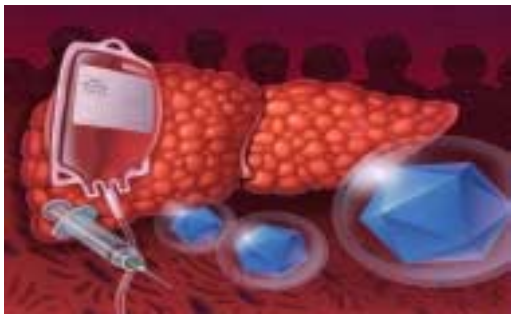
Submission by the

Tainted Blood Product Action Group



To:

SENATE COMMUNITY AFFAIRS REFERENCES COMMITTEE

INQUIRY INTO HEPATITIS C AND BLOOD SUPPLY IN AUSTRALIA

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Contents

1 Executive summary

- Hepatitis C Viral (HCV) infection was a known complication of blood and blood products from the mid 1970s in Australia, and it was well established as a cause of significant symptoms, including progressive liver disease. The outcome in about 10-20% of patients was cirrhosis of the liver and liver cancer. Death was therefore a known complication of this infection.

- In 1974, a study conducted in the United States, the Transfusion Transmitted Viruses Study, followed the progress of 1500 elective surgery patients who had received blood transfusions that were monitored for ALT levels. In 1978, the study concluded that the ALT test could reduce the incidence of HCV in a blood supply by discarding blood donations where the donors had elevated ALT (liver enzyme).

- The Transfusion Transmitted Viruses (TTV) Study's primary investigator, James W. Mosley, visited Australia in 1978 and spoke at a conference of blood bankers. He explained that the ALT test could decrease the number of HCV cases transmitted by blood transfusions. He received a cold reception from members of the Australian Red Cross, who chose to reject Mosley's recommendations to implement ALT testing, preferring to adopt a 'wait and see' approach.

- Choosing not to spare hundreds and perhaps thousands of lives, the Australian Red Cross Blood Service (ARCBS), used obscure, nonsensical reasoning to justify conducting further study and waiting for a more specific test. The desire to place commercial considerations before the primary responsibility of maintaining a safe blood supply, demonstrated a limited regard for the interests of blood transfusion recipients.

- **The Tainted Blood Product Action Group (TBPAG) has been approached by people who claim to have been offered money by the ARCBS in exchange for them signing secrecy clauses**. One such individual was infected by a blood transfusion administered to her while giving birth; tragically her child was also infected during this process. Upon approaching TBPAG she claimed to be frightened of repercussions from the ARCBS should they catch her speaking to other victims, and in particular to a victims' support group. She had been told by lawyers representing the blood service that any attempt to share her story would see her at risk of legal action for breaking her confidentiality clause.

- The division of the Red Cross that manages the blood service today is a business. It may not be widely recognized as such, due to it being registered as a charity, but those that work within it and along side it, know it to be a business. In the last ARCBS annual report executives are reported to receive basic salaries of up to $390,000 p.a. That's more than a lot of executives earn in corporations around Australia; more than many of our key public servants; more than Australia's Prime Minister, John Howard; and certainly significantly more than most charity workers receive.

- Blood is for sale and it *is* massive business. A parallel can be drawn with the oil business when it is considered that: **A barrel of crude oil costs about US$30, while a barrel of plasma can yield products easily worth US$90 000 and much more**.

- Blood has clearly been a big financial concern in Australia over the years. Executives of the ARCBS and CSL are paid handsomely to preside over the responsibilities of the collection and distribution of blood. But the most generous rewards are reserved for the hierarchy of the Australian blood business. This hierarchy truly make millions from the blood business: Brian McNamee (CSL):$5.2 million p.a, Peter Dehart (CSL): $1.4 million p.a, Peter Turner (CSL): $1.2 million p.a, Colin Armit (CSL): $1 million p.a.

- The Australian public have been, and are being, exploited for financial gain by an organisation which intentionally hides behind the humanitarian veil of their corroborator, the ARCBS. It is within this climate and culture that the ARCBS has been distracted by the desire to maintain the volume of the blood supply, to the detriment of what should be their primary focus: the safety and integrity of the blood supply.

- Australians could be forgiven for being perplexed at the contrasting fortunes of the executives of Australia's blood business and the plight of the victims of tainted blood, like the 80% of Australia's Haemophilia population who acquired HCV from blood products manufactured by CSL and distributed by the ARCBS. **Compare this reality with a hypothetical scenario that places another multi-billion dollar company in a similar situation. What would the ramifications be if: The hamburger restaurant, McDonald's, sold burgers contaminated by *Escherichia coli* or *salmonella* and other groups of potentially deadly bacteria, to 80% of its customers?**

- How have the humanitarian organisation, the Australian Red Cross Blood Service, and the now commercial plasma fractionator, CSL, responded to this crisis? By covering up the worst medical calamity in our history and by authorising massive pay increases for the executives who oversaw, and who were responsible for, a blood supply that failed thousands. A blood supply, whose managers wave the banner of humanitarianism, but extend none to the victims of a crisis which they helped create.

- In 1996 CSL admitted that it had mixed Australian blood with blood from several foreign countries for distribution in Australia.

- **'Australia has imported blood products from companies that are known to have dealt in US prison blood. They have dealt in material that was manufactured using blood plasma sourced from US Prison inmates, many of whom were infected with HIV/AIDS and Hepatitis C'.**

- **The Australian Red Cross collected blood from Australian prisons.** Disturbing information has been obtained that the Australian Red Cross collected blood from Australian prison inmates. A 'whistle blower' knew of inmates that had donated blood to the Australian Red Cross. They knew of a former Red Cross Blood Service worker who recalled that mobile blood collection units were sent to Australian prisons.

- What is essential here is that blood donor screening relies on the honesty of the donor in answering screening questions. **It is hard to understand how the Australian Red Cross could decide to place a system based on honesty, with life-and-death repercussions like blood donation, inside a prison. Scientific and medical knowledge in the 1970s was advanced enough to understand the threat of hepatitis and the increased dangers of encouraging and accepting blood donations from prison inmates**.

- **The Australian Red Cross knowingly collected blood from IV drug users**.

- Lookback is a tracing program that tracks contaminated blood. It is a multi-million dollar cooperative undertaken by the Australian Red Cross Blood Service (ARCBS) and the state health departments. **A disturbing result of a recent survey was that 81% of the respondents had never been officially contacted nor offered any medical or support services by the ARCBS**.

- Members of TBPAG know that their criticisms in media interviews of the blood service are all too frequently countered by blood service press releases claiming chronic shortages in the blood supply. It is the view of members of TBPAG that this is a convenient and dishonest strategy utilized by the blood service to counter their concerns about the Hepatitis C issue. TPBAG is of the view, which is reflected by blood services around the world, that the safety and availability of the blood supply are not mutually exclusive positions. TBPAG believes that blood donation is extremely important. Blood donors are true life savers.

- The deliberate and unfeeling denial of the Hepatitis C contamination issue by the Australian Red Cross was fully realised in a pivotal statement made on ABC radio on July 1 2002, by the chairman of the donor and product safety committee of the Australian Red Cross Blood Service, Tony Keller. He responded to the Hepatitis C controversy surrounding the blood service's policy of deliberately mixing donations from infected donors into the blood supply in 1990 by saying: ***"Nobody knew what the hepatitis C virus was or what it did."*** One would expect that such acknowledged ignorance would have warranted a careful, rather than a complacent approach.

- The studies conducted by the Australian Red Cross into surrogate testing need to be made public. It is only then that a perceived culture of secrecy can give way to the admirable, but as yet unrealised, objectives set out in the ARCBS's own mission statement: transparency and accountability.

- In the last three decades thousands of Australian hospital patients have been infected with the deadly virus Hepatitis C from contaminated blood transfusions and blood products. Victims of this tragedy include adults, children, accident victims, the sick, the anaemic, pregnant women, and those having had elective surgery. They have not been isolated to the acutely ill who would have died without an urgent transfusion. While this is a medical disaster, it is in essence, first and foremost, a human tragedy that has destroyed the lives of many men, women and children.

2 TERMS OF REFERENCE

On 19 August 2003 the Senate referred the following matters to the Senate Community Affairs References Committee for inquiry and report by the first sitting day of the 2004 winter session:

(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.

3 The history of post transfusion Hepatitis in Australia: The failure to screen blood donations

The Australian Red Cross Blood Service (ARCBS), including its previous state run incarnations prior to 1996, have long been aware of the threat that Hepatitis C (or non -A, non -B Hepatitis or NANB as it was known prior to 1989) posed to the Australian blood supply.

Hepatitis C Viral (HCV) infection was a known complication of blood and blood products from the mid 1970s in Australia. In fact it was well established by 1975 that HCV was a cause of significant symptoms (See case study below). It was also a cause of progressive liver disease. The outcome in about 10-20% of patients was cirrhosis of the liver and liver cancer. Death was therefore a known complication of this infection.

Since the 1950's physicians around the world have employed a diagnostic known as the alanine aminotransferase (ALT) test to determine liver damage in patients. The ALT test is essentially a measure of a liver enzyme. Simply, increased expression of these liver enzymes commonly represent liver dysfunction and increased potential for liver damage. In the early 1970s responsible blood banks in Austria and Germany utilized the ALT test as a means to screen their respective blood supplies for Hepatitis, as by definition the liver is the organ that the hepatitis viruses target.

3.1 The Transfusion Transmitted Viruses Study

In 1974, a study conducted in the United States, known as the Transfusion Transmitted Viruses Study (RD Aach et al. New England Journal of Medicine 1981: vol 304, pp989-994) followed the progress of 1500 elective surgery patients who had received blood transfusions that were monitored for ALT levels. The patients enrolled in the survey had their blood tested over a period of time to ascertain whether they had developed signs of what was then known as Non -A, Non- B Hepatitis. In 1978, the study concluded that the ALT test could reduce the incidence of HCV in a blood supply by discarding blood donations where the donors had elevated ALT (liver enzyme).

The Transfusion Transmitted Viruses (TTV) Study's primary investigator, James W. Mosley, visited Australia in 1978 and spoke at a conference of blood bankers. He explained that the preliminary findings of the TTV study had found that the ALT test could decrease the number of HCV cases transmitted by blood transfusions. He received a cold reception from members of the Australian Red Cross. The blood service, even though it was by now alerted to the problem of HCV infecting blood recipients, chose to reject Mosley's recommendations to implement ALT testing, preferring to adopt a 'wait and see' approach.

In January 1981 in the Unites States, a group of blood banking officials gathered together to discuss the merits of ALT testing and its potential to screen the American blood supply for HCV. The group included a top FDA blood expert, a pioneering HCV researcher at the National Institutes of Health, and representatives of the American Association of Blood Banks, the Red Cross and the Council of Community Blood Centres. In November 2003, an American newspaper, the Kansas City Star, published an extensive investigation into the 1981 meeting, where it reported:

Documents from the meeting show the 1981 group reached several conclusions:

• ALT testing would decrease the number of patients who got infected, based on at least two studies. The participants "agreed that there was evidence that the introduction of ALT testing would reduce the incidence of post-transfusion non-A, non-B hepatitis."

• Evidence for the test was so strong, in fact, that it would no longer be possible to conduct studies in which patients received blood known to have high ALT levels. Participants at the meeting agreed that such studies would no longer be ethical.

• Much needed to be done before testing could begin. The group appointed a working committee to sort through such issues as how to make testing consistent and what to tell donors who have high-ALT blood.

The blood industry would also have to address the loss of up to 3 percent of donors, including many who were not actually infected but tested positive nonetheless. But that shouldn't stand in the way of testing, said Alfred J. Katz, a blood centre director who soon would become executive director of the Red Cross Blood Services.

A week after the January 1981 meeting Katz wrote to a colleague:

"This concern did not outweigh the medical, scientific, ethical, legal, and public relations judgment that it was incumbent upon us to prepare to implement ALT as a donor screening procedure, in order to decrease NANB (non-A, non-B) hepatitis in recipients."

(See Reference 'A' for full Kansas City Star story).

In the early 1980s the Australian Red Cross reported on a study of its own. This time it was an investigation into another way of screening the blood supply for markers for HCV. The findings of the study were published in a letter to the prestigious medical journal, *The Lancet*, in January 1982 (Cossart YE, Kirsch S, Ismay SL. Lancet 1982 Jan 23;1(8265):208-13). The study reported on the potential of a marker for Hepatitis known as hepatitis B core antigen test (anti-HBc). It concluded that the rejection of blood with markers of past exposure to hepatitis B may reduce the incidence of post-transfusion non-A, non-B hepatitis from blood transfusion by up to half (See Reference 'B').

By 1982 the New York Centre for blood transfusion in the United States had already employed the ALT test as a means to screen their blood supply for Hepatitis viruses.

In 1986 the American Food & Drug Administration's (FDA) blood products advisory committee recommended that all blood donations in the United States be tested for both ALT and anti-HBc as surrogate tests for non-A, non-B Hepatitis.

3.2 State of inconsistency: Queensland Red Cross addresses the blood crisis

In Australia by 1988 the Queensland Red Cross blood transfusion service decided that the blood supply in their state could no longer hold off on the screening of its blood supply for Hepatitis C. In a letter to the medical Journal, *Pathology*, (July, 1988, vol 20, pp 271–4) Dr

Catherine Hyland, of the Queensland Red Cross Blood Transfusion Service, reported the following:

"In the current social climate, the introduction of another screening test for a viral marker has clear medico legal implications. These rest on the need for a transfusion service to be seen to maintain a safe blood supply that has been tested according to the highest acceptable professional standard, and to be able to defend a claim of negligence. However, the need to screen blood donations for ALT is currently debated within Australia because of the absence of a specific diagnostic test for post-transfusion NANB, and the paucity of data concerning this disease in the Australian population.

The recent judgement in a legal suit that concerned the Queensland Red Cross Blood Transfusion Service has indicated that, provided the transfusion service is implementing screening procedures appropriate to published professional knowledge at the time of transfusion, there should not be a case for negligence at law.
In the light of this experience, and given the development of an assay that is cheap and convenient, it was decided that concern regarding chronic effects of NANB hepatitis transmission outweighed the arguments against implementation of surrogate testing.

In conclusion, the method adopted for ALT screening using microtitration trays as reactant vessels is extremely convenient for a routine blood transfusion service. It allows formulation of computer generated work sheets and handling of the work load in a manner analogous to the routine microtitre enzyme-linked immunosorbent assays (ELISA) used in screening tests for other viral markers. ***Furthermore, the total cost is less than $0.05 (Australian) per test and, therefore, it is our view that arguments against the introduction of such surrogate non –A, non –B testing on the basis of economic constraint are not valid."*** (My emphasis.)

3.3 The response of the Australian Red Cross to the HCV crisis

The Australian Red Cross Blood Service and its state run bodies in the 1980s elected not to implement any kind of blood screening for HCV (with the exception of Queensland in 1988). By 1986 blood banks in America and other European blood centres had implemented all available screening for HCV. The Australian reaction in the main was to wait for a test that was specific in screening for the virus and therefore more accurate than the two available surrogate tests for HCV, which were reported at the time as being able to reduce the incidence of HCV by more than 50%, with a loss to the donor pool of only 3% of blood donors. Given that the Queensland Red Cross had already published that the failure to implement appropriate testing could result in negligence at law it is intriguing why the other states did not follow suit.

Over time officials from the Australian Red Cross Blood Transfusion Service have given differing reasons as to why surrogate testing was not employed to screen the blood supply. One of the arguments put forward is that Australia had a voluntary donation service, which meant that blood donors would donate blood for the good of the community rather than for financial reward. The rate of Hepatitis C was lower in a voluntary donation pool than in one that paid for donations like in the United States. It was estimated that the rate of post transfusion hepatitis in Australia was 2% per unit transfused. It is this inconsistency between blood services of the same Australian donor pool that is inexplicable. This is now more relevant when it is considered that other countries with a voluntary donation system that chose not to employ surrogate testing have since been proven to be negligent.

3.4 Accountability overseas: Canadian Red Cross criminally charged

Canada had a voluntary donation system. This difference did not change the fact that a Canadian Royal Commission (the Krever Report) in the 1990s found that the Canadian Red Cross had been negligent in not introducing surrogate testing to minimise the threat that Hepatitis C posed to their blood supply. On November, 26, 1997, the head of Canada's Commission of Inquiry, Justice Horace Krever, damned the Canadian Red Cross. He named individuals who were central to the tainted blood tragedy, which left tens of thousands of Canadians contaminated with Hepatitis C. The Canadian government's response to this negligence was to make C$1.2 Billion available in compensation to the thousands of victims of this negligence.

The Royal Canadian Mounted Police (RCMP) Blood Task Force was established just months after the release of the Krever inquiry's final report on the Canadian blood system. In his report Krever made 50 recommendations, but did not assign criminal liability. That was left up to the RCMP task force.

In their investigation, launched on Feb. 12, 1998, police conducted more than 700 interviews and reviewed several million documents. They set up a national toll-free line to encourage people to provide them with more information.

Investigators travelled to Australia and other countries including the United States, Costa Rica, France, Britain, Switzerland, and Belgium.

On November, 20, 2002, the RCMP Blood Task Force, after a five-year investigation, laid charges against the Canadian Red Cross for not introducing 'ALT' testing to screen for Hepatitis C, they included criminal negligence causing bodily harm. There were also charges of common nuisance by endangering the public and one charge of failure to notify under the Food and Drugs Act Regulations.

Superintendent Rod Knecht of the RCMP Blood Task Force said at a press conference, that the charges related "to decision-making within the structures and systems of the blood distribution system in Canada between the years 1980 and 1990."

"The responsibility of the RCMP as Canada's national police service is to ensure safe homes and safe communities," said Knecht. "The RCMP Blood Task Force was to gather the facts on behalf of the Canadian public, and to lay criminal charges if the evidence supported reasonable grounds that a criminal offence had occurred."

"The charges we have announced today reflect the fact that our investigation has met the requirements to lay these particular charges," Knecht added.

3.5 1999: The Australian Capital Territory establish a compensation fund

In 1999, the Australian Capital Territory (ACT) established a government compensation fund for people in their territory who had received HCV contaminated blood transfusions between the years 1985-1990. Michael Moore, the ACT minister for Health and Community Care, gave the following explanations as to why the fund was created (ACT Legislative Assembly March 1999):

The hepatitis C virus was first discovered in 1989. However, the existence of a form of hepatitis which was neither Hepatitis A nor Hepatitis B was known for at least twenty years before this. It was also known that this form of hepatitis occurred relatively commonly after blood transfusion.

In 1985 medical specialists started to collect more information on this Non-A Non B Hepatitis and its relationship to blood transfusions. Therefore from 1985, the blood banks in the United States began screening donors for liver disease using a nonspecific liver enzyme test (ALT) in order to reduce the prevalence of Hepatitis C in the donor pool and thereby prevent transmission to the transfusion recipient. In Australia, the Queensland Red Cross Blood Bank was the only blood bank to introduce this screening test in donors. It is assumed, that if the ACT Red Cross Blood Bank had introduced ALT testing at the same time as in Queensland, the risk of transmission of Hepatitis C may have been reduced. Once Hepatitis C was discovered then preliminary testing was introduced, although at times even these tests were inaccurate.

The failure of all Australian States, except Queensland, to introduce ALT testing for all blood donors may have created a situation where the Red Cross Blood Service in those states is legally liable to pay compensation.

Where a person who is now hepatitis C positive was transfused with blood from a hepatitis C positive donor between 1985 and 1990 and where it is more probable than not that the blood transfusion was the source of infection, then that person is eligible for financial assistance;

· that the amount of financial assistance should be based on the impact that the disease has had on the person's health and life;

· that the cost of litigation over Hepatitis C transmitted by blood transfusion, both to Government, the Red Cross and litigants be minimised.

All persons who believe that they are eligible for compensation are first referred for independent legal advice. Once details of the case are known, the Lookback will commence to determine if the donor is in fact Hepatitis C positive. The process of financial settlements also requires a number of specialists tests to be undertaken to assess the clinical condition of patients and the establishment of a causative link between the infection with Hepatitis C and a previous transfusion. Additional investigation needs to be undertaken in relation to the substantiation of loss of earnings and for quality of life and life expectancy estimates for patients. This is consistent with normal legal practice in ascertaining settlement sums. If a causative link has been established, the ACT Government Solicitor will attempt to negotiate settlements with the plaintiff's solicitor in all cases.

Financial arrangements in association with Hepatitis C infection are difficult to quantify, however, the Department has estimated a potential outlay of $8.7million over two years. This figure is the worst case scenario and would have to include substantial loss of earnings for some of the individuals affected. As the Commonwealth jointly funds the Red Cross Blood Service in each state, it has agreed to contribute 40% of legal settlement costs. In the ACT it is unlikely that any settlements will be agreed before July 1999. In other States the experience is that settlements so far have been between $20,000 and $60,000 for each individual. However, where loss of earnings can be proved, this can result in a substantial settlement. One case currently being negotiated in another state is in the order of $1m- $1.2m.

It is again not clear why different states and territories have approached this matter of negligence in such disparate fashions.

3.6 The Australian Red Cross: Dr Gordon Archer purports that Hepatitis C is extremely mild

One of the most succinct explanations on the Australian Red Cross Blood Service's rejection of surrogate testing came from the former director of the NSW Red Cross Blood Transfusion Service, Dr Gordon Archer, on channel Nine's the *Sunday* programme, which aired on the 10th of November 2002 (See Reference 'C'). Dr Gordon Archer gave the following explanations in this transcript of his interview:

DR GORDON ARCHER, FORMER DIRECTOR NSW RED CROSS BLOOD SERVICE: "*The incidence of Hepatitis following blood transfusion was very very much less in Australia than it was in America and also, at that time, the disease was agreed by everybody to be extremely mild."*

REPORTER: "*Dr Gordon Archer was director of the NSW Blood Service up until the early 1990s. He was just one of a number of senior health decision-makers on blood issues in the mid- to late-1980s."*

DR GORDON ARCHER: "*1986 we had the feeling that Australia didn't have the problem as they did in America and that maybe surrogate testing may not be any use. So the decision was made rather than introduce an ALT testing at that time, maybe we should do another post-transfusion Hepatitis study."*

REPORTER: "*Was there a worry about losing donations?"*

DR GORDON ARCHER: "*Of course there was, because it was just at the end of the AIDS time and we were extremely short of blood."*

REPORTER: "*So I guess what you're saying is it's really a constant juggle between the need to have blood but the need to reject some blood because it might be carrying a virus?"*

DR GORDON ARCHER: "*That's right. That's the position at that time."*

REPORTER: "*The study took almost four years. So did that show that if you had done an ALT surrogate test on those donors, you may have prevented Hepatitis C infections in three of the four cases?"*

DR GORDON ARCHER: "*I'm not going to answer that question, that's an unfair question."*

REPORTER: "*Why is that? I'm just trying to say what did that show about the value of ALT tests?"*

DR GORDON ARCHER: "*No, I can't answer that question. I can't. You can't lob that on me."*

REPORTER: "*The ALT tests...*"

DR GORDON ARCHER: "*What you're trying to get me to say is that we should have been ALT screening and I honestly don't believe that. I think we had to do the survey and what we would have decided after the survey was finished, who knows? You know, you could predict that you might, but who knows?"*

ANDREW GRECH (Lawyer for plaintiffs): "*That judgment was wrong. The clear evidence is they had an opportunity to prevent people from being infected with Hepatitis C and they made, in my belief, a genuine but nonetheless wrong decision not to introduce those tests, and as a result of that decision, hundreds and potentially thousands of Australians have been infected when potentially their infections could have been avoided."*

REPORTER: "*Do you think you and other health senior managers have to wear some responsibility for those people having got Hepatitis C through blood transfusions?"*

DR GORDON ARCHER: "*That's an unfair question to me. I'll answer it strongly no. I think we had the interests of our donors and the interests of our patients at heart and we tried to do the best thing we could."*

Dr Gordon Archer's assertion on the *Sunday* programme that Hepatitis C in 1986 was 'agreed by everybody to be extremely mild', does not reflect the medical opinion of the time. Hepatitis C had been considered internationally to be a chronic and deadly disease from the mid 1970s. In the *Sunday* interview, Dr Archer also explained the reason surrogate testing was not implemented: he stated that 'Australia didn't have the problem as they did in America and that maybe surrogate testing may not be any use'. His views on this can only be judged on what constitutes a 'problem' for the blood service in Australia. The Tainted Blood Product Action Group (TBPAG) has members who were diagnosed in the early 1980s as having acquired post transfusion Hepatitis C (or non-A, non-B Hepatitis). The blood services were well aware of infections occurring from blood transfusion from the 1970s. In fact, Hepatitis C was the most common serious complication of blood transfusion at that time.

What then, constitutes a problem? Hundreds of people were infected with a chronic and persistent virus, which is frequently life threatening: would this not have been a problem worth preventing? What of the problem of costs to the state for Hepatitis C contaminated blood? What are the ramifications of Dr Archer ignoring this problem and not introducing screening? The need to provide sickness benefits and increased health care to victims. The extra burden on liver transplantation lists as HCV is the most common reason for liver transplantation in Australia. And what of the costs to the humanitarian principles of the Red Cross? Choosing not to spare hundreds and perhaps thousands of lives, they used obscure, nonsensical reasoning to justify conducting further study and waiting for a more specific test. (This meant in effect that nothing was done to address the immediate threat of HCV in the blood supply, in spite of awareness of the more cautious approaches taken by blood officials from countries such as the US.) The desire to place commercial considerations before the primary responsibility of maintaining a safe blood supply, demonstrated a limited regard for the interests of blood transfusion recipients. (Commercial considerations may be defined as the costs of implementing surrogate testing, and more significantly, a *temporary* reduction in the volume of blood on which state funded products were based.)

4 Secret compensation schemes: Money in exchange for silence

In recent years a number of victims of Hepatitis C have been compensated by the ARCBS in Australia. These compensation schemes have been shrouded in secrecy. No Hepatitis C matter has ever made it to a full court judgment. Matters have either been withdrawn, or the ARCBS and the Commonwealth government have resolved them out of court. What is known about Hepatitis C compensation is that the Melbourne based legal firm, Slater & Gordon, has achieved compensation for hundreds of victims outside of court. In the majority of these cases *Slater & Gordon* acted on behalf of people who had acquired HCV from fresh blood transfusions (not Haemophiliacs with HCV) between the years 1986-1990.

A small number of tainted blood victims have been infected outside of the temporal window of 1986-1990. The majority of people infected outside of these years have received no compensation at all from the ARCBS, while some who were infected outside this time frame have been. The full reasons for why some people are compensated and others are not is unclear. The Tainted Blood Product Action Group (TBPAG) has been approached by people who claim to have been offered money by the ARCBS in exchange for them signing secrecy clauses. One such individual was infected by a blood transfusion administered to her while giving birth; tragically her child was also infected during this process. Upon approaching TBPAG she claimed to be frightened of repercussions from the ARCBS should they catch her speaking to other victims, and in particular to a victims' support group. She had been told by lawyers representing the blood service that any attempt to share her story would see her at risk of legal action for breaking her confidentiality clause. This, all because she had signed a secrecy clause in exchange for cash. The amount she had been given was paltry, given that she had the virus herself, and that her child was also coping with being infected with the disease.

In the interests of protecting her identity, it is not possible for her name or any of her personal details to be revealed. However the wording of the secrecy clause that she signed is given below:

DEED

The Releasor is a Claimant pursuant to the "Standard Proposal" entered into by the Releasee to compensate certain recipients of blood transfusion acquired HCV infection and to resolve any claims against the Releasee for damages for personal inuries and other loss arising from the Releasee's provision of blood and/or blood products for the Releasor.
The Releasee denies that the claim is due to any breach of contract or negligence on its part, or on the part of its servants or agents, and it denies that it is liable in any manner to the Releasor in respect of the claim.

The Releasor hereby RELEASES AND FOREVER DISCHARGES the Releasee, its servants, agents, successors and assigns from all actions, suits proceedings, causes of action, costs, claims and demands whatsoever present and future which the Releasor now or at any time hereafter may have or which but for the execution of this Deed might have has against the Releasee, its servants, agents, successors or assigns for or in respect of any matter or thing in any way arising out of the claim or in any way connected with the facts or circumstances giving rise to the claim

The Releasor further releases and forever discharges any Area Health Service responsible for collecting the blood/blood products, any hospital at which the blood/blood products was administered to the Releasor an/or any medical practitioner involved in the administration of the blood/blood products referred to from all actions, suits, proceedings, causes of action, costs, claims and demands whatsoever present and future which the Releasor now has or at any time hereafter may have or which for the execution of this Deed might have had against such Area Health Services, Hospitals and or medical practitioners for or in respect of any matter or thing in any way connected with the claim or the Releasor's acquired HCV infection.

Denial of Liability and bar to suit

The consideration is given with an express denial of liability by the Releasee, solely for the purpose of avoiding litigation,

The agreement may be pleaded by the Releasee in bar to any action, suit, claim, demand, indemnity or other proceedings now or hereafter commenced by the Releasor, his/her heirs, or relations.

INDEMNITY
The Releasor hereby indemnifies and agrees to forever indemnify the Releasee, its servants, agents etc. Against all actions, suits, proceedings, causes of action, costs, claims and demands now made or which hereafter may be made against the Releasee or which the Releasee may be liable to pay pursuant to any legislation either to the State of NSW or of the Commonwealth in respect of any of the matters the subject of the claim.

CONFIDIENTIALITY
The Releasor agrees for the Releasor and members of the Releasor's family not to disclose the Terms of Settlement herein or any part thereof or any details of the claim, or any of the matters giving rise to this claim to any person other then to members of the Releasor's family and in particular, either directly or indirectly, to the media including press, radio or television.

4.1 The terms of silence

Within the terms of this confidentiality agreement it is stated that the releasor (the victim) and members of their family not disclose the terms of settlement, or any details of their Hepatitis C claim. It makes a special point to demand that the victim not disclose the full nature of the tragic circumstances that surrounded their infection to the media, including press, radio and television.

5 The great misnomer: That blood is not business

One of the great misnomers about the Australian blood supply is that it is run by charitable institutions with humanitarianism at its core. It is the case that Australian blood donors give their blood freely; they exhibit true altruism. But the managers of Australia's blood supply do not operate with the sole motivation of freely giving to the community. The Australian Red Cross Blood Service (ARCBS) has over many decades successfully used the symbol of the Red Cross to promote the idea of humanitarianism, and Australians have responded positively to a blood service with this kind of marketing. It could be argued that without the symbol of the Red Cross the blood service might find it more difficult to encourage blood donation. Since the First World War the symbol of the Red Cross has held a special place in Australian hearts. And for good reason. But its modern incarnation is a very different organisation to the one that began in the early part of the 20th Century.

The division of the Red Cross that manages the blood service today is a business. It may not be widely recognized as such, due to it being registered as a charity, but those that work within it and along side it, know it to be a business. Big business. In the last ARCBS annual report executives are reported to receive basic salaries of up to $390 000p.a. That's more than a lot of executives earn in corporations around Australia; more than many of our key public servants; more than Australia's Prime Minister, John Howard; and certainly significantly more than most charity workers receive.

In recent times it has been reported by sections of the media that the Red Cross sells blood to commercial organizations. Semantic manipulation and renaming by their accountants see this described as 'cost recovery', but closer scrutiny reveals that this is blood for sale. Blood is for sale and it *is* massive business. A parallel can be drawn with the oil business when it is considered that: A barrel of crude oil costs about US$30, while a barrel of plasma can yield products easily worth US$90 000 and much more. The blood and plasma industry is as international as oil, with the Red Cross and CSL in the role of a cartel.

5.1 The Australian Red Cross: The shop front of big business

Dr Brian McNamee, the chief executive of CSL (formerly known as the Commonwealth Serum Laboratories), knows the blood business intimately. He was with the government controlled Commonwealth Serum Laboratories back in 1990. Making millions of dollars in the process, he presided over the organization as it became a publicly listed company. CSL is now a multi-billion-dollar colossus of the world blood business. It is predicted that CSL will become the world's largest manufacturer of blood plasma products, with its pending acquisition of the Franco – German pharmaceutical group, Aventis, which CSL intends to purchase for US$925 million. This latest acquisition comes close on the heels of CSL's purchase of the blood products manufacturer, ZLB, from the Swiss Red Cross for AUD$1 billion in 2000.

Over the years CSL has enjoyed a long and prosperous business relationship with the Red Cross in Australia. Indeed many Red Cross staff have ended up working for CSL, and vice versa. To many the ARCBS is the shop front of CSL. The symbol of the Red Cross gets donors through the door, and CSL makes medical products, behind the scenes, from that donated blood. Significant amounts of money changes hands in the process. In a very honest address to an international conference hosted by the National Blood Safety Council of Canada in March of 2001, Brian McNamee described the process (See Reference 'D').

DR. McNAMEE: *"You see, the reality is the Red Cross is a franchise and is a retailer. It has actually got to be out there in the marketplace. This is really new thinking within the Red Cross, that they have to use their brand, they have to use their image and they have to be a much better marketer to get people in."*

On the process of blood money, Brian McNamee informed guests at the conference of the following:

DR. McNAMEE: "*I think there are two separate issues. One is that we in the Australian Red Cross, particularly for the Australian Red Cross, accept that they should have a baseload funding for their infrastructure but should be paid on performance in a marginal sense. So if they achieve targets then they actually get more funds to invest into the things they want to do. So it's a mix for the Red Cross."*

Dr McNamee described the strategy of secrecy that is used to maintain the unquestioning confidence of the altruistic Australian blood donor:

DR. McNAMEE: *"Actually, the whole strategy is to keep us hidden to some degree - that we provide a service for the government, the Australian Red Cross - because there is a concern that the voluntary donor system would be troubled if a greedy commercial fractionator was seen to be profiting from their donations. So, in essence, we stay way below the radar in Australia. It is not a positive."*

The Australian public have been, and are being, exploited for financial gain by an organisation which intentionally hides behind the humanitarian veil of their corroborator, the ARCBS. It is within this climate and culture that the ARCBS has been distracted by the desire to maintain the volume of the blood supply, to the detriment of what should be their primary focus: the safety and integrity of the blood supply.

5.2 Australian blood barons making millions

Blood has clearly been a big financial concern in Australia over the years. Blood barons, like the executives of the ARCBS and CSL are paid handsomely to preside over the responsibilities of the collection and distribution of blood. But the most generous rewards are reserved for the hierarchy of the Australian blood business. This hierarchy truly make millions from the blood business:

Brian McNamee (CSL): $5.2 million p.a
Peter Dehart (CSL): $1.4 million p.a
Peter Turner (CSL): $1.2 million p.a
Colin Armit (CSL): $1 million p.a

Perhaps the blood executive with the most to smile about would be Brian McNamee, for not only is this former public servant now on a multi-million dollar salary, but in 1994, he made millions from the float of the Commonwealth Serum Laboratories. The Australian Financial Review describes McNamee as the only manager of a privatised public company to make serious money out of a float. With financial windfalls like this, Brian McNamee and his colleagues in Australia's blood business are undoubtedly the envy of business executives around the world.

6 CSL infects 80% of its core customers with HCV

Those who require blood and blood products in Australia include adults, children, accident victims, the sick, the anaemic, the pregnant, and those having elective surgery etc. These people, who are the main customers of Australia's blood business, are not just the acutely ill who would die without an urgent transfusion. Australians with the blood disorder Haemophilia are the core customers of CSL. CSL is Australia's sole fractionator of blood products made to treat this condition. Over the years Australian Haemophiliacs have been devastated by the delivery of contaminated blood. In the 1980s HIV was passed on through medical products to unsuspecting Haemophiliacs. A significant number of whom went on to die from the development of AIDS as a result. But another virus was also contaminating the Haemophilia population in Australia before and after the advent of HIV/AIDS contamination of the blood supply. That virus was Hepatitis C (HCV). For those Haemophiliacs who survived the AIDS crisis (many of whom are living with HIV today), they were to face the terrible consequences of Hepatitis C as well. Many Haemophiliacs in Australia are co-infected with HIV and HCV. In Australia 80% of Haemophiliacs have been exposed to HCV via blood products administered to them.

While the managers of Australia's blood supply go on to enjoy financial rewards beyond most people's wildest expectations, their core customers are literally fighting for their lives, coping with the aftermath of the worst medical disaster in Australian history: Tainted blood. Australians could be forgiven for being perplexed at the contrasting fortunes of the executives of Australia's blood business and the plight of the victims of tainted blood, like the 80% of Australia's Haemophilia population who acquired HCV from blood products manufactured by CSL and distributed by the ARCBS.

Compare this reality with a hypothetical scenario that places another multi-billion dollar company in a similar situation. What would the ramifications be if:

The hamburger restaurant, McDonald's, sold burgers contaminated by *Escherichia coli* or *salmonella* and other groups of potentially deadly bacteria, to 80% of its customers?

In this hypothetical scenario the health authorities would act to contain the crisis. McDonald's, in the interests of preserving their business and their good name, would call internal investigations. There would be a public outcry. Affected customers would be admitted to hospitals in their droves. Deaths would occur. Legal action would ensue. Reports of the event would cram the airwaves. Front page headlines would adorn every major newspaper. McDonald's would dismiss staff found to have been lax in food preparation standards. Criminal investigations would be entered into. These are the hypothetical outcomes of such a disaster. None of them are certain. But perhaps one thing is more logically certain: The company in this scenario would experience a down turn in fortunes. Their company may even be forced out of business through a lack of clientele. Certainly it is logical to assume that the managers of this company would not go on to enjoy multi-million dollar pay increases. They would not have the temerity to make insensitive remarks about the underhanded way in which they dupe the public, or the true secretive nature of their business and how it is run.

It is reasonable to suggest that we would not accept this kind of performance from a fast food chain. We would shut them down, either through legal means or a refusal of custom. Yet we accept this kind of performance from a manufacturer of medical products like CSL. A very

sad fact for Haemophiliacs and other hospital patients in Australia is that unlike disgruntled customers of a fast food chain, they cannot simply take their custom elsewhere. The CSL and the ARCBS have a monopoly over the blood supply in Australia. Patients who need blood and blood products have no choice. They are forced to accept that the managers of Australia's blood supply are the ARCBS and CSL.

The crisis of Hepatitis C contamination of the Australian blood supply is real. It has occurred. Thousands of Australians are infected. Hundreds have died. Hundreds are gravely ill. 80% of Australians with Haemophilia have been hit by Hepatitis C from contaminated products delivered by CSL.

Suffering of the greatest magnitude is being endured by people whose only mistake was to place their faith in the managers of Australia's blood supply. How have our authorities responded to this crisis? How have the humanitarian organisation, the Australian Red Cross Blood Service, and the now commercial plasma fractionator, CSL, responded to this crisis? By covering up the worst medical calamity in our history and by authorising massive pay increases for the executives who oversaw, and who were responsible for, a blood supply that failed thousands. A blood supply, whose managers wave the banner of humanitarianism, but extend none to the victims of a crisis which they helped create.

7 Foreign blood importation

The self sufficiency of Australia's blood supply is a myth. In 1994, Senator John Coulter of the Democrats helped to expose this myth, when he raised attention to the blood products manufacturer, CSL, bringing in foreign sourced blood for mixing into the Australian blood supply. Senator Coulter told the Senate (18 October, 1994 Hansard):

That the Senate take note of the answer given by the Minister for Trade (Senator McMullan), to a question without notice asked by Senator Coulter on 12 October week, relating to blood supply products distributed by the Commonwealth Serum Laboratories.

Senator Cook said today that an indemnity had indeed been given with respect to the documents covering the sale of CSL and that that indemnity covered plasma which had been mixed from sources from Australia and, in this case, from Papua New Guinea. The background to the question is that, while the incidence of hepatitis infection in Australia in the general community is about one in 500, the incidence of hepatitis infection among those who have received CSL products and are suffering from haemophilia is over 80 per cent. Over 80 per cent of the 1,600 haemophilia sufferers are so infected.

The relevance of this to CSL lies in two observations. One is that there is on the record—and I have already drawn attention to this—a letter from CSL dated 1986 in which CSL admits that it was mixing plasma not only from Australia and New Zealand but also from Papua New Guinea, from Pacific islands and from South-East Asia. So concerned was the Australian Red Cross about this practice that the Australian Red Cross wrote to CSL asking it to desist from this practice. The Red Cross had had legal advice that it could not therefore guarantee the safety of CSL products, which the Red Cross itself was then using to treat patients with a variety of diseases, including haemophilia.

CSL refused to comply with the request from the Red Cross and continued with the practice—as far as we are aware—until December 1992. There is a letter in existence—to which I have also drawn attention—in which the Red Cross said that it would therefore, on legal advice, refuse to continue with the use of CSL products.

The minister has replied that the government gave an indemnity to the purchasers of CSL, when CSL was privatised, with respect to plasma from Papua New Guinea but not from these other countries. Also, the prospectus did not, when CSL was sold, give any information to prospective buyers of CSL shares that CSL had been mixing plasma from these other sources.

The other bit of information relevant here is that there is considerable evidence that plasma from Hong Kong was heavily contaminated with hepatitis C and that the pooled plasma from Hong Kong was not tested for it. As CSL said, hepatitis C infection was endemic in Hong Kong, so it assumed that all the blood plasma would be contaminated. But donors of blood in Hong Kong were not tested before the samples were taken. Here we have a clear link between the mixing of these plasmas by CSL and the real possibility that the infection rate is so high in haemophilia sufferers in Australia because they have been treated with a contaminated CSL product.

I conclude by pointing out that, although this information is in the record as a result of the two questions I have asked and the two short speeches I have made taking note of answers, the media seem rather uninterested in taking up this matter. It seems that either the government or CSL or both are attempting to disparage the status of Catherine Beauchamp, the author of Red Alert, by spreading stories that she is against blood transfusions, which she is not, or that she has fabricated the letters to which I have drawn attention, which I believe she has not. It seems that the government or CSL or both are very worried about the effect of these revelations on the possible value of CSL.

7.1 CSL admits overseas blood is mixed into the blood supply

In 1996 CSL admitted that it had mixed Australian blood with blood from several foreign countries for distribution in Australia. In 1999 the Australian National Audit Office released a report entitled, Commonwealth Management and Regulation of Plasma Fractionation (See Audit Office site at www.anao.gov.au).The Auditor-General reported that, in October 1998, a Health Department officer on a visit to the US discovered that CSL had breached safety regulations by importing and processing plasma from at least one US source without the Health Department's knowledge and without submitting the records of the plasma importation.

Following this discovery, Health Department officials raided CSL's Broadmeadows facility on November 24, 1998. They confirmed that breaches of safety protocols had occurred. In spite of these safety breaches, between December 1998 and June 1999, CSL continued to process foreign-sourced blood without the approval of the Health Department.

7.2 Clinton's Arkansas: The U.S. prison blood scandal

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 for 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.

7.3 Australia imported blood from U.S. Prison blood dealers

A number of pharmaceutical companies in the U.S. distributed blood manufactured from high-risk U.S. Prison blood sources. Three companies of interest to Australia are Baxter, Alpha and Bayer. They are of interest because Australia has imported plasma products manufactured by these companies. Baxter in particular has been implicated in the worldwide distribution of medical products derived from material such as plasma that was collected from Arkansas prisons. Baxter's European distribution plant based in Lessines, Belgium, has been subject to scrutiny from numerous legal actions carried out on behalf of Haemophiliacs around the world. Baxter's plant in Belgium is known to have distributed product (factor concentrate), which was made using U.S. prison plasma, throughout the European continent, to Africa, and Asia. Baxter has also distributed medical products from its plant in Belgium to Australia.

This year 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 advice from the health department informed that this was due to Australian product being insufficient to meet clinical demand, and because 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. Since 1991, the Therapeutic Goods Administration (TGA) has held records of certain imports of medical products made from plasma. Companies that have dealt in US prison blood such as Baxter, Alpha and Bayer are on the TGA's list. There are a lot of Australians that do not know about the importation of high risk and potentially deadly medical products, such as plasma product made using blood donations from inmates in gaols (from the United States). What we can ascertain is this:

'Australia has imported blood products from companies that are known to have dealt in US prison blood. They have dealt in material that was manufactured using blood plasma sourced from US Prison inmates, many of whom were infected with HIV/AIDS and Hepatitis C'.

'Hundreds of Australians were infected with HIV/AIDS in the 1980s from medical products made from blood plasma'.
'80% of Australians with the blood disorder Haemophilia have been infected with Hepatitis C from medical products made from blood plasma'.

8 The Australian Red Cross collected blood from Australian prisons

At a meeting of the Tainted Blood Product Action Group (TBPAG) held in Ashfield, Sydney, in August of 2003, a number of people came forward with information about Hepatitis C and the blood supply. One of the people that came forward with shocking information was a member of TBPAG. They brought forward disturbing information that the Australian Red Cross had collected blood from Australian prison inmates. They knew of inmates that had donated blood to the Australian Red Cross in the past. They knew of a former Red Cross Blood Service worker who recalled that mobile blood collection units were sent to Australian prisons. In 1999, this member of TBPAG sought advice from Nick Crofts, the Head of Epidemiology and Social Research at the Macfarlane Burnet Institute based in Melbourne. Nick Crofts is something of an expert on Hepatitis C; his major interests are epidemiology and blood borne viruses. Crofts advised our member that the Victorian blood bank used to collect blood from prisoners up until May/June 1983.

This information is extremely serious. For example, the practice of collecting blood from prison inmates in Canada stopped in the 1970s as it was deemed too dangerous. Canada, like Australia has a voluntary donation system. A system which is underpinned by the honesty and altruism of its donors. What is essential here, is that blood donor screening relies on the honesty of the donor in answering screening questions. It is hard to understand how the Australian Red Cross could decide to place a system based on honesty, with life-and-death repercussions like blood donation, inside a prison. What is even more remarkable about this situation is that Hepatitis C infection was a known complication of blood and blood products from the mid 1970s in Australia. Scientific and medical knowledge in the 1970s was advanced enough to understand the threat of hepatitis and the increased dangers of encouraging and accepting blood donations from prison inmates.

8.1 The Australian Red Cross knowingly collected blood from IV drug users

A Federal Government investigation into the use of potentially contaminated blood to make medical products in 1990 was ordered by the former Federal Health Minister, Kay Patterson in July 2002. The inquiry was called the Expert Advisory Group Hepatitis C and Plasma in 1990 Claims. It was chaired by Professor Bruce Barraclough.

In evidence submitted to this inquiry the case of a donor known as HCVD 292 (and also known as implicated donor 368419) raised particular concerns. This person had been a frequent donor of whole blood and platelets in the 1980s, but failed to reveal a true medical background on their donor declaration forms, which included a history of illegal drug use and needle sharing, as well as a sexual relationship with a prostitute. Upon discovery that a false and misleading statement had been made on a donor declaration form by a donor, the blood transfusion service could report the breach, one that carried penalties of a fine, imprisonment for one year, or both. [cf s.21D, *Human Tissue Act* 1983 (NSW)].

Alarmingly evidence exists that the ARCBS did not always report breaches in the early 1990s, even when they had knowledge of a particular breach immediately after its occurrence. On April 9, 1990 the ARCBS found the donor known as HCVD 292 to be Hepatitis C positive following a donation. Yet none of the previous recipients of this donor's blood were informed. Instead, the donor in question went on to make further visits to the blood donation centre. The donor made a further false declaration on August 6, 1990, and blood was again taken from donor HCVD 292 on that date. Incomprehensibly, the Blood Service even then failed to report the false declaration, which carried heavy penalties under the *Human Tissue Act* 1983 (NSW). But more importantly, the Blood Service also failed once again to contact all the recipients of this donor's whole blood and platelet donations in the 1980s.

8.2 The Australian Red Cross neglected to warn victims

Recipients of HCVD 292s blood had been placed at high risk of exposure to the potentially deadly virus, Hepatitis C, through receipt of this donor's blood. And subsequent to August 6, 1990, the Blood Service again saw donor HCVD292 on July 18, 1991. Once more, the blood service failed to notify all previous recipients of this person's blood. (It should be noted that this donor was also seen by the blood service on March 3, 1993 but it is unclear whether blood or plasma was drawn on this occasion.)

Therefore, it was both legally and morally imperative that the ARCBS should have immediately notified all recipients of HCVD 292's previous blood, platelet and plasma donations in the 1980s. Yet, they failed to do so. And it also appears that in the 1990s they also failed to report this donor to the relevant authorities for criminal investigation. On the face of the evidence in relation to this particular donor, the Red Cross Blood Transfusion Service in NSW may well be found to have been substantially complacent in a great number of very serious failures.

It is failures like those in HCVD 292's case that raise very serious questions about the ARCBS, and indicate an unthoughtful disregard for recipients' safety and welfare by adopting a policy that tolerated the questionable inclusion of blood donations like those of HCVD 292's into the blood supply, thereby subsequently producing numerous problems. This is

further highlighted by their failure to enforce the legal requirements of the *Human Tissue Act* 1983 (NSW) on blood donation. Their clear negligence in not informing recipients of infected blood has produced tragic consequences for the victims of this failure.

8.3 Hepatitis C tracing service a multi-million dollar failure

The failure of the blood service to warn recipients of contaminated blood in a timely fashion is nothing new. It has been an ongoing problem for the past twenty years. Lookback is a tracing program that tracks contaminated blood. It is a multi-million dollar cooperative undertaken by the Australian Red Cross Blood Service (ARCBS) and the state health departments. In January 2003, The Tainted Blood Product Action Group conducted a survey into the effectiveness of the Lookback program. A cohort of 100 people with HCV from blood transfusions were selected to take part in the survey. A disturbing result of the survey was that 81% of the cohort had never been officially contacted nor offered any medical or support services by the ARCBS. Of the remaining patients the Lookback program directly notified only 14% of the cohort, and the average length of time to notification was 9.8 years. The Lookback program indirectly notified 5% of the cohort of their prior infection, with an average length of time to notification of 13 years (For full report See Reference 'E')

9 Public outcries from victims: The response of the Australian Red Cross

In recent times victims of blood transfused Hepatitis C have spoken out against the Australian Red Cross Blood Service, through the media and via public protests. These public outcries have come in the wake of decades through which victims were ignored by the managers of the blood service. It is largely through frustration with the Australian Red Cross, and the organization's continued denial of the tainted blood disaster, that the Tainted Blood Product Action Group (TBPAG) was formed. Victims united to form an action group capable of supporting one another: A group that wanted the Australian public to know that they were the victims of a tragedy that deserved acknowledgement and investigation by appropriate authorities. But crucially, like many victims of tragic circumstances, they want to see an investigation that is open to public scrutiny, so that the chances of a similar disaster occurring again might be lessened, or ultimately avoided.

The attitude displayed by the ARCBS to the contaminated blood crisis and its victims has been one of apparent self righteous complacency. Victims have had to endure the full brunt of this. They have felt it through insensitive comments and press releases made by the blood service to the media. These comments talk of the risk to the public's confidence in the blood supply due to criticism. They talk of the perils to the blood supply if it were to receive less blood donations as a result of victims of a tragedy voicing their concerns about their situations. Not one comment talks of the horror that surviving tainted blood victims experience on a daily basis. Not one line suggests anything resembling an apology or sentiments of real sympathy.

Members of TBPAG know that their criticisms in media interviews of the blood service are all too frequently countered by blood service press releases claiming chronic shortages in the blood supply. It is the view of members of TBPAG that this is a convenient and dishonest strategy utilized by the blood service to counter their concerns about the Hepatitis C issue. This strategy can only be described as a threat, designed to imply that an investigation of the

blood service's practices would have a negative impact on the blood supply and the voluntary donor system. In many ways this tactic is tantamount to exchanging 'future' lives with a ransom of unacceptable standards of risk. TPBAG is of the view, which is reflected by blood services around the world, that the safety and availability of the blood supply are not mutually exclusive positions.

TBPAG believes that blood donation is extremely important. Blood donors are true life savers. Heroes in every sense of the word. Victims wanting to discuss the full nature of the tainted blood tragedy in no way suggest that they wish to see less people making blood donations in Australia. Tainted blood victims have suffered enough; they do not want other Australian's to suffer in the same way ever again, whether that be due to a shortage to the blood supply or from contaminated blood. It should be said that Australian blood donors are modern day heroes who deserve Australia's applause and encouragement. It should also be noted that criticism of the blood system is unlikely to affect *donations* as this is universally accepted to carry minimal if any risk.

The deliberate and unfeeling denial of the Hepatitis C contamination issue by the Australian Red Cross was fully realised in a pivotal statement made on ABC radio on July 1 2002, by the chairman of the donor and product safety committee of the Australian Red Cross Blood Service, Tony Keller. He responded to the Hepatitis C controversy surrounding the blood service's policy of deliberately mixing donations from infected donors into the blood supply in 1990 by saying:

"Nobody knew what the hepatitis C virus was or what it did."

One would expect that such acknowledged ignorance would have warranted a careful, rather than a complacent approach.

10 The death of Dr Ian Young: Addressing the culture of secrecy

As has been noted above, The Queensland Red Cross Blood Transfusion Service introduced surrogate testing to screen for Hepatitis C in 1988. The head of this body at the time was Dr Ian Young, who was a strong advocate of surrogate testing, having made numerous submissions to the Australian Red Cross which recommended the implementation of this procedure. It is known that he had many quarrels with his state-based counterparts, and was seen by many in the Red Cross as a voice of dissent.
Dr Young was not alone in his recommendation with regard to surrogate testing. A highly regarded specialist, the head of the liver unit at Brisbane Hospital, Dr Graham Cooksley, wrote submissions to The Red Cross in the 1980s endorsing surrogate testing.

After having been subpoenaed by the legal firm, *Slater & Gordon*, to give evidence in an Australian court case regarding Hepatitis C in the blood supply, Dr Ian Young was found dead before he could testify. This situation has caused confusion and fear among victims, and those concerned with the issue of tainted blood. The untimely death of this pre-eminent doctor has been the subject of conjecture.

These submissions from the exponents of surrogate testing, and the manner in which they were addressed by the Australian Red Cross, need to be made public. The studies conducted by the Red Cross (mentioned above in a transcript by Dr Gordon Archer) into surrogate

testing also need to be made public. It is only then that a perceived culture of secrecy can give way to the admirable, but as yet unrealised, objectives set out in the ARCBS's own mission statement: transparency and accountability.

11 The impact that blood transfused Hepatitis C has had on its victims and their families

In the last three decades thousands of Australian hospital patients have been infected with the deadly virus Hepatitis C from contaminated blood transfusions and blood products. Victims of this tragedy include adults, children, accident victims, the sick, the anaemic, pregnant women, and those having had elective surgery. They have not been isolated to the acutely ill who would have died without an urgent transfusion. While this is a medical disaster, it is in essence, first and foremost, a human tragedy that has destroyed the lives of many men, women and children. Recipients of blood contaminated by Hepatitis C are *innocent* victims, who have acquired the virus through no fault of their own. These are people who went into hospital, received transfusions, and ended up with this life-changing disease. Many of them now face a lifetime of disability, increasing the pressure of every day responsibilities like being a parent, paying a mortgage and putting food on the table for their families.

In recent times these victims and their loved ones have attempted to seek much needed financial assistance and health care from authorities. But all too frequently their path has been blocked by legal challenges and discrimination (the Anti-Discrimination Board of NSW recently found that there is widespread discrimination against sufferers of Hepatitis C).

A significant proportion of the victims of contaminated blood had pre-existing conditions (e.g. cancer, haemophilia) for which blood and blood products were used as part of the treatment. These pre-existing conditions often become more complex to manage as a result of Hepatitis C infection. Haemophiliacs who had previously acquired HIV/AIDS from blood products face uncertain treatment scenarios when co-infected with HCV. Co-infected individuals are less likely to respond to drug therapies used to combat Hepatitis C.

Cancer patients who need to donate their own stem cells for possible autologous transplantation (self-donation) are denied tanks to store their stem cells, because they have HCV. Patients with chronic pain who have Hepatitis C frequently feel uncomfortable when asking for pain relief. There can on occasion be suggestions from medical practitioners that the patient may have used IV drugs in the past, because of incorrect assumptions that their HCV infection occurred as a result of sharing dirty needles, and that they should not be prescribed strong pain relief for fears that they are asking for medication under false pretenses.

Haemophiliacs, cancer patients, and people who are recovering from trauma are often in situations where they experience chronic pain. Patients in these circumstances should not be discriminated against, or made to feel as though they are drug addicts looking for a 'fix', because they have medically acquired HCV. They should be able to access appropriate medication without being made to feel uncomfortable.

Issues surrounding medical discrimination are only part of a myriad of problems that tainted blood victim's face on a daily basis. Others include:

- Difficulties in obtaining life and medical insurance cover
- Discrimination in the work place
- Difficulties in receiving pain relief and other prescribed drugs
- Discrimination from surgeons (e.g. patients with HCV are more likely to face difficulty in getting surgery etc.)
- Financial hardship
- Difficulties in accessing social security
- Loss of sexual libido, and loss of sexual partners
- Marriage breakdowns (as a result of tiredness from HCV, among other reasons)
- Difficulties in maintaining an active role in the family unit
- Psychological problems
- Dental problems
- Pregnancy/childbirth issues
- Problems obtaining liver transplantation
- Travel issues to and from medical appointments
- Reduced life expectancy

11.1 Mothers with transfused Hepatitis C

In 2002, Charles MacKenzie of the Tainted Blood Product Action Group wrote a report on women who had acquired Hepatitis C from contaminated blood transfused during childbirth. The tragic consequences of this are described within the report 'Mothers with transfused HCV' (See Reference 'F').

12 Recommendations

Financial Assistance:

The establishment of a Compensation Tribunal for recipients of Hepatitis C contaminated blood or blood products, where each claim is heard and accessed individually.

Health and home care assistance:

- A Health Care Package which covers: GP visits; All prescribed medication & Surgical Aids; Dental, Aural, Optical, Physiotherapy, & Chiropody treatments; and, Alternative treatments i.e. - Reflexology & Aromatherapy / Massage.
- The establishment of a special blood transfused Hepatitis C medical/counselling/welfare team specially trained in the issues and sensitivities that surround the tainted blood tragedy.
- Home Nursing service and Home Help (housework) Service.
- Priority listing for liver transplantation.
- Travel assistance to medical appointments.

- Recombinant Factor (synthetic product) to be freely available to individuals with the blood disorder Haemophilia.

That the Senate Community Affairs References Committee interview the following individuals:

- Professor James Mosley (The senior scientist of the TTV survey)
- Dr. Harvey J. Alter (infectious disease specialist at the National Institutes of Health Clinical Center)
- Justice Horace Krever (Head of Canada's blood inquiry and author of the Krever Report. Canada)
- Superintendent Rod Knecht (Royal Canadian Mounted Police Blood Task Force)
- Dr Robert Hetzel (CEO Australian Red Cross Blood Service)
- Dr Gordon Archer (former director of the NSW Red Cross Blood Transfusion Service in the 1980s).
- Dr Brenton Wylie (Australian Red Cross Blood Service)
- Dr Anthony Keller (Australian Red Cross Blood Service)
- Dr Peter Schiff (Commonwealth Serum Laboratories and currently of CSL LTD)
- Dr Catherine Hyland (Queensland Red Cross Blood Service)

That the Senate Community Affairs References Committee request the public release of the following:

- The post-transfusion Hepatitis study commissioned in 1986 and completed in 1990 and as referred to by Dr Gordon Archer (formerly of the NSW Red Cross Blood Transfusion Service).
- All minutes of meetings of the Australian Red Cross Blood Service (and the previous state run body's) from the 1970s, 1980s, to 1996 be made public so as to allow transparency in the decision making process when it comes to making policy on blood safety.
- All minutes of meetings of the Commonwealth Serum Laboratories (when it was government owned) from the 1970s, 1980s, to 1994 be made public for the same reason as above.

- All written communication by Dr Ian Young (former head of the QLD Red Cross Blood Transfusion Service) to the Australian Red Cross Blood Service from the 1970s, 1980s and 1990s.

- All written communication from Dr Harvey Alter (of the NIH) to the Australian Red Cross Blood Service in the 1980s.

- All relevant written communication regarding surrogate testing for Hepatitis and heat treatment of blood products to the Australian Red Cross Blood Service and the Commonwealth Serum Laboratories in the 1970s and 1980s.

- Complete records from the 1960s of blood importations from overseas countries be made public.

That the Senate Community Affairs References Committee examine issues relating to blood shortages in Australia:

- Including the correlation between the appearances in the media of claims of blood shortages by the ARCBS and media stories on either victims of tainted blood, or concerns with the safety of the blood supply. (The spectre of blood shortages should be in no way used to alarm the community, or mitigate concerns over the safety of the blood supply.)

That the Senate Community Affairs References Committee review current Australian Red Cross Blood Service donor screening policy:

- Donor screening safety policy to be upgraded in response to the threat of Creutzfeldt-Jakob Disease (variant CJD):

Current ARCBS donor deferral policy for Variant CJD (at time of writing) is:

- *People who spent a cumulative period of six (6) months or more in the United Kingdom between 1 January 1980 and 31 December 1996 or received transfusions of blood or blood products in the United Kingdom from 1 January 1980 to the present, cannot donate blood until further notice.*

This is clearly inadequate given the current threat, and the Tainted Blood Product Action Group's recommendations for increased donor screening policy for Variant CJD are:

- *People are not eligible to donate blood or plasma if they have spent a cumulative total of three months or more in the United Kingdom (U.K.) since 1980, or if they have spent a cumulative total of three months or more in France since 1980, or if they have spent a cumulative total of five years or more in Western Europe outside the U.K. or France since 1980. In addition, people are not eligible to donate blood or plasma if they have had a blood transfusion in the U.K. since 1980.*

References

Reference 'A'

Sun, Nov. 09, 2003 THE KANSAS CITY STAR.

Disease spread as blood test was delayed

By KAREN DILLON

WASHINGTON, D.C. - Guardians of the nation's blood supply gathered in 1981 at American Red Cross headquarters to consider a way to prevent hepatitis C from spreading through transfusions.

For more than four hours they talked about using a test that was available and could help screen out blood carrying the virus.

The so-called ALT test was far from perfect. But evidence that it would slow a disease infecting hundreds of thousands of patients each year seemed so persuasive that the blood industry needed to act.

The group concluded:

"Blood collection agencies in the U.S. should prepare to test ALT levels of all blood units."

But that didn't happen. In fact, the blood industry would delay testing for another six years.

It's impossible to know how many hepatitis C infections could have been prevented by the ALT test during those years. But that figure might be more than 300,000 people, based on data from some studies.

Arguments made in January 1981 to use the ALT test, revealed in reports and documents obtained by *The Kansas City Star*, surprise some of those who were trying to contain the virus.

"I did not know this (report) existed," said Ron Gilcher, head of the Oklahoma Blood Institute. "I was really shocked."

In 1983, Gilcher's blood center broke from the industry to become one of the first to use the ALT test, but he now wishes he had known two years before that the report existed.

"Certainly if I had seen this information I would have had the test in place in 1981," Gilcher said. "What amazed me was the results of this were not communicated to the transfusion community."

Instead, the blood industry reversed course.

Five months after the 1981 meeting, industry groups began recommending a delay in testing, and the government never forced the issue.

Blood leaders who opposed the test said it did a poor job of detecting hepatitis C. More study was needed to show it would actually reduce the number of cases. It would cost blood banks too much, especially to replace donors who would be barred from giving blood. And it would be difficult to implement.

Besides, the disease didn't seem that deadly.

Today, many blood bank officials say they shouldn't be blamed for the decision to delay ALT testing.

"Nobody did anything wrong as far as I'm concerned," said Paul Holland, who in 1981 was chairman of a blood industry committee on hepatitis testing.

"In hindsight, maybe we could have done differently, but that's hindsight."

A researcher who backed the ALT test said he nonetheless understood how hard it was for blood bankers to make decisions at the time.

Armchair quarterbacking is easy 20 years later, said F. Blaine Hollinger, director of an HCV and HIV research center at Baylor College of Medicine.

"When you are going through it, it doesn't quite hit you," he said.

But after the January 1981 meeting, some blood officials clearly felt heavy responsibility.

In fact, one of the participants wrote a week later that some at the meeting "were talking about preventing a disease that we in fact help create through blood transfusion."

Another participant, Johanna Pindyck, began using the test at her blood bank.

"This was a serious disease, and it was a preventable disease," says Pindyck, who was director of the Greater New York Blood program.

The Canadian Red Cross also was concerned about hepatitis C and sent a representative to monitor American discussions in 1981. But Canada waited even longer than the United States to test, and that decision resulted in criminal charges last November against the Canadian Red Cross.

Back in the United States, up to 450,000 people who got hepatitis C through transfusions before 1992 are believed to be alive today. Many of them still don't know they have the disease, which has been called the Silent Epidemic.

There is no way to tell how many of those cases occurred in the early 1980s and could have been prevented by ALT testing.

Need for a test

By the mid-1970s, early studies indicated hepatitis C was infecting 10 percent of all transfusion patients, or about 300,000 a year.

A test for hepatitis B, licensed in 1972, had screened most of that virus out of the blood supply, but there was no test for hepatitis C, or non-A, non-B hepatitis, as it was known then.

One test, ALT -- which stands for alanine aminotransferase, a liver enzyme -- had been used by physicians since at least the 1950s to find damage to the liver. Blood banks in Germany and Austria, but not the United States, had used it since at least 1970 to screen blood for hepatitis.

A study began in 1974, in part to determine the link between transfusions and hepatitis, said Richard D. Aach, principal author of the study and now an associate dean at Case Western Reserve University's

medical school.

The Transfusion-Transmitted Viruses Study enrolled 1,500 elective surgery patients who received blood that was measured for ALT levels. They were followed to see whether they developed non-A, non-B hepatitis.

By 1978 the study had reached a preliminary conclusion: The ALT test could reduce cases of hepatitis if used to screen blood donated for transfusions, removing the blood that had high levels of the liver enzyme.

"It became clear after several years, a few years into this study, 1976 or 1978, that ALT was an excellent marker," said Hollinger, an investigator for the virus study and a former chairman of a Food and Drug Administration advisory committee.

James W. Mosley, the study's principal investigator, said he encouraged blood banks to use the ALT test but they remained skeptical.

"We probably should have called more attention to it," he said.

By January 1981, though, government and blood bank officials were ready to talk about ALT testing. The American Red Cross invited a group of blood experts to its Washington headquarters.

The group included a top FDA blood expert, a pioneering HCV researcher at the National Institutes of Health, and representatives of the American Association of Blood Banks, the Red Cross and the Council of Community Blood Centers.

Documents from the meeting show the 1981 group reached several conclusions:

• ALT testing would decrease the number of patients who got infected, based on at least two studies. The participants "agreed that there was evidence that the introduction of ALT testing would reduce the incidence of post-transfusion non-A, non-B hepatitis."

• Evidence for the test was so strong, in fact, that it would no longer be possible to conduct studies in which patients received blood known to have high ALT levels. Participants at the meeting agreed that such studies would no longer be ethical.

• Much needed to be done before testing could begin. The group appointed a working committee to sort through such issues as how to make testing consistent and what to tell donors who have high-ALT blood.

The blood industry would also have to address the loss of up to 3 percent of donors, including many who weren't actually infected but tested positive nonetheless. But that shouldn't stand in the way of testing, said Alfred J. Katz, a blood center director who soon would become executive director of the Red Cross Blood Services.

A week after the January 1981 meeting Katz wrote to a colleague:

"This concern did not outweigh the medical, scientific, ethical, legal, and public relations judgment that it was incumbent upon us to prepare to implement ALT as a donor screening procedure, in order to decrease NANB (non-A, non-B) hepatitis in recipients."

But within five months the industry changed direction based on recommendations of at least two

advisory committees.

"The Committee concluded that the available data are insufficient for a decision on introduction of routine ALT testing of blood donors at this time," one blood group wrote in June 1981.

Some of those who met in January 1981 won't talk about the dramatic change, including Katz and Roger Dodd, who wrote the report of the meeting and today is still with the Red Cross.

But a spokesman for the blood banks association describes the rapid turnabout as an evolution, not a reversal.

"Although some of the initial documents could be read to indicate the way is clear and this is what we are going to do, I think the environment in which that conclusion was reached was one of change," said James P. AuBuchon, medical director of the blood bank at Dartmouth-Hitchcock Medical Center and former member of a federal blood advisory committee.

"Additional concerns were raised."

Joseph P. O'Malley, who attended the January 1981 meeting, said a few persuasive people seized control of it and influenced the recommendation to implement ALT testing. The decisions the group reached didn't reflect the thinking of the blood industry, said O'Malley, who retired after 32 years with the Red Cross and FDA.

Indeed, Thomas Zuck was surprised to discover the true thinking of blood bankers in the months following the meeting.

"I think we left that '81 meeting with the expectation that this was going to happen within a year," said Zuck, who at the time worked for the blood banks association. "I don't think we realized the resentment there was in some quarters. They really didn't want to do it."

In fact, Zuck thinks, the Red Cross put the meeting together actually expecting that the group would reject ALT testing.

"The Red Cross was leading the band mainly because they wanted a blockade," said Zuck, who remains a consultant to foreign countries investigating blood contamination.

The Red Cross has refused to talk about the meeting, but it has characterized the conclusions as only preliminary in documents it filed in response to a lawsuit.

Obstacles

For the next five years, the industry debated using the ALT test but left it on hold. Among the reasons it offered:

• **Lack of evidence.**

Despite the January 1981 conclusion, it wasn't clear, after all, that ALT screening would reduce hepatitis C cases, blood leaders said.

The major studies only predicted that ALT testing would decrease hepatitis but did not confirm it, some researchers said. In fact, ALT testing might even have minimal impact.

As a result, instead of being unethical, another study on humans was needed, some top blood officials said in meetings and articles. It could take up to six years and involve thousands of patients and donors.

But Hollinger and some other experts said another study was senseless.

"That was just a bunch of crap," he said.

Indeed, the study was never performed in the United States.

Some say the proposed study wasn't the real point -- the point was to delay the ALT test.

"Was that a ruse for the blood bankers?" said Mosley, a professor emeritus at the University of California-Los Angeles medical school. "Did they say, `Oh my God, we need to study this some more and then we can just prolong everything'? Oh yes."

• **Difficulty in testing.**

Because ALT levels in the population tended to vary from region to region, blood banks would have a hard time setting a nationwide rate that would signal dangerous donations.

But the working group that was appointed at the January 1981 meeting to write those guidelines never met. A national conference on ALT screening was scheduled by the government for June 1981, but it never happened either.

• **Donors.**

The numbers of lost donors would not be worth the infections that would be prevented. Of the donors who tested positive in the ALT test, for example, only a third might have hepatitis C.

The loss of so many other donors who weren't really infected would unnecessarily alarm the donors and also create a dangerous shortage of blood, leaders said.

Two extensive studies had estimated, however, that only 1.5 percent to 3 percent of all donors would be excluded.

• **Partial solution.**

Many thought a better test -- one actually triggered by the virus, not just by a liver enzyme -- would be worth waiting for because studies predicted the ALT test would prevent only a third of the infections.

But the January 1981 group knew a better test could be years away -- and, in fact, it was. Besides, said Pindyck, the former New York blood director, that debate just didn't make sense:

"If a group of firemen were outside a burning building and they could only save 30 percent of the people in the building, and they sat around and debated and said, `It's not worth our effort to do it,' what would happen?"

Voluntary testing

Only a few blood banks, including Pindyck's, bucked the industry.

After the January 1981 meeting, the Greater New York Blood Center, which had been part of the TTV study, decided to use the test. An independent committee of doctors, business leaders and others studied data for the blood center and concluded unanimously that the $2.77 cost of each test -- to cover the test itself and loss of donors -- was worth the drawbacks.

In fact, by 1983, Pindyck and a colleague had published an article that confronted some of the industry's objections. The ALT test was not difficult to conduct, and the center easily absorbed the loss of donors, Pindyck said.

The report's impact? "Nobody paid any attention," Pindyck said.

Ironically, even though the federal government didn't require the ALT test anywhere in the nation, it wanted to protect its own blood. The National Institutes of Health ordered ALT screening at its largest research hospital.

The FDA also took no position on another screening test, known as the hepatitis B core antibody test, which was available by 1983. Used together, it appeared, both tests could flag hepatitis C in more than 40 percent of the cases.

At the time, the value of the tests still seemed unproven and the costs in donors too high, said Jay Epstein, director of the FDA's Office of Blood Research and Review. And a better test still seemed near.

"On the other hand, the FDA did not discourage blood banks that elected voluntarily to implement those tests," Epstein said.

Indeed, blood banks finally did decide in 1986 to use the tests following an FDA blood advisory committee meeting. The committee heard about increasing reports that hepatitis C patients were dying.

"If we were the ones that caused their death with transfusion, I think that is something we should try to prevent," Harvey Alter, an NIH scientist credited as perhaps the nation's pre-eminent hepatitis C researcher, told the committee.

The Red Cross and other blood associations asked blood banks in 1986 to use the ALT test and the hepatitis B core antibody test. By 1987, most did, including the Community Blood Center in Kansas City.

As for the FDA, it never set guidelines or required the ALT test to be used.

As a result, some infected blood that would have been detected was used for transfusions, Mosley said.

Action in Canada

The years of delay have attracted little notice in the United States.

But in some countries, such as Canada and Australia, delays in hepatitis C testing have created a scandal, prompting public protests.

In fact, the Canadian Red Cross and its former top blood official were charged last year for not using available screening tests between 1986 and 1990, and for not warning the public that blood was unscreened. The charges are pending.

"This is a crime," said Mike McCarthy, a hepatitis C patient and until recently senior policy adviser to the ministry of health in the province of Ontario.

"People were harmed and people suffered egregious injuries and many people died."

Canada has paid millions of dollars in compensation to people infected with hepatitis C through transfusions. In fact, in 1994 Canada began searching for those people to make sure they knew they had received infected blood.

In the United States, however, hundreds of thousands of infected patients have never been notified.

And there is no compensation, despite prodding by a congressional committee and others. No strong lobby has ever formed around the disease to force the government to set up a fund.

And one American blood official doesn't believe there should be a fund. A lot of medical procedures are risky, and the blood industry did the best it could with hepatitis C, said Holland, former head of a government blood bank and now director of a Sacramento blood bank.

"It was really nobody's fault," Holland said. "Life is full of risks."

Treatment has limited success
Surge of patients worsens liver crisis
Job-related infections hard to prove
Researchers struggle to scrape up funding
ALT testing: How many were infected?

The TTV Study

http://www.kansascity.com/multimedia/kansascity/archive/hepatitis_c/ttv_study.pdf

A Red Cross warning hepatitis c 1981

http://www.kansascity.com/multimedia/kansascity/archive/hepatitis_c/red_cross_testing_message.pdf

ALT testing of donors

http://www.kansascity.com/multimedia/kansascity/archive/hepatitis_c/jan_9_meeting.pdf

Reference 'B'

: Lancet 1982 Jan 23;1(8265):208-13 Related Articles, Books, LinkOut

Post-transfusion hepatitis in Australia. Report of the Australian Red Cross study.

Cossart YE, Kirsch S, Ismay SL.

Post-transfusion hepatitis developed in 2% of 842 cardiac-surgery patients surveyed in Sydney (4 cases per 1000 units of transfused blood). 3 of the 18 cases were caused by hepatitis B virus even though all units of blood which contained hepatitis B surface antigen (HBsAg) had been rejected. 1 case was caused by cytomegalovirus, and there were 14 (78%) cases of non-A, non-B hepatitis. A significantly higher proportion of the units of blood given to the patients in whom non-A, non-B hepatitis developed contained antibodies against both hepatitis B core antigen and HBsAg than the units of blood given to the other patients. Rejection of blood with these markers of past exposure to hepatitis B may reduce the incidence of post-transfusion non-A, non-B hepatitis by up to a half.

PMID: 6119566 [PubMed - indexed for MEDLINE]

Reference 'C'

Tainted Blood

HELEN DALLEY, REPORTER: 11-year-old Corey McCullagh looks and plays like most normal young boys. But Corey is dealing with more than most. Unlike normal healthy boys, he has the potentially fatal disease that attacks the liver, Hepatitis C.

COREY McCULLAGH, HEP C SUFFERER: It's been a pretty bumpy ride.

REPORTER: A bumpy ride, has it?

COREY McCULLAGH: Mmm. Up and down.

REPORTER: The best thing would be to get rid of the virus.

COREY McCULLAGH: Yep. I'd love to get rid of it and like, live a normal life instead of worrying about me liver.

REPORTER: Corey was infected with the life-threatening Hepatitis C virus as a newborn baby in December 1990. Just 20 hours old, he received a blood transfusion to save his life. But it turned out to be contaminated with Hepatitis C.

TRACEY McCULLAGH, COREY'S MOTHER: I think I've been in shock pretty well. I think I was still in shock then, I'm probably even still, maybe, a little bit in shock even now, even though it's been so long. Um, it was the more so what are we going to do? Nobody knew anything about Hep C, like, nobody could give me any answers, nobody offered me any answers.

REPORTER: Hepatitis C is disparagingly known as the injecting drug users' or junkies' disease since it's spread by blood-to-blood contact mainly through dirty needles and syringes. But Corey McCullagh embodies the medical tragedy of the estimated 10,000, possibly 20,000 Australians, infected with Hep C-contaminated blood during the 1980s. Some were even infected into the 1990s after screening for the disease was introduced by blood banks. People were infected by Hep C who weren't in high-risk groups, including women in childbirth and people needing blood during surgery.

CHARLES MACKENZIE, TAINTED BLOOD ACTION GROUP: This is the single greatest medical disaster in Australian history and we've had no inquiry and no special assistance for the victims of this tragedy.

CHARLES MACKENZIE - ADDRESSING MEETING: I think we should submit a petition to Government for a commission of inquiry into our blood services...

REPORTER: What happened to those trying to cope with the disease that can take 25 years to turn into liver failure or cancer is a scandal.

CHARLES MACKENZIE - ADDRESSING MEETING: ..the most common complaint is a total lack of sympathy. It's almost like you're ringing up your newsagent and asking where your Sunday paper is. Um, you know, I think you probably get more from them. But the main issue here is, and I have to ask this...

REPORTER: According to this support group for sufferers, the Red Cross Blood Service has not been fully frank about tainted blood transfusions, giving little or no information to recipients of infected blood or blood products. Any legal action has been shrouded in secrecy clauses imposed by the blood service.

WOMAN AT MEETING: So I just don't know where we can turn to because I feel that they didn't want to know about this situation and I really... (Sighs) It's for everybody, it's not just for my son, it's for everybody in our country who have been contaminated by this. Thank you.

REPORTER: Sufferers say the blood service downplayed risks of infection even after first-

generation screening tests were introduced in February, 1990. According to many, they've had scant support in dealing with the disease they acquired from blood. You found out in '93.

TRACEY McCULLAGH: Yep.

REPORTER: Did the Red Cross ever offer you any counselling?

TRACEY McCULLAGH: No.

REPORTER: Did the Red Cross ever offer you any financial assistance?

TRACEY McCULLAGH: No.

REPORTER: Did the Red Cross ever offer you any medical assistance?

TRACEY McCULLAGH: No.

REPORTER: There are allegations, too, that the program specifically set up to trace suspect donors and infected blood - called Lookback - is flawed. Despite assurances from the blood service, Lookback has not contacted all people given contaminated blood. There are also claims it cannot accurately trace all suspect blood donations.

JACINTA JACOBSON, HEP C SUFFERER: If I can find these records why can't they? Where it took me so long to get it but I found it and I've got a letter from them saying "You weren't transfused" and I've got records from the hospital saying I was.

REPORTER: Some sufferers have gone for years not knowing they contracted Hep C from blood transfusions, so losing the opportunity of receiving treatment while possibly infecting those around them.

NIEL LAKE, HEP C SUFFERER: Had I not found out for myself, what the problem was, I'd be putting everyone else at risk in the community too.

REPORTER: Were you worried in that period when you did find out whether you'd given it to your family - or wife?

NIEL LAKE: Absolutely - my wife had to go off and be tested and thankfully she came back negative and that's a terrible thing to do to a person.

ANDREW GRECH, SLATER AND GORDON: What's always concerned us about Hepatitis C and in particular, blood transfusion related cases of Hepatitis C, is that there are probably still hundreds of individuals who don't now know that they've been infected.

REPORTER: The Red Cross Blood Service still prefers to avoid public scrutiny and deal with media questions on this whole episode by ignoring them. The Red Cross Blood Service refused to be interviewed for this program.

ANDREW GRECH: The attitude of the Red Cross was to put down the shutters and try and downplay the claims being made by claimants and to some extent, to hope that it would go away. It hasn't gone away. It's been an ongoing problem for them.

REPORTER: There are concerns, too, that before the specific Hepatitis C test was available in 1990, most Australian States, except Queensland, failed to implement other tests - such as one called the ALT liver function test - that could have prevented some Hepatitis C infections.

ANDREW GRECH: At the end of the day, the clear evidence now is that judgment was wrong.

REPORTER: One of the cruellest blows, say many of those infected, is that the Red Cross Blood Service has never explained how such a tragedy happened to them.

SUE BELL, HEP C SUFFERER: Oh, I've been swept under their carpet and forgotten about.

REPORTER: Sue Bell - who got a Hep C-infected blood transfusion after giving birth in August 1991 - feels let down by a service she trusted. Her transfusion was 1.5 years after screening began. Somehow, infected blood still slipped through. You've heard nothing from the Red Cross?

SUE BELL: Not directly, no.

REPORTER: No explanation?

SUE BELL: No.

REPORTER: No apology?

SUE BELL: No.

REPORTER: Nothing.

SUE BELL: Nothing - at all.

REPORTER: And how do you feel about that?

SUE BELL: Oh, I feel a bit sad in a way that they can't, if nothing else, just apologise for, if it was a mistake, a hiccup, whatever terminology you'd like to use, that they can't just sort of ring me or write me a sort of a sorry letter, if you like, because it has changed my life.

REPORTER: In January 1992, the blood service conclusively established that the donor for Sue's transfusion had been Hepatitis C-positive, but Sue wasn't contacted until March 1993. That was 14 months after they knew her donor was infected.

SUE BELL: My then surgeon had called me up to ask me to come and have a blood test, just as a matter of course, and after the results had come through, he rang me up and said that he had been notified by the Red Cross that the donor of some of the blood that I had received was Hepatitis C-positive and that they were just tracking back who had received his blood and I was unfortunate enough to be one of the recipients.

REPORTER: Sue still has the virus, but fortunately no symptoms.

SUE BELL: Having this thing hanging over my head for the rest of my life, it is a bit unnerving and upsetting at times.

REPORTER: Hepatitis C is an insidious disease, 10 times more infectious than the AIDS virus but slower to damage the body. Of the 200,000 people infected in Australia, three-quarters of them have chronic Hep C infection. In some, that will mean intense pain in the liver, nausea and loss of quality of life. In some, it will develop into cirrhosis or scarring of the liver. The only option for those who develop liver failure is a liver transplant, Hep C being the most common cause of such transplants in Australia today. Hep C can also lead to a painful death from cancer. Like many other sufferers, Sue doesn't yet know her own prognosis.

SUE BELL: I'm scared about what may happen. I look to the future of having a long life with a wonderful husband, beautiful daughter and just living live to the fullest, and that is how I see my future being. There is something in the back of my mind that says it may not always be that way.

NIEL LAKE: I suppose I do face the prospect of cirrhosis of the liver and if I'm not lucky, possibly cancer of the liver, which...

REPORTER: How do you feel about that?

NIEL LAKE: Well, I suppose it just puts me in a situation where I've got to optimise my time in what I can do to provide for my family.

REPORTER: 13 years ago, Niel Lake was a rising star in the Australian Federal Police - highly commended, just had a promotion to superintendent - when he needed a blood transfusion during a bowel cancer operation in late 1989. Nine weeks later, he became jaundiced and severely lethargic.

NIEL LAKE: I did go back to the surgeon who had performed the operation for me and his final opinion was that it was transfusion-related Hepatitis.

REPORTER: But Niel never heard anything from the Red Cross Blood Service.

NIEL LAKE: I did phone the Red Cross on one occasion and they suggested that I write to them, which we did through a solicitor, and their initial response was see our solicitors and they really didn't want anything to do with us.

REPORTER: So how do you feel about the way the Red Cross has treated you?

NIEL LAKE: Well, I think at this stage, no-one has ever bothered to contact me, no-one has ever counselled me, no-one has ever said to me "Is there any way that we can support you to make sure that your lifestyle is a little better?" and I think that's just a pretty shabby deal.

REPORTER: Niel Lake says he's only coping with this disease and the constant fatigue and sickness, because of the love and support of his family. His wife was forced to work to financially support them as he became more debilitated.

NIEL LAKE: I was down to very simple goals like getting out of bed and getting to the shower and I really had to reassess everything that I did, and at the end of the day I really had no alternative but go out on early retirement. It's destroyed my career, it's had a major impact on my family, and I suppose, if one considers the number of other members in the community that are in the same boat, I would feel that a lot of people have been left on the sidelines out of this, and certainly, it has destroyed a lot of lives.

REPORTER: Single mother-of-two Jacinta Jacobson, has so far had a bitter experience with the Red Cross Lookback program that is supposed to trace suspect donations. Earlier this year, she inadvertently discovered she has the more serious Type One Hepatitis C which has already damaged her liver.

JACINTA JACOBSON: Oh, I was flabbergasted, I was just floored because I had no way of knowing how I got this. I thought it was something that happened to junkies or, you know, people who did awful things to themselves. But I had had a really bad motorcycle accident about 15 years ago and as it transpired, I did actually have a transfusion.

REPORTER: Jacinta contacted Lookback in Tasmania. They said they'd check hospital records. Lookback later admitted that units of blood were cross-matched for her ready for transfusion during her emergency operation, but insisted that hospital records showed these were not transfused. Incredibly, it was then up to Jacinta to find out the truth. Her persistence unearthed this chart, which recorded that she had received one unit of packed blood cells the day of her operation. In other words, whatever Lookback had said, she had been transfused.

JACINTA JACOBSON: If I can find these records why can't they?

REPORTER: Have you contacted Lookback again?

JACINTA JACOBSON: Yes, I called them again and said "Excuse me, I've got this here to say I have been transfused. What are you going to do about it?" And they all went into a mad flap and said "Oh OK, well we'll look into it again for you." They have tracked down one of the donors and they've come up clear, but they can't find a second... I was cross-matched with two units. One of the units has come back clear, the other one they can't find. So 'Too bad, so sad we can't help you' was virtually the message that I got.

REPORTER: 10 days ago, Jacinta was diagnosed with cirrhosis of the liver. She'll now

undergo a year of drug treatment to have any chance of preventing liver failure in the future.

JACINTA JACOBSON: It's awful, I'm a single mother with two children. What's going to happen to my kids? My youngest is four. You know, I'm hopefully - if I can get 20 years, if I can get her out into the world I'll be happy with that, but who says I can? There's got to be some more compassion, more information, telling us what you're doing, keeping me informed about what's going on. Not have me calling and calling and saying "What's going on?" and leaving me wait for three and four weeks between letters. You know, it's awful.

MAN AT MEETING: First they said I only had five blood transfusions. Then they admitted I had six...

REPORTER: The Tainted Blood Product Action Group, started by Hep C campaigner Charles MacKenzie with help from the Reverend Bill Crews, wants more support and compensation for those with transfusion-acquired Hep C.

REV BILL CREWS, EXODUS FOUNDATION - ADDRESSING MEETING: We know some people got compensation but they signed secrecy clauses so they're not allowed to tell what happened. We know that. And that is just blatantly unfair, blatantly unfair.

REPORTER: To date, compensation has been arbitrary, paid to some victims of an infected blood donation, but not to others. The very fact that compensation has been paid, let alone how many hundreds of people have received payouts, is an issue the Red Cross and its insurers want to keep quiet. But it's an issue the Hepatitis C Council, among others, want to see open to scrutiny. How many people got compensation?

STUART LOVEDAY, HEPATITIS C COUNCIL OF NSW: We have no idea at all because...

REPORTER: Why not?

STUART LOVEDAY: Because the inquiries that were carried out were subject to confidentiality agreements.

REPORTER: And do you think that's the right way to go, it's all shrouded in secrecy?

STUART LOVEDAY: No, I don't. I think it should be out and up front and in the public domain, certainly. Openness and honesty is a very important thing because without the full facts we're not going to be able to reduce the impact of Hepatitis C as much as we would like.

REPORTER: Andrew Grech, of solicitors Slater and Gordon, has handled much of the legal action on this issue.

ANDREW GRECH: Over the last, almost a decade, this firm has acted for 700 to 800 individuals and some 400 to 500 of those have now resolved their claims and received compensation as a result of that litigation.

REPORTER: Corey McCullagh is one of the lucky ones, finally compensated after an eight-year legal battle. But for the other people in this story, they have received nothing. For many of those infected through blood in the late 1980s, before the specific Hep C test was available, there's the added bitterness that their infection could have been prevented if other tests, known as surrogate or substitute tests, had been done on blood donations.

CHARLES MACKENZIE: What had happened in the US from as early as 1982 and across the country of America from 1986 was the implementation of substitute tests, a combination of markers that would look for signs that someone has a virus like Hepatitis C, and they were said said to decrease the incidents of post-transfusion Hepatitis C very significantly. They weren't used. So it is my understanding from expert witness from around the world and in fact from information from several commissions of inquiry, from around the world, that there were very real tests and very real opportunities to reduce the chance of me getting it.

REPORTER: Do you think Australia should have adopted the surrogate market marker tests at least when the USD did in 1986 to try and reduce transfusion-acquired Hepatitis?

PROFESSOR GEOFF FARRELL, LIVER SPECIALIST, WESTMEAD HOSPITAL: I know at the time I wish they had, but you know, I'm a liver specialist, I see people with liver disease and my brief is to, you know, look after them well and ideally, to prevent this sort of problem. So I do have a bias there. Uh, I know...

REPORTER: But your view at the time?

PROF GEOFF FARRELL: My view at the time was that I would like to have see that done. The problem of course was that that would have meant about 15% fewer blood donations and I know that the balanced judgment of the blood bankers was that would put a real strain on blood supply and so, you know, as a community we have to balance risks of blood transfusion versus the importance of having blood there if we have a car accident or a big operation.

DR GORDON ARCHER, FORMER DIRECTOR NSW RED CROSS BLOOD SERVICE: The incidence of Hepatitis following blood transfusion was very very much less in Australia than it was in America and also, at that time, the disease was agreed by everybody to be extremely mild.

REPORTER: Dr Gordon Archer was director of the NSW Blood Service up until the early 1990s. He was just one of a number of senior health decision-makers on blood issues in the mid to late 1980s.

DR GORDON ARCHER: 1986 we had the feeling that Australia didn't have the problem as they did in America and that maybe surrogate testing may not be any use. So the decision was made rather than introduce an ALT testing at that time, maybe we should do another post-transfusion Hepatitis study.

REPORTER: Was there a worry about losing donations?

DR GORDON ARCHER: Of course there was, because it was just at the end of the AIDS time and we were extremely short of blood.

REPORTER: So I guess what you're saying is it's really a constant juggle between the need to have blood but the need to reject some blood because it might be carrying a virus?

DR GORDON ARCHER: That's right. That's the position at that time.

REPORTER: The study took almost four years. So did that show that if you had done an ALT surrogate test on those donors, you may have prevented Hepatitis C infections in three of the four cases?

DR GORDON ARCHER: I'm not going to answer that question, that's an unfair question.

REPORTER: Why is that? I'm just trying to say what did that show about the value of ALT tests?

DR GORDON ARCHER: No, I can't answer that question. I can't. You can't lob that on me.

REPORTER: The ALT tests...

DR GORDON ARCHER: What you're trying to get me to say is that we should have been ALT screening and I honestly don't believe that. I think we had to do the survey and what we would have decided after the survey was finished, who knows? You know, you could predict that you might, but who knows?

ANDREW GRECH: That judgment was wrong. The clear evidence is they had an opportunity to prevent people from being infected with Hepatitis C and they made, in my belief, a genuine but nonetheless wrong decision not to introduce those tests, and as a result of that decision, hundreds and potentially thousands of Australians have been

infected when potentially their infections could have been avoided.

REPORTER: Do you think you and other health senior managers have to wear some responsibility for those people having got Hepatitis C through blood transfusions?

DR GORDON ARCHER: That's an unfair question to me. I'll answer it strongly no. I think we had the interests of our donors and the interests of our patients at heart and we tried to do the best thing we could.

MICHAEL POLLACK, HEP C SUFFERER: I had a major motorcycle accident at the end of 1983, August 1983, and my blood pressure was 60/0 when I arrived at the hospital, so I was practically had bled to death, so yeah, I required quite a few transfusions in...

REPORTER: Those transfusions saved Michael Pollack's life, but he believes they also gave him Hepatitis C. Michael didn't become aware he was infected until he tried to donate blood in 1990, and what happened then reveals another alarming aspect of this tragedy. After giving blood in 1990, Michael got a letter from the transfusion service telling him he could be carrying the Hep C virus, but incredibly, he was invited by the blood service to keep donating his infected blood to be made into plasma products that are used by haemophiliacs and hospital patients.

MICHAEL POLLACK: They gave me a donor card and asked me to donate again at three months and six months.

REPORTER: So just a minute. This is the Red Cross, they've found out that you're Hepatitis C positive...

MICHAEL POLLACK: That's correct...

REPORTER: ..and they give you a donor card and encourage you to come back and donate blood?

MICHAEL POLLACK: Yes, they did, and they said they would make it safe, OK, they have ways of killing the disease and they would use products to make other things, they would use my blood to make other products.

REPORTER: This practice of collecting Hep C- infected plasma no longer happens, but the Red Cross Blood Service continued to collect it until possibly the end of 1990.

DR GORDON ARCHER: Well, the policy at the time was that plasma goes to the Commonwealth Serum Laboratories. They make fractions from that - heat-treated fractions, immunoglobulin fractions - and then they come back to the blood banks for distribution. It's not blood that goes there, it's plasma, the plasma is treated by chemical means so there's absolutely no risk of virus transmission from those products.

REPORTER: Michael says he donated his infected blood plasma into the early months of 1991. Did you stop donating blood yourself or were you asked to stop by the Red Cross?

MICHAEL POLLACK: I stopped. I had their assurance that everything was OK but, as I said, it just didn't sit well with me and I thought the less infected blood going out into the system may help. So I stopped after the six-month donation.

REPORTER: When Michael's letter was revealed in newspaper articles earlier this year, it sparked a Federal Government inquiry into this very practice. That inquiry is due to report by Christmas. But according to many experts, the practice of collecting Hep C plasma for use in the blood supply system would never be acceptable today because it would totally contravene all blood safety guidelines.

PROF GEOFF FARRELL: You know, in the health care system - in any sort of system that involves human beings - there's potentially an error that one would not like any infected unit of blood in the system whereby it could be accidentally mislabelled and, you know, used, et cetera. So I think a safety is, you know, to really start at the beginning and not let any infected blood into the system.

REPORTER: Most experts agree that testing of donations by the blood service these days has so improved that the risk of Hep C infection through a transfusion is now extremely low, but it's the legacy of Red Cross Blood Service practices a decade ago and the inadequate way the service has handled victims of transfusion-acquired Hep C that now needs to be openly faced up to by the blood service, with greater compassion and support for those it infected.

ANDREW GRECH: Notwithstanding that it does great work in the community, and not withstanding that this is a great service to the community, it still has responsibilities, and also to be accountable for its decision making. So when errors of judgment occur, as we believe occurred in the Hepatitis C situation, that they are fully accountable for those like any other public institution.

DR GORDON ARCHER: I think you have to feel sympathetic to anyone who got Hepatitis C from a blood transfusion. Maybe the whole thing needs to be looked at with a view to seeing what can be done for these people who picked up the virus this way.

NIEL LAKE: I believe the proper way to deal with this matter is a full judicial inquiry to deal with all aspects of our transfusional service. We need to be assured any victim can go into hospital and be assured that what they are receiving has the optimum purity available at that time.

Tainted Blood

November 10, 2002

Reporter : Helen Dalley
Producer : Nick Farrow

Eleven-year-old Corey McCullagh looks and plays like most normal young boys. But Corey has the potentially fatal disease that attacks the liver, Hepatitis C.

Corey was infected with the Hepatitis C virus as a newborn baby in December 1990. Just 20 hours old, he received a blood transfusion to save his life. It turned out to be contaminated with Hepatitis C.

Hep C is disparagingly known as the "injecting drug users", or "junkies" disease — since it is spread by blood to blood contact, mainly through unsafe needles and syringes. But an estimated 10,000, possibly 20,000, Australians were infected with Hep C-contaminated blood during the 1980s. Some were even infected into the 1990's — *after* screening for the disease was introduced by the Red Cross Blood Service. Many weren't in high-risk groups — including women in childbirth, and people needing blood during surgery.

"This is the single greatest medical disaster in Australian history and we've had no inquiry and no special assistance for the victims of this tragedy," says long-time Hep C campaigner Charles MacKenzie.

Hep C is an insidious disease, ten times more infectious than AIDS, but slower to damage the body. Of those infected, three-quarters have chronic Hep C infection. In some it will mean intense pain in the liver, nausea and loss of quality of life. In others it will develop into cirrhosis, or scarring of the liver. Some will progress to liver failure. The only option for those who develop liver failure is a liver transplant. Hep C is the most common cause of such transplants in Australia today. It can also lead to a painful death from cancer.

What happened to those trying to cope with this insidious disease is a scandal. According to sufferers, the Red Cross Blood Service has not been frank about tainted blood transfusions, giving little or no information to recipients of infected blood or blood products. Any legal action has been shrouded in secrecy clauses imposed by the Red Cross Blood Service.

These sufferers say the blood service down-played risks of infection even after first-generation screening tests were introduced in February 1990. According to many, they've had scant support in dealing with the disease they acquired from blood.

Some say they were never offered counselling, financial or medical assistance. Others have gone for years not knowing they contracted Hep C from blood transfusions, so losing the opportunity of receiving treatment — while possibly infecting those around them.

According to Andrew Grech, of solicitors Slater and Gordon, there are probably still hundreds of individuals who don't know now that they've been infected.

"The attitude of the Red Cross was to put down the shutters and try and down-play the claims being made by claimants and to some extent hope that it would go away," says Grech. "It hasn't gone away — it's been an ongoing problem for them."

The Red Cross still prefers to avoid public scrutiny, and deals with media questions on the whole episode by ignoring them. The Red Cross Blood Service refused to be interviewed for this program.

There are concerns too that before the specific Hepatitis C test was available in 1990, Australia failed to implement other tests, such as one known as the ALT liver function test, that could have prevented some Hep C infections.

Corey isn't the only one who feels betrayed by the Red Cross Blood Service — a life-saving organisation so respected in our community.

"I've been swept under the carpet — forgotten about," says Sue Bell, who got a Hep C-infected blood transfusion after giving birth in August 1991. Her transfusion was a year and a half *after* screening began. Infected blood still slipped through, somehow. But she's had no explanation from the Red Cross.

In January 1992, the Blood Service conclusively established that the donor for Sue's transfusion had been Hepatitis C positive. But it took a further 10 months before an investigation began to trace the recipients of his blood. Sue wasn't contacted till March 1993, 14 months after they knew her donor was infected with Hepatitis C.

"I feel a bit sad that there's nothing they feel they have to apologise for. If it was a mistake, a hiccup, that they can't just ring me or write me a sorry letter — because it has changed my life."

Some victims, like former Superintendent of the Australian Federal Police, Niel Lake, have had to pay for their own medication to treat transfusion-acquired Hepatitis C. The treatment of Interferon cost thousands of dollars out of Lake's own pocket.

As Lakes observes, with remarkable understatement, "I just think that's a pretty shabby deal."

People living with Hep C are often the target of discrimination, because of its association with injecting drug use. A typical victim, "Anne" is so traumatised by her Hep C infection, she won't publicly reveal her identity for fear of recriminations against her child.

Anne is proof that Hep C infection through transfusion was happening long after blood screening started. She was transfused with Hepatitis C-infected blood during a complicated childbirth in July 1992 — two and a half years after testing began. That testing, the Red Cross assured the community, was supposed to eliminate tainted donations.

Then out of the blue, seven years after her transfusion, she received a bombshell letter from the Victorian Department of Human Services, stating: "You may remember that in 1992 you received a blood transfusion." The letter informed her "one of the donors… may

have been infected with Hepatitis C”.

"Originally I was just shocked," she says. "But it sort of made sense when I looked at my health because I had gone to the doctor several times before trying to find out what was wrong with me."

The letter told her to contact the Lookback program — set up to trace suspect donors — and get testing done. But it wrongly stated “at the time the blood was donated, there was NO test available for screening blood donors for Hepatitis C". In fact, specific Hep C screening *had* been introduced in Australia in February 1990, two and a half years before her transfusion.

To date compensation has been arbitrary, paid to some victims of an infected blood donation, but not to others. Young Corey McCullagh is one of the lucky ones, finally compensated after an eight-year legal battle. But his mother Tracey isn't allowed to talk about the settlement.

The mere fact that compensation has been paid, let alone how many hundreds of people have received pay-outs, is an issue the Red Cross, and its insurers, seems determined to keep hidden.

Reference 'D'

Open Forum
Plasma Self-sufficiency in Canada - is it a matter of safety?
National Blood Safety Council

March 29-30, 2001
Hyatt Regency Vancouver Hotel, 655 Burrard Street
Vancouver

Day 2

Friday, March 30, 2001 at 8:30 a.m.

Vancouver, British Columbia

--- Upon resuming on Friday, March 30, 2001
at 8:36 a.m.

THE CHAIRMAN (MR. LEFEBVRE): Thank you very much.

Just a couple of quick housecleaning things.

The translation headphones that everybody was using yesterday, they all need to be returned. At the end of the day yesterday we were missing one. We get billed for them if they don't returned so please check to make sure that one didn't accidentally get dropped in your bag or your briefcase.

You may need them again today, so you can pick them up. If they weren't on the seats they will be at the back, so you can collect them for -- I don't believe we have any presentations in French, but if you want to hear the translated proceedings, then please pick one up.

So, without further ado, I am going to reintroduce Ted Vokes who will continue to lead us through our discussion for the rest of the day.

It's all yours.

DR. VOKES: Thank you.

Good morning. I hope you all slept well, ate well. Whatever you did, I hope you did it well.

We have just one housekeeping item, aside from the translations that Allen already covered, and that is to say, please be attentive to the fact that the agenda today goes until 1:30. So that means you need to keep your coffee and food level up throughout the day to get through to a delayed lunch. Okay? So I am just giving you fair warning in advance that this is what is going to happen. If you think we worked you hard yesterday, well, you know, today all the more so.

We want to open today's session with three presentations that are going to offer us an international perspective, successful models from around the world. Each of our speakers are going to take about 10 minutes to give us an overview of those solutions.

I would like to start by introducing Dr. Brian McNamee -- did I pronounce that correctly?

DR. McNAMEE: McNamee.

DR. VOKES: McNamee, thank you.

Who is going to speak about the Australian context.

DR. McNAMEE: Thank you, Ted.

It is certainly a great pleasure for me to be here and hopefully share with you some of the experiences from the Australian system. I thought I would just quickly go through the way in which plasma fractionation is undertaken in Australia and CSL's role.

For those who don't know CSL, we were actually founded in 1916 as really Australia's Biologicals Manufacturer and we have manufactured biological products for a long time since then, manufacturing a range of products. We use to ferment penicillin, we used to extract insulin, we certainly make a large number of vaccines, human and animal health, and we also process human plasma.

In 1994 we became a publicly listed company. Really for the last almost 50 years now, we have been processing plasma on behalf of the Australian Red Cross and the Australian community.

I think it is noteworthy that really until 1994 CSL was an arm and an instrument of the Department of Health. They are our shareholder, they are our regulator and very much they are our customer. To some degree the privatization was an attempt to break that complex relationship that we had with the department and try and put the organization on a firm footing.
The final thing I would like to say, is, of course, we are Australia's sole plasma fractionator and the federal government reimburses CSL for the costs of producing a full range of plasma derivatives. Those products then are distributed by the Australian Red Cross. They are actually not distributed by CSL, they are distributed by the Australian Red Cross to the hospital community.

I think one of the things that sort of we heard a lot of discussion yesterday was about self-sufficiency and I think that it's fair to say that certainly Australia has a long commitment to it. Very much it is enshrined in both federal and state legislation.

We have a Human Tissue Act that all States have enacted and that means you cannot economically trade in human tissue. That not only is important for blood, but also underpins our belief and our value system whether it be for kidney transplants, kidney donations, corneas, bone marrow, whatever. There can be no economic trading in human tissue in Australia.

Australia endorsed, in 1975, guidelines and in fact that World Health Organization resolution was incorporated in the 1989 guideline for Registration of Drugs, which state, amongst other things, a policy commitment to self-sufficiency, that we shouldn't be reliant on donors in other countries because as a nation we believe it is not only in our national interest but it is an international responsibility.

That is what is enshrined in the legislation for drugs and the system we have in the country.

What that has meant, in the plasma protein area, is that foreign products, foreign manufactured products could be registered in Australia but they needed to demonstrate a significant clinical advantage over the Australian product.

In essence, at CSL we do have an excellent range of products and in reality there are very few registered products in our country.

In 1997, that foreign registration was supplemented by a system whereby a blood replacement list was put together of international companies who may be able to provide products to Australia if there is a shortage. That list has now been put together.

If I move to what Australia sees as the benefits of self-sufficiency, I think it is very much, first and foremost, we believe that a voluntary blood system provides the safest and most ethical means of securing the blood supply.

From a personal perspective, I don't think any of us are saying that a remunerated donor is not also a potentially positive thing to do, but in the Australian context we have tried to encourage and support and fund the notion of a voluntary donor system.

I think that one of the other benefits that we see in the system is that we have full integration of our system through the whole value chain from collection through to the marketplace. Probably we have the best system in the world, I think, from monitoring the usage of blood products, for actually enacting recalls if they are necessary. The whole traceability strategy that Australia has put in place, I think, puts us in a very good position.

The government, when they entered into contracts with both the Australian Red Cross and CSL, did so on very much a performance basis. I might add here that although we are the sole fractionator in Australia, and in one sense CSL owns our plant, there is complex legislation that enshrines the Commonwealth control over our activities.

To give you an example of that, CSL is a publicly listed company, it's head office must always remain in Australia, the majority of directors must be Australian. Similarly, if the Department of Health believes that we are not doing something in the interests of the national blood system the Health Minister has it within his powers to actually order me to jail, as Managing Director of the company, if we do not comply with his direction.

There is no negotiation in this, it is enshrined in legislation, and it gives him extraordinary powers. Clearly we take notice of what the Commonwealth says. Clearly.

So Australia, therefore, tried to get the balance right of having a commercial fractionator like CSL, but one that is significantly controlled.

The other significant control placed over CSL is that the fractionation asset that we have cannot be used as collateral for us to borrow money, as an example. So if CSL wants to borrow money to grow our business internationally, we cannot use the fractionation asset, which the Commonwealth believes is so central to public health policy in this nation that they do not want it to run the risk of falling into the hands of a bank or some other creditor.

So, in essence, it is a complex system to try to get a balance right between the needs of a commercial organization, the requirements of the domestic market and the belief that Australia has in the self-sufficiency model.

I think, on balance, we in Australia have achieved a degree of public confidence in our blood system that is superior to most countries and it is because, I think, of the way we have balanced and the checks and balances between a voluntary system, between the public confidence in the Red Cross system and the way the Commonwealth has handled the legislation.

I do believe that we have done well with regard to the issues of safety and quality.

If I now move to the issue of: Well, that's great, but happens if there is a shortage of product, particularly IVIG, which is always very topical. In fact, if you look at the Australian system I guess there are two products that you would argue are in short supply in which medical rationing does occur. The first is IVIG and the second is Anti-D(ph).

Now, if we look at IVIG, in Australia we have categorized now the use of IVIG into three areas. They rank from priority one through to priority three usage. The clinicians who did a report for government recommended that Australia -- we have a population of 18 million people, about 50 per cent less than Canada -- required last year about 900 kilograms of IVIG.

In effect, our system was able to provide about 90 per cent of that. So it is true that we are

about 10 per cent short of what the clinicians of government believe to be an optimal usage of the drug.

I think for those who have been exposed to Australia, you would recognize that we have some of the most complex and rigorous pharmaco-economic analysis for the use of any drug and very much plasma derivatives and blood products are similarly put through the same rigorous process to ensure the clinical use is appropriate.

The other one is Anti-D, and again we are trying to gear up to collect more Anti-D immunoglobulin.

I think the other strategy the government put in place to ensure that the national fractionator didn't put pressure unnecessarily on a regulator being a sole producer -- because that is a legitimate concern I think of anyone -- that if you have a sole fractionator, if we have a problem, then what happens?

We, in the government, have agreed to put in a place a three month buffer of stock for all products that are in short supply. So we today actually have three months in the fridge so if we have a problem in manufacturing or a problem in testing or a problem in availability, the government can manage that system through the use of this stock situation.

So when we have looked at -- I have with government, saying: Well, what is the best model for us to reach what we are looking for from an IVIG perspective? The government always comes down with a view that providing additional funding to the Red Cross to collect plasma in Australia, under the voluntary donor system, is the best dollar they can spend. So first and foremost a strategy to increase plasma collections in the Red Cross is the number one priority.

They have periodically purchased some product. We do have some sandiglobulin(ph) also in Australia. I guess now that we own ZLB that is a sort of an interesting position for us to be in, but that is the only other product that actually does come into the country. That is what is used to titrate, from a clinical perspective, any shortage.

The other option we have all looked at is whether or not CSL should import plasma. There has been a debate whether we should get into the plasma procurement market. Again, the government's belief -- the Australia ethos at least is, for the moment, we would prefer to have a local solution and fund the Australian Red Cross and provide them with the skills necessary.

You see, the reality is the Red Cross is a franchise and is a retailer. It has actually got to be out there in the marketplace. This is really new thinking within the Red Cross, that they have to use their brand, they have to use their image and they have to be a much better marketer to get people in.

I think that there is a whole skillset change going on in the Red Cross to recognize that is their first and foremost job, to actually support the system, get the people in the door, deal with them properly and deal with them professionally. I think we are going through that system and I think that we are seeing some significant improvements.

To give you an idea of the sort of volumes that we do in Australia, we do about 250 tons of plasma. That is what the Australian Red Cross collects. It has been growing around 10 to 15 tons per annum for the last many years and we certainly hope that this is sort of the minimum growth that can be achieved by the Red Cross.

I thought, listening to yesterday's conversation, I have been, I guess, in the government system, because I was in CSL since 1990 through the privatization.

I guess my advice, if I had any for the Canadians here, would be that the blood system is complex enough without you trying to fix all the Canadian systemic issues that you see. So whether it be transfer processing of products, whether it be clinical effectiveness or clinical usage, I think that fundamentally the issue always comes down in Australia: How do we get

more done? What can we do to improve? That is the first and foremost thing we always come back to.

The second thing is, IVIG clinical guidelines. Critically important that we actually understand that the right patients are getting the right dose at the right time. So sure, that means an effort, but we in have worked very hard to try to do that, to try to ensure that whatever rationing occurs, it occurs in the most clinically sensible way.

I guess, the third comment I would make is that we are obviously a national fractionator and with the Swiss Red Cross now we are clearly a fractionator that works closely with the Red Cross organization and blood transfusion services all around the world. I think that to some degree there is plenty of capacity in the industry today to support Canada's needs.

I don't believe that there is an issue of shortage of capacity at all. So you wouldn't be building a facility for that reason. You might want to do it for Canadian reasons, I don't know, but you shouldn't be doing it if you believe that there is a shortage of capacity. That is not the case.

There is quality capacity available. I think there are quality fractionators willing to support you, and I think that -- my view is, again, it is professionally dealing at the retail end to actually get the donors who I believe are there if we can manage the system more effectively.

Thank you.

-- Applause

DR. VOKES: I think we are going to have lots of questions.

If we could take some questions for Dr. McNamee.

Chris.

MR. HEALEY: Good morning. Chris Healey.

Dr. McNamee, you may have said it and I missed it, but what percentage of the donors in Australia are plasmapheresis or apheresis versus recovered?

The second part to the question would be: With that acquisition of ZLB, how does that factor into the Australian objectives of self-sufficiency, and so forth?

DR. McNAMEE: With regard to -- clearly the Red Cross is working aggressively to increase plasmapheresis as part of their collections. They are probably now at around 30 per cent plasmapheresis, with a realistic objective around 50 per cent I think would be a sensible target.

With regard to our acquisition of ZLB, I guess it provides Australia with further comfort that if we had a problem at our plant or if a jumbo landed on it -- it's near the airport -- there would be a mechanism, in a risk-management sense, to support Australia continuing fractionation of plasma.

I guess that I heard yesterday that the Canadian Blood Services are contemplating whether they should have more than one fractionator. I think in a risk management sense certainly you would want more than one plant. Whether you need more than one fractionator is a debate.

MR. HEALEY: Just a very quick question.

Because IVIG drives your volume being processed, what would you do with the surplus product?

DR. McNAMEE: We do have a small amount of surplus product. With regard to albumin as an example -- again, we have gone through the debate: Do we give it to the Africans? Do we

give it to Papua New Guinea? That is so complex when you try and do it. The best will in the world, it is very difficult to achieve.

So the Commonwealth has basically changed its view now and said: Look -- to the donor organizations -- if you want those products, buy them, but otherwise we, CSL, will sell them internationally and pay a royalty back to the blood transfusion service to help fund the overall system.

So, in one sense, we make some small incremental revenue and clearly the transfusion services gets the predominant benefit of it.

MR. HEALEY: Could you tell me what "small" and "incremental" is in percentage terms?

--- Laughter

DR. McNAMEE: To be honest, we are in the middle of these negotiations at the moment. We do with New Zealand also. So I would prefer not to answer that.

MR. HEALEY: You would rather not. That's fine.

Thanks.

DR. VOKES: Denis.

MR. MORRICE: Brian, that was an excellent presentation. Thank you very much.

The Australian government, do you guarantee, then, CSL a level of profit. I am just thinking of our Bell Canada years ago under the CRTC, basically as one telephone company, it was going to guarantee a profit and therefore you have a standard of service, et cetera.

Do you do the same? Is that how it's done?

DR. McNAMEE: When we are publicly listed the government guaranteed a minimum volume throughput through the plant. At the prices that we had negotiated that meant that we didn't lose money but, in essence, that was it.
So to some degree the profitability is controlled by the pricing. For those who know the Australian system, we have a very tough pricing regulator. Our prices, you know, in essence, are probably only 50 per cent, 60 per cent of what are achieved internationally.

It is sufficient because, I guess, we don't have huge marketing costs because the product is then provided back. So there is a volume value trade-off that the Commonwealth gets a significant discount, yet we make reasonable money. But, in essence, we make more money by selling our surplus capacity internationally.

MR. MORRICE: A second question: What do you think would happen in Australia if in fact the Australian government took over the Red Cross and took over collection?

DR. McNAMEE: Well, having worked with the government -- I don't want to insult them, but you know, governments are good at some things. They are certainly not good at that. So our view would be that it is important that the Australian Red Cross continues to be funded on performance and that it is a national funding system.

We have found that in Australia the account system whereby the funding is 50/50 between the States -- which is really like a province here -- and the federal government has led to great difficulties in some States, where the budgetary problems in New South Wales would impact on blood. So the system is moving more to a federalist system and, again, essentially being performance-based for the Red Cross.

MR. MORRICE: But I guess I was trying to get more at the collection, the philosophy of it, how the citizens of Australia would perceive that.

DR. McNAMEE: I think if you ask the Australian citizens, the Red Cross is a great brand and a great image. Government doesn't have either of those things.

--- Laughter

MS CUMERFORD: Sheila Cumerford.

I would just like you to speak to us a little bit about your marketing strategy for your donors. I don't know if you have television ad campaigns.
Are there any incentive programs for employers to let people who desire to give blood or plasma to do that?

Could you give us an idea of the average time it takes to give blood in your system in Australia and plasmapheresis as well?

DR. McNAMEE: Okay. There are a lot of questions there.

I think that where I see it, to be honest, from the CSL side, is we have seen a tremendous improvement in the way the Australian Red Cross markets to people, particularly through radio and print.

TV I'm not sure is a very cost-effective mechanism, but certainly radio and print is used much more effectively nowadays.

But the other issue is, we are now getting the donor collection sites out to where the people are. In Australia we had a problem that, you know, we had one big centre in Melbourne and one big centre in the middle of Sydney. Well, for those who have been to Sydney, it is impossible to get around Sydney, even on the -- except during the olympics.

--- Laughter

DR. McNAMEE: So, in essence, they have a much more effective system now of getting mobile collection units out to employers. So certainly many employers have been very supportive when we bring it to their site of manufacturing or industrial use. That is how we are trying to handle it.

Plasmapheresis centres, again we are trying to make it a quality experience. In the old days -- I don't know what it is like in Canada, but there were dingy, crummy facilities. I mean, who would want to go to them, in Australia anyhow, the ones that they had. So they are much nicer now, bright lights, good cup of tea, nice lounge to sit on. They are actually making it a positive experience.

Because it is a very generous gift. I mean, that is what it is, it is a very generous gift and we made it very hard for them.

So I think the whole thinking now has changed to say: How do we make it easier for donors? What do we do to encourage them, retain them and make it an enjoyable and fulfilling experience? We find we don't have to pay them for that.

DR. VOKES: Graham.

DR. SHER: A quick question.

Graham Sher, Canadian Blood Services.

You said that Australia is currently using around 900 kilograms of IVIG. What has been the annual growth in that over the last few years and did the guidelines that you referred to have any impact on slowing the growth of demand for IVIG?

DR. McNAMEE: Okay. I think the annualized growth outlook is about 10 per cent per annum.

Now, we have optimized our yields inside CSL so we have probably achieved what we are hoping to be anything up to a 15 to 20 per cent yield guide shortly. So we think through yield we are achieving a lot to meet some of the growth.

I'm sorry, what was the second part of the question?

DR. SHER: The guidelines.

DR. McNAMEE: Yes. The clinical guidelines are always interesting. I also heard yesterday, of course: Well, it's given for free and let's charge for people and they will really notice it.

Personally, the experience in Australia is most systems have an impact initially and then they drift away again. Because fundamentally this is quite a useful medical product and the consumers and the doctors actually want to use it.

I personally don't think there is a lot of inappropriate use. I don't think there is a lot of waste in the system. I mean, people don't unthinkingly volunteer for blood product nowadays, they actually have a clinical need.

So I'm not convinced -- I heard one speaking yesterday saying: Let's put like a radiation label on them to really scare people away from them. Well, I'm not sure that clinically is correct. I mean, I think people use it generally because it is providing a significant clinical benefit.

So all those strategies are important I think, mainly to explain to the people and the doctors who can't get the product that we have a system. I mean, people understand the system and it is fair and equitable. It is not based on how much you earn or whether you have insurance or not. It is fair and equitable. I think people would understand it and, I think, accept it.

MS CUMERFORD: I think when we were talking about payment yesterday it wasn't actually on the part of the patient but rather out of the budgets of different providers.

But my question is about the performance measures. You are saying that it is performance-based on the part of your company. What are these measures and how are you rewarded for achievement of them or -- apart from being sent to jail -- for not achieving them. How is performance actually assured?

DR. McNAMEE: I think there are two separate issues. One is that we in the Australian Red Cross, particularly for the Australian Red Cross, accept that they should have a baseload funding for their infrastructure but should be paid on performance in a marginal sense. So if they achieve targets then they actually get more funds to invest into the things they want to do. So it's a mix for the Red Cross.

With regard to us, we have a two-tier pricing system, which means that we get higher prices for the initial volume, but as volume grows we clearly have already recovered our overheads in the business so the government and we get a reasonable deal then.

So the second tier pricings are in fact anything as low as 50 per cent of the first tier pricing. So the Commonwealth gets a great deal. I mean, they love our incremental business because they are the cheapest plasma proteins the world.

MS CUMERFORD: What about quality?

DR. McNAMEE: Well, quality -- the TGA is a tough regulator. I think we have had to -- we have very high quality products. We could not survive if we didn't. In fact, we could never remain an exclusive manufacturer if people didn't recognize our products were truly world class.

We would argue in Australia we have the best range of products from any fractionator internationally. People might debate that, but we have a very good range of products.

We keep investing in it. We keep doing more and more work in that field and that is a part of the trade-off. Because we know if we don't continue that very high standard the pressures will be enormous for people to import products, et cetera, and the economics of our business would suffer.

So it is in our interest to ensure that we have that. It is in our contract and the TGA comes and regularly audits that.

MR. DICKLAND(ph): Brian Dickland, Murphy Novens.

I remember last year, I think last year one of your regulators made a presentation in Washington -- I forget her name -- but she was saying because of the increased indications for IVIG that Australia probably would have to import plasma for those products.

Has that come to pass or where does that stand right now?

DR. McNAMEE: The government did buy some sandiglobulin to put the national reserve together, but because of our yield guide it hasn't been necessary for us to bring in plasma at this stage.

MR. DICKLAND: Do you think it might be?

DR. McNAMEE: I think the Red Cross -- I think a bit like a spokesperson yesterday, that if we sensibly deal with our community I think that is where we should put our dollars, if we can. So at the moment I think that -- we certainly are not bringing in plasma and that is not in the plan today.

MR. DICKLAND: Sure. Thank you.

DR. VOKES: Durhane.

MR. REES: Wes Rees, CBS.

How many plasma proteins has the TGA approved for use therapeutically?
DR. McNAMEE: That's a tough question.

I guess we must have -- probably we would manufacture, with specials, we must have 8 to 10 or 10 to 12 products ourselves and there would probably be another, I would say 5 to 6 -- 5 to 10 special products that come into the country also. So probably 25.

MR. REES: Does CSL make all those?

DR. McNAMEE: No. Australia would be about 95 to 98 per cent self-sufficient.

MR. REES: In all the products that the TGA has approved?
DR. McNAMEE: Yes.

MR. REES: Thank you.

DR. VOKES: Durhane.

DR. WONG-RIEGER: Given that CSL has been, I think, a presence in terms of fractionation for a good while in Australia you may not actually be good to sort of comment on the base of experience, but maybe you can in terms of your own sense of it.

--- end of tape 1, side 1

March 29-30, 2001
Hyatt Regency Vancouver Hotel, 655 Burrard Street
Vancouver

Day 2

-- beginning of tape 2, side 2

... having a fractionation plant in Australia and having the commitment to the plant in terms of providing plasma to it. To what degree do you think that having that plant has actually stimulated the collection of plasma in Australia, either from the point of view of the Red Cross in terms of focusing on it as part of their business or from the point of view of the Australian public and donors in terms of donating?

DR. McNAMEE: Actually, the whole strategy is to keep us hidden to some degree - that we provide a service for the government, the Australian Red Cross - because there is a concern that the voluntary donor system would be troubled if a greedy commercial fractionator was seen to be profiting from their donations. So, in essence, we stay way below the radar in Australia. It is not a positive.

DR. VOKES: The gentleman back here and then we will move to the Council.

MR. HAUN: Mathias Haun, Canadian Blood Services.

If I understand correctly, then, CSL is essentially a sole supplier for most of the plasma-derived products in Australia. What would ensue in a scenario where the user population perceived that there was some issue around a given product and, therefore, were telling the government that they would not want to use that product- How would that be handled?

DR. McNAMEE: Well, that is true. We live in a democracy, not an autocracy, so if there is a lot of political pressure then clearly products can be imported.
As I said, the TGA and the government have two strategies to deal with that. One is: any product that can demonstrated to be clinically superior to ours can be registered, no problem, and supported by the government.

The second thing is, the government has put in place a list of fractionator products. Again, in a short supply situation they would be able to be brought in and reimbursed.

So the onus is on us, CSL, to demonstrate that our products are world competitive and continue to be at the cutting edge. If they are not, in my view, we would lose the business.

DR. VOKES: Jerry.

DR. TEITEL: I just want an idea of - well, first I have two questions.

First of all, Factor VIII and Factor IX. What proportion of Factor VIII and Factor IX is recombinant in Australia?

DR. McNAMEE: Today the proportion would be about 25 per cent.

What we are seeing, in both Factor VIII and Factor IX is in fact the market has grown rather than necessarily plasma-derived being used less.

So when we were the sole fractionator before recombinant there was a lot of rationing of haemophilic patients, probably as low as - we only probably had about 1.6 IUs per head of population. We now have a target in Australia of 3 international units per hit of population, of which I think plasma will represent 1.8 to 2 and recombinant 1.

Again, there are clinical guidelines as to who should get recombinant, clearly of all the PUPs(ph) and different things.

But, in essence, I know Canada has gone to a different solution in that scenario. I think it is an expensive solution. I'm not sure clinically it is superior, but it is what it is. I think that in Australia, because we believe in pharmaco-economics, the recombinant products for patients who are well stabilized on plasma-derived there is no evidence that it is a useful thing to do.

DR. TEITEL: That may well be true, but when you look at the rest of the developed countries, the demand from the consumers has pretty universally been for recombinant products.

The Australian advocacy societies and the Australian haemophilia community, they seem to be out of step with the rest of the developed world.

DR. McNAMEE: No, I don't think so. I think that even if you look at the U.S. today, you have had dramatic market expansion. People talk about market shares, but the problem is they are - recombinant is much more expensive and has grown the market significantly. So certainly recombinant is major part of the market in the U.S.

But actually, today there is almost a shortage of plasma-derived Factor VIII in the U.S. Prices have come down and people are using more of it.

So I am not completely sure you are right there in your analysis. Patrick may come and argue with me, Patrick Robert, but I am quite confident of that.

So it was a political decision, in my view always, the people going to recombinant VIII because in very few other areas of medicine have we seen such an expensive - such a lot of money spent for such little clinical gain.

DR. TEITEL: Can I just have one other question, just a different - I just want to get a question of the scale here.

I think you said that you collect 250 tons of plasma per year, a population of 18 millions. Could maybe someone from the CBS just put it in scale? Can we have a figure for the number of tons of plasma we collect in Canada?

DR. VOKES: Anybody from CBS want to jump on that one?

UNIDENTIFIED SPEAKER: That Is plasma that comes to us?

DR. TEITEL: Assuming a ton is a 1,000 litres. Is that -

UNIDENTIFIED SPEAKER: Is a ton 1,000 litres?

DR. TEITEL: Yes, 1,000 litres. Sure.

UNIDENTIFIED SPEAKER: Well, 150 tons per year.

UNIDENTIFIED SPEAKER: The just of the fractionation, that's doesn't ?

DR. TEITEL: That is for fractionation.

Total collections?

UNIDENTIFIED SPEAKER: We add another 35,000 litres, approximation.

DR. McNAMEE: We have that as well. There are clearly some plasma users, you know, FFP, et cetera. So there are probably 30 to 50 used other clinically. So Australia may well collect more like 300.

DR. VOKES: Bill.

MR. BEES: Could you comment on your process recoveries compared to traditional Cohn-Oncley with your chromatographic process?

And could you comment on your cost of products relative to North American products?

DR. McNAMEE: I think with regard to chromatography the benefits are somewhat on yield but predominantly purity. So we have very high purity, very high purity IVIG, et cetera.

With regard to yields, we get a very good yield. We are about 4.3. We hope to get to 4.5 or more with our chromatographic process when optimized.

It partly depends on your batch sizes as well. For reasons of the size of the Australian market we have stayed at 15 ton. Obviously if we move to - I'm sorry, 10 ton. If you move to 15 ton your recoveries might be a little better.
The cost, I think that whether you use the Cohn process or chromatography the cost is in the infrastructure and in the engineering. I think the marginal cost is probably pretty similar for both technologies.

I don't really see a significant cost difference. We believe there is a product improvement that really drives the it, and a yield.

DR. VOKES: Tina.

MS MORGAN: I just really had a question about the patient culture in Australia. I deal a lot with a patient organization there and I have never really got to the bottom of it.

I am just wondering why they seem so much more aware, so much more educated as far as blood and blood products.

And if you could quickly comment on informed consent in Australia and how that works.

DR. McNAMEE: Certainly, again, there has been a lot of effort put in by the hospitals and the Red Cross to ensuring that patients and clinicians are well informed.

Informed consent, clearly for any new patient, that is an issue that is gone through with them. So it again, I guess, is just part of the strategy of the government to both risk manage, so that they feel that the people are well informed, and also to get awareness of if rationing is necessary.

MR. ROBERT: Thank you very much for a very nice presentation.

I have two very simple questions.

The first one, I am not well informed and I apologize for this, but it is my understanding that plasma expanders and some of the starches are not approved by the TGA in Australia, which sort of gives CSL an advantage in being able to sell all its albumin. So if you could clarify on that.

The second question is: Does CSL bioplasma have any reserve capacity to fractionate, let's say Canadian plasma, and how much would it cost?

-- Laughter

DR. McNAMEE: Patrick, on the first point, there is absolutely no impediment to the registration of competing colloids and other things. If they are cost-effective they will be - haemocoel is registered and fully reimbursed. There is really no impediment.

Australia is a very tough market. Very competitive, prices are not great. So there are some of

the reasons, I think more, that people don't necessarily come there with all their products.

Fractionation capacity, certainly we believe between ZLB - I'm learning to pronounce it like an American now, "Zee" LB instead of "Zed", ZLB - and CSL, yes. Yes, we certainly would be interested in talking to Canadians if they would like to talk to us.

DR. VOKES: Thank you, Brian.

That was terrific and really helpful in terms of providing us with -

-- Applause

Reference 'E'

The Lookback Report

By Charles MacKenzie
Administrator
Tainted Blood Product Action Group **6th February, 2003**

Outline:

'Lookback' describes a process undertaken by the Australian Red Cross Blood Service. It involves tracing the recipients of possibly contaminated blood and blood products. In January 2003 The Tainted Blood Product Action Group conducted a survey into the effectiveness of the Lookback program

Contents:

Executive summary

In Australia it is estimated that up to 20 000 Australians received blood products contaminated by Hepatitis C (HCV), a deadly virus that can reside in the bloodstream for years without symptoms. Warning those transfused during high risk periods is vitally important as many patients are unaware that blood product(s) were administered to them during their hospital treatment.

Lookback is a tracing program that tracks contaminated blood. It is a multi million dollar cooperative undertaken by the Australian Red Cross Blood Service (ARCBS) and the state health departments.

In January 2003 The Tainted Blood Product Action Group conducted a survey into the effectiveness of the Lookback program. A cohort of 100 people with HCV from blood transfusions were selected to take part in the survey.

A disturbing result of the survey was that **81% of the cohort had never been officially contacted nor offered any medical or support services by the ARCBS**. Of the remaining patients the Lookback program directly notified only 14% of the cohort and the average length of time to notification was 9.8 years. The Lookback program indirectly notified 5% of the cohort of their prior infection, with an average length of time to notification of 13 years.

An independent judicial inquiry needs to be entered into in order to protect future recipients of blood transfusions from similar mismanagement. It is also the only appropriate way to protect the victims of this tragedy from further preventable harm and in order to offer them explanations as to why there have been such terrible shortcomings in the management of Australia's blood supply.

The Lookback report

The importance of Hepatitis C notification

In Australia it is estimated that up to 20 000 Australians received blood products contaminated by the Hepatitis C virus (HCV), a deadly virus that can reside in the bloodstream for years without symptoms. Warning those transfused during high risk periods is critical as it alerts them to seek clarification of their status through blood testing. This alert process is vitally important as many patients are unaware that they received blood product(s) during their hospital treatment.

Upon notification, an individual exposed to HCV can seek treatment, counselling and general education about what HCV exposure may mean for them, their families and the community at large. They can be advised on ways to minimise the risk of passing the virus on to others. Lifestyle changes can also be encouraged, in particular a reduction of alcohol consumption, an important factor in HCV management. Medical treatment in the early stages of HCV exposure can slow the progression of the virus and in some cases eliminate it.

'Lookback'

Lookback is a term widely used in blood banking circles. It is the term used to describe the processes involved in tracing recipients of blood transfusions that may have been compromised by a transmissible virus. Lookback is a multi million dollar cooperative undertaken by the Australian Red Cross Blood Service (ARCBS) and the state health departments. Prior to 1990, Lookback's primary focus had been the tracing of recipients of HIV infected blood. However post 1990 and with the introduction of HCV testing, Lookback needed to redirect its focus, to the most common serious complication of blood transfusion: HCV.

A tainted blood survey

In January 2003 The Tainted Blood Product Action Group conducted a survey into the effectiveness of the Lookback program. A cohort of 100 people with HCV from blood transfusions were selected to take part in the following survey. The survey examined the length of time between the initial infection of HCV and the discovery of exposure. The cohort were also asked about how they became aware of their status and about their health and general well being.

The results of the survey are summarised in graphical form in Figure 1.

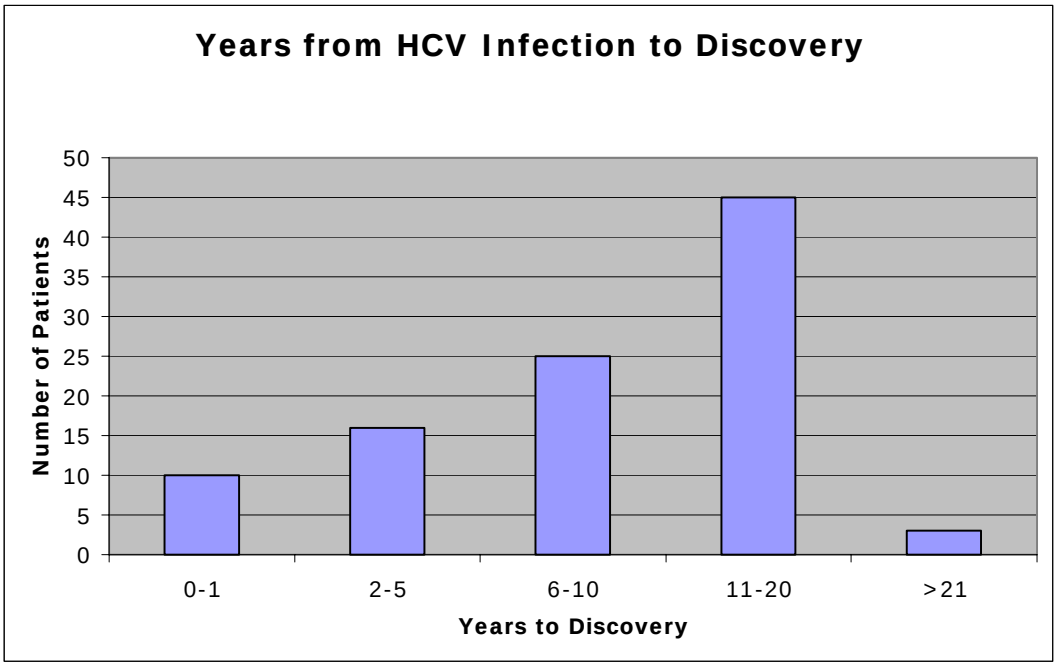


Fig 1. Length of time in years from exposure to discovery of status

Of the 100 people surveyed, one patient (1%) was not able to verify their exposure date. The most striking result of the remaining patients was that 45% of respondents had to wait between 11-20 years for their HCV exposure to be confirmed. It is a worrying fact that given the benefits of early notification (discussed above) only 10% were aware of their HCV status within 1 year of exposure.

The average time for notification in this cohort was a disturbing 10.1 years. Whilst the length of time to notification is disturbing, the above results indicate the amount of time to notification through any means (independent of lookback). Most of the cohort was alerted to their HCV status through his or her own vigilance, and failing health. It is however equally alarming when the results are analysed for the role that Lookback played in alerting this cohort. Most worrying is that 81% of the cohort had never been officially contacted nor offered any medical or support services by the ARCBS. Of the patients notified through the Lookback program, only 14% of the cohort were directly notified and the average length of time to notification was 9.8 years. The Lookback program indirectly notified 5% of the cohort of their prior infection, with an average length of time to notification of 13 years.

Lookback a public health duty

The ARCBS acknowledges that they have a public health duty in conducting a vigilant Lookback program in order to identify people who acquired HCV from blood transfusions.

On June 12 2002, the ARCBS distributed a press release in relation to blood safety and in particular their HCV Lookback program (See reference 1). The ARCBS refuted allegations that the Lookback program was flawed. The ARCBS stated that claims from victims that they had failed to notify people

who contracted HCV via blood transfusion were unfounded, noting that the Blood Service had carried out a rigorous Lookback program, which had been in place for many years. The ARCBS also advised that routine screening of all blood donations for HCV had commenced in February 1990, with the further introduction of even more sensitive screening methods in 1991.

Lookback contradiction

One of the respondents of the survey submitted a copy of their Lookback notification letter that they had received in 1999 (See reference 2). The Victorian Department of Human Services sent the letter to inform the victim that they had received a blood transfusion in 1992 from a donor who had subsequently been found to have HCV. The 1999 letter correctly informed this recipient of their exposure risk (the exposure was later confirmed through subsequent blood tests); the letter however incorrectly stated:

'It is important to realise that at the time the blood was donated there was no test available for screening blood donors for Hepatitis C'

This is false and misleading advice. The ARCBS have categorically stated in the past (most recently in the above mentioned press release) that the screening of blood donors for HCV commenced in Australia in February 1990, two years prior to this recipient receiving a blood transfusion post childbirth in 1992. Misleading advice of this nature suggests that the Victorian Department of Human Services is either not in possession of the full facts from the blood service, or that it sought to provide false information.

Lookback fails to alert those in danger

Three other respondents in the survey provided alarming information that Lookback had failed to notify them of their risk of exposure to HCV in a timely fashion even after the Lookback program itself had identified their donor(s) as having HCV.

Case 1: In January 1992, the blood service conclusively established that the donor for a recipient's transfusion (given following childbirth) had been HCV positive. But it took a further 10 months before an investigation began to trace all the recipients of that donor's blood. The recipient in this case wasn't contacted till March 1993, 14 months after they knew the donor was infected with HCV.

Case 2: In 1990 the blood service identified a frequent donor of blood in the 1980s as having HCV. Instead of contacting all the recipients of this donors blood, the blood service continued to take blood from the donor for a number of years even though they had established that the donor had HCV. A recipient in the survey who had received blood from this donor in 1988 was never contacted by the blood service, instead they discovered their infected status years later due to their own vigilance.

Case 3: Another submission to the survey was a case where a woman had been infected with HCV in 1999 following a blood transfusion administered

during a surgical procedure in NSW. The hospital was aware of the infected units delivery in 1999, however the patient was not notified till late 2001.

Hepatitis C warnings neglected

In the early 1990s, HCV was known to be the most common complication of blood transfusions and blood products. Even after the introduction of HCV antibody screening, HCV infections still occurred. But it was widely acknowledged that those at greatest risk of medically acquired HCV were patients that had received blood prior to 1990. In 1993, Professor Geoffrey Farrell, professor of hepatic medicine at the University of Sydney, publicly called on the health authorities to alert those who were at risk of having contracted HCV through blood transfusions (See reference 3). Professor Farrell asserted that the health department had a responsibility to inform all people who had received a blood transfusion prior to 1990.

The health authorities neglected to do this. Instead the ARCBS and the state health departments employed a multi million dollar funded program known as 'Lookback'

Conclusion- Accountability and transparency of process needed

Australians who acquired HCV from contaminated blood transfusions weren't anonymous intravenous drug users. They were patients trusting their health to government regulated hospitals and in the ARCBS. In the event that a deadly virus should be transmitted to them via a blood transfusion, they had reasonable expectations that timely warnings, medical treatment and other appropriate assistance would be made available to them.

The blood service enjoys a considerable deal of trust and support from the Australian community. But for victims of one of Australia's worst medical disasters, transfused HCV, trust has given way to anger and suspicion due to despair over the way their lives have been so adversely affected by the handling of the HCV crisis.

The ARCBS has consistently refuted allegations from victims that their response to the HCV crisis has been flawed. However, it appears that the ARCBS total denial of any failures regarding Lookback is self-righteous and complacent. Especially for the 81% of the people in the tainted blood survey who were not officially contacted nor offered any appropriate medical or counselling support.

The response to the medically acquired HCV disaster from the ARCBS and public health authorities is a scandal. A public health scandal characterised by incredible bungling, ineptitude, inefficiency and non-disclosure. An independent judicial inquiry needs to be entered into, in order to protect future recipients of blood transfusions from similar mismanagement. It is also the only appropriate way to protect the victims of this tragedy from further preventable harm. An inquiry of this kind might also offer victims explanations as to why there have been such terrible shortcomings in the management of Australia's blood supply.

References

Reference 1

BLOOD SAFETY A TOP PRIORITY FOR RED CROSS BLOOD SERVICE

Publish Date: Wednesday, June 12, 2002

The Australian Red Cross Blood Service (ARCBS) has refuted allegations made today at a public forum on Hepatitis C (HCV) organised by the Reverend Bill Crews and members of a group known as the Tainted Blood Action Group.

ARCBS believes claims that it failed to make people aware they may have contracted HCV via blood transfusion are unfounded, noting that the Blood Service has had a rigorous Lookback Program in place for many years.

“Our Lookback Program has dual systems to identify recipients who may have been exposed to an infection such as Hepatitis C via blood,” says Dr Tony Keller, Chair of the ARCBS Donor and Product Safety Committee.

“We follow up notifications of persons who may have contracted Hepatitis C through blood transfusion by tracing donors. All recipients of blood donations from donors found to be positive for Hepatitis C are also identified and encouraged to undergo testing.

“In all situations, we treat people with the utmost sensitivity and ensure they are referred to the appropriate medical and support services,” he added.

Australia was one of the first countries in the world to introduce routine screening of all blood donations for HCV, commencing in February 1990 and using the first licensed testing kits available.

A second generation testing kit using a more sensitive detection system became available in 1991 and was introduced immediately. Successive generation tests have been introduced, keeping pace with emerging technology.

In June 2000, the safety of the blood supply was taken to a new dimension with the introduction of Nucleic Acid Testing (NAT) which identifies the presence of viral particles for both HCV and HIV.

Since the introduction of NAT, the estimated risk of transmission of HCV via blood transfusion has been reduced from 1 in 300,000 to 1 in 900,000.

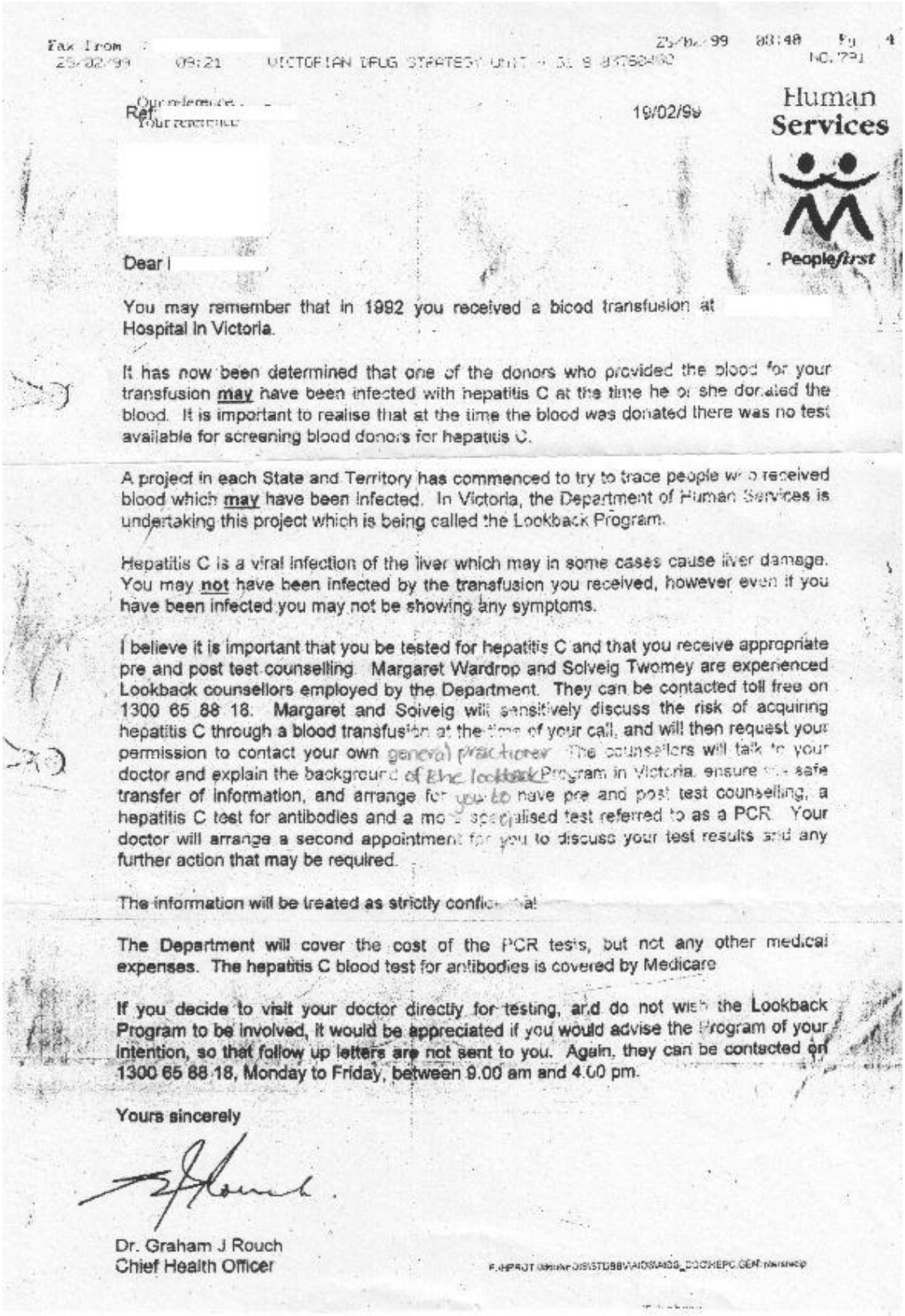
Australian Red Cross Blood Service (ARCBS) has always been and continues to be totally committed to providing the safest possible blood and blood products for the community by adopting world’s best practice through the use of the best technology available.

As well as using state-of-the-art technology, ARCBS undertakes rigorous screening of donors to ensure their suitability via a detailed pre donation questionnaire, personal interview and signed safety declaration by people wishing to donate blood.

Dr Keller emphasised “No blood service in the world can or will guarantee 100 per cent safety of its blood or blood products.

“The reality is “zero risk” is not achievable because we’re dealing with human tissue and technology has its limitations,” he said.

Reference 2



Fax from
25/02/99 09:21 VICTORIAN DRUG STRATEGY UNIT + 61 3 [illegible] 25/02/99 08:48 Pg 4 NO. 731

Our reference:
Ref Your reference

19/02/99

Human Services

People first

Dear [redacted]

You may remember that in 1992 you received a blood transfusion at [redacted] Hospital in Victoria.

It has now been determined that one of the donors who provided the blood for your transfusion **may** have been infected with hepatitis C at the time he or she donated the blood. It is important to realise that at the time the blood was donated there was no test available for screening blood donors for hepatitis C.

A project in each State and Territory has commenced to try to trace people who received blood which **may** have been infected. In Victoria, the Department of Human Services is undertaking this project which is being called the Lookback Program.

Hepatitis C is a viral infection of the liver which may in some cases cause liver damage. You may **not** have been infected by the transfusion you received, however even if you have been infected you may not be showing any symptoms.

I believe it is important that you be tested for hepatitis C and that you receive appropriate pre and post test counselling. Margaret Wardrop and Solveig Twomey are experienced Lookback counsellors employed by the Department. They can be contacted toll free on 1300 65 88 18. Margaret and Solveig will sensitively discuss the risk of acquiring hepatitis C through a blood transfusion at the time of your call, and will then request your permission to contact your own general practitioner. The counsellors will talk to your doctor and explain the background of the lookback Program in Victoria, ensure the safe transfer of information, and arrange for you to have pre and post test counselling, a hepatitis C test for antibodies and a more specialised test referred to as a PCR. Your doctor will arrange a second appointment for you to discuss your test results and any further action that may be required.

The information will be treated as strictly confidential

The Department will cover the cost of the PCR tests, but not any other medical expenses. The hepatitis C blood test for antibodies is covered by Medicare

If you decide to visit your doctor directly for testing, and do not wish the Lookback Program to be involved, it would be appreciated if you would advise the Program of your intention, so that follow up letters are not sent to you. Again, they can be contacted on 1300 65 88 18, Monday to Friday, between 9.00 am and 4.00 pm.

Yours sincerely

Dr. Graham J Rouch
Chief Health Officer

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Reference 3

HEPATITIS C WARNINGS NEGLECTED: PROFESSOR

Byline: By ALICIA LARRIERA Health Writer

The Department of Health was refusing to warn people who may have contracted the potentially fatal hepatitis C virus because it feared a repeat of the funding demands created by the HIV/AIDS crisis, according to a professor at the University of Sydney.

Five times as many people were infected with the hepatitis C virus (HCV) as were infected with HIV but the department had also refused to allocate extra resources to cope with the problem, Professor Geoff Farrell, the Professor of Hepatic Medicine at the University of Sydney, said.

The Department of Health was refusing to warn people who may have contracted the potentially fatal hepatitis C virus because it feared a repeat of the funding demands created by the HIV/AIDS crisis, according to a professor at the University of Sydney.

Five times as many people were infected with the hepatitis C virus (HCV) as were infected with HIV but the department had also refused to allocate extra resources to cope with the problem, Professor Geoff Farrell, the Professor of Hepatic Medicine at the University of Sydney, said.

"There's actually been a political antithesis towards this disease, and to a certain extent I think partly because the AIDS lobby was so successful in making sure that a lot of special funds were made available for that disease,"he told the Herald.

"I think health authorities were very sure to ensure that never happens again."

Professor Farrell, who is attached to Westmead Hospital's liver unit, said one in 250 Australians was HCV-positive. It is believed that about one quarter of these people will progress to cirrhosis of the liver, with half of this group progressing to liver cancer.

The department had been urged "for years" to alert people at risk of having contracted HCV to be tested, he said.

The department had a responsibility to inform all people who had received a blood transfusion prior to 1990, when screening for HCV was introduced, or those who had ever injected drugs, to be tested.

Although transmission through sexual contact was rare, Dr Farrell knew of at least two cases in Sydney.

The chief health officer of the NSW Department of Health, Dr Sue Morey, rejected Professor Farrell's criticisms last night, saying the department had done everything it could.

"I don't know what else we can do to keep (Professor Farrell) happy other than give him a million dollars for his personal research.

"We don't actually fund special diseases ... AIDS gets special funding because of Federal Government funding."

Dr Morey said it was up to the area health services to allocate their funding as they saw fit: "The reality is that there is no treatment.

"I just don't go along with the (line) that everyone needs to go along to Westmead to get tested."

Professor Farrell said funding had to be allocated as a matter of urgency, to provide a counselling service and to increase the capacity of the State's liver units. He also said that Interferon, the only

known treatment, had to be listed on the Pharmaceutical Benefits Schedule (PBS). Although Interferon is approved for use, it has not been listed on the PBS for the treatment of HCV. It was recently listed for treatment of hepatitis B.

Dr Morey said Interferon was not working as well as people had thought, assisting only a certain group of people which had yet to be defined.

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LETHAL HEPATITIS STRAIN SPREADS

Byline: By ALICIA LARRIERA Health Writer

The potentially fatal hepatitis C virus (HCV) is now the most common infectious disease in NSW, as the number of cases has grown by 10 per cent and continues to rise.

The potentially fatal hepatitis C virus (HCV) is now the most common infectious disease in NSW, as the number of cases has grown by 10 per cent and continues to rise.

It is believed that about one in four people infected with HCV will develop cirrhosis and half of those will get liver cancer.

The only known treatment for HCV is Interferon, which costs about $6,000 for a three-month course and has been a success with only 20 per cent of people who have hepatitis C.

In the first six months of this year, 2,195 new cases of HCV were reported, compared with 1,995 during the first half of last year.

The figures, released by the NSW Department of Health yesterday, indicate a 10 per cent increase and compare with 800 cases for the whole of 1991. An average of 12 people a week are now testing positive.

HCV has overtaken hepatitis B - which is more aggressively infectious because it is commonly transmitted through sexual intercourse - as the most common infectious disease in the State.

Between January and June this year there were 1,501 cases of hepatitis B, compared with the 2,195 cases of HCV.

During the whole of 1992 there were 2,953 cases of hepatitis B and 3,903 cases of HCV.

Research published in the Australian Medical Journal this week calculated that the Australia health system would have to deal with 8,000 to 10,000 new cases of HCV a year.

The release of the latest infectious diseases figures in the department's Public Health Bulletin comes just a week after the Professor of Hepatic Medicine at the University of Sydney, Professor Geoff Farrell, attacked the Department of Health for refusing to warn people who may have contracted the virus because of fears of a repeat of the funding demands created by the HIV/AIDS crisis.

In an interview with the Herald, Professor Farrell, who is also attached to Westmead Hospital's liver unit, said the department had been urged "for years"to alert people at risk of contracting the virus.

Reference 'F'

1. THE STORY OF MOTHERS WITH TRANSFUSED HEPATITIS C

1.1 The story unfolds

Three years ago I started researching the issue of tainted blood products in Australia on a full time basis. I set up a telephone line on which people with transfused Hepatitis C could call me. Prior to setting up this line, I had assumed that the majority of the calls would come from regular users of blood and blood products, such as males with the blood disorder Haemophilia. I made this assumption based on evidence that 80% of Australian Haemophiliacs who were given blood products in the 1980s had acquired Hepatitis C. To my surprise, the bulk of the calls came from women.

1.2 A pattern emerges

I initially thought the reason that so many women were calling in with their stories was due, perhaps, to them being more open and willing to discuss personal health matters. However, it soon became apparent that a pattern was emerging. Their stories were almost identical. They had complications during pregnancy or had experienced heavy bleeding during or following childbirth. All required blood transfusions.

Many of these women were claiming that they had been infected in the 1990s. Yet information distributed by our health authorities suggested that the risk of Hepatitis C being transmitted by blood transfusion was minimal in the 1990s, given that specific Hepatitis C screening was implemented from February 1990.

Another point of concern was that the majority of these women only discovered that they carried the Hepatitis C virus in recent times, years after their exposure. Again this was surprising as the Australian Red Cross Blood Service had made proud boasts in the past about its 'Lookback' program, a program designed to identify high risk donors and track recipients of potentially contaminated blood.

1.3 Half a parent, half a partner

There was a definite pattern here. Not only in the circumstances surrounding their infections, but also on the tragic toll that Hepatitis C had taken on their lives. The majority of these women described having experienced symptoms of tiredness, confusion and nausea

following childbirth. Their treating doctors suggested that these symptoms could be attributed to the pressures of family life or even postnatal depression. But these women would continue to experience these and other more chronic symptoms in the years ahead.

Many women found themselves unable to manage effectively as mothers. They would feel the need to sleep during the day. Their role as a parent would be inhibited by constant feelings of lethargy. Their children would question why they weren't able to be as active as their friend's mothers.

Husbands and partners of these women would suggest that they weren't contributing enough to their families or to their relationships. They were accused of laziness. The men in their lives would incorrectly think that they had lost interest in their children and in them.

These women were lost. They were unable to explain why they felt so tired and confused. In the main, they weren't given the compassion or support that they needed and deserved; no one in their families knew that they were suffering from the symptoms of a deadly disease. A deadly disease brought upon them through no fault of their own.

1.4 Damage to the family structure

Perhaps the most tragic effect that this as yet undiagnosed illness had on these women was the detrimental effect it had on their families. Many lost their marriages and relationships. They were left to fend alone. Their capacity to bring money into the home had been affected. Given the fact that they still had children to raise, this compounded the damage done to the family structure. For many, government welfare was the only means left by which to survive. Feelings of social inadequacy and lowered self-esteem began to surface.

1.5 A dark discovery

In most cases, these women would go from one doctor to another in an effort to try and get to the bottom of what was wrong. After years of being told that it may be due to psychological problems or 'women's' issues, horrifying discoveries were finally made.

More thorough investigation from better informed doctors would begin to yield answers. On the surface of it, their symptoms were consistent with some sort of liver condition or hepatitis infection. Many had already tested negative to Hepatitis A and B, so what kind of Hepatitis could this be? Hepatitis C was another known form of the virus. But this was normally associated with IV drug users who had shared needles. Many of the women were asked if they had ever injected

drugs. Hepatitis C antibody blood tests were ordered. These blood tests would confirm they had been exposed to the Hepatitis C virus.

For those women who had been transfused with blood in the 1980s, suddenly everything made sense to their medical practitioners. They had acquired Hepatitis C in the 1980s from untested but tainted blood. For those given blood or blood products in the 1990s questions were still being asked as to whether they had ever engaged in high risk activity. Blood transfusions and blood products were safe after February 1990 they were told. This further traumatised women in this category. It led to even greater confusion.

2. FAILURE TO WARN

2.1 Hepatitis C a known complication of blood products

Hepatitis C was not specifically described in medical terms until about 1989. Until then it was known as non 'a' non 'b' Hepatitis (NANB) or post transfusion Hepatitis. NANB infection was a known complication of blood and blood products from the mid 1970s in Australia. It was established by 1980 that NANB was a cause of significant symptoms. It was also a cause of progressive liver disease. The outcome in about 10-20% of patients was cirrhosis of the liver and liver cancer. Death was therefore a known complication of this infection.

2.2 The cost of non disclosure

Most of the women that came forward with their own stories about transfusion transmitted Hepatitis C had not found out about their infections until years after they acquired the virus. Typical cases consisted of women transfused in the early to mid 1980s who would discover in 1999 that they had acquired Hepatitis C from these transfusions. They usually discovered their status due to their own vigilance, rarely from letters of notification from the Australian Red Cross Blood Service.

Why had things gone so horribly wrong for these women? Why weren't they informed of the well known risks of Hepatitis C from blood transfusions? Had they been informed earlier they could have been tested. Important treatment options could have been made available to them. They could have made lifestyle adjustments in a bid to try and minimise the damage that the Hepatitis C virus would have on their livers, and on their lives. They could have explained to their employers that their perceived tardiness was the result of tragedy, rather than their own failings as human beings.

Had they known why they were so ill, they may well have received greater support and compassion from their families. This kind of support is beneficial to people facing health difficulties.

2.3 A litany of failures

From my inquiries into Lookback, the unit charged with tracing tainted blood, I have been disturbed by what I have found. I have heard excuses about the complexities of tracing infected donors and the tracing of infected blood. Budgetary limitations have also been mentioned.

Yet Hepatitis C was a well known complication of blood in the 1980s. It was far more common than HIV transmission; in fact it had been a concern for blood authorities long before the advent of HIV/AIDS. Letters informing of potential risk could have been sent to recipients of blood products in high risk periods like the 1980s. Better information could have been made available to general practitioners. Public health campaigns could also have been established.

2.4 Positive Action in Ireland lend their support

A group in Ireland known as Positive Action advocate on behalf of mothers with transfused Hepatitis C. In 1997, Positive Action forced a Tribunal of Inquiry into the Irish Blood Transfusion Board. The tribunal discovered that the blood authorities in Ireland had knowingly taken blood from risk donors and that tainted blood had infected hundreds of women with Hepatitis C. The Irish Blood Transfusion Service Board had also failed to warn these women, even though the board knew of the risk that Hepatitis C posed to blood products in the 1980s and 1990s. Following the tribunal's report, government sponsored compensation was made available to all those who had been infected with transfusion transmitted Hepatitis C. To date hundreds of millions of dollars have been made available to victims and their families in order to assist them.

I decided to contact Positive Action. They sent me a copy of the tribunal's findings. What I discovered had happened there, had happened here. There were differences however, more safety breaches and greater numbers of infections occurred here in Australia, than in Ireland. The natures of the tragedies were the same, yet the responses from our governments were very different.

I asked the chairperson of Positive Action, Detta Warnock, if she could help me to help women in the same position here in Australia. She agreed. I now receive support and advice from Ireland (See Attachment 1).

3. HEPATITIS C IN PLASMA IN 1990

3.1 Evidence given to the Sydney Morning Herald

In June 2002, I obtained evidence that individuals found to be carrying the Hepatitis C virus were encouraged by the Australian Red Cross Society to donate blood plasma. This encouragement took the form of written invitations sent to donors with Hepatitis C. Their donated plasma was forwarded to the Commonwealth Serum Laboratories (CSL Limited) for use in plasma fractionation. The end product was then made into medical goods for therapeutic use.

This, I could not believe! Since 1990 we had been told by our Health Authorities that Hepatitis C screening ruled out donations from individuals with this type of infection. I approached the Sydney Morning Herald, and after much scrutiny by their lawyers, they agreed to run the story. On July 1 2002, the Sydney Morning Herald published the story. That same day, the federal minister for Health and Ageing, Kay Patterson, ordered a departmental investigation into the matter.

3.2 A policy of accepting blood plasma from Hepatitis C carriers

Given that a policy existed to accept blood plasma from known Hepatitis C carriers in 1990, it is unfortunate that the Australian Red Cross chose not to contact previous recipients of their donations. Some of the Hepatitis C donors that were encouraged to donate plasma in 1990 had previously donated whole blood in the 1980s. Evidence of this failure is held within my research files. I have Australian Red Cross documents that suggest donors, who were found to have lied about their risk activities in their donor declarations of the 1980s, were encouraged to keep donating blood plasma in 1990 and beyond. This practice occurred even though interviews conducted with them in 1990 had established that they had been IV drug users in the past, that they had made false statutory declarations on their donation forms, and that they were Hepatitis C carriers. Little or no effort was made to contact previous recipients of their blood.

Summary

I could not have imagined when I started researching tainted blood that I would come across a human tragedy of the proportions that I have. Thousands of Australians are known to have acquired the deadly virus Hepatitis C from blood transfusions and blood products. Aside from any debate on the preventability of this tragedy, the failure to alert those exposed to medically acquired Hepatitis C is possibly the greatest public health scandal in Australia's history.

Given that we now know that a significant number of Hepatitis C carriers were identified and then encouraged to keep donating blood plasma in 1990, why weren't investigations ordered in an effort to try and trace previous recipients of their blood? Had this been done, then perhaps some of the women with transfusion transmitted Hepatitis C might have been alerted. Health authorities could have acted. These women could have accessed medical treatment for Hepatitis C sooner. Marriages might have been saved. Important family structures could have been preserved.

Excuses from the Australian Red Cross about the complexities of tracing recipients of infected blood are highly questionable in light of recent discoveries. If they could send out letters to individuals with Hepatitis C asking them to donate in 1990, could they not have at least sent letters to possible recipients of their bad blood in the transfusion disaster period of the 1980s and early 1990s?

After three years of full time investigation into this matter, I have come to several conclusions. This is a scandal: A public health scandal characterised by incredible bungling, ineptitude, inefficiency and non-disclosure. But in its essence, it is first and foremost, a terrible human tragedy which has destroyed the lives of many men, women, children and their families.

Charles MacKenzie
Administrator
The Tainted Blood Product Action Group
Email: tbpag@taintedbloodnetwork.com
Web: www.taintedbloodnetwork.com

Attachments

Attachment '1'

POSITIVE ACTION

THE SUPPORT GROUP FOR WOMEN INFECTED WITH HEPATITIS C
THROUGH CONTAMINATED ANTI-D IMMUNOGLOBUBLIN

56 FITZWILLIAM SQUARE
DUBLIN 2

TEL : 003531-6762853
FAX : 003531-6620009
E-MAIL : posact@indigo.ie

29th October 2003

Charles MacKenzie
The Tainted Blood Product Action Group
Australia

Dear Charles,

I write on behalf of Positive Action the Irish support group for women who were "State Infected" with Hepatitis C. We have 750 members who were infected from 1970 onwards. The majority of them were infected in 1977 –79.

As our members are all women who have Rh Negative blood any of those who were blood donors were repeatedly called to donate blood. Therefore from 1970 – 1994 our members were innocently donating infected blood which in turn contaminated others.

As a result of our campaign our members and also members of 3 other support groups who backed our campaign - Transfusion Positive; The Irish Haemophilia Society & The Irish Kidney Association who were subsequently infected as a result of our members have a Statutory Compensation Package which includes:
A Compensation Tribunal where each claim is heard and accessed individually.
A Health Care Package which covers : GP visits; All prescribed medication & Surgical Aids. Dental, Aural, Optical, Physiotherapy, & Chiropody treatments.

Counselling services. Alternative treatments ie - Reflexology & Aromatherapy / Massage. Home Nursing service and Home Help (house work) Service.

An Expert Group was set up in 1994 to investigate & report on the contamination of Anti-D with Hepatitis C. A Tribunal of Inquiry sat in 1996 and reported in 1997 A second Tribunal of Inquiry relating to the Haemophiliacs also sat and reported in 2002.

In 2003 A Medical Doctor who was the Chief Medical Consultant, in the Irish Blood Transfusion Service and a Scientist who was a Bio Chemist in the Irish Blood Transfusion Service were arrested and criminally charged with causing Grievous Bodily Harm to named persons by administering to them infected Anti-D. They will re-appear on Friday 31st October in the Circuit Criminal Court to set a Trial Date.

We believe than any victims of contaminated blood products deserve support, compensation and a Health Care system to meet their needs. It is our belief that those persons who have been State Infected are in a different category to those who have acquired Hepatitis C from IV drug use and the sharing of needles. State Infected persons have Hepatitis C through no fault of their own whilst the other group have a self inflicted illness.

Detta Warnock