



Submission to the Review of Australia's Plasma Fractionation Arrangements

About the Independent Blood Council:

Tainted blood represents one of Australia's worst medical tragedies. In the last three decades, thousands of Australian hospital patients have been infected with Hepatitis C, a potentially life threatening liver disease, from contaminated blood transfusions and blood products.

Caring members of the community help us to provide support to victims of what is not just a medical disaster, but also a human tragedy that has had life changing consequences for many men, women and children.

In addition, the Independent Blood Council is also dedicated to preventing future medical disasters by endeavouring to ensure that the health, therapeutic goods and pharmaceutical sectors operate with the highest regard for public safety.

Ensuring the plasma supply of the future by investigating the past:

In recent years Australia's plasma supply has come under increased scrutiny, due in part to the high rate of Hepatitis C infection among Australia's Haemophilia population. The tainted blood tragedy reminds us that every reasonable measure must be taken in order to secure the safety of this country's blood supply. It is the position of the Independent Blood Council that the safety of the blood supply must be paramount.

Whilst reviewing the future of Australia's plasma sector, urgent attention must be given to some of the safety issues concerning the history of Australia's blood plasma supply.

To what extent has Australia been self sufficient in the supply of plasma? In 2003, the federal health department informed the Australian Senate, via answers to questions on notice, that Australia has not been fully self sufficient in the past for the supply of medical products derived from plasma. The health department advised that this was due to Australian product being insufficient to meet clinical demand, and the fact that there were a small number of products which the Australian company CSL does not manufacture. According to the federal health department, details of actual products imported into Australia are not kept by the Commonwealth government.

One of the biggest scandals regarding tainted blood internationally is what has become known as the US prison blood scandal. The scandal first came to light in the 1990s, when it became known that blood plasma collected from prison inmates in the United States was used in the manufacture of blood products. Blood products processed using these contaminated materials were shipped all over the world by unscrupulous blood brokers and pharmaceutical companies. In the 1980s the American FDA decided that blood plasma collected from prison inmates was unsuitable for therapeutic use in America, as it was known to be unsafe. In 1984 the FDA investigated the prison plasma collection system in the state of Arkansas, which was at the time governed by former US president Bill Clinton, and revoked the operating license for the prison collection programs there. The FDA cited a litany of problems:

- 1. Disqualified donors were allowed to continue to donate.*
- 2. Plasma was inadequately stored, allowing it to be contaminated.*
- 3. Records were altered.*
- 4. There were instances of intentional and wilful disregard of standards.*
- 5. Plasma centre staff were inadequately supervised.*
- 6. People in management positions at the centre attempted to hide the fact that they were either initiating or condoning the destruction or alteration of records concerning these activities.*

However, the FDA did not stop American companies from exporting this product to other countries and notably to its neighbour, Canada. Between 1980 and 1985, over 1,000 haemophiliacs in Canada were exposed to U.S. prison plasma, which was collected from convicts who were known to be at high-risk of carrying hepatitis and, by implication, AIDS. As much as half of the Canadian Haemophilia population that were given plasma products made from this lethal material have died as a result of their consequential infections.

This year the British government admitted that Haemophiliacs were exposed to plasma derived from US prison inmates. A host of other countries in Europe and Asia have also seen their Haemophilia communities exposed to this dangerous material. Worryingly for Australia, in 2004, it was established that New Zealand had imported medical products made from US prison plasma in the 1980's.

The Independent Blood Council has been conducting its own inquiries into whether blood products manufactured using US prison plasma were ever imported into Australia.

Through documents obtained under Freedom of Information we have ascertained that licences to import foreign plasma into Australia were sought in the 1980's.

Given the gravity and possible legal and criminal implications of the matter of US Prison plasma and whether medical products made from this material were ever imported into Australia, the victims of tainted blood and their loved ones ask that this issue be investigated. Did any plasma sourced from the US or Europe enter Australia in the decades prior to 1990? If so, what government bodies or companies were involved in its importation? Was any of this material derived from donated plasma implicated in the US prison blood scandal?

It is only through learning from the past that we can hope to ensure the safety of Australia's blood supply now and into the future. Only on a solid foundation of openness, transparency and accountability may the blood supply's future safety be based.

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