2006; references to the report 'Self-Sufficiency in England and Wales'. An

internal minute from Dr Diana Walford, a former DCMO, 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."

5.7. 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."

5.8. 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.

6. Recommendations

6.1. The options identified are to hold a public inquiry, commission an independent review by a QC or publish the documents reviewed as part of the internal review. Lord Warner has already agreed to release the report to Lord Jenkin of Roding.

6.2. A Public Inquiry. We have not to date recommended a public inquiry for the following reasons:

6.2.1. There is no evidence that any wrongful practices were employed. This is supported by the outcome on the internal review of all available documents

6.2.2. 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.

6.2.3. A Public Inquiry under the Inquiries Act would be very expensive, time consuming and labour intensive; it is a disproportionate measure and cannot be justified. The Bristol Royal Infirmary public inquiry cost over £14m and ran for three years; there would also be internal costs to supporting the public inquiry, estimated at £300,000.

6.3. Commissioning an Independent Review by a QC.

6.3.1. Such a review is likely to cost in the region of £150,000 and the internal costs of supporting the review estimated at £46,000 (c£200,000).

6.3.2. An independent review by a QC would not be able to compel witnesses to give evidence.

6.3.3. The review may have some standing with external parties although unless it was to reveal any significant new information we strongly suspect campaigners will dismiss such a review and fuel calls for a public inquiry.

6.4. In addition to the release of the report on the internal review with the associated references there is the option to release all documents reviewed (6,500), either in line with FOI or as 'business as usual'.

6.4.1. To release the documents in line with FOI, it is estimated that the preparation and processing of the documents will take approximately four to five months. To achieve this timescale would require a member of staff to be dedicated to the task full time with some administrative support. The cost is estimated at £40,000.

6.4.2. Based on the release of documents in August and November 2006, 12% of document would be withheld, the majority under Section 35 of the FOI Act as they relate to Ministerial submissions and formation of policy. Experience to date suggests that those campaigning for a public inquiry are likely to assume that any documents withheld would be potentially useful to them.

6.4.3. To release the documents as part of 'business as usual', it is estimated that preparation to comply with the Data Protection Act by removing individuals names would take three to four months. Again a dedicated member of staff would be needed at an estimated cost of £32,000.

6.4.4. Should the documents be released as part of 'business as usual', rather than in line with FOI, there will be no protection under the FOI Act and all documents would be released. This would include documents that, at that time, were not disclosed in civil litigation on grounds of the public interest. These documents include ministerial submissions, drafts of submissions, correspondence between officials and Ministers and free and frank discussion in the formulation of policy. Such a release may set a precedent across Government as a whole by their voluntary disclosure. The reasons for which they were withheld in 1990 still have some force today and would be relevant on a claim for an FOIA exemption (section 35). Government Departments are reluctant to release documents that are exempt under Section 35 as there is a concern that this will place pressure on the Department and other Government Offices to release documents previously withheld. While none of these policy documents gives rise to any real concerns over liability, some are sensitive in respect of potential for criticism or embarrassment. Examples are provided at Annexe D.

6.4.5. Under either option for release, the documents will provide considerable information on blood safety during this period.. They cover the redevelopment

of BPL and DHSS concerns regarding financial control and project management, the strive towards self-sufficiency, correspondence and notes of meetings regarding AIDS and Hepatitis B vaccine.. This may lead to further questioning and requests for information that will require a response.

6.4.6. The release of the documents may go some way to support the SoS position in not holding a public inquiry; the Department have released a significant number of documents that demonstrate a careful and considered approach to NANBH during this period.

6.4.7. External parties may welcome the release of documents under either of the alternatives outlined above, being suspicious of any withheld, but as they do not show negligence on the part of the Department concerning NANBH we strongly suspect calls for a public inquiry will continue in order to enable questioning of those involved at the time.

7. Ministers are asked to agree to the release of the report on the internal review with the associated references. Ministers are asked for direction on the course of action they wish to take in addition to this.

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