ADDITIONAL COMMENTS BY SENATOR STEVE HUTCHINS

The Decision to Not Introduce Surrogate Testing for Hepatitis C in Australia

There are thousands of Australians who have acquired hepatitis C as a result of a blood transfusion or receiving a blood product. Each of those people have at least suffered terrible hardship and pain, while some face the possibility of death as a result of their illness. In weighing up the evidence presented to the committee, the effect this illness has had on the individuals concerned must be at the heart of any conclusions drawn.

In deciding whether the relevant authorities made appropriate decisions with regard to the introduction of surrogate testing for hepatitis C in donated blood, the following issues must be considered:

- when the seriousness of non-A, non-B hepatitis was generally accepted by the medical profession;
- how effective surrogate testing is in excluding non-A, non-B hepatitis; and
- whether the deliberative processes of the relevant authorities regarding the implementation of ALT testing were carried out in a comprehensive and expeditious manner.

Concerns have been raised that the inquiry, by its very nature, threatened the quantity of blood available because negative publicity for the Australian Red Cross discourages donors from providing blood. As the Tainted Blood Action Group stated at the hearing in Sydney, the two years (2002 and 2003) when the issue of tainted blood received the greatest media attention coincided with record levels of donations of blood[1] . In other words, fear that findings of this committee would impact upon the future viability of the blood supply are unfounded.

At the heart of any decisions made regarding the implementation of surrogate testing is what appears to have been the ethical balancing act at the time: whether excluding hepatitis C infected blood was worth the exclusion of a certain amount of blood which was actually uninfected.

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[1] Committee Hansard, 6 April 2004, CA 44.

Understanding of hepatitis C

In determining whether the actions of the Australian Red Cross and CSL Ltd were appropriate, it is essential to consider the knowledge of the seriousness of hepatitis C (or non-A, non-B hepatitis). Clearly, one would expect any organisation to introduce measures to prevent the transmission of an illness which was known to be harmful, and which could potentially be life-threatening. As a result, the knowledge of hepatitis C and its impact upon the lives of its victims should be essential to the conclusions of this inquiry.

Professor Burrell, the very first witness to give evidence to the Committee, informed us that in 1974-75 'two key publications identified a percentage of cases of hepatitis after blood transfusion not caused by hepatitis A or hepatitis B'. At the same hearing Professor Burrell gave evidence that the following was known about the infection:

> 'unless the blood recipients were tested for liver function, it would not be evident that they had become infected. It was known that chronic infection occurred in a percentage of these, though the exact rate was not known. It was also known that some of these people remained infectious for a long time. It was also known that there was a link to chronic active hepatitis and to cirrhosis. The proportion of individuals was not known and the time frame was not known.'[2]

So, it was clear from as early as the mid-1970's that an unidentified type of hepatitis was in the blood supply, and that it was detectable through testing for liver function (also known as surrogate or ALT testing). The seriousness of the illness, at least in terms of its longevity and its link to cirrhosis of the liver, were known at the same time. There is no doubt that blood authorities across the world were aware of the same information to which Professor Burrell referred.

Further evidence to the Committee from the Australian Association of Pathology Practices stated that 'by 1987, the problem of hepatitis C was well known. International strategies to reduce the incidence of post transfusion hepatitis caused by NANB in donated blood had been in place internationally since 1984'[3]. By 1986, the threat of hepatitis C was deemed serious enough for the United States Food and Drug Administration to implement mandatory anti-NANB hepatitis strategies. Not until February 1990 did Australia routinely test for hepatitis C in donated blood when the first licensed testing kits became available.

There was clear evidence more than a decade before the introduction of hepatitis C testing in Australia that thousands of Australians were being

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[2] Committee Hansard, 1 April 2004, CA 1.

[3] Australian Association of Pathology Practices, Submission 61, p. 3.

regularly exposed to an illness which can have long-lasting and terrible effects.

The Effectiveness of Surrogate Testing

The evidence presented to the inquiry undoubtedly agreed that, if surrogate testing for hepatitis C had been implemented, the following results, on the balance of probability, would have occurred: a certain amount of hepatitis C infected blood would have been excluded from the blood supply; and a certain amount of hepatitis C free blood would have been mistakenly excluded. In other words, the organisations and governments involved in the National Blood Transfusion Advisory Committee knew that the decision not to implement testing for hepatitis C would result in blood recipients acquiring hepatitis C. That is the essence of this inquiry: whether it was right to keep blood which was known to be infected to preserve the availability of blood which most likely was not infected.

Prior to 1990, the Australian Red Cross Blood Service estimates that the likelihood of risk of hepatitis C, per unit of blood, was 1 in 333. That figure has, thankfully, fallen to less than 1 in 3 million. When ALT testing and anti-Hbc testing was introduced in the United States of America, the risk profile of infection reduced from 5.5% to 4.1% from a transfusion[4]. While the arguments made concerning the higher incidence of hepatitis among donors in the United States are compelling, it would have been foreseeable that the implementation of the same tests in Australia would have reduced the incidence of blood transfused hepatitis C by the same ratio. This is because surrogate testing removes a fixed percentage of infected blood despite the overall level of infected blood in the blood supply. As such, whilst Australia has a safer population and hence a lower overall risk, this means that that overall risk would have been reduced by a similar ratio to a much smaller overall rate of infections.

That means that the 1 in 333 likelihood could have been reduced to 1 in 500 at the higher limit of ALT effectiveness.[5] While, in statistical terms, this may seem insignificant, it would have undoubtedly saved some lives and would have improved the quality of life of hundreds, if not thousands, of people. This would have also meant a net saving by up to 1/3 in the total costs of health care, running possibly into the hundreds of millions, of persons now unfortunately infected with hepatitis C through the blood supply.

The Department of Health and Ageing's submission dismisses the usefulness

[4] Australian Red Cross Blood Service, Submission 64, p. 45.

[5] Australian Red Cross Blood Service, Submission 64, p. 37.

of surrogate testing by stating that it is only as effective in ruling out hepatitis C as using a 'random marker' such as a person's initials[6]. This assertion does not take the cumulative nature of risk associated with exposure to infected blood, as is highlighted in the Australian Red Cross Blood Service's submission, 'For instance, if the risk for a single unit is 1 in 1 million, then receiving a second unit means the cumulative risk to the recipient is 2 in 1 million'[7]. One of the Department's most significant justifications of the decision not to implement surrogate testing is based upon the false premise that each patient only receives one unit of blood. The conclusions based on those calculations are misleading because they fail to focus upon the victims of hepatitis C infection.

The Australian Red Cross Blood Service estimates that 1.5% of all donations would have tested positive using surrogate testing (based on findings in the United States), and that 70% of blood excluded would have, in fact, been the result of a false positive[8]. It is undeniable that the Commonwealth, the States and Territories, the Australian Red Cross Blood Service and CSL were placed in an unenviable position. They were compelled to choose between the quantity of the blood supply and its quality.

The fact that the Queensland Red Cross Blood Transfusion Service, under leadership of Dr Catherine Hyland, chose to implement surrogate testing and that no other Red Cross Blood Transfusion Service chose to demonstrates the difficulty of the question. But it also shows that a blood supply could be maintained and function without the 1.5% of false positive donations. The lesson from Queensland is that other Australian blood services may have been unnecessarily cautious in their protection of the quantity of blood available.

Deliberative Processes

The role of various governments and organisations in providing direction for the collection of and transfusion of blood, prior to 1996, were undoubtedly complex. As far as the Department of Health and Ageing could advise in hearings in Canberra, the Australian Red Cross regularly convened meetings of a national blood transfusion advisory committee, and that committee had representatives from the Red Cross, the Commonwealth and State and Territory governments. Each state Red Cross blood authority made its own decision regarding the implementation of surrogate testing for hepatitis C, but was advised by the national committee. At no stage did the national committee advise that surrogate testing should be implemented, although

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[6] Department of Health and Ageing, Submission 54, p.8.

[7] Australian Red Cross Blood Service, Submission 64, p. 94.

[8] Australian Red Cross Blood Service, Submission 64, p. 30.

Queensland later decided to introduce surrogate testing of its own accord.

The Red Cross commenced a study of the effectiveness of surrogate testing in 1987 (a study into the transfusion rate of hepatitis C was conducted in 1979). So, significantly after knowing the seriousness of the illness and years after the test became available, an Australian study was first instigated. By the time the study was concluded, the first generation test for hepatitis C was on the verge of being widely available.

By international standards, Australia was slow in studying the prospective effectiveness of surrogate testing. In fact, Australia did so at the recommendation of 'experts from the US and Europe'[9]. It would appear that, up until the establishment of that study, Australia relied upon information from overseas, much of which was seen as irrelevant because of differences in the way blood was collected.

Without timely and relevant domestic studies, the true impact of surrogate testing could not have been adequately ascertained.

Conclusions

It is undeniable that thousands of Australians have acquired hepatitis C as a result of receiving a blood transfusion. The seriousness of hepatitis C (or non-A, non-B hepatitis) was known in the early 1980's. By 1978, according to Professor James Mosley, it was well-known that surrogate testing could reduce the incidence of hepatitis C[10]. In fact, he delivered a lecture in Melbourne on this matter, a lecture which representatives of the Australian Red Cross Blood Service attended[11]. Yet Australian blood authorities chose not to recommend that surrogate testing be implemented because its effectiveness was not deemed great enough to justify the exclusion of some blood which returned 'false positive' results to surrogate testing.

A decision had to be made, and no amount of retrospection can replicate the difficulties faced by those people at that time. Nonetheless, it remains that many Australians today suffer from what can become a debilitating illness as a result of the decision not to implement surrogate testing outside Queensland.

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[9] Committee Hansard, 7 April 2004, CA 38.

[10] Professor James W Mosley, Submission 89, p. 1.

[11] Ibid.

If surrogate testing had been introduced, the incidence of post-transfusion hepatitis C would most probably have been reduced from 1 in 333 to 1 in 500. As a statistic the difference is negligible. But the negligible difference has had a profound and sad effect on the lives of thousands of Australians.

The decision not to introduce surrogate testing was what created that effect.

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