CHAPTER 1

INTRODUCTION

Terms of reference

1.1 On 19 August 2003 the Senate referred the following matters to the Committee for inquiry and report:

(a) the history of post-transfusion Hepatitis in Australia, including when Non-A, Non-B Hepatitis (Hepatitis C) was first identified as a risk to the safety of blood supplies in Australia and internationally;

(b) the understanding of Hepatitis C by blood bankers, virologists, and liver specialists during the past 3 decades, including when Hepatitis C was first identified as a virus transmissible through blood;

(c) when the first cases of post-transfusion Hepatitis C were recorded in Australia;

(d) when the Australian Red Cross and the plasma fractionator Commonwealth Serum Laboratories first become aware of infections from blood contaminated by Hepatitis C, and the actions taken by those organisations in response to those infections;

(e) the process leading to the decision by the Australian Red Cross not to implement testing (such as surrogate testing) for Hepatitis C once it became available;

(f) the likelihood that Hepatitis C infections could have been prevented by the earlier implementation of surrogate testing and donor deferral;

(g) the implications for Australia of the world's most extensive blood inquiry, Canada's Royal Commission (the Krever Report);

(h) the implications for Australia of the recent criminal charges against the Canadian Red Cross for not implementing surrogate testing for Hepatitis C in the 1980s;

(i) the Commonwealth's involvement in the provision of compensation to victims of transfused Hepatitis C, including the use of confidentiality clauses in those compensation payments;

(j) the high infection rate of Hepatitis C for people suffering from haemophilia;

(k) the extent to which Australia has been self-sufficient in blood stocks in the past 3 decades;

(l) the importation of foreign-sourced blood plasma for use in the manufacture of blood products, and its potential role in the proliferation of Hepatitis C infected blood;

(m) the number of Australians who have been infected with Hepatitis C through blood transfusion;

(n) the impact that blood-transfused Hepatitis C has had on its victims and their families; and

(o) what services can be provided or remedies made available to improve outcomes for people adversely affected by transfused Hepatitis C.

1.2 The Committee was to report to the Senate by the first sitting day of the 2004 winter session. This was subsequently extended to 17 June 2004.

Conduct of the inquiry

1.3 The inquiry was advertised in *The Australian* and through the Internet. The Committee also wrote to interested individuals and groups inviting submissions. The Committee received submissions from the Commonwealth, organisations and individuals. In total, 93 public submissions and 60 confidential submissions were received. The majority of these submissions were from individuals outlining their personal story on the circumstances of contracting hepatitis C and the impact it has on their lives and that of their families. A list of individuals and organisations who made public submissions is at Appendix 1.

1.4 The Committee heard evidence in Canberra, Melbourne and Sydney (two days). In organising its hearing program, the Committee endeavoured to hear from the major organisations which made submissions to the inquiry, including all the groups who represent or support the individuals who have contracted hepatitis C through blood transfusions. A number of these individuals also gave personal testimonies about living with hepatitis C as part of their daily life. The list of witnesses who appeared at the public hearings is at Appendix 2.

1.5 The Committee also visited the Australian Red Cross Blood Service facilities at Garran, ACT, to examine the process of blood collection, screening, processing and distribution. The Committee appreciated the opportunity to talk to staff and gained a valuable insight into the operation of the Service.

1.6 In Sydney on 27 May 2004, members of the Committee, at the invitation of the Australian Red Cross Blood Service, attended as observers a meeting chaired by Sir Laurence Street. The meeting involved representatives of the Australian Red Cross Blood Service and stakeholder organisations, many of whom had appeared before the Committee to speak on behalf of those affected with hepatitis C. The outcome of the meeting is discussed in Chapter 6.

Background to the inquiry

1.7 Throughout the 1980s and 1990s, there were a growing number of concerns about the challenges facing the supply of blood and blood products both here in Australia and overseas. The transmission of HIV/AIDS and hepatitis C through the blood supply had raised issues about the adequacy of arrangements to ensure the

safety of the blood supply. Community expectations were also rising as was demand for products.

1.8 Three major reviews of aspects of the blood system were conducted in Australia:

- *Commonwealth Review of Australian Blood and Blood Product System,* (McKay and Wells Review), 1995.[1] The review examined consultative mechanisms, coordination and management at the national level, the role of the Australian Red Cross in blood banking and the impact of pricing signals and charging on the supply and demand in blood and blood products.
- *Review of the Australian Blood Banking and Plasma Product Sector* (Stephen Review), 2001.[2] The review examined the blood banking and plasma product sector and made recommendations aimed at ensuring Australia was equipped to meet emerging and future challenges, to provide an adequate and secure supply of safe, high quality blood and blood products and to promote appropriate clinical use. Recommendations included the establishment of the National Blood Authority, strengthening governance and financing arrangements, quality assurance in supply and use, and ongoing monitoring and review.
- *Report of the Expert Advisory Group on Hepatitis C and Plasma in 1990* (Barraclough Report), 2003.[3] The Expert Advisory Group was appointed to examine claims that plasma positive to hepatitis C antibody was used in the manufacture of plasma products for several months in 1990. The Expert Advisory Group found that the blood system was fragmented and there was limited capacity to provide integrated governance and management. However, evidence was not found to establish a connection between the claims investigated and an incident of hepatitis C infection in a recipient of fractionated plasma products. The Expert Advisory Group supported the establishment of the National Blood Authority.

1.9 During this time, the impact of hepatitis C was also being recognised. In 1998, the NSW Legislative Council Standing Committee on Social Issues tabled its report, *Hepatitis C: The Forgotten Epidemic*.[4] The Committee reported on the social and economic impact of hepatitis C, the extent of the disease, the adequacy of policies and

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1 McKay B & Wells R, *Commonwealth Review of Australian Blood and Blood Product System: Final Report*, Department of Health and Human Services, Canberra, 1995.

2 Stephen, Sir N, *Review of the Australian Blood Banking and Plasma Product Sector*, Department of Health and Aged Care, Canberra, 2001.

3 *Report of the Expert Advisory Group on Hepatitis C and Plasma in 1990*, Department of Health and Ageing, Canberra, 2003.

4 Parliament of NSW, Legislative Council Standing Committee on Social Issues, *Hepatitis C: The Forgotten Epidemic Inquiry into Hepatitis C in NSW,* Report No 16, Parliament of NSW, Sydney, 1998.

treatment services, those at increased risk of infection, the risks involved for health care workers and the adequacy of policies and procedures on occupational health and safety.

1.10 Over the last year, Senator Steve Hutchins has, in the Senate and through a series of questions on notice, raised issues relating to the transmission of hepatitis C through blood and blood products.[5]

Governance and blood banking in Australia[6]

1.11 Blood banking in Australia derived from the need to supplement blood and its components following natural deficiency or traumatic blood loss. Broadly, the components of the system currently comprise:

- the volunteer donors;
- the Australian Red Cross, and its operating division, the Australian Red Cross Blood Service (ARCBS);
- CSL Limited, the national blood fractionator and public company; and
- the Commonwealth, State and Territory Governments, which jointly fund and govern the sector.[7]

1.12 The Australian Red Cross has been involved in blood transfusion services since 1929 when the first service was established in Victoria. Similar services were then developed in all States. The Red Cross Division in each State and Territory established and maintained a Blood Transfusion Service (BTS). This reflected the federal system of governance of Australia and the organisation and funding of public health services. Each State or Territory BTS was responsible for the collection, processing, screening and distribution of blood and blood products in their respective geographic areas. Throughout the 1980s and 1990s, there were also other blood banks operating under the jurisdiction of State Departments of Health.[8] For example, the NSW Department of Health hospital system ran 28 country blood banks.[9]

1.13 The Commonwealth's role in the blood service was limited to a contribution to State and Territory Governments of some of the funding for the operation of blood services. The Department of Health and Ageing (DoHA) commented that regulation

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5 Senate, *Hansard*, Question No. 1352, 15.5.03, p.11099; Question No. 1781, 18.9.03, p.15651, 26.1.03, p.18140; Question No. 2003, 24.11.03, pp.17616-17; Question No. 2004, 10.2.04, p.19742; Question No. 2005, 7.11.03, p.17463.

6 Information in this section is drawn largely from the Stephen Review and Barraclough Report.

7 Summarised in the Stephen Review, p.8.

8 *Submission* 64, p.16 (ARCBS).

9 Barraclough Report, p.24; *Submission* 54, Supplementary Submission, 21.5.04, p.4 (DoHA).

of blood services was fragmented, with much of it in the hands of State and Territory Governments.[10]

1.14 At the national level, until the formation of a national blood system, a committee structure was responsible for considering issues relating to safety and the blood supply. Decisions relating to national policy in relation to blood transfusion were coordinated at regular meetings of the Blood Transfusion Service Executive Sub-committee, National Blood Transfusion Committee (NBTC) and the Fractionation Liaison Advisory Group.[11] The Blood Transfusion Service Executive Sub-committee existed with membership including all the directors of the State blood transfusion services, the Medical Chairman of the NBTC (see below), the Medical Director of the Australian Red Cross Society (ARCS), two representatives from the Commonwealth Serum Laboratories, and a representative from the Commonwealth Department of Health and Community Services.

The National Blood Transfusion Committee

1.15 The National Blood Transfusion Committee (NBTC) was formed in 1941 and managed by the Australian Red Cross Society. Membership of the NBTC included representatives from the Red Cross; the directors of the divisional blood transfusion services; two representatives of the Commonwealth Serum Laboratories, including either the managing director or acting managing director; a representative of the Australian Department of Community Services and Health; and the Surgeon General or his nominee (from the Department of Defence). Commonwealth officers regularly attended committee meetings and on a least one occasion, representatives from the NSW Department of Health attended.[12]

1.16 The NBTC's duties included:

- responsibility to the Executive of the Australian Red Cross Society for national projects;
- submission of an annual report to the Executive of the ARCS;
- responsibility for relationships with relevant Departments of the Australian Government; matters of mutual concern to the Society and Commonwealth Serum Laboratories; international blood transfusion matters; and other activities of national concern. The constitution lists 'quality control and standards' as one activity of national concern; and
- review of the operations of the blood transfusion services throughout the society and to advise the council on all matters of policy.

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10 *Submission* 54, p.2 (DoHA). Note: the Commonwealth had responsibility for the ACT prior to self government in 1989.

11 *Submission* 64, p.16 (ARCBS).

12 Barraclough Report, p.24.

1.17 The deliberations of the NBTC and BTS Executive Sub-committee were reported to divisional blood transfusion service committees by individual directors. The divisional committees, who were responsible for the safety of the blood supply within the State or Territory, made final decisions.

1.18 The Barraclough Report stated that the divisional units had autonomy. However, they were influenced by their respective State and Territory health departments. Thus while NBTC and BTS Executive Sub-committees approved policy, it was entirely up to Red Cross Society divisions in the States and Territories, as to whether the policy was implemented.

1.19 DoHA commented that the NBTC 'had no power to impose its policy decisions on the various transfusion services, which sometimes followed their own preferences'.[13]

1.20 Following the 1995 review of the Australian blood and blood product system, steps were taken to establish a national blood service. In 1996, the blood services of the States and Territories united to form a national blood service, the Australian Red Cross Blood Service (ARCBS). The ARCBS was established as the operating division of the Australian Red Cross. With the advent of ARCBS, the NBTC ceased operations.

1.21 The commencement of the *Therapeutic Goods Act 1989* in 1991 saw the Commonwealth begin to play an increasing role in coordination and regulation. Nevertheless, it was only in 2000 that the Therapeutic Goods Administration (TGA) was given the power to regulate fresh blood components manufactured by the ARCBS.[14] The TGA is recognised as the national regulator of the efficacy, safety and quality of blood and blood products. The TGA is responsible for a range of communications activities such as auditing of Good Manufacturing Practice, product recalls, modifications to safety standards and the issuing of directives regarding a range of issues including donor deferrals.[15]

National Blood Authority

1.22 A National Blood Authority (NBA) was established in 2003 with the passage of the National Blood Authority Act. A national authority had been recommended by the Stephen Review and supported by the Barraclough Report.[16] The role of the National Blood Authority is to enhance the management of Australia's blood supply by ensuring that Australia's blood supply is safe, secure, adequate and affordable. The NBA achieves this through the following functions:

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13 *Submission* 54, p.2 (DoHA).

14 *Submission* 54, p.2 (DoHA).

15 http://www.nba.gov.au. Accessed on 21 May 2004.

16 Stephen Review, p.xiv; Barraclough Report, p.5.

- coordinating demand and supply planning for blood and blood products from suppliers on behalf of all States and Territories;
- negotiating and managing national contracts with suppliers of blood and blood products;
- working with all governments to ensure that they get the blood and blood products they require, according to an agreed single national pricing schedule;
- undertaking research to support policy development and operations within the blood sector through transparent evidence-based processes;
- developing and implementing national strategies to encourage better use of blood and blood products;
- promoting adherence to national safety and quality standards; and
- taking responsibility for national contingency planning.[17]

1.23 Under the National Blood Agreement, Commonwealth, State and Territory governments have specified roles and responsibilities.[18] For the States and Territories, these include:

- fostering the development of, and implementing, best practice planning and management systems to promote efficiency in the use and minimisation of wastage;
- ensuring the provision of information and advice to the National Blood Authority in relation to demand for blood and blood products; and
- managing local issues such as those involving clinical practice.

1.24 The Australian Government, through the Department of Health and Ageing, is charged with:

- the Commonwealth's policy and financial participation in the National Blood Authority;
- the National Cord Blood Program, the Bleeding Disorder Registry and the Bone Marrow Transplant Program;
- contracts with the Haemophilia Foundation of Australia and the Australian Haemophilia Centre Directors' Organisation; and
- responsibilities in relation to quarantine as it may affect the blood supply.

1.25 DoHA concluded:

> Thus, at the beginning of the new century, Australia has a blood system operating with a high degree of safety at all levels, underpinned by

17 http://www.nba.gov.au. Accessed on 21 May 2004; National Blood Authority Act, s8.

18 http://www.nba.gov.au/pdf/national_blood_agreement.pdf. Accessed on 21 May 2004.

coordinated arrangements which support strategic national policy direction.[19]

CSL Limited

1.26 Commonwealth Serum Laboratories (CSL) was established by the Commonwealth Government in 1916 to assist with Australia's wartime needs for pharmaceutical vaccines. In 1961, CSL was incorporated as a statutory authority (the Commonwealth Serum Laboratories Commission). In 1991 it was corporatised and converted to a public company (CSL Ltd) while remaining wholly owned by the Commonwealth. In May 1994, the Commonwealth sold CSL by means of a 100 per cent public float.

1.27 CSL's principal activities are the production and distribution of human pharmaceutical products and the manufacture of plasma products sourced from human blood. Plasma collected by the ARCBS from Australian donors is supplied to CSL to be manufactured into plasma derived products. The manufactured products are either returned to the ARCBS for distribution to hospitals and medical practitioners or provided directly to authorised individuals and organisations.

1.28 CSL has two main agreements that relate to the manufacture of plasma products:

- the Plasma Fractionation Agreement was entered into by the Commonwealth and CSL with effect from 1 January 1994 and governs the manufacture of a specified range of plasma products; and
- the Plasma Supply Agreement between the ARCBS and CSL came into effect on 28 April 1994 and covers the supply of plasma by the ARCBS to CSL for the manufacture of plasma products.[20]

1.29 On 23 December 1993, CSL and the Commonwealth entered into formal agreements which provided indemnities for claims arising from the use of some CSL products.

19 *Submission* 54, p.2 (DoHA).

20 See also *Committee Hansard* 5.4.04, p.43 (CSL).