

## CHAPTER 4

### THE KREVER REPORT

4.1 Terms of Reference (g) and (h) require the Committee to examine, respectively:

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

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.

4.2 This Chapter provides a summary of the findings of the Krever Report,<sup>1</sup> the subsequent criminal charges, and then comments on its applicability to the Australian situation.<sup>2</sup>

#### **What did Krever say?**

4.3 Justice Horace Krever was appointed in October 1993:

[T]o review and report on the mandate, organization, management, operations, financing and regulation of all activities of the blood system in Canada, including the events surrounding the contamination of the blood system in Canada in the early 1980s, by examining, without limiting the generality of this inquiry:

1. The organization and effectiveness of past and current systems designed to supply blood and blood products in Canada;
2. The roles, views, and ideas of relevant interest groups; and
3. The structures and experiences of other countries, especially those with comparable federal systems.<sup>3</sup>

4.4 An Interim Report was released in February 1995 and the Final Report in November 1997.

4.5 The Canadian experience in relation to the implementation of surrogate testing reflected a similar lack of clarity and consensus to that which occurred in the United States, as outlined in Chapter 2. The difference, however, was that the discourse had not concluded by the time antibody testing became available in 1990, and hence, was largely obsolete upon completion.

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1 Krever H, *Commission of Inquiry on the Blood System in Canada*, 1997.

2 Much of Krever's discussion of the Canadian situation, particularly in relation to the evolution of opinion regarding surrogate testing, has been integrated into discussion in Chapter 2.

3 Krever Commission, Final Report, Volume 2, p.5.

4.6 It should be noted that Justice Krever's investigation concerned itself primarily with the Canadian response to HIV/AIDS. The Report is particularly critical of the delay in the introduction of HIV testing in Canada, which did not occur until March 1986. In contrast, Australia's comprehensive introduction of testing was complete by May 1985, placing it in the first few countries to do so.

4.7 With respect to surrogate testing for HCV, in the Canadian context, Krever concluded:

Although, when used together, the tests were thought to reduce the incidence of non-A, non-B post-transfusion hepatitis by only 60 per cent, they were introduced because, in the United States, there were high rates of post-transfusion non-A, non-B hepatitis and because as many as 20 per cent of the persons infected were developing serious liver disease. During the years 1986 to 1989, the question of whether the two tests should be introduced in Canada was under active consideration. One of the reasons why the tests were not introduced is that, although data from U.S. studies showed that the introduction of the surrogate tests would probably reduce the rate of post-transfusion hepatitis significantly, they did not prove conclusively that the tests would have that effect. Instead of introducing the tests in Canada, a study was conducted to determine whether the tests would be effective in reducing the rate of post-transfusion hepatitis. Before the study could be completed, a specific test to detect the presence of hepatitis C (the most prevalent form of post-transfusion non-A, non-B hepatitis) was introduced in 1990. The study demonstrated that, before the hepatitis C test was introduced in 1990, the introduction of the surrogate tests would have greatly reduced the occurrence of post-transfusion non-A, non-B hepatitis. Rather than awaiting full scientific proof, the Red Cross could and should have accepted the estimates of the efficacy of the surrogate tests. If the Red Cross had introduced appropriate risk-reduction measures promptly, without awaiting full scientific proof, fewer persons would have been infected with HIV and hepatitis. In the words of a U.S. authority, public health has never clung to the principle that complete knowledge about a potential health hazard is a prerequisite for action.<sup>4</sup>

4.8 While Krever's findings implicitly recognise the role which surrogate testing may have played in reducing incidence of post transfusion hepatitis in Canada, it should be remembered that his findings were made in a context which could be contrasted with that of Australia in at least three key areas.

4.9 First, Krever was extremely critical of the time taken by Canadian authorities in deciding on, undertaking, reporting on, and then acting on, studies into the usefulness or otherwise of surrogate testing. This was in sharp contrast to Australia. For example, due to resource allocation and other bureaucratic delays, an authoritative

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4 Krever Commission, Final Report, Volume 2, p.990.

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study into surrogate testing was not undertaken in Canada until September 1989. In Australia, the equivalent study began a full two years earlier, in September 1987.<sup>5</sup>

4.10 Secondly, the epidemiological situation with which decision makers were presented varied substantially between the two countries. Throughout this inquiry, the Committee has been told of the importance of the rate of post transfusion hepatitis as a key factor in rating the usefulness of surrogate testing in a given blood supply, due to the incidence of false positive and false negative results.<sup>6</sup>

4.11 Krever's analysis of the culpability of the Canadian Red Cross was based on his acceptance that the American rate of hepatitis incidence could serve as the basis for estimating incidence in Canada. Krever's analysis was subsequently supported by a study of incidence in Toronto which arrived at a figure of 9.2 per cent, compared with an incidence of around 10 per cent in certain locations in the United States.<sup>7</sup> It was in this context that Krever found the inaction of the Canadian authorities to be wanting. He stated:

In the absence of evidence that the rate [of incidence] was different in Canada, there was no sufficient reason to refrain from relying on the US data and introducing the surrogate tests.<sup>8</sup>

4.12 Professor Barraclough agreed that incidence rates were important, saying:

The balance swings if the donor population has a high probability of having non-A, non-B or hep C. Those decisions become a little easier when the benefit is likely to be a little greater by excluding those. When the risk to the patient is a little over one percent, it becomes a doubtful proposition.<sup>9</sup>

4.13 The Australian situation was very different. In the study conducted by Professor Cossart in 1982, the incidence of post transfusion infection was reported at 1.7 per cent.<sup>10</sup> (This study is referred to in Chapter 2.) Krever observed that:

In general, countries in which the incidence of post-transfusion Non-A, Non-B hepatitis was low were most likely to decide not to implement surrogate testing routinely.<sup>11</sup>

4.14 Thirdly, Krever found a series of systemic problems between the Canadian Federal and Provincial Governments, the Canadian Blood Transfusion Service, commercial fractionators and Boards of Governors charged with evaluating evidence

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5 *Submission 64* p.53 (ARCBS). The importance of incidence of Post-transfusion hepatitis in the Canadian context is discussed in Krever Commission, Final Report, Volume 2, pp.650-651.

6 See, for example, *Committee Hansard* 6.4.04 p.65 (Prof Barraclough).

7 Feineman *et al*, as contained in *Submission 64*, p. 53 (ARCBS).

8 Krever Commission, Final Report, Volume 2, p.993.

9 *Committee Hansard* 6.4.04 p.65 (Prof Barraclough).

10 Cossart YE *et al*, Post-transfusion hepatitis in Australia, *Lancet* 1982, 1:208-13.

11 Krever Commission, Final Report, Volume 2, p.706.

and making decisions.<sup>12</sup> There is no compelling evidence before the Committee suggesting that such a situation was replicated in Australia. Indeed, the Committee received strong evidence that the decisions in relation to surrogate testing, and the manufacture of plasma products, were taken with due consideration of the evidence at hand, in a timely fashion and with the agreement of each jurisdiction except Queensland.<sup>13</sup>

### **Implications of criminal charges**

4.15 While a number of Submissions called for the charging of the ARCBS following Krever's findings, the Committee received very little evidence going to the implications of the charges laid in Canada in the Australian context.

4.16 Consistent with its commentary with respect to the findings of the Krever Report itself, the ARCBS submitted that:

It would be wrong to assume or infer that any of the identified systemic problems of the [Canadian Blood Transfusion Service] applied to the Australian Blood Transfusion Services in the eighties and indeed it would be submitted to the contrary. The Krever Report should be seen in its proper context. It was an inquiry relating only to the activities of the Canadian Health Services including Governments, commercial fractionators, and the CBTS.<sup>14</sup>

4.17 The ARCBS concluded that:

The findings of the Krever Commission and the recent criminal charges against the Canadian Red Cross are not relevant in any way to the Australian situation.<sup>15</sup>

4.18 The Department of Health and Ageing also submitted that the charges raised in Canada had no implications for Australia.<sup>16</sup>

### **Conclusion**

4.19 The Committee considers that although the Krever report provides a useful analysis of the state of knowledge at the time important decisions were being made in both Australia and Canada, those decisions were being made in markedly different contexts. In making this conclusion, the Committee is particularly mindful of Justice Krever's observation, as well as those from other experts during the inquiry, that the significant distinctions between the two scenarios were the basis for the different decisions made in each case.

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12 Krever Commission, Final Report, Volume 2, pp.985-1001.

13 See, for example, *Committee Hansard* 6.4.04 p.65 (Prof Barraclough); *Committee Hansard* 5.4.04 p.46 (Dr Maher).

14 *Submission* 64, p.50 (ARCBS).

15 *Submission* 64, p.50 (ARCBS).

16 *Submission* 54, p.10 (ARCBS).