Draft

PS(PH)

From: William Connon

Date: xx May 2005

Copy: See attached list

REVIEW OF PAPERS: SUFFICIENCY IN BLOOD PRODUCTS

ISSUE

1. This submission is to inform you of the outcome of the internal review of papers on the issue of self sufficiency in blood products, during the 1970's and 1980's. Attached is a copy of the final report which summarises the results of the review and includes a chronology of events.

TIMING

2. Urgent. Since the Freedom of Information Act came into force in January 2005 we have had numerous requests for the release of papers dating back to the 1970's. We have also had Parliamentary questions and correspondence about when the outcome of the review will be finalised.

BACKGROUND TO THE REVIEW

3. Almost all haemophilia patients treated with blood products in the 1970's and early 1980's were infected with hepatitis C, and or HIV. Lord (David) Owen, a Health Minister in the 1970s, has publicly suggested that this might have been avoided had the UK achieved self sufficiency in blood products, a policy he initiated in 1975. Haemophilia campaigners have also raised other concerns about policy decisions taken at the time in the context of demands for compensation and a public inquiry.

4. In 2002, Yvette Cooper the then Health Minister asked officials to undertake an internal review of the surviving documents, roughly between 1973-1991, to produce a chronology of events and an analysis of the key issues. The remit of this work is attached at Annex I. Without this it is difficult to answer any detailed accusations levelled against the Department by Lord Owen and others.

5. The review does not address comments by Lord Owen about the destruction of papers from his Private Office.

CONCLUSIONS OF THE REVIEW

6. The review of papers concludes that about [3000] patients with haemophilia treated with blood products supplied by the NHS in the 1970's and early 1980's were infected with either Hepatitis C and or HIV. Available evidence suggests that during the 1970's and 1980's the Government pursued the goal of self-sufficiency in factor

VIII, in line with the World Health Organisation and Council of Europe recommendations.

7. In 1975, the Government allocated £0.5m, about half of which was recurring, to the NHS in order to increase plasma production. At the time this was thought adequate to achieve self-sufficiency in factor VIII by 1977. However, the demand for factor VIII in the UK increased dramatically in the late 1970's. This was owing to i) longer life expectancy in patients with haemophilia ii) the increased provision of home therapy and iii) the trend towards the use of factor VIII in bleeding prophylaxis. Therefore despite the increase in both the plasma collected by the Regional Transfusion Centres (RTCs) and the amount of factor VIII produced by the NHS, it was still necessary to import factor concentrates.

8. The review considered the developing understanding of the seriousness of Non-A Non-B Hepatitis (NANBH; later known as Hepatitis C). It concludes that the prevailing medical opinion in the late 1970's and early 1980's was that NANBH was perceived as a mild, and often asymptomatic disease, and the advantages of treatment with factors VIII concentrates were perceived to far outweigh its potential risks. This view was supported by patients, their clinicians, and the Haemophilia Society.

9. From the early 1980s, Bio Products Laboratory (BPL – a plasma fractionation plant) attempted to devise an effective viral inactivation procedure. Progress was hindered by the heat sensitivity of factor VIII and lack of an appropriate animal model to investigate the efficacy of heat-treated products. However, by the time it became apparent that NANBH was more serious than initially thought, all domestic and imported concentrates were already routinely heat-treated and therefore conferred little risk of infection with NANBH or HIV.

DN: William there may be other points you would wish to highlight following discussion with BPL and others

HAEMOPHILIA CAMPAIGN

10. There are a few haemophilia pressure groups who have campaigned for, compensation and a public inquiry into why haemophilia patients received infected blood products. They argue that the Government and some clinicians knew about the risks, yet allowed infected products to be used in their treatment. Publication of this report is unlikely to satisfy these groups. They will continue to make demands for a public inquiry. There are four key points to make:

- At the time, the HIV and Hepatitis C viruses had not been isolated and there was no way of knowing that they were present and no way of screening donations.

- There was no test to identify the presence of either the HIV and Hepatitis C viruses, scientists could not be sure that any particular heat treatment had actually worked until they reviewed the effects of the resultant products on patients.

- Many patients would have died or suffered permanent joint damage without treatment with blood products, and when concentrate factors became available, there was pressure on clinicians from patients, patient groups, and parents of children with haemophilia to provide this treatment. This was because it could revolutionise the lives of many haemophiliacs by providing much more effective treatment and by enabling many of them to treat themselves (thus avoiding the need to attend hospital).

- There was no professional consensus that infection with the Hepatitis C virus was a serious condition until the end of 1980s – many experts believed it was a mild non-progressive condition.

11. The combination of these factors meant that initially clinicians prescribed blood products without all the knowledge that would have enabled them to make a properly informed judgment about the balance of risk involved. Even after the risks became better understood there were many cases where it was considered that the benefits far outweighed the risks.

12. The analysis of the review of papers confirms that:

- We do not believe that anyone acted wrongly in the light of the facts that were available to them at the time. The RTC's [BPL?] did their best to ensure that blood products were as safe as possible. Clinicians acted in the best interest of their patients.

- The more serious consequences of hepatitis C, which may take 20-30 years to develop, only became apparent after full characterisation of the virus in 1989 and the development of tests for its recognition (in 1991).

- Viral inactivation processes, heat treatment and screening tests were developed and introduced as soon as practicable (and in line with developments in other countries) whilst continuing to maintain essential supplies of blood and blood products.

- There was no alternative treatment which could have been offered to haemophiliacs at that time.

- Self sufficiency in blood products would not have prevented haemophiliacs from being infected with hepatitis C. Blood products are made with pooled plasma. Even if the UK had been self sufficient, the prevalence of hepatitis C in the donor population would have been enough to spread the virus throughout the pool. That is why the infection of haemophiliacs with hepatitis C is a world wide problem

- [Risk management and the precautionary principle are key issues for the Health Service today. We are committed to better communication between clinicians and patients – especially on risk].

DELAY IN CONCLUDING THE REVIEW

13. Due to a number of pressures, there has been a long delay in finalising the report. A draft report was submitted to the Blood Policy Team in January 2003. However there were a number of outstanding issues which had to be resolved before the report could be finalised and submitted to Ministers.

14. There were a number of unsubstantiated statements in the report which had to be checked for accuracy, we had to draw up a lengthy list of references to the report and include an executive summary. In 2004, officials commissioned consultants to analyse the papers and finalise the report. We have also had to consult with haemophilia doctors, [colleagues in the devolved administrations and BPL **DN:** still need to do this]. William – we will need to do some quick work to get some of those quoted in the report to verify the statements. Richard originally had it the other way round. A submission first then checking round with people

RECOMMENDATIONS

15. We recommend that this report is made public. [**DN**: William we need to give this further thought] It is likely to generate media interest and will need careful handling. We will liaise with COMMS appropriately and provide more detailed briefing nearer the time.

16. We would also recommend that a copy of the report is sent to Members of Parliament and Peers, including Lord Owen, and pressure groups who have expressed an interest in the outcome of the review.

17. The report contains a number of references to not only published scientific papers but also to internal documents. We see no reason why the latter cannot be released on request but for reasons of sheer volume would resist supplying a complete set of documents.

18. Are you content for officials to proceed with arrangement to make public the report?

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Annex I

Review of Internal Trawl of Papers into Self Sufficiency in Blood Products

Remit

(i) Review documents held by the Department and other bodies for the period 1971 to 1985, identify key documents and produce a chronology of events. Interviews with officials, clinicians and others active in this area at the time may be necessary to build up a full picture.

(ii) Produce an analysis of the key issues, including:

- the development of policy on UK self sufficiency in blood, the factors that influenced it and the reasons why it was never achieved;

- the ability of NHS blood products fractionators to produce the volumes of product required;

- the evolving understanding of the viral risks associated with pooled blood products, both domestically produced and imported, and how this influenced policy;

- the extent to which patients were informed of these risks;

- the developing technologies to enable viral inactivation of blood products and the timing of their introduction in the UK.

(iii) Summarise these findings in a report for Ministers.