COMMONWEALTH OF AUSTRALIA

Official Committee Hansard

SENATE

COMMUNITY AFFAIRS REFERENCES COMMITTEE

Reference: Hepatitis C and blood supply in Australia

WEDNESDAY, 7 APRIL 2004

SYDNEY

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SENATE

COMMUNITY AFFAIRS REFERENCES COMMITTEE

Wednesday, 7 April 2004

Members: Senator McLucas *(Chair)*, Senator Knowles *(Deputy Chair)*, Senators Humphries, Hutchins, Lees and Moore

Participating members: Senators Abetz, Bishop, Carr, Chapman, Coonan, Crossin, Denman, Eggleston, Chris Evans, Faulkner, Ferguson, Ferris, Forshaw, Harradine, Harris, Lightfoot, Ludwig, Mackay, Mason, McGauran, Murphy, Nettle, O'Brien, Payne, Tierney, Watson and Webber

Senators in attendance: Humphries, Hutchins, Knowles, Lees, McLucas and Moore

Terms of reference for the inquiry:

To inquire into and report on:

(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 became 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.

WITNESSES

Committee met at 9.36 a.m.

CARROLL, Mr Shelton Keith, (Private capacity)

LEWIS, Mrs Maureen Patricia, (Private capacity)

CHAIR—I declare open this public hearing. The Community Affairs References Committee is conducting its inquiry into hepatitis C and the blood supply in Australia. I welcome everyone to the hearing today. The number of people here today again shows the high level of interest in this inquiry. Information on parliamentary privilege and the protection of witnesses and evidence has been provided to you. The committee prefers evidence to be heard in public, but evidence may also be taken in camera if you consider such evidence to be of a confidential nature. We have your submissions before us and we thank you for them. I invite you to make an opening presentation, to be followed by questions from the committee.

Mr Carroll—This is the first time I have been to a hearing as such, and I really do not know what format it takes. Having said that, if each of you has a copy of my submission you will have a pretty good idea of where I am coming from. Fundamentally, I did not realise I had hep C until 1994, when I had a routine blood test done by my endocrinologist because I am a diabetic. When he confronted me with the issue and asked, 'How are you tackling your hep C status?' I was, needless to say, dumbfounded. Subsequent to all that, I have been referred to a hepatologist and to a gastroenterologist and have had biopsies and different blood tests done. I am a hep C victim, for want of a better term, and I decided to respond to this Senate inquiry purely because I would like to be heard, to tell my side of the story and perhaps add a bit of weight to those hundreds of thousands of others who either are not in a position to put words to their feelings and emotions or have not been inclined because of whatever their bureaucratic statements might have turned out to be. Essentially that was my idea. I did not expect it to be this far up the line. That is all I have to say.

CHAIR—Thank you, Mr Carroll.

Mrs Lewis—I found out through a routine pregnancy blood test in 1995 that I had hep C. I was unaware of the situation. The doctor really did not inform me; he told the medical student over my head, 'This patient has C antibodies and is also hep C positive,' at which point I sat up and said, 'Hepatitis C? I haven't got hepatitis C.' He just looked at me and said, 'Yes, you have,' but I was not informed. I had a blood transfusion in 1984 and it has been traced back to then. It answered a few questions as to why when I came out of hospital in 1984 I was always sick. I was told that I had chronic fatigue syndrome, that I had post-trauma syndrome, that I was a malingerer—you know, get off your arse and get on with life. I lost the baby after that blood transfusion. I was basically told I was wallowing in self-pity and that I should just get on with it and start playing my sport and being a proper mother again. That is my story.

CHAIR—Mrs Lewis, you have subsequently had children.

Mrs Lewis—Yes, I had a daughter in 1987 and I had my other little girl in 1995. The only reason I found out I was hepatitis C positive was because of the routine blood test. Throughout all these illnesses I have had, no-one thought to test me for hepatitis C because I was not high

risk. It has been a bit of a blessing in disguise because, if I had known I had hepatitis C, I probably would not have had any more children.

CHAIR—Would either of you like to explain to us your experiences with the Red Cross through their Lookback program, and tell us how that occurred?

Mr Carroll—From my standpoint, Dr Phil Craig, as far as the hepatologist was concerned, referred me to the Waratah Clinic, which is a hep C clinic in association with the St George Hospital. It was through them that I got in touch with the Red Cross. Not knowing what to do and how to go about doing things I suppose I needed that directive. I got in touch with the Red Cross. I was given the name of somebody, and I have to say that the Red Cross were extremely helpful as far as that was concerned. They went through their Lookback procedure and established the fact that I had a transfusion in 1982 down at Prince Henry Hospital, following a heart attack, and that I had been donated blood from four different donors. One of those donors subsequently proved to be hep C positive, one was hep C negative and the other two, at the stage of the Red Cross writing to me and sending me a copy of their findings, were untraceable. So, effectively, from one of those four people I had the hep C virus transfused into my system. I have to say that the Red Cross were quite good and were in contact with me all the way through. They sent me out leaflets and brochures et cetera.

CHAIR—We have had other evidence from people who have acquired hep C through the blood supply that contact from the Red Cross has not always been prompt, but you have found that to be quite different.

Mr Carroll—I found they were quite good. It took them time because the Lookback procedure, I presume, takes a few months—like most things—but that is basically what I did.

CHAIR—But you were informed through that process.

Mr Carroll—Yes.

Mrs Lewis—I have never been in touch with the Red Cross. I have never heard from them. I got a letter from Slater and Gordon telling me—the only reason I thought of compensation was that I saw an ad in the paper for people who had contracted hep C from a blood transfusion to please get in touch if they had had their transfusion between 1985 and 1990, I think. I have a letter here from them. I rang them and they said, 'Sorry, you got it in 1984. That is too early and there is not much we can do for you. Maybe you should get in touch with the Red Cross and tell them that you contracted hepatitis C from a blood transfusion.' I did not do that because I did not know how to go about it. There has been no contact between the Red Cross and me, ever.

CHAIR—Did your doctor tell you to contact the Red Cross?

Mrs Lewis—No.

CHAIR—Were you in a major hospital?

Mrs Lewis—I was in the Royal Hospital for Women at Paddington, but because I had gestational diabetes the hepatitis C was just by the bye. No-one seemed to know much about

hepatitis C, except that my records were stamped 'highly infectious'. There were big yellow stamps over all my medical records and that was as far as it went. I was admitted to hospital a few times with pyelonephritis and other ailments. The nursing staff assumed that I must have been a drug addict or a sex worker, because they asked me questions such as: 'Are you still injecting? Are you on the methadone program?' But I have never been directed to the Red Cross and there has been no contact with them. It was just as though I had the flu and that was it. I was never directed to go to anyone or to contact anyone. It was only when I saw this letter from Slater and Gordon in the paper that I realised that there were avenues where I could seek help.

Senator KNOWLES—Mrs Lewis, you have just answered the question I was going to ask about whether you had tried to access compensation. I want to ask about community attitude. You have just touched on being asked about being a drug user, a sex worker or whatever. What form do you believe a community awareness program should take so that people know and understand the circumstances that surround hepatitis C for so many people?

Mrs Lewis—I would like it to be addressed not as a sexually transmitted disease, which is how it is addressed quite often in the newspapers. I would like it known that it can be spread by means other than sharing needles or getting tattoos. That is how it is advertised—that you can only get it from sharing needles, so obviously only drug addicts get it and members of the public do not. If you have it, obviously you have a deep dark secret. When I inform doctors or medical people that I have hepatitis C, I always say that it is from a blood transfusion and I feel as though I am protesting too much. They think you are telling them the old story that you got it from a blood transfusion. It is very stigmatising. I would like it known that it is not a sexually transmitted disease and that a lot of us got hepatitis C from blood transfusions.

Senator KNOWLES—Are you still suffering that discrimination?

Mrs Lewis—Yes.

Senator KNOWLES—By the medical profession?

Mrs Lewis—Not so much anymore, but I only see my GP. It was very strong while I was in hospital. I have my medical records and one note from Dr Lamaro to the nursing staff, says: 'Please make it known that Mrs Lewis contracted her hep C from a blood transfusion and stop asking her questions,' and something about her moral—

Senator KNOWLES—When was that note made?

Mrs Lewis—It is in my 1995 medical records. I sat up all last night going through them but I cannot find that note. I did read it and I will find it. I just could not find it last night. I have a few notes from the medical records, saying: 'Mrs Lewis has C antibodies, but she hasn't got hep C.' Then there is another note from another nurse: 'No, Mrs Lewis has got hep C as well as hep.' So it is contradictory.

Senator KNOWLES—It is contradictory.

Mrs Lewis—That is what I mean. I was never informed officially that I had it. I just overheard the obstetrician telling the medical student that I was hepatitis C positive.

Senator KNOWLES—How have you found the treatment that you have accessed?

Mrs Lewis—I did not know where to go for any sort of treatment. Finally, through a women's health group, I was put onto the Sexual Health Clinic at Sydney Hospital. That was the only place where I think anyone knew anything about hepatitis C. No GPs knew about it; nobody seemed to know anything about it.

Senator KNOWLES—When was that?

Mrs Lewis—In 1995-96.

Senator KNOWLES—You say in your submission that you now 'just' cope with the struggle of everyday living.

Mrs Lewis—'Just' cope and sometimes I don't. Last May I was admitted to the psychiatric ward at the Prince of Wales Hospital for six weeks because I was at the end of my tether. I was suicidal, to tell you the truth. I am not coping very well at all anymore. I cannot work, so I am living on $480 a fortnight. I have two children to support. I find it very hard to get the housework done and feed the children and cope with the utter fatigue that I suffer. I have clinical depression. I am not coping very well at all. I am a strong woman; I have always coped. I have been a mother since I was 12 to my younger brother and sister, but it is all getting a bit too much.

Senator MOORE—Mr Carroll and Mrs Lewis, you have both come forward today. What exactly do you want out of this inquiry?

Mr Carroll—I have been procrastinating on that very question since last night. In fact, I said to my wife, 'I wonder what questions I'll be hit with and whether somebody asks what I want out of it?'

Senator MOORE—I am glad I butted in there.

Mr Carroll—As I said earlier in my opening speech, I have a hell of a lot more to lose than to gain. But if I knew that I had hepatitis C and you were to ask whether my life would be the same, I could not say yes or no. I am fortunate in the sense that I tend to have a reasonably active life. I do a lot of sailing, play golf etc. But I do know my mental capacity has changed. Having said that, currently I work as a storeman rather than as a senior manager in large corporations, where I have held positions before. Mentally, I have an inability to retain things which I used to before. I am not as quick thinking on my feet. All this may be to do with age. I turn 60 in a couple of weeks time. Knowing very well that I contracted hepatitis C in 1982, I do not know whether it is age catching up with me or what. I do not know what to expect out of this. Having said all that, I decided to put my thoughts on paper purely for the hundreds of others who may need that little bit more support in some form or another.

I know there is a new process being opened up now with Charles MacKenzie and Reverend Bill to help those who are in a position like me or Maureen and to support them either mentally, physically or whatever. I know of hundreds of other cases and I have seen a number of other people who are suffering pretty badly with this problem. If you saw me on the street and you said, 'I don't think you have a problem,' I would tend to agree with you. My whole ulterior

motive is if I can add a little bit of substance to the whole Senate committee hearing about what is happening with hepatitis C throughout Australia—throughout the world for that matter—and what it means to people, it would mean one heck of a lot more to others than to me at this stage. Fundamentally, I do not know what the future holds for me. I have been told that, since I have been on the twin treatment of ribavirin-interferon, my viral load has diminished from 100,000 units down to about 80,000. Having said that, they stopped it because it did not do me any good. The side effects were far worse than actually carrying the disease. That was my major criteria. Since I stopped the treatment—I think it was March last year—I started to get a little bit more hair back on my head, believe it or not, and a little bit more colour in my face and so forth. But I am certainly not as mentally active and I have mood swings that my wife will tell you about.

To touch on things like how people think and react to me because they know I have hepatitis C, I am fortunate that I have a family who understands. A couple of people on both sides of the family are in the medical profession, doctors et cetera. My very close friends are totally aware of my situation. Even when I was involved in Scouts, I used to donate blood many years ago, right up to 1979-80. Every third or fourth week we used to go to the Red Cross here at York Street, I think it was, and stick the arms out. Having said all that, I do not know what else I can add, except that if a committee decides that hepatitis C needs to have some sort of assistance for research—whether it be moral, physical or financial—then that is great for people in the future, but what about those who are suffering badly today? What about those people who, like me, are in the middle group, say, five years down the track suddenly find their liver has packed in? Who do I turn to for some help one way or the other? I do not know. To answer your question, Claire, that is why I am here. I have not been in touch with any solicitors, lawyers—nobody. I was speaking to Peter Rohl and he said to me, 'What do I do? I said, 'I don't know, Peter.' He said the same thing, too: 'What can you do?' He is my endocrinologist. That is my situation at this moment.

Mrs Lewis—My story pretty well mirrors that one. I do not think that going for compensation is frivolous—I think everyone who has hep C deserves compensation. My family does not understand. They think that I have given up the ghost. No-one understands. A couple of weeks ago I was quite depressed and quite sick, and my sister said to me, 'What's wrong with you? What can I do?' I said, 'It's probably the hepatitis C.' She said, 'There's lots of people with hepatitis C; they're doing fine. It's not such a bad thing.' It is just not recognised for what it is. If I had HIV I think I would be better off because at least there would be that recognition and I would have an excuse for being sick. I have no avenue. I feel that I cannot work because I am not reliable enough. Some days I am fine and some days I am just so sick that I cannot get off the lounge. I just want someone to help me. I want someone to turn to.

Senator MOORE—Your submission refers to the fact that you have now contacted Reverend Bill and some groups. Has that given you another option for support? You said that since 1985 you have been facing this problem alone. You have not accessed help.

Mrs Lewis—It has given me hope. At least there are a few answers to the questions. I did not realise the degree hepatitis C affected the population. There is still no-one you can ring or go to. It is just not recognised.

Senator MOORE—You are all alone.

Mrs Lewis—Yes, I am very alone. As I said, my family do not know the degree that it affects you. Friends do not know, and I do not bother saying anything. I had seen the notice in the paper from Slater and Gordon and I had had a blood transfusion, so I thought I would ring and find out what this was all about and that led to things. I happened to hear Bill on the radio one night. I was flicking stations and I heard him mention hepatitis C or something. I ended up going to Ashfield. It has been some guidance for me at least. It is some little thing to hang onto.

Senator MOORE—Out of this inquiry, both of you are hoping to receive some form of support?

Mrs Lewis—Yes.

Senator MOORE—You are not sure what form it will take, but you are hoping that at least something will come out of it?

Mrs Lewis—Yes.

Senator HUMPHRIES—Can I just say that reading both of those accounts has been quite moving. I think that the committee would certainly want to do its best to make sure that no other Australians are put through the kind of trauma that you have experienced through contracting this virus. There was only one thing that I took a bit of a step back from when I read it. In your submission, Mr Carroll, you say that your situation was:

… due to the lack of due care taken by so called responsible persons by the Hepatitis C blood that I received from the Red Cross … in 1982.

What the committee has been examining is the question of what tests were becoming available to identify hepatitis C in blood products. It is generally agreed that there was some means of identifying some indicators of contaminated blood from 1985 or 1986 onwards. But I think it is pretty well agreed by all parties that before 1985 there was no known test—not only in Australia but anywhere in the world—to identify contaminated blood. Do you feel it is fair in those circumstances to blame the Red Cross for passing through to you blood which neither they nor anybody else anywhere in the world would have been able to know was contaminated with this virus?

Mrs Lewis—Can I just say something? The thing is that I am sick. I have a liver that is not working properly any more. I do not want to blame anyone; I would just like some help. I do not want to put anyone down or put them before a firing squad or anything like that; I just need help. I think it is up to someone, the Red Cross or whomever, to put their hand up and say, 'Yes, we made a mistake. We're sorry'—of course, that has never been mentioned anyway—'and we think you deserve some sort of compensation and help.' I am not really interested in blaming anyone.

Senator LEES—Are you able to access a healthcare card?

Mrs Lewis—I have a healthcare card. I am on a supporting parent's benefit.

Senator LEES—Mr Carroll, do you have a healthcare card?

Mr Carroll—No.

Senator LEES—So it gets quite expensive.

Mr Carroll—Tell me about it!

Senator LEES—Sorry, Senator Humphries. I just wanted to ask that.

Senator HUMPHRIES—My question was to Mr Carroll. I do not know whether he can answer.

Mr Carroll—I do agree with you, Senator Humphries, from what little I have heard and read, that they were not screening on any consistent basis for hep C prior to about 1984 or 1985. That is why, just to reiterate what I said previously, I do not know what to expect out of this inquiry. I just want to add my little tuppence worth. Having said that, I believe that someone somewhere along the line has to take some responsibility. After all, we are dealing with a public institution—that is, the Red Cross—that supplies blood to virtually every person who needs blood, in some form or other. I think it was their responsibility to screen as best they could with the technology and medical advances that applied at that stage. But, from a financial standpoint, I do not know whether they could afford to do it or whether they had the technology to do it. So the answer to your question is I do not know, unfortunately.

Senator HUMPHRIES—Mrs Lewis, you said that you went to somebody who said to you that you contracted your hep C before 1985 and therefore they could not help you. Who was that organisation?

Mrs Lewis—Slater and Gordon. I have the letter here if you would like to see it.

Senator HUMPHRIES—Thank you.

CHAIR—Are you happy to provide a copy of that letter to the committee, Mrs Lewis?

Mrs Lewis—Yes.

CHAIR—Thank you.

Senator HUTCHINS—How long is the letter? Is it one or two pages?

Mrs Lewis—Three pages. It is a copy.

Senator HUTCHINS—Is that copy for us?

Mrs Lewis—Yes. I also have letters from Mr Refshauge to Bob Carr, if you would like those as well.

Senator HUTCHINS—Yes, thank you.

Senator MOORE—Mrs Lewis, is that Mr Refshauge, the then health minister for New South Wales?

Mrs Lewis—He was at the time.

CHAIR—Are they copies?

Mrs Lewis—Yes.

Senator HUTCHINS—The committee might like to have a copy of the Slater and Gordon letter.

CHAIR—Now?

Senator HUTCHINS—Maybe before the Red Cross appears.

CHAIR—Thank you.

Senator HUTCHINS—You mentioned your children. What sort of an effect has it had on your children? Does it have an impact at school?

Mrs Lewis—It has had a big effect.

Senator HUTCHINS—We have heard evidence that people with hepatitis C get lethargic, cranky.

Mrs Lewis—Yes. My youngest has behavioural problems.

Senator HUTCHINS—How old is she?

Mrs Lewis—She is eight. She is seen at the Avoca Clinic at the Prince of Wales Hospital. My 16-year-old has gone to live with her father because of all the tension and the fact that sometimes I could not get up to cook a meal and do things like that. She left to go and live with her father because I was not looking after her very well. I do not think I am being the mother I should be to this eight-year-old. My son is 31. He was 12 when I had the blood transfusion. Before that, I used to play soccer, basketball and netball. I would go training and take him to his football games. I came out of hospital and I expected to have a bit of time to get over it. I was in hospital for 2½ months when I had the blood transfusion. I came out. I lost the baby; the baby died. I had him at 28 weeks. I was not the same mother after I came out of hospital. I was tired. I gave up all sport. I could not manage the sport. I was not doing the tuckshop for him anymore. I feel I have let him down. I feel that he has missed out a lot by me being sick.

Senator HUTCHINS—Have you been able to talk to him since?

Mrs Lewis—Yes, we have a pretty good relationship. He always says, 'It's all right, Mum, I realise now,' but it doesn't make it go away.

Senator HUTCHINS—What sort of employment did you have or have you been involved in that you can no longer do or apply for?

Mrs Lewis—I used to work at Teletrading just doing the copytaking there. I worked for a courier company. I worked at Phone TAB. I held down two jobs most of the time, working part time at the TAB and doing receptionist work or RVD computer work. I have always worked since I was 17 and I have always worked when I had my children.

Senator HUTCHINS—Would you have been eligible for any government assistance in that period that you recall?

Mrs Lewis—Yes, I was eligible for a supporting parent payment, which I receive but it does not go very far.

Senator HUTCHINS—But you were still working at the same time?

Mrs Lewis—No, if you work you do not get any assistance, so you either work and get—

Senator HUTCHINS—So when you were working you got no government assistance.

Mrs Lewis—Yes.

Senator HUTCHINS—Then you had to go onto the supporting parent payment.

Mrs Lewis—Yes.

CHAIR—I thank both of you for the evidence you have provided both today and in your submissions. We have had a lot of submissions from people in the same situation as you. It has been terrific that people have been able to share their experiences with the committee in the way that you have. Thank you very much.

[10.13 a.m.]

PALOMBI, Mr Luigi, (Private capacity)

CHAIR—I welcome Mr Luigi Palombi. Do you have any comments to make on the capacity in which you appear?

Mr Palombi—I am appearing in a private capacity, but I am a PhD candidate in the faculty of law at the University of New South Wales.

CHAIR—Information on parliamentary privilege and the protection of witnesses and evidence has been provided to you. The committee prefers evidence to be heard in public but evidence may also be taken in camera if you consider such evidence to be of a confidential nature. We have before us your submission, which is very useful, thank you. I now invite you to make an opening presentation, to be followed by questions from the committee.

Mr Palombi—I would like to first present my credentials and then to follow on with a brief summary of my submission. I was awarded degrees in law and economics from the University of Adelaide in 1981 and 1986 respectively. I began my legal career in 1982 as a solicitor and barrister of the Supreme Court of South Australia, the Federal Court of Australia and the High Court of Australia. I subsequently signed the roll of the supreme courts of the Northern Territory, New South Wales and Victoria. I have specialised in intellectual property law since 1986. Between 1992 and 1994 I was Vice-President of the Intellectual Property Society of Australia. The society is now called the Intellectual Property Society of Australia and New Zealand. It is a professional association of solicitors, barristers, patent attorneys and law academics in Australia and New Zealand.

In March 1994 I was retained to act for Murex Diagnostics Australia Pty Ltd, an Australian company, in the Federal Court of Australia lawsuit number NG 106 of 1994. The lawsuit was commenced on instructions that I received from Murex Diagnostics Ltd, a UK company, and a subsidiary of International Murex Technologies Corporation, a Canadian company. The respondents were Chiron Corporation, the owner of Australian Patent No. 624,105, which was granted in 1992 and entitled ‘Non-A Non-B Hepatitis Diagnostics and Vaccines’ and Ortho Diagnostics Systems Inc, a subsidiary of Johnson & Johnson, both US companies.

The lawsuit was the first challenge brought against the validity of a genetic sequence patent in Australian legal history. Included within the scope of the patent’s monopoly was the importation and the manufacture in Australia of any purified HCV proteins for use in diagnostics or treatment of HCV infection. For example, claim 33 of this patent claimed a 20-year monopoly for ‘a vaccine for [the] treatment of HCV infection’. The patent disclosed only 77 per cent of the genetic sequence of HCV strain 1a but this information, which could have been used by any diagnostic laboratory in the world to develop HCV diagnostics tests, was kept secret by Chiron between January 1987, when Chiron first discovered the causative agent of HCV, and May 1989 when the sequence was eventually published. Chiron elected not to publish this vital information so that it could maximise its exploitation of the international patent system. It did not even disclose this information to the Centers for Disease Control, a US government agency that it had

collaborated with since 1982 for the purpose of cloning the causative agent of non-A non-B hepatitis. The CDC is a world renowned expert organisation in transmissible human diseases.

The suit was the subject of a part-heard trial before Justice Burchett that commenced in June 1996 and concluded in August 1996 when Chiron and Murex came to a settlement that ceased all litigation between them globally. Consequently, Justice Burchett never delivered a decision regarding the merits of the suit. Presently there is still no judicial authority in Australia on whether an isolated or purified gene, genome or genetic sequence is patentable subject matter within section 18(1)(a) of the Patents Act. In any event, it is noteworthy that some seven years after the grant of the patent Dr Michael Houghton, one of the three Chiron employed scientists named by Chiron as the inventors of the hepatitis C virus, finally admitted in a scientific paper entitled *Perspectives for a vaccine against hepatitis C virus* and published in 1999 in the *Journal of Hepatology* 31 supplementary 1 at pages 259 to 263 that 'there is no vaccine for HCV'. The submission by Dr Houghton made a mockery of the sworn evidence that he gave in the Patents Court in England in 1993 while defending Chiron's HCV patent vaccine claims. Under cross-examination, he was asked:

Is it right that your perception at the time of writing this document, January 31st [1993], was that successful vaccination against HCV infection had been achieved for the first time ever?

His answer was, 'Yes.'

In early 1997, I ceased practising law in Australia and commenced consulting internationally with respect to HCV patents in other countries. In September 2001, I commenced my PhD candidature at the Faculty of Law of the University of New South Wales. The focus of my PhD research is directed to what I term 'genetic sequence patents' in Australia, Europe, the United Kingdom and the United States of America. A genetic sequence patent is a patent that claims within the scope of its monopoly, genes, genomes and genetic sequences and their corresponding proteins. During my candidature I have lectured in patent and trademark law to both undergraduate and postgraduate law students of the University of New South Wales.

In January 2002, I filed a 196-page submission entitled 'Patenting genetic information' with the Australian Law Reform Commission in response to a referral made by the then federal Attorney-General, Mr Williams, and the Minister for Health, Dr Wooldridge, in January 2001. My submission addresses the terms of reference of that inquiry with respect to 'emerging issues about the control of, ownership of, and intellectual property rights in relation to human genetic samples and information'.

In October 2003, I filed a 119-page submission with the ALRC concerning a separate referral made by the then federal Attorney-General, Mr Williams, to the ALRC in December 2001 entitled 'Intellectual property rights over genetic materials and genetic and related technologies'. In December 2003, I filed a 43-page submission and four documentary attachments with this Senate committee.

In summary, my submission questions the implication contained in the terms of reference to this inquiry that the consequences of the failure of the Australian Red Cross to implement surrogate non-A, non-B hepatitis testing in the early to mid-1980s were resolved in 1990 with the introduction in Australia of the first generation Chiron licensed HCV immunoassays. It also

provides evidence that proves beyond a reasonable doubt, firstly, that by the early 1980s it was reasonably foreseeable that the failure to implement surrogate non-A, non-B hepatitis testing would contribute significantly to the continuing spread of post-transfusion hepatitis and, secondly, that by 1993 it was reasonably foreseeable that the failure to have available in Australia a variety of differently manufactured HCV immunoassays containing HCV proteins diverse from the Chiron produced or licensed HCV proteins would result in the continuing spread, albeit at a much lower rate than before 1990, of post-transfusion hepatitis C.

Although it may be convenient with the benefit of hindsight to point the finger at the Australian Red Cross, the truth implicates not only the Australian Red Cross but Chiron Corporation, Johnson and Johnson, Abbott Laboratories and every Australian government and their departments of health. The failure to introduce surrogate non-A, non-B hepatitis testing in the early eighties was bad enough, but the failure of all Australian governments to follow through on the recommendations of two critical reports into hepatitis C by using powers available to them under the Patents Act 1990 is terrible. For example, chapter 12 provides for the grant of compulsory licences to third parties and chapter 17 provides for the use or acquisition of the patented invention by the Crown.

A plethora of independent expert opinions were backed up by scientific studies and the 1993 National Health and Medical Research Council's hepatitis C task force's report, entitled *Report on the epidemiology, natural history and controls of hepatitis C,* recommended that Australian research laboratories 'be encouraged to undertake full nucleotide sequence studies on Australian strains of hepatitis C virus' and the 1995 Victorian government Department of Public Health and Community Services published a report, entitled *Management, control and prevention of hepatitis C,* which recommended:

> ... [a]ll hepatitis C diagnostic strategies should include, as a minimum, the repeat testing of all initially reactive specimens in a second independent EIA to confirm reactivity. The basis of this approach is that the second EIA test kit should use different antigens from both the structural and non-structural regions of the hepatitis C virus [so that] the second EIA should employee HCV antigens from an independent expression system, or alternative regions of the HCV polyproteins, or different genotype of the virus.

Despite all that evidence, no Australian government took any action to ensure the application of these recommendations. This was the case, despite the fact that Chiron Corporation, the absolute owner of the intellectual property rights to HCV in Australia—thanks to the negligent and perfunctory examination by the Australian Patent Office of their patent application or of any of its licensees, such as Abbott Laboratories—failed to take any steps that would have addressed the concerns expressed in the growing body of scientific literature that questioned the reliability of the first, second and possibly the third generation HCV immunoassays.

Despite Murex's repeated requests for patent licences, Chiron refused those requests and vigorously pursued Murex—and anyone else for that matter—for infringement of its HCV patents in whatever available jurisdiction. Chiron's global patent litigation strategy was like a finger of ice pointed at the body of HCV research and it exploited the international patent system ruthlessly to satisfy its own greed. Dr Stephen Locarnini, Chairman of the NHMRC's HCV task force on hepatitis C, said in his evidence in the Murex litigation:

The concern of the Hepatitis C Task Force is the strong and unequivocal evidence indicating that, despite the use of second generation anti-HCV screening assays as supplied in Australia, there were antibody negative HCV infectious blood donors in Australia. So in the opinion of the Hepatitis C Task Force there is sufficient evidence to indicate that there are genotypes of hepatitis C in Australia which may not be detected by the current anti-HCV screening assays.

The hepatitis C task force reported to the NHMRC, the Australian Health Ministers' Advisory Committee and the Chief Medical Officer of the federal department of health, which in turn reported to the federal minister for health.

It was not until August of 1996 that Chiron eventually capitulated. After 10 long weeks in the Federal Court of Australia, Chiron raised the white flag to Murex internationally. The settlement of Murex's lawsuit in Australia foreshadowed the grant by Chiron of global HCV patent licences that enabled Murex to sell and supply in Australia a vitally important HCV immunoassay that contained HCV proteins different from those contained in Chiron-licensed HCV immunoassays. In 1998 Murex was fully acquired by Abbott Laboratories.

Since the introduction of an HCV nucleic acid test in Australia in 2000 the spread of post-transfusion HCV has been conclusively halted. Nevertheless, my submission demonstrates that for a period of nearly 20 years innocent recipients of whole blood or blood products were subjected to an unnecessary and largely avoidable health risk of contracting HCV. It also demonstrates that the failure of all Australian governments to apply powers provided to them under chapters 12 and 17 of the Patents Act, after the grant to Chiron of a 20-year patent monopoly over all HCV proteins and their uses and diagnostic treatments—a patent that in my opinion is invalid—exacerbated the unfair and inappropriate use of that patent monopoly by a foreign corporation with disastrous effects on the lives of a not insubstantial number of Australian citizens and on the health budgets of this country, then and in the future.

Although HCV nucleic acid tests have now halted the spread of post-transfusion HCV, that technology existed and was capable of being applied in Australia from as early as 1991. Moreover, Chiron, the possessor of information vital to the safety of global human health, deliberately withheld this information for two years to satisfy a commercial objective. The reasons behind the deliberate delay in the publication of this information and the use of Chiron licensed HCV immunoassays that were unable to detect 99.4 per cent of all HCV tainted blood donations after 1990 are relevant to this inquiry.

While it is true that the Australian Red Cross's failure in the early eighties to implement surrogate non-A, non-B testing of blood donations is regrettable, it marks only the beginning of this despicable story. If a fair and balanced answer is to be arrived at by this inquiry this committee must look into the actions of Chiron Corporation, Abbott Laboratories, Johnson and Johnson, the Australian Patent Office and the departments of health of all Australian governments. Only then will the truth be known and the blame fairly apportioned.

CHAIR—Thank you, Mr Palombi. Senator Lees and I have been talking about the need for a chronology and you have given us a lot of evidence. You said a couple of times in your oral submission that the failure of the government in the early eighties not to introduce surrogate testing was an error.

Mr Palombi—It was a failure of the Australian Red Cross.

CHAIR—Sorry, it was a failure of the Australian Red Cross.

Mr Palombi—Yes. The failure of the government was in allowing Chiron to monopolise the use of HCV diagnostics in this country when there was a clear need to have other tests available. The Australian government does have power under the Patents Act to have made that possible through compulsory licensing.

CHAIR—I will come to that in a minute. It has been my understanding throughout this inquiry that surrogate testing only became feasible around 1985, so I am interested that you say 'in the early eighties'. Can you explain the chronology to me?

Mr Palombi—Information that I have been able to obtain through my research indicates that, at least in the United States, there were some discussion about surrogate testing—what is called ALT testing—from as early as 1981. One of the documents that I submitted to the committee is a letter from Dr Katz to the American Red Cross in which he summarises the results of a meeting that took place in early January 1981. It is pretty clear from what he says that there was solid evidence then that ALT testing could be used to reduce the incidence of post-transfusion non-A, non-B hepatitis. It is true that in the United States that clearly did not translate into any action until the mid-1980s, but I think that the scientific evidence at least was there before 1985 that a test, even though it was non-specific, could have been made available or at least produced. Certainly the technology was available in Australia to do so. I can only refer you to the evidence Dr Locarnini gave in the Murex case when he talked about his work at Fairfield. They probably recognised from the mid-seventies that non-A, non-B hepatitis was going to be spread through the blood system.

CHAIR—Was that test evaluated in 1981? Was it a test that could be applied to the blood supply at that point?

Mr Palombi—My understanding is that it was feasible but a number of issues were troubling the members of that meeting, and one of those issues was the fact that it was non-specific. It is not an invalid concern that perhaps it might have resulted in too many false positives, which would have had drastic effects on the available blood supply. That is an issue that most blood banks are concerned about. For example, in England the North London blood bank in 1990 when the Chiron first-generation test became available decided not to implement even the Chiron first-generation test because they were concerned that there would be too many false positives which would lead to the removal of blood donors from the blood supply. I think there were a number of issues that were creating limitations on the implementation of the test, and that probably has something to do with it.

CHAIR—It has been put to us by a range of submitters that the decision making process—the whole management of the blood supply, in fact—in Australia was extremely fragmented, that it was essentially a state based service and that decisions were made on a state by state jurisdiction basis. There was a national committee, but essentially its purpose was advisory. You have said that the Red Cross should have introduced tests at different times and that governments and health departments should have done things at certain times. Can you put that in the context of the decision making process that existed at the time and tell us where, in your view, the mistakes were made?

Mr Palombi—The scientific literature which started to come through in the late seventies was showing that elevated ALTs were connected to non-A, non-B hepatitis. Certainly the work of Dr Bradley and other scientists in the United States in the late seventies was showing that. I think that the fact that by the early eighties the American Red Cross and other scientists who were working in the field of hepatitis were getting together to discuss ALTs as a surrogate test for non-A, non-B indicates that it was clearly in their minds that it was a feasible test to undertake.

I would have thought that that scientific literature would have been available to Australian scientists and to the relevant advisers of the Australian Red Cross and the various departments of health. So I would have thought that, certainly by 1981, there would have been discussion—even if it was unofficial—amongst scientists that they should be producing some sort of test to try and eliminate to some degree non-A, non-B hepatitis in the blood supply. It was not until 1987 that Chiron discovered the causative agent of hepatitis C. It was a very difficult agent to track down, but they managed to do it. They were the first to do it. I suppose if they had published their discovery, their sequence, at that point then laboratories around the world could have used that sequence to develop immunoassays pretty much straightaway.

There was nothing fantastic about the development of a HCV immunoassay; what was difficult was actually providing the relevant proteins into the assay. ELISA assay, which is what these were, technology had been available. Moreover, I think that by 1991 the use of what they call polymerase chain reaction technology would have seen the development of nucleic acid based tests. That is why I say that it is was feasible to look not only for the antibody to hepatitis C infection but actually look for the virus in patients with hepatitis C or potential blood donors. So in terms of a timeline I think that by about 1992 there was a fair body of scientific literature coming through suggesting that the first-second generation HCV tests for Chiron were not doing the job as well as they should be and that there were donors being missed. Moreover, there were donors being falsely classified as infected with hepatitis as well. So there were problems at either end. I would have thought that, at that point, the Australian government should have taken a great interest in the hepatitis C patent.

One of the obstacles for the development of an Australian based immunoassay was the fact that Chiron's patent was so broad in its claims. Its monopoly was vast. Any laboratory—and any research laboratory for that matter—that produced an immunoassay using HCV polypeptides was technically infringing their patent. It was obvious to me at the time that the Australian government should be doing something, but there was absolute deathly silence. Eventually when the case started and there was some publicity, I was interviewed on *Lateline* by Kerry O'Brien. I know that is a program that is widely seen and yet again there was deathly silence from all relevant governments. So we had Chiron with this massive patent and there was virtually no action. It was not until Murex succeeded in negotiating a settlement—a very hard-fought settlement—that a legal alternative HCV immunoassay was available in Australia. That is no thanks to anyone other than Murex and its shareholders.

Senator LEES—Was the key issue with the Chiron test that it was missing certain types of hepatitis, particularly type 3, or was it just a general problem?

Mr Palombi—The Chiron licensed immunoassays used polyproteins from strain 1a, which is a predominant North American strain. In Australia, because of our cultural diversities, we have

all sorts of different strains. From my recollection, and from my reading of the expert reports, that factor was critical in explaining the error rates that were happening in Australia.

Senator LEES—Did we pick that up in the various research facilities that were working on hep C here in Australia? Was a pattern emerging that the testing that was being done was missing certain bits of the spectrum?

Mr Palombi—Yes, that was picked up. That was basically one of the issues that was raised in the 1993 National Health and Medical Research Council report. That was being expressed in writing as early as 1993. Of course, beforehand it was showing up and it would have been discussed privately, I have no doubt.

Senator LEES—So how many people are we talking about in the nineties, given that most of the focus has been on what was not done in the eighties? We are now moving into 1992 and 1993. Are we talking 100 people or 1,000 people?

Mr Palombi—I do not know the answer to that question. Unless there is a thorough Lookback program instigated, I do not think anyone could really answer that question. There is no doubt that the introduction of the first, second and possibly third generation HCV tests had a significant impact on the post-transfusion spread and would have reduced it. But the information I have been getting from the scientists and from experts who were involved at the time is that that was not good enough. I remember talking to Dr Nick Cross, who was then at the McFarlane Burnett Research Centre, and he told me that, if we compare what happened with HIV to what is happening with HCV, it is like comparing black to white. With HIV there was enormous enthusiasm to encourage the production of many different types of tests so that the sensitivity and specificity of these tests would be as high as 99.4 per cent—in fact, that was the gold standard that we should have been striving for, according to Dr Locarnini. But with HCV somehow, because of this global patent monopoly that Chiron obtained, it was not possible to do that. What Chiron had done was carve up the application of the proteins amongst three critical companies. One of those was Johnson and Johnson and the other was Abbott. It held tight with those companies onto the manufacture of the proteins. For example, Chiron would not permit Abbott to produce its own kits that did not use Chiron supplied polypeptides. That is how tight this control was. So even if Abbott wanted to produce a kit for Australia, it was not permitted to.

Senator LEES—It had to stick with the 1a material?

Mr Palombi—It could only use the polyproteins supplied to it by Chiron. It could certainly use those in the manufacture of an assay, which it did—and it sold those assays in Australia. But the information that I have is that it was not free to actually produce an Australian HCV assay.

Senator LEES—And this continued until 2000? We date the really effective tests now from 2000?

Mr Palombi—Effectively, in mid-2000. It is a Chiron licensed test. Gen-Probe are the manufacturers of that test and they have an exclusive contract with, I think, the Australian Red Cross.

Senator LEES—Given Chiron's activities through the nineties, as we look at the Red Cross's response and the fact that it seems people have slipped through and been infected, your argument is basically that as this is all the Red Cross had available—this was the only test governments had given the green light to, by not challenging Chiron—the Red Cross, while we might as a committee look at other issues, cannot be held solely liable for problems, particularly in the nineties?

Mr Palombi—I think from the moment the Chiron patent was granted—

Senator LEES—What was the specific date of that?

Mr Palombi—It was granted in, I think, September 1992. It was applied for in November 1988. I think we should go for November 1988 as the critical date because even though it was granted some years later, in terms of infringement suits, once a patent is granted a patentee can seek damages from the date the application was made public. From the late eighties, everyone was pretty well frozen out of HCV diagnostics, and the Australian Red Cross really would have had no alternative, unless it wanted to risk an infringement suit, than to acquire its HCV immunoassays from Abbott Laboratories, which I think was probably the only licensee. There might have been a Chiron test available through Ortho Diagnostics, but I am not sure.

Senator HUMPHRIES—Can you explain again what process is used by the patent office to pick up potentially utilitarian or valuable patents which are put before it for granting that would allow it to advise the Australian government, presumably, that it should not grant an exclusive patent to a certain corporation or individual but rather acquire that patent for public use?

Mr Palombi—I am not aware of any system or procedure in place within the Australian patent office to advise the Australian government to acquire particular inventions.

Senator HUMPHRIES—You said before that you thought that the patent office was negligent in the way in which it dealt with the granting of the patent to Chiron. You mentioned there was some other body which made a recommendation that the patent should not be granted exclusively to Chiron.

Mr Palombi—No.

Senator HUMPHRIES—Can you explain why you say that the patent office was negligent?

Mr Palombi—Gladly. A patent application goes through a series of steps in the process before it is granted. Because this was a patent application that emanated from the United States, it was what they call a PCT application. That patent application is essentially replicated in all the countries that are listed and basically ticked off on this PCT application. That is the way it works. Australia was one of those countries which was scheduled to apply under the relevant treaty. Once the patent application arrived in Australia, it started with the specification and the claims as applied for. The Australian patent office is the only patent office that I am aware of that granted to Chiron that patent in virtually unamended form, as applied for.

Senator HUMPHRIES—When you say the only patent office, do you mean compared to patent offices around the world?

Mr Palombi—Anywhere in the world. Every other patent office—including the United States patent office, for that matter, which only granted a patent in 2000—rigorously examined it. In Europe, for example, the European Patent Office objected to the original claims and that forced Chiron to file amended claims. Those amended claims were the subject of seven oppositions by a number of companies, including Hoffmann-La Roche. The examining office section of the European Patent Office granted those claims. The opposition continued all the way to the technical appeal board of the European Patent Office. The technical appeal board is not a court, but it is a review body within the European Patent Office. The patent had been granted but, seven years after the grant of the European patents, the technical appeal board effectively knocked back just about every claim that was granted by the European Patent Office. Chiron was forced to file amended claims in June 2000. It now has only five claims, and all of those claims relate to nucleic acid tests. There are no claims that relate to immunoassays, antibodies or vaccines—none of those now exist.

Senator HUMPHRIES—So why did the board knock back those claims?

Mr Palombi—It did not think that the disclosures provided by Chiron in the patent specification justified those broad claims. It was a very detailed decision, but in a nutshell it thought Chiron had really overstepped the mark. The Australian patent office, on the other hand, has essentially rubber-stamped the patent application. It went through in record time and there was only one minor amendment to it and that was it. It was only after Murex challenged the patent that Chiron eventually amended its Australian patent claims and it did not do so until 1997. Essentially, the amendments are identical to the claims that were subsequently rejected by the technical appeal board. We have a patent in Australia that is essentially invalid in Europe, but no-one has challenged it in Australia since Murex—I think Hoffmann-La Roche tried but they eventually did a deal with Chiron and disappeared—so unless someone challenges this patent it will be there on the register for 20 years.

Senator HUMPHRIES—You say there should have been some public interest—which was identified by the patent office—which should have led it to reject or modify the application that was being made?

Mr Palombi—Perhaps it might be going too far to expect the Australian patent office to recognise that there is a public interest issue, but I think there is an issue over whether the isolated or purified genetic sequence of HCV is patentable subject matter within section 18(1)(a) of the Patents Act. I would have thought that it was incumbent upon the patent office to reject the patent application and to then have Chiron lodge an appeal so that at least we would have judicial authority on the subject. As it stands, we have no judicial authority on whether or not a genetic sequence is patentable subject matter and we are unlikely to because the companies which have the money to challenge these patents are also patentees of their own genetic sequence patents. On top of that, we have the Australian patent office essentially going around saying that genetic sequences are patentable. Consequently, significant numbers of genetic sequence patent applications are being made and granted in this country.

Senator HUMPHRIES—So the patent application by Chiron was not the first application for a genetic patent?

Mr Palombi—No, I think there was a patent application for HIV2 by the Institute Pasteur that preceded the Chiron patent.

Senator HUMPHRIES—That may be outside the scope of this inquiry. I do not want to comment on that. Coming back to the issue you raised about what you call the regrettable failure of the Red Cross to institute surrogate testing, at what point do you say that their decision to not do so was regrettable? What date?

Mr Palombi—From the moment that it was reasonably obvious that they could have implemented some sort of ALT testing.

Senator HUMPHRIES—When was that?

Mr Palombi—The evidence that I have indicates that that could have been as early as 1981.

Senator HUMPHRIES—We have heard from a succession of witnesses in areas of medical practice who perhaps were not asked directly whether there should have been testing before US surrogate testing was implemented in 1985 or 1986, but none of them volunteered in their submissions or in oral testimony that it was reasonable for there to have been testing, certainly in Australia, before that point. Are there any experts in this field whom you could cite as supporters of your view that there should have been testing prior to 1985?

Mr Palombi—Australian scientists?

Senator HUMPHRIES—Yes.

Mr Palombi—Specifically, no.

Senator HUMPHRIES—You talk about the process of reaching a decision that testing was reasonable and you say that it was regrettable that the Red Cross did not do it from about 1985. But, surely, the identification of the possibility of testing at a meeting in the United States in 1981 still is a long way from reaching the point where it is both efficacious and safe in terms of public policy to be implementing that testing. You know from your involvement with patents that it takes a long time from the development of a patent, an application and lodging before there is in some cases commercial application of the matter that has been patented. Equally, wouldn't it be fair to say that where a test is involved that has literally a life or death implication for patients that the process of evaluating, discussing, getting consensus about and testing these sorts of devices would have taken some time. Isn't that reasonable?

Mr Palombi—Yes, it is reasonable.

Senator HUMPHRIES—Would you accept that there was no medical or scientific consensus in Australia before 1985 that there should be such testing?

Mr Palombi—I am not able to answer that question.

Senator HUMPHRIES—With respect, you are able to say that before 1985 the Red Cross ought to have been developing tests. If you can say that, why can't you say whether there is any scientific consensus?

Mr Palombi—I do not know as a matter of fact whether there was scientific consensus. It is my view based on the material that I have before me that there was 'solid evidence' of a correlation between elevated ALTs and post-transfusion non-A, non-B hepatitis. I do not know why it may have taken a number of years for various scientific bodies to get their heads together to eventually formulate some sort of test that met all the policy concerns that might have been raised, but I doubt very much that if we were talking about HIV it would have taken a number of years.

Senator HUMPHRIES—You are saying that after 1990 people were continuing to receive HCV through blood transfusions—

Mr Palombi—Yes.

Senator HUMPHRIES—because of the failure of the Chiron immunoassays to be effective in completely excluding those sorts of viral transmissions.

Mr Palombi—Yes. The evidence indicates that that is the case.

Senator HUMPHRIES—I have to go back and examine the evidence, but I do not believe that any of the technical evidence we have received in the inquiry so far has made that claim. Are you aware of other medical opinion in Australia that supports the view that there was continuing transmission of hepatitis C from transfusions after these tests were put in place in 1990?

Mr Palombi—I refer you to those two reports: the National Health and Medical Research Council report in November of 1993 and the Victorian government report in 1995. Both of those reports refer to extensive literature, including overseas literature, showing that there were individuals being missed in the testing of donated blood. They were getting through the system.

Senator HUMPHRIES—I will have a look at those. How do you feel an Australian government—or for that matter a state government in Australia—should have received information about the existence of available tests to prevent the spread of HCV and, to the extent that they were not acting on that information or advice, is that reprehensible?

Mr Palombi—I think the 1993 National Health and Medical Research Council report which was made available to the Australian ministers would have been passed on to the chief medical officer of the federal department of health. I would have thought that that was an excellent way of getting the message across to the relevant state departments of health that there was an issue that needed to be addressed. The appropriate thing to have done would have been to source the production of alternative HCV polypeptides either from overseas or to have somehow exempted Abbott so that it was able to manufacture alternative HCV polyproteins for use in an Australian environment. It could have been done. All the Australian health departments had to do was to provide some sort of compulsory licence. It would not have resulted in Chiron missing out on any royalties because there would have been fair remuneration and fair compensation to Chiron

for the issuing of that compulsory licence. The problem was that Chiron was just not interested in licensing outside of its very tight group of companies. I suppose no-one within the relevant departments of health were putting any pressure on it to loosen its grip even though they did have the power to do it under the Patents Act.

Senator HUMPHRIES—You are sure that they knew about this problem.

Mr Palombi—I would be very surprised if they did not know about this problem.

Senator HUMPHRIES—I have not seen the 1993 report that you are referring to. How many people does it say were infected with HCV between 1990 and when the report was completed?

Mr Palombi—I am sorry, I do not have that information at my fingertips. I am happy to search my archives and make whatever documents available to this committee, if it believes it would be helpful to its deliberations.

Senator HUMPHRIES—I am sure we can find the document concerned.

CHAIR—Thank you for the offer anyway.

Senator HUMPHRIES—Going back to the question of patents, to what extent is it normal for a patent office to initiate in effect an internal challenge to a patent that might have public policy implications if there are no third party challengers coming forward to do that?

Mr Palombi—The patent office has an obligation to apply the law. The law says in section 18(1)(a) that a patent will be granted if it is a matter of manufacture. 'Matter of manufacture' is defined by reference to section 6 of the Statute of Monopolies. If there is a hint of doubt that the genetic sequence of a virus is patentable subject matter, frankly, I do not understand how an isolated genetic sequence of a virus which is not an invention in any shape or form is going to satisfy section 18(1)(a). I would have thought the first thing the patent office would have said is: 'We've got an obligation to apply the law. We can't grant this patent.'

Under the Patents Act, the patent applicant could then have appealed that to a single judge of Federal Court and that could have in turn been appealed to the full court of the Federal Court and ultimately to the High Court. That would have been a very neat way of determining judicially whether or not under Australian patent law a genetic sequence is patentable subject matter. But the patent office took a very proactive stand, which was that all of this is patentable. They did not challenge it and effectively left it to a third party to bring a very expensive lawsuit. You have to understand that to bring a lawsuit like this in the Federal Court not only is expensive but you have to get the right experts to put it together. That process took an enormous amount of time both in Australia and overseas.

Senator HUMPHRIES—The point I am getting at is that they had already granted at least one other genetic sequence patent before this time. Had patent offices in other parts of the world granted patents to genetic sequence applications?

Mr Palombi—In the late eighties and early nineties we are talking about the very beginning of these patents coming through. Certainly patent applications had been lodged, but it would

have been very difficult to assess at that point whether there was a trend internationally. Generally, and with the benefit of hindsight, it can be said that most patent offices are very keen to grant patents for pretty much everything. The only exception to that was the United States patent office. It gave Chiron and a number of other patentees that were seeking genetic sequence patents a thorough examination, and that is why it took so much longer for those patents to ultimately be granted in the United States. When they were granted, they were not granted on the broad terms on which they were granted in Australia; they were quite specific. It is important to recognise that patents can be granted but you can have broad claims or you can have narrow claims. The broader the claim, the broader the monopoly and the more difficult it is to have substitute goods or products that do not come within that broad monopoly.

Senator HUMPHRIES—But genetic sequence patents had been granted, or were being granted, by patent offices in other parts of the world and had previously been granted by the Australian patent office before this application came forward?

Mr Palombi—I think that is fair to say.

Senator MOORE—Mr Palombi, I am not sure whether I followed all your argument. Given that there has been no chance for this to go through the neat process of challenge—to have all the arguments put forward and argued through—do you have any indication from your own research about the motivation or rationale for the patent office to take this decision and why it was done, from your point of view, so differently here to what happened overseas?

Mr Palombi—The patent office has not given any indication as to why it rubber-stamped this application the way it did.

Senator MOORE—And because it has not gone through the legal process it has not had to justify those reasons and put them forward?

Mr Palombi—Even if it were to go through the legal processes, there is no guarantee that the patent office would have to justify anything to anyone.

Senator MOORE—Ever?

Mr Palombi—It certainly has the power to intervene either to support a challenge or to support the validity of a patent, but that is a matter entirely at its discretion.

Senator MOORE—This may or may not be within your area of expertise. We heard evidence in Melbourne on Monday from the National Serology Reference Laboratory, which does the quality assurance on the current testing kits. Would it have had any role in the discussions or processes in the early eighties looking at the kinds of tests you were talking about?

Mr Palombi—I am not able to answer that question.

Senator MOORE—Chair, can I have that put aside for reference back to them?

CHAIR—Yes, I think that is a good idea.

Senator MOORE—It is my understanding from the evidence given by that organisation that they test the kits that do the tests for the current process. They were working in the HIV area from the early eighties. The way I read it, they only came into the HCV area in about 1996, which was after this period. But it would seem to me that they have some role here.

Mr Palombi—By 1996 the third-generation assays were available. They were much more refined. That is not to say that there were not problems associated with them, but they were a much more refined product.

Senator MOORE—And your concern was the first- and second-generation tests and their quality?

Mr Palombi—There was also evidence coming through that the third-generation tests were not up to standard—and the gold standard as it was put to me by Professor Locarnini is 99.4 per cent sensitivity and specificity.

Senator MOORE—Which is what was achieved in the HIV experience?

Mr Palombi—That is correct.

Senator HUTCHINS—Mr Palombi, on pages 27 and 28 of your submission you quote Dr Locarnini, who quotes Dr Beal. Point 5 refers to a letter published in the *Medical Journal of Australia* dealing with the testing in this period. Is that your recollection? It says 1995.

Mr Palombi—Yes.

Senator HUTCHINS—So I am assuming that there is a positive hepatitis C enzyme test in a low-risk population. You emphasise in point 6:

> A significant finding by the authors of the said letter was that with third generation anti-HCV EIA a repeatedly reactive test result was "interpreted as false positive reactions in approximately 75% of cases".

Does that mean that this test was still having 75 per cent false positives? Is that the way we should interpret that?

Mr Palombi—I do not wish to mislead the committee. My answer would be that the deponent to this affidavit which I referred to here is Professor Stephen Locarnini. It probably would be safer if you referred that question to him.

Senator HUTCHINS—But that is his supposition: that there was still 75 per cent of false positives?

Mr Palombi—Correct.

Senator HUTCHINS—On page 37 you go to the UK blood supply and the concern about them introducing this test in 1990. You say—I think it is you, tell me if I am wrong:

They recognised that the first generation tests would produce too many false positives and that would place enormous pressures on the UK blood supply to keep up with demand for blood.

Mr Palombi—They are the words of Dr Crofts.

Senator HUTCHINS—And he is from the McFarlane Burnett Research Centre?

Mr Palombi—Yes. That was his evidence in the Murex case.

Senator HUTCHINS—Was Dr Locarnini from the Murex case as well?

Mr Palombi—Yes. All the evidence that is referred to, except for the attachments at the end, are from evidence given in the Murex litigation.

Senator HUTCHINS—So both Dr Locarnini and the UK are saying that there are still false positives coming up in this generation of tests?

Mr Palombi—Yes.

Senator HUTCHINS—In your submission at the bottom of page 37 at point 24 you say:

The Australian blood banks, however, did not hesitate in 1990 to introduce HCV screening because of the potential for litigation. Most Australian blood banks at that time were being sued with respect to HIV transmissions in the 1980's.

Were the Australian blood banks concerned that there was some connection between people starting this litigation because they had received transfused blood that had AIDS in it at the same time as people were starting to realise there might have been these tests available for HCV that were not used?

Mr Palombi—This is not my opinion but, from reading Dr Crofts's affidavit, certainly that seems to be the logic.

Senator MOORE—This question relates directly to your previous evidence, where you said that your interest in this issue has been longstanding, that in the late nineties you were involved in some media around the issue and you had some interviews—

Mr Palombi—It was in the mid-nineties.

Senator MOORE—but there was a lack of response. There was no community pickup or response to the quite serious issues you were raising.

Mr Palombi—Other than the ABC.

Senator MOORE—That is good to note. Can you give some indication, from the thought you have put into it, as to why? You are raising very serious issues about safety. You have drawn a comparison with the issues around HIV, but you have not been able to find the same degree of

anger, concern or interest in relation to these issues. Have you thought about why and what could be done about that?

Mr Palombi—When I spoke to Dr Crofts about it, he ventured an opinion. That was that, essentially, by the mid-nineties hepatitis C was seen to be a problem that only affected intravenous drug users and sex workers—essentially, undesirable people—whereas HIV was always seen to be a disease that could affect anyone. So there was almost this moral comparison created. I do not know if that is true or not, but that was certainly his view and that is the way he explained it to me at the time.

Senator MOORE—Is there anything we can do about that?

Mr Palombi—I think educating people is the thing to do.

Senator HUMPHRIES—I turn to the decision or nondecision by the Australian Red Cross to implement surrogate testing—you say from the early eighties; let us say from the mid-eighties at the least—when such testing was going on in other parts of the world. The argument that has been put to us is that the reason it should not have been done in Australia—whereas it was being done in the United States—is that there was a very low rate of post-transfusion infection with hepatitis C in Australia and that, on the other hand, there was a high cost to the effectiveness of blood services in that they would lose a significant proportion of their donors who would be rejected by this fairly broad test. What is your response to that argument? Is there weight to be given to those arguments? If so, why is not enough weight given to those arguments to support the decision they took generally in Australia not to have such testing?

Mr Palombi—I have to answer this by saying that I am not an expert in blood borne diseases and policy issues relating to blood banks. But I as an individual would have thought that, given the solid evidence that was coming through from the United States and given at least the lead taken by the United States, there should have been at least some study done in Australia—some verifiable study—or some steps taken towards justifying the decision not to introduce ALT testing. I am not sure that there was or was not. In my view, given what was available scientifically about the connection between ALT and the incidence of post-transfusion hepatitis, some form of ALT testing should have been introduced. It is a matter of being cautious, but I think I would prefer to err on the side of caution rather than take the risk that you are going to infect innocent people because of cost.

Senator HUMPHRIES—Cost is not the only issue. There is a question about loss of potential blood donors as well and the capacity—

Mr Palombi—That is part of the cost as well, I suppose.

Senator HUMPHRIES—You can characterise that as simply not having capacity to deliver blood services to people who are extremely ill. Bound up in your judgment that the Red Cross's decision not to do surrogate testing in most places is 'regrettable', in your words, is an assessment necessarily about weighing those factors? You say you are not really in a position to make a decision about those countervailing factors which at the end of the day persuaded the Red Cross not to have that testing in most places and which have been supported by a number of experts who have come to this committee in the last few days.

Mr Palombi—In my opinion the information I have shows that there was solid scientific evidence based on a US study and on US literature that there was a correlation between elevated ALTs and the transmission of post-transfusion hepatitis.

Senator HUMPHRIES—That is not disputed.

Mr Palombi—I suppose it is a decision ultimately of morals. For what it is worth, I think it was reprehensible to allow a situation to continue where innocent people could contract hepatitis C through blood transfusions. I am of the view that if it meant a loss of the blood donor population then steps should have been taken to encourage an increase from the pool. Only three per cent of people in this country donate blood. If it was foreseeable that by instigating ALT testing there could be a reduction of that potential blood donor pool the thing to do would have been to encourage a greater number of people to donate blood. All of that was clearly foreseeable. It might have taken some time to implement it. I do not think it is an answer to simply say that a potential loss of blood donors was a good enough reason not to introduce ALT testing. The scientific evidence is just too strong.

Senator HUMPHRIES—We have had scientists who have put a different perspective on that during this inquiry but perhaps this is not the place to debate that. Thank you for your evidence.

CHAIR—Thank you, Mr Palombi, for your submission and your evidence. If you have anything further you would like to add do not hesitate to contact the committee.

Proceedings suspended from 11.23 a.m. to 11.40 a.m.

HOLLAND, Dr Paul Vincent, Medical Director/CEO, BloodSource; Australian Red Cross Blood Service

PEPPER, Mr Brian, Donor, Australian Red Cross Blood Service

ROSENFELD, Dr David, Head of Haematology, South Western Sydney Area Health Service; Australian Red Cross Blood Service

TOZER, Mrs Carole Janice, Recipient, Australian Red Cross Blood Service

WYLIE, Dr Brenton Russell, National Blood Products Manager, Australian Red Cross Blood Service

CHAIR—Welcome. Information on parliamentary privilege and the protection of witnesses and evidence has been provided to you. The committee prefers evidence to be heard in public but evidence may also be taken in camera if you consider such evidence to be of a confidential nature. The committee has before it your submission, for which we thank you. I now invite you to make an opening presentation, to be followed by questions from the committee.

Dr Wylie—Firstly, on behalf of the Australian Red Cross Blood Service and the Australian Red Cross Society, of which it is a part, I would like to thank the committee for the opportunity to present to you today. I am a specialist haematologist and the National Blood Products Manager for the Australian Red Cross Blood Service. Before I begin, we would like to extend our sympathy to each Australian who has acquired hepatitis C. We particularly extend our sympathy to those who have or will develop symptoms and complications. We have heard, and we hear, the concerns of those who have made submissions to the inquiry and presented to the committee. On reading each of the submissions, it is impossible not to appreciate the powerful and moving accounts of the challenges faced by the individuals, and their bravery. They reflect the experiences that we at ARCBS have had from all of our interactions with patients with hepatitis C over the past years. We recognise the impact that this disease can have on the person and their family.

We know that the real focus of this inquiry is on issues such as risks associated with blood transfusion, the difficulties of this chronic illness, the discrimination encountered, the lack of notification of infection and the cost of medical treatment. We will address many of these concerns today and will provide recommendations for the committee's consideration. The ARCBS supports outcomes that will improve the situation of those affected by hepatitis C. In particular, we wish to lend our support to the principle of improving services through the provision of optimal personal, medical and social support. We also particularly acknowledge the difficult situation faced by patients with haemophilia who have hepatitis C, as described in the submission from the Haemophilia Foundation of Australia. Sadly, the high infection rates of people with haemophilia illustrate the risk/benefit dilemma inherent in the use of blood and blood products for treatment purposes.

In my presentation today I will speak to the key issues of the inquiry, including how the blood service operates within the Australian Red Cross Society, what the risks of hepatitis C are, the

debate about surrogate testing, how many people have acquired hepatitis C through blood and blood products, and ARCBS recommendations. Presentations will also be made by one of our long-time blood donors, a blood recipient, a Sydney haematologist, and an international expert in transfusion medicine.

I will begin by explaining how the ARCBS operates within the Australian Red Cross. The Australian Red Cross Society is part of an international humanitarian non-profit movement active in 181 countries throughout the world. More than 80 million units of blood are collected annually worldwide. Over 30 per cent of this blood is collected directly by the Red Cross and Red Crescent societies, and Red Cross assists with blood donor recruitment for another 30 per cent of the global blood supply.

In Australia, Red Cross was first established by royal charter in 1941. In January 1996 ARC changed its charter and rules to provide for a national blood service, with a board of management and a CEO, accountable to the ARC council for the management of a newly created operating division of the society: the Australian Red Cross Blood Service, ARCBS. This new national management structure replaced what were previously eight state and territory based operations. This change, instigated by ARC in 1996, resulted in a single national blood service. This has helped to create and ensure uniform policies. Common tests could be introduced universally throughout Australia, once approved and with the necessary funding secured. The Commonwealth, state and territory governments primarily fund ARCBS, with a limited financial contribution provided by ARC. ARC also assists ARCBS through the contribution of volunteers in the recruitment and welfare of donors.

It is important to note that ARCBS do not work alone in the provision of blood and tissue products to the Australian community. As in the past, we continue to work very closely with state, territory and Commonwealth health departments, and all major decisions about safety and sufficiency are made in consultation with governments. Providing a quality service for Australian patients also depends on a close partnership with blood donors, clinicians, scientists and nurses in the health care system. Our mission is to share life's best gift by the provision of quality blood products, tissues and related services for the benefit of the community. This also encompasses significant programs in the management of organ donation.

ARCBS can only achieve its mission through the goodwill and commitment of approximately 500,000 dedicated, voluntary, unpaid donors. Whilst a very large proportion of Australians will have given blood at least once in their lifetime, only three to four per cent of the adult population are active, regular donors. With me today is one of Australia's blood donors, Mr Brian Pepper, whose lifelong effort in donating blood has saved many lives. Brian has been a donor since 1967 and has made over 600 donations. I invite Brian to share with you his story of becoming and being a regular blood donor.

Mr Pepper—It is my privilege to speak on behalf of the donors of the Red Cross Blood Service. I have a gift: the ability to donate my blood, Rh negative, which produces anti-D antibodies for the treatment of Rh disease in newborns. I have been doing this for 37 years. Donating is part of my life. The doctors, sisters and nurses at the Red Cross Blood Service are more than friends; they are family. Knowing how important my antibodies are, I am driven to keep every appointment, as I realise how critical each visit is for every Australian. I am aware that my commitment plays an important role in the ability of the Red Cross Blood Service to

provide life-saving products for those in need. I am conscious of the importance of each donation in this day and age, where shortages are a weekly occurrence. Recently, my job situation changed and I have endeavoured to find a new job which gives me the flexibility to donate each fortnight. It is such an important part of my life.

The importance became very real when my daughter-in-law was helped with the birth of her first child by antibodies donated by me. My family realise how significant giving blood is for another very personal reason. A close family member has bone cancer and over the past few weeks has had two blood transfusions. Because of the strict criteria surrounding who can and who cannot donate, my son and daughter-in-law were frustrated as they could not donate blood during this period. These precautions had to be taken with the safety of blood in mind.

I have a passion for what I do, and I would be devastated if told by the Red Cross Blood Service that they would reject my blood. I understand that at times this happens because of infections and other health reasons. But I would require a medical reason why my blood was rejected. It is hard for donors to accept rejection when it is for a precaution of safety. However, the professionalism I have experienced from the doctors and nurses gives me the confidence to state categorically that it is done for the wellbeing of others.

There are so many health reasons and strict criteria for donating blood that the chosen people are very precious. The public must be reminded of the real and valued work that the Red Cross Blood Service staff do behind the scenes. I remain friends with many of the people I have met through what I do. If others could be inspired like I am to make a small gesture themselves, it would make such a big difference to other people's lives. Thank you.

Dr Wylie—What do we know about the people who receive blood? Many patients receive multiple transfusions in one year; hence, it is not possible to say exactly how many individuals benefit each year from transfusion. However, we have estimated that approximately 100,000 patients benefit from fresh products each year and another 100,000 Australians benefit from plasma products. We know from comparative studies in other developed countries that the average age of blood recipients is 60 to 65 years old. The majority are seriously ill, including cancer patients and trauma victims.

Sadly, because these people are so sick, survival of blood recipients is quite poor in that around 50 per cent of blood recipients die from their underlying disease or condition within 12 months of any given transfusion. Nevertheless, many recipients do recover and go on to lead healthy lives, while others face a lifetime of dependence on blood products because of their particular disease. We would like to introduce to you one recipient of blood, Carole Tozer, to tell her story.

Mrs Tozer—My personal story is that in 1998 I was diagnosed with intermediate grade non-Hodgkin's lymphoma. I had the standard chemotherapy and radiotherapy treatment, and I was told that there was an 80 per cent chance that I would have a cure from that process. In 2000 the non-Hodgkin's lymphoma returned. I was the one in five where the standard treatment did not work. I was then offered by my oncologist a final chance at a possible cure. I would undergo high-dose chemotherapy, and that high-dose chemotherapy would go beyond bone marrow toxicity; in fact, it would fall short of liver and kidney toxicity.

All of my existing blood and bone marrow would be killed in that process, but it offered me a chance of a cure. In that situation, blood products needed to be transfused into me to keep me alive and for my body to start working again. I went through the process and, even as new bone marrow was being produced in my body, it still took many weeks before I had the levels required in my blood to lead a relatively healthy life.

There were a lot of risks attached to what we were doing, but I believe that there are risks associated with everything in life. We do not do anything without there being some risk. I had to make a decision after weighing the facts that were presented to me and the facts that I researched. The procedure that was offered to me had a 30 to 40 per cent chance of a cure. There were no guarantees. If it did not kill me, at least it would put me into a longer remission period. If I did not have the treatment I would have been given more drugs. They would give me short periods of remission, I would deteriorate physically and it would finally lead to death. With the procedure itself, there was a one to two per cent chance that I would not survive. All of these facts were presented to me. There was an extremely high risk of infection because of the procedure and I would have had no resistance to infection at all.

I was naturally very nervous about the procedure, including the necessary and attendant blood transfusions. But I researched the information that was available on the Net and the relevant web site. My haematologist answered all the questions I asked of him and presented to me honestly a great deal of information. The risks associated with transfusions were insignificant compared to the risks associated, for me, with either not having the procedure or the other aspects of the procedure such as the infection that I was likely to get. The blood products available allowed me to undergo a procedure that offered me a second and final chance of a cure. I think the critical words are the 'blood products' being 'available'.

One other thing I would like to share with you are the multiple tensions for patients going through this sort of procedure. I still clearly remember the whole process. When you are awaiting results of a daily blood test—where they drain blood from you at 4 o'clock in the morning and send it off for testing to see what your daily cocktail needs to be, how many bags of red cells and how many bags of platelets you need to just keep you going at the minimal level that is required for health—the waiting period between when you get the results and when those bags appear is particularly stressful. You are in a rather stressed state and you are not quite sure what is going on with your body. One day I can clearly remember the medical team coming in to me and apologising because the blood that had been ordered for me for that day had been used elsewhere in the hospital for an immediate need that was greater than mine. I completely understand now, but at that time for me the tension was extreme. The blood arrived and it was given to me in the early evening. But what would happen if there was no supply? Objectively, I can now rationalise and understand that the availability of products is totally reliant on donors and services offered by the Australian Red Cross Blood Service. But I can assure you that shortages and delays result in extreme tension for those already in a stressful situation.

I am confident today that I speak on behalf of many blood recipients. I have great admiration and respect for blood donors like Brian Pepper who so willingly and graciously donate blood. I also have great admiration and respect for the ARCBS, which provides blood and tissue products for the Australian community. Nothing in life is without risks. In fact, only this morning I heard about our horrific road statistics. Think about the risks we take every time we go out on the roads—they are incredible. But when you are confronted with a life-threatening condition you

grab any opportunity that is offered to you for a cure. I would like to thank you for listening to me. But, most importantly, a very huge, heartfelt thank you to the blood donors and to the Australian Red Cross Blood Service for the critical roles that they play in providing quality blood products to save, lengthen and enhance Australian lives.

Dr Wylie—In summary, blood collection, component production, testing for blood group and infectious markers, and distribution of blood products are essential parts of the health care service. Haematology is the specialist area of medicine which has the expertise in managing blood transfusion and maintenance of normal blood function, including clotting factors. We have here today an experienced Australian haematologist Dr David Rosenfeld, Head of Haematology at the South Western Sydney Area Health Service, one of the biggest and busiest in Sydney.

Dr Rosenfeld—I have worked in the public hospital system for over 30 years and have been head of haematology at South Western for over 20 years now. We presently serve a population of around 820,000 and have about 2,000 public hospital beds in our area. We run a very busy clinical haematology service which cares for patients with leukaemia, lymphoma, myeloma and other anaemias.

I am responsible for the hospital blood bank. After receiving supplies from the Red Cross it supplies blood to the patients. I am one of those people who treat patients like Mrs Tozer. Nearly all of the blood diseases that we treat require blood products in some form. The diseases themselves cause deficiencies in the production of blood cells, white cells and platelets and these require replacement. Treatment of these diseases comprises chemotherapy and radiotherapy, and this also stops the production of blood cells. The haematologists are major users of blood products in the South Western Sydney Area Health Service, followed closely by other services such as trauma, which looks after patients from motor vehicle accidents and the like.

Easy availability of blood products is an essential requirement for the treatment of cancer patients. To treat this disease and other diseases such as thalassaemia, haemophilia and other anaemias we need to have ready access to a quality blood supply. We need to have confidence in the supply, and our patients need to have confidence in the supply and not be overly concerned that they may be getting a product that has been labelled as possibly risky.

Whenever we start patients on a transfusion program or supply a blood product we explain to the patients that the product is the safest it has ever been and is extensively tested, however there remains a small risk of infection with known and unknown viruses. This risk continues to diminish all the time. We spend a lot of time discussing these risks with our patients. If we were to need to cajole patients into accepting blood to save their lives, the situation would become untenable.

The supply of blood products is an issue. Recent shortages in the supply of red cells, platelets and Intragam have led to problems treating our patients. This has led to delays in resuscitation and treatment and obvious increases in morbidity and mortality.

Australia has had the safest blood supply in the world. The New South Wales Red Cross was one of the first to attempt to exclude risk groups from donating blood, which was to prove the correct decision. By and large, blood is only administered to save lives or reduce mortality and

morbidity. If there were alternatives, most of us would certainly use them. The Red Cross has always, to the best of my knowledge, supplied the safest product available.

I have also been involved with the Lookback program. This can be a very laborious process, often without positive outcomes. I remain concerned that our patients will lose confidence in the quality of our blood products.

Dr Wylie—So how can we reconcile the risk for an individual patient with the overall benefit? The major infections in blood transfusion over the last 25 years have been human immunodeficiency virus, HIV, and hepatitis. The declining risk of transfusion acquired hepatitis due to non-A, non-B hepatitis—now known as hepatitis C—in Australia over the last three decades is shown in a table provided in our written submission. It is on page 27 of our original submission or page 9 of the document provided to you today.

Analysis of the data shows three things. The blood supply has generally carried a higher risk of hepatitis infection in the USA than in Australia. The risk of acquiring hepatitis in Australia fell from approximately one in 300 per bag of blood transfused to approximately one in 300,000 by the mid-1990s and to less than one in three million today. A table detailing this has also been provided in our written submission. The blood supply today is extremely safe in respect of hepatitis C.

Australia was the second country in the world, after Japan, to introduce hepatitis C screening in 1990. A table detailing these dates is included in our written submission—on page 30 of our original submission or page 8 of the document given to you today. It should also be noted that while the introduction of first generation hepatitis C antibody testing was a major advance, it did not detect all donors who were infectious. It was not perfect, but was the best available at that time. It should also be noted that some true hepatitis C positive donors were not detected. With regard to the second and third generation tests, when they were introduced they were an improvement and were even more sensitive.

Does a risk of post-transfusion hepatitis remain today? Blood is a biological product and, as such, there is always a small degree of risk. Even with the best testing available today, it is not possible to completely eliminate the window period, which is now approximately seven days for hepatitis C. The risk for hepatitis C is very small—in the range of one in three million for each unit transfused. How does this compare with other risks that Australian patients face? The risk of death definitely attributable to an anaesthetic is one in 150,000 procedures. The risk of hospital-acquired infection from clean surgery is currently one in 100. The risk of an adverse event occurring to a patient admitted to an Australian hospital was estimated recently to be one in 10. We provide these risks to convey an understanding that all medical and hospital procedures do carry an element of risk, and to put into context transfusion-associated risks, which are currently low by comparison. We urge the committee in its recommendations and public statements to be aware of the real danger of alarming today's patients unnecessarily

How was the link established between hepatitis C and transfusion? The history of non-A, non-B and the growth of knowledge have already been described to the committee, and I will not repeat it. I refer you to a brief time line at the back of today's submission. In Australia there was concern amongst the blood services about non-A, non-B hepatitis, although very few cases were reported to the blood services throughout the 1980s—something of the order of dozens of cases

through the whole decade of the eighties across all states and territories. Because of this, it was not seen as being a common problem and it was seen as a disease which often had no symptoms and was very hard to diagnose. However, it was taken seriously—sufficiently seriously that the Red Cross commissioned a study in 1979 of a group of 842 multiply transfused patients undergoing heart surgery in Sydney. The details of this study are included in our written submission. In brief, the study revealed a post-transfusion hepatitis rate of two per cent per patient, less than one-fifth of the rate found in similarly constructed studies in the US and Canada at the time.

Why was surrogate testing debated? Until 1990 there was no specific test for non-A, non-B hepatitis, later known as hepatitis C. However, during the mid-eighties there was much debate in the literature about whether any good might be achieved by testing donors with surrogate or substitute tests, and this proved controversial. Two surrogate tests were proposed. They were not direct tests specific for non-A, non-B hepatitis but were indirect tests used for other purposes. They were the ALT test, one of the various tests that monitor liver function, and the anticore test, as a marker of past infection with hepatitis B.

A major concern in Australia was that it was estimated that at least five per cent of voluntary blood donations would be rejected, although they were mostly expected not to be infectious. This was because the ALT test might give a positive result if the donor was overweight or had had a heavy night drinking before donating or was taking certain medications. It was a time of great concern about the adequacy of the blood supply following the fall in blood collections associated with the AIDS era. Red Cross was very concerned about serious blood shortages occurring if they threw away at least five per cent of their blood. Added to this, what were the blood banks to tell these donors? Should they be referred to liver clinics for investigations and biopsies when in all probability they did not have infectious hepatitis? Was it right and fair to worry people unnecessarily when there was very little evidence that they were ill?

The US blood banks adopted these surrogate tests at various time intervals up to mid-1987. The FDA, which is the regulatory agency in the US and the equivalent of the Therapeutic Goods Administration, met to consider these tests three times and never decided to recommend that the tests should be done. However, the American Association of Blood Banks, an industry association, recommended to its members their introduction in June 1987. This was in spite of the fact that the US National Institutes of Health Hospitals had adopted ALT screening in 1981 but in the first three years had found no decrease whatsoever in the risk of non-A and non-B hepatitis after transfusions.

The debate then continued through the rest of the world as to whether there was any value in the tests being adopted elsewhere. The countries which introduced surrogate testing in the mid-1980s were in the minority. Most countries did not introduce them. Very few European countries performed anticore testing and only parts of Germany and Italy were doing ALT testing. Germany had had ALT testing in place since the 1970s but still had a very high reported rate of post-transfusion hepatitis of 17 per cent, which suggested that ALT was not an effective test in their population. At its meeting in May 1987 the Council of Europe's Committee of Experts on Blood Transfusion and Immunohaematology concluded:

Arguments against the introduction of surrogate testing include the variability of data from one country to another, the non-specific nature of the tests proposed, loss of apparently healthy donors, difficulty in follow up of the donors and the continuation of transfusion-transmitted NANBH in spite of the tests.

After studying the situation the Council of Europe's Working Group on surrogate tests reported in November 1987:

The introduction of non-specific tests could lead in some countries to a severe depletion of blood donors which could compromise the blood supply and this is a factor which must be taken into account.

How did Australia respond? The decision was taken through the National Blood Transfusion Committee in Australia not to recommend the introduction of surrogate tests, following an evaluation of the scientific evidence for surrogate testing, because it was not convincing. This was the case in all except one state, Queensland, which took a contrary view to the rest of Australia and elected to introduce the ALT test only. The NBTC, which included representation from all Australian blood services and the Commonwealth government and the Commonwealth Serum Laboratories, strictly speaking a part of the Commonwealth in those days, closely monitored all the available scientific evidence both locally and internationally. It made the decision not to recommend either of the surrogate tests, because they were considered to be blunt and inaccurate tools with the potential to create blood shortages without any demonstrated benefit to public safety. The surrogate tests had not been proven to be effective in reducing post-transfusion hepatitis. Several studies in European countries such as England and France had shown no benefit.

The introduction of surrogate testing would have meant referring many thousands of donors for investigation and possibly even a liver biopsy, a procedure with risks of its own, even though the great majority of donors would be healthy. Such a move might also have been counterproductive due to the fact that, to replace the lost donors, there would need to be a consequent increase in the number of new donors, which also brings an increase in risk. New donors were known from experience with HIV and hepatitis B to have much higher rates of infectious disease markers than repeat donors. Commercial considerations played no part in the decision making. It is important to note that cost was not a consideration and has never been claimed to be an issue in the decision making on surrogate testing in Australia.

Was it the right decision? We believe it was and remains so. Surrogate testing meant that a lot of good blood was discarded for no good reason, and the tests were poor at actually detecting infectious donors. Anticore antibody testing, a test for hepatitis B virus, was shown not to be effective in several countries—including France and the Netherlands—in reducing post-transfusion hepatitis. Retrospectively, it was shown in the post-transfusion study in Australia not to have been of any benefit at all. Retrospectively, it was shown using the new test in the US that 91 per cent of US blood donors with an elevated ALT were hepatitis C antibody negative—that is, 91 per cent of the rejected blood was perfectly okay. Not only that but the surrogate test also missed around 80 per cent of the real positives—that is, ALT normal but hepatitis C antibody positive donors. The AABB admitted in the nineties that it was impossible to say in retrospect whether the surrogate test had been of any value in the US. Essentially, surrogate testing was casting a very wide net in which you caught just a few of the infectious donors but also a lot of good, safe donors. You might say you were throwing out the baby with the bathwater.

I now introduce Dr Paul Holland, Medical Director and CEO of BloodSource in Sacramento, USA, an international expert on transfusion medicine, to provide an international perspective on the debate surrounding the efficacy of surrogate testing. We have invited Dr Holland to appear before the committee at our expense because we think he is uniquely placed to provide you with an expert opinion.

Dr Holland—As Brenton said, I have been asked by the Australian Red Cross to state my opinion regarding the issue of whether or not the Australian Red Cross blood program should have implemented non-specific so-called surrogate tests for non-A, non-B viral hepatitis in the 1980s. I am a physician. I have been involved in the field of blood banking and transfusion medicine for over 40 years. I was the director of the blood bank department at the National Institutes of Health in Bethesda, Maryland, from 1974 to 1983. For over 20 years I have been the medical director and chief executive officer of what is now known as BloodSource but was previously the Sacramento Medical Foundation Blood Centers. BloodSource, where I have been since 1983, is a large regional not-for-profit community blood centre which collects over 200,000 units of blood a year.

During my time at the NIH my major research interest was in finding ways to reduce the risk of transfusion associated hepatitis, primarily by evaluation of surrogate or substitute tests to identify blood donors with what we were then calling, for lack of a better term, non-A, non-B hepatitis. I was an investigator and a co-author—along with Dr Harvey Alter, who I am sure you have heard about—on a number of studies which came out of our research work at NIH on the possible value of screening donors for an elevated ALT as well as the antibody to the hepatitis B core antigen, which we generally just call anticore.

Our major findings on the potential value of these two surrogate tests were published in 1981 and 1986. They showed a correlation, an association, between elevated ALT or presence of this anticore antibody in a donor and non-A, non-B hepatitis in multiply transfused patients. However, we did not perform a randomised, controlled trial to prove this association. Instead, in 1981 we began routinely screening all units of blood for ALT. We continued our study to evaluate the rest of transfusion associated hepatitis in recipients over the next three years. We showed that ALT testing failed to decrease the risk of non-A, non-B hepatitis in these patients.

During the same time I was at NIH, I was the chairman of the oversight committee for a National Heart, Lung and Blood Institute study called the transfusion transmitted virus study, or TTV study, in which Dr James Mosley was the principal investigator. This was a nationwide study involving over 3,000 patients, about half of whom were transfused and half of whom were not. Again, this study showed a correlation between elevated ALT in a donor, and also the presence of anticore antibody in a donor, and non-A, non-B hepatitis in recipients. However it should be pointed out that in this TTV study a lot of the blood came from individuals who were paid for it, so-called paid donors. Another fascinating finding of this study was that the rate of hepatitis—3.2 per cent—in patients followed in this study who were not transfused was almost double that found in Australia at the same time for non-A, non-B hepatitis.

During the 1980s, I was also involved with three committees of the American Association of Blood Banks. The first AABB committee was called the ad hoc committee on ALT testing. It was active from 1981 to 1982. It concluded, based upon the two American studies I have mentioned as well as other studies in the literature, that it was not appropriate at that time to

perform ALT screening of blood donors. This was a national committee composed not only of blood bankers but also of hepatitis experts and infectious disease experts. Subsequently, in fact, it became the AABB Transfusion-Transmitted Diseases Committee. After multiple additional meetings and ma evaluations over the next four years, this committee recommended to the AABB in 1986 that the two surrogate tests, specifically ALT and anticore, be put in place potentially to reduce the risk of non-A, non-B hepatitis for transfusion recipients. This was published in the 12th edition of the standards of the American Association of Blood Banks in 1987 as an, 'interim measure to attempt to reduce the risk of transfusion associated non-A, non-B hepatitis'.

This standard to adopt the surrogate test was adopted despite a lack of specific evidence of efficacy. As noted, there was never a government requirement in the USA for such surrogate testing for non-A, non-B hepatitis due to transfusions. It should be pointed out that, while it appeared initially in one widely quoted study that the implementation of the surrogate tests for non-A, non-B hepatitis in the United States reduced the risk of hepatitis C transmission by transfusions, a subsequent more complete study by the same authors revealed a negligible impact on the risk of hepatitis C transmission in these multiply transfused patients before the specific test was implemented in 1990.

It should also be pointed out that, in a number of countries—such as Australia—the risk of hepatitis caused by transfusions from the early to the late 1980s decreased as much or more than in the USA without implementing the surrogate testing. This was probably due to the means we put in place in the mid-1980s to reduce the risk of the transmission of HIV by transfusion. If I had been asked at the time, I would have recommended against the institution of surrogate tests for non-A, non-B hepatitis transmission by transfusions in Australia. Even in retrospect I believe this was the correct decision. The risk of transmission of viral hepatitis by transfusion was already much lower in Australia. Unlike Australia, in the USA we used paid donors—those who sold their blood. These are not illegal in the USA even today.

I want to finish with five brief points regarding the potential impacts of the implementation of surrogate tests, ALT and anticore. The first point is again the relationship between an elevated ALT and a reactive anticore, and what happens as far as resultant hepatitis or not in patients is concerned. In the NIH and TTV studies there appeared to be about a 30 per cent correlation between an elevated ALT in a donor or presence of anticore and resultant hepatitis in multiply transfused recipients. Again, this is just a correlation, not proof that they were connected. It should be noted along with that that 70 per cent of the time when blood had an elevated ALT or had anticore, hepatitis did not result in carefully followed transfusion recipients. So the vast majority of individuals carrying these markers, these surrogate tests, are not infected with hepatitis C. In addition, with that high background rate of hepatitis—3.2 per cent of the patients in the TTV study were getting hepatitis and not being transfused, it was really not clear that the hepatitis that others got that was attributed to transfusions was really due to those transfusions.

The second point to make is that when the hepatitis C antibody tests became available in the US, the vast majority of individuals who were tested and were found to have hepatitis C antibodies specifically did not have an elevated ALT or reactive anticore. This probably explains why the testing was not effective and why in multiply transfused patients the surrogate test did not have the desired effect.

The third point to consider is what you do in terms of replacing the discarded blood both in the USA when we implemented the tests and here in Australia if you had implemented the tests? Through that period of time the United States was already importing hundreds of thousands of units of blood every year to supplement its own supply. When it did implement this testing it just imported more blood from Europe to replace it. In Australia you did not have that possibility; you could not import fresh blood or fresh components from other countries. It is not clear how you would have made up for an immediate and quite a devastating loss of donors. Certainly, there would have been some potential jeopardising of patient safety, including the deferral of these regular, repeat, mostly safe donors and replacing them with new, first time, less safe, more at risk donors.

The fourth point has to do with what you do with donors found to have a reactive anticore or elevated ALT? These tests had no means of being confirmed, especially when they are found in healthy individuals without risk factors. Donors whose blood was discarded because of an elevated ALT or reactive anticore test might or might not have, when they were sent to their doctors, follow-up testing with the same findings. In fact, different assays for ALT and different tests for anticore do not reveal the same findings even when the individual really does have a hepatitis virus. Further, without confirmation tests to indicate that the elevated ALT or reactive core tests were due to non-A, non-B hepatitis you would really confuse a lot of the donors, upset many of them when they were informed about these non-specific findings and I believe that in many cases they would discourage other people from being donors.

Finally, when you implement a test to prevent the transmission of a transfusion transmitted virus such as hepatitis C some individuals may actually donate to get your test, or donate knowing that they have risk factors with the belief that the test will pick them up and so no harm will be done. We and others have seen this behaviour when we instituted the test for AIDS—anti-HIV. The point is that you can institute a surrogate test which is very non-specific in the belief or hope that it will reduce risk but if individuals come in because of that test or despite that test and have the hepatitis C virus in them then they may pass the test—in fact they would usually pass the test as you have heard—their blood would be transfused and you might actually increase risk for patients, not decrease it. In summary, in the 1980s I would have recommended that Australia not implement these surrogate tests to reduce the risk of non-A non-B hepatitis by transfusions; my opinion is the same today. Thank you for your attention.

Dr Wylie—How much blood did surrogate testing waste? We can estimate from figures in Queensland that 4,400 donations were discarded over the three-year period that ALT testing took place. This created problems for Queensland because they suddenly increased the number of new donors to make up for the shortfall they had. New donor rates rapidly increased in Queensland in the period 1987 to 1990 and exceeded the new donor rate per thousand population in other Australian states by a factor of about 30 per cent. New donors are known not to be as safe as regular repeat donors and hence this introduced a countereffect potentially increasing other infectious risks in the blood supply. Moreover, the volume of plasma forwarded by Queensland for fractionation into plasma products fell during that period by nine per cent—the only time there was a fall in a six-year period of otherwise growing volumes negatively affecting supplies of plasma products in that state.

Retrospectively, it was clear that 92 per cent of the blood rejected in Queensland was in fact good blood. The Queensland figures also suggest that at least 75 per cent of the infectious

donors were not detected by the ALT tests, so it is not surprising that there were still many hepatitis transmissions in Queensland during this period. In summary, Australian blood services and health authorities very seriously considered surrogate testing. However the evidence was not there to support its introduction across Australia.

What else was done about the threat of hepatitis to the blood supply? The Blood Service undertook a number of initiatives. Firstly, during the 1970s and 1980s, the Red Cross consistently warned doctors and hospitals that in spite of hepatitis B tests there was still a risk of transmitting hepatitis through transfusion. Information explaining non-A non-B hepatitis and the risks of transmission were included in the following Blood Service publications: *Blood components and their uses*; the circular of information; information sheets issued to resident medical officers; *Notes for Nurses*; the *Guide to Blood Transfusion*; and *Blood and its Products: A Practical Guide to Handling and Usage*.

Secondly, experts from the US and Europe advised Australia in the mid-1980s to conduct its own study to determine how great the problem was and what impact the introduction of tests would have on the Australian population. The Red Cross endorsed such a study and over 1,200 patients were enrolled from 1987 and followed for 52 weeks. When the results were analysed in late 1989, it was found that the rate of post-transfusion non-A non-B hepatitis in patients who had had multiple transfusions had fallen considerably from 1.7 per cent in 1979 to 1.1 per cent in 1987 to 1989. There are eight cases of post-transfusion hepatitis recorded, and seven of these were shown to be due to hepatitis C. Not one unit of anticore positive blood was actually infectious for hepatitis C. Overall, ALT testing failed to detect 22 of the 26 hepatitis C positives.

The results of this study were published in the *Medical Journal of Australia* in July 1995. During the 1980s there were a number of other initiatives introduced by Red Cross to make the blood supply safer: the development of the first Australian donor guidelines, the introduction of donor interviews with stricter donor questioning and a signed safety declaration form before every donation.

How good are the systems for identifying post-transfusion hepatitis C in Australia? There is no requirement for Australian hospitals to maintain a national register of blood component use or to report centrally on usage. An important point is that the ARCBS does not know the identity of patients who are transfused. The privacy of the patient is protected in this way. ARCBS issues the blood component or product to a hospital or doctor and it becomes their responsibility from that point.

The Lookback program for hepatitis C had to be developed differently in each state and territory to meet their different policy and legislative requirements. It is important to know that the ARCBS pursues every avenue it can in tracing individuals through Lookback. However, the process has significant limitations. The Lookback process is difficult to understand. To assist the committee we have provided an additional submission addressing the various types of Lookback and some of the issues surrounding them.

Senator HUTCHINS—Madam Chair, prior to the commencement of this section of the hearing we were given this document, which is nearly 58 pages. I have not had an opportunity to read it or summarise it. I understand Dr Wylie is making his point, but he is reading out this document.

Dr Wylie—If I could respond. I am reading out an abbreviated version of the document.

CHAIR—Dr Wylie, how much longer do you have in your opening presentation?

Dr Wylie—Approximately five to 10 minutes.

CHAIR—It is important to have it on the record, but there are lots of questions we need to ask. Please proceed.

Dr Wylie—Thank you. How many people have contracted hepatitis through transfusion? The ARCBS is concerned that, although it has identified 2,050 recipients of fresh products, there are others it cannot currently identify. The ARCBS does have concerns that there are people who may never have been notified.

Recently we completed the modelling of numbers, taking into account survival rates of people receiving transfusions. We estimate the maximum possible number of Australians alive today with transfusion acquired hepatitis C is 8,764. This applies to people receiving only fresh blood products and not plasma products. Twenty-five per cent of these people might be expected to have cleared the virus, which would result in 6,573 people with an ongoing infection.

To this number we need to add the number of people with haemophilia who have hepatitis C. In our written submission we estimated 1,350 people to be living with hepatitis C. We note, however, that the estimates from the Haemophilia Foundation of Australia, the Australian Haemophilia Centre Directors Organisation and the Commonwealth Department of Health and Ageing are all somewhat lower than our estimate. Thus, in total we have estimated that there are in the range of 3,500 to 8,000 people living with hepatitis C as a result of transfusion of blood and blood products. To put these figures into context, in the past 20 years blood services in Australia have issued in excess of 30 million blood products.

We would now like to look specifically at the Canadian situation and the Krever report. It deserves some attention here with regard to its proper context. Primarily the Krever inquiry was instigated to investigate the management of the Canadian blood supply with respect to HIV. In relation to HIV, Krever made the following comments:

The information known ... was sufficient for public health officials, regulators, and blood bankers in ... Australia to take preventive action ... It should have prompted a similar response in Canada.

A minor focus of the Krever inquiry was hepatitis C. In relation to hepatitis C there are major differences between Canada and Australia. The key being that Australia had a much lower incidence rate of post-transfusion hepatitis C than Canada or the US. Assumptions and/or inferences about the Red Cross cannot be drawn from the examination of a different system operating in another jurisdiction.

Now to address the issue of litigation. We have great sympathy for those with hepatitis C. We recommend that personal, social and medical support be provided to anyone with hepatitis C. As a humanitarian organisation and charity which is dependent on the goodwill of the Australian public, the ARCBS fully recognises the importance of transparency in all its activities. The

question of litigation is therefore difficult and frustrating for us, due to the constraints of the legal process in Australia.

It is on the public record—in our annual report—that there are legal proceedings in relation to hepatitis C. The society has denied liability in all these proceedings. Financial exposure to claims relating to events prior to 30 June 2000 are subject to commercial and government indemnities and are dealt with under a variety of arrangements. We are unable to comment on the specific situation or outcome of any individual case. There are sometimes confidentiality issues when litigation is resolved and, as you would understand, confidentiality clauses are standard practice in legal agreements. Given the issues canvassed by this inquiry regarding discrimination, confidentiality agreements can also act to the benefit of plaintiffs. Any decisions about specific financial assistance to people who have hepatitis C should be resolved by the whole community, and involve a number of parties, including governments. Such matters cannot be resolved by the ARCBS in isolation.

I turn to the recommendations we are making to address the issues and concerns of this inquiry. We are focused on the future and have considered what more could be done to alleviate the problems of those Australians who have contracted hepatitis C through transfusion. We have a number of recommendations and suggestions for the committee's consideration. These cover areas that other submissions have also identified. Our first recommendation is that, as supported by the Australian Hepatitis Council and TRAIDS, measures to ensure appropriate personal, medical and social support services should be considered and made available to those suffering complications as a result of post-transfusion hepatitis C.

Secondly, we strongly support the recommendation of the Australian Hepatitis Council, particularly regarding the improvement of community education and awareness of hepatitis C and its causes. Such initiatives can only curb the discrimination felt and spoken about by those living with the disease. Our third recommendation is that we support and recommend expediting consideration of and access to anti-hepatitis C drugs for Australian patients. Our fourth recommendation is that governments facilitate access to recombinant factor VIII and factor IX as recommended by the Commonwealth working party and the Haemophilia Foundation Australia. More specifically, we support efforts to enable doctors treating patients with haemophilia to prescribe recombinant factors VIII or IX where they are the most appropriate product for the patient.

Fifthly, we recommend and support research into hepatitis C and epidemiological studies. Our sixth recommendation is that we support the timely introduction of a national government sponsored haemovigilance system in Australia. Such a system linking all hospitals with ARCBS would provide valuable data to detect hepatitis C transmission, other emerging blood borne infectious diseases and other non-infectious complications of blood transfusion. This would ultimately enable us to maximise patient safety and care for the longer term.

We have three additional suggestions. The first is that, if the committee wishes to explore Lookback further, it would be worth focusing on younger patients transfused in the 1980s. The majority of transfusion patients were quite elderly when transfused, but young patients would be much more likely to be alive today. They may have experienced the burden of disease—perhaps undiagnosed disease—for a considerable part of their life. They would be likely to both qualify for treatment and to benefit from treatment once diagnosed. Secondly, we suggest that the

government consider mandatory reporting to the ARCBS by medical practitioners or healthcare professionals of suspected transfusion transmitted cases of hepatitis C, to enable more timely tracing and adequate support of those affected. Thirdly, in agreement with many of the submissions, we suggest support for an educational program for the medical community about hepatitis C generally, including transfusion acquired hepatitis.

In conclusion, I have spoken about how Australian management and decision making about blood and its safety have been based on knowledge available at the time and have been in line with best international practice. Like all in the health-care system, we strive to reduce risks wherever possible. However, all medical procedures involve risk, and there has been and continues to be risk in blood therapy. As mentioned earlier, blood is a biological material and, therefore, it is never possible to say that there are no associated risks. Accordingly, there is inherently a balance of risks and benefits involved in its use. The current risk of receiving a hepatitis C infection through blood is less than one in three million.

I reiterate that we extend our sympathy to each Australian who has acquired hepatitis C. It is a sad fact that some people have contracted hepatitis C through blood transfusions. We recognise the impact that this disease can have on the person and their family. The heartfelt accounts within the submissions of those affected speak directly to the problems they have faced and we particularly extend our sympathy to those who have, or will develop, symptoms and complications.

We remain committed to continuing to provide services, working with the Australian and state and territory governments to improve options and remedies for those in need. We have a collective responsibility, with clinicians and health authorities, to understand levels of risk and to manage them and to inform the community. We look forward to hearing the findings of this inquiry and we would be happy to answer your questions. Thank you for your time today.

CHAIR—Thank you, Dr Wylie and the other participants in the presentation. There are many questions, and to deal with them in a sensible way I propose to go to some questions and then defer to other senators. I say to my colleagues that if we are pursuing a line of inquiry let us pursue it rather than chop and change. I would like to go to the question of donation levels. Dr Wylie, Mr Pepper and you said that about three to four per cent of the population donate. That is an important figure and it is important for us to understand why that seems to be quite static, which is what I think you are saying. What are the barriers to increasing that donation level?

Dr Wylie—This is one of the most difficult questions that face any blood transfusion service or blood bank anywhere in the world. If the answer was clear and remediable all the blood banks around the world would have lots of blood all of the time. The primary factors—other than inability to donate through deferral criteria—that really impact on donors in this day and age are awareness and understanding of the good that it can do. But perhaps in recent times the most compelling factor is the time it takes to donate due to the stringent requirements and guidelines that we must necessarily have in place to protect the recipients of donated blood.

CHAIR—Is there any international experience where people have trialled other ways to encourage donation—or is there any experience that you have had?

Dr Wylie—An important point to make here is that in order to maintain a blood supply you need regular donors all of the time. In common with all blood banks around the world, the problem that we face is that without a crisis or something to bring attention to the need to donate blood, in the busy lifestyles that we all lead today, it is difficult for people to think of donating blood and to find the time. One of the paradoxes that we face in our work is that when there is a crisis blood donors come forward without our having to ask. The most recent example of that was the tragedy of the Bali bombing where, without appealing, we were flooded with blood donors. But the reality is that for the remainder of the year, and between crises, there is a constant struggle to attract sufficient blood donors to maintain the supply.

CHAIR—On page 66 of your original submission there is a table where you describe the increase that occurred in Queensland in the late eighties and early nineties. Could you explain why that occurred?

Dr Wylie—Are you referring to the blue line?

CHAIR—Ours is not coloured, unfortunately.

Senator LEES—It is the line with crosses on it.

CHAIR—It is the line that is higher than the others.

Dr Wylie—That is the direct result of the introduction of the surrogate test for ALT in Queensland, where, to make up for the loss of the 4,400 donations I described as being discarded over a three-year period, they had to recruit new donors to a level 30 per cent greater than for the rest of the country.

Senator LEES—How did they do that?

CHAIR—They did it. The question I am asking is how did they do it.

Dr Wylie—They would have done it through repeated and intensive public campaigns. The point to make is that, in achieving that, they greatly increased the proportion of the donations being made by new donors. Both Dr Holland and I have described that that process brought with it an inherent increase in risk of the very viruses we were trying to keep out of the blood supply, in particular at that period of time there was immense concern about HIV.

Senator LEES—So people would have come in so that they could have a test. They came in to donate because they were, perhaps, slightly suspicious that they may have had either HIV or hep C.

Dr Wylie—In the 1980s that was, and even today still is, one of the fears and concerns of people running blood transfusion services. Dr Holland referred to personal experiences, and he may wish to add to my comments, but we took extraordinary steps in Australia through posters and signs saying, 'Please do not use us as a test centre.' It was the same as each of these tests came along—and let us start with HIV: the blood bank was one of the few places that you could get an HIV test, and the alternative sites really were sites that not every person wishing to have a test wished to be tested at. Similarly, when the specific test for hepatitis C came along, because

we moved so fast and were ahead of the health industry in the sense of having the test available, the same problem potentially could have occurred.

Dr Holland—I can add three points to that. When we surveyed and interviewed our HIV positive donors back in the 1980s, a third of them told us that if we had not had that test they would not have donated. They came in to get the test. It was a free, confidential, anonymous place to get a test because they knew that we would not report them at that time to anyone. Secondly, many people who had stopped donating because they knew they had risk factors now felt it was safe to donate. Even though they had done things they knew should have prevented them from being donors, they thought that the test would pick them up so no harm would be done. Finally, we have had to really work hard on educating doctors who often, when told by a patient, 'Oh, I did something last week,' or 'I went somewhere and did something,' will then say to the patient: 'Just go to the blood bank and donate. They do hepatitis tests, they do AIDS tests.' In fact, they would be the riskiest of all people because they might be in that window period before they will test positive. So we have had to work very hard to educate physicians, saying to them, 'Please, please, don't do that—you will actually increase risk.'

CHAIR—I do not think this graph shows that the increase in donations is purely from those who were using the blood bank as—

Dr Wylie—No, and there is no intention to show that. That graph simply shows that there was an increase in the proportion of new donors as opposed to regular donors in Queensland, compared with the rest of the country.

CHAIR—I understand the point you are making about new donors needing to be cleared. Are those donors ongoing donors? Once they have gone through that process and the donor screening has occurred, you then have that person on your books regularly donating uninfected blood.

Dr Wylie—That raises a really crucial point. Not only do new donors bring with them this risk that we have discussed but it is also a very inefficient way to run the blood supply, because over half of all new donors never return to make a second donation. In fact our experience is that for someone to be committed as a regular donor we really need them to have made six donations before we can be confident on the evidence available to us that they will then become a committed regular blood donor. So it is a very wasteful exercise. As you say, you have recruited them, you have bled them once and you have them on your books, but half of them never return.

CHAIR—This is quite a crucial issue, because the balance that we are asked to understand in terms of the decision made about surrogate testing is the fact that the supply issue had to be factored into the discussion. That is why I am starting with that question; it is to get an understanding of what could have been done to mitigate the supply issue. What sort of thinking comes to the decision-making table on behalf of the blood bank to inform that decision? What sorts of things would the committee have had to discuss? How unrealistic would it have been to suggest another appeal to continuing donors? Can you explain to me that sort of discussion and decision making that would have been happening in the late 1980s?

Dr Wylie—A lot of things would have been discussed. One crucial fact to understand is that the solution is not just in appealing for blood. One of the other problems that unfortunately we face is that if we appeal for blood infrequently we generally do get a reasonable response. As we

appeal for blood more and more frequently the appeals become less and less effective and, ultimately, they become almost ineffective. That is a problem. So appeals and campaigns would have been discussed, but that is an inherent problem. Then you are left with how to give more donors access to the system. This would involve new facilities, going to new centres and mobile collection units—all of which would have obviously required resources to achieve. I reiterate that all this is in the context not only of concern about donor losses but also without any scientific evidence that the surrogate tests were effective.

CHAIR—I am trying to separate the two issues so that we can deal with one at a time.

Senator HUTCHINS—On the issue of blood and what might have affected donations, we have an idea of when the Red Cross ceased to collect blood from prison inmates. If you look at the figures for Victoria, there were fewer new enrolments from 1983 when they stopped collecting blood from prisoners. You can see on the graph you have there that the number of donors goes down and again in 1984 and then it starts to come up and go all over the place. But if you look at South Australia, which stopped collecting blood from prisoners in 1975, the number of people who started to donate blood rises. If you stopped collecting more blood from, say, prisoners in 1975 in South Australia, why did it rise the next year, the next year and the next year? Was that just good marketing by the blood bank?

Dr Wylie—I think there are two issues in your question. The collection of blood from prisons, whilst we would not condone it today, was undertaken at that time. But the amount of blood collected from prisoners was microscopic compared to the total blood supply, and so it has no relevance whatsoever to the total amount of blood.

Senator HUTCHINS—It should. If you stopped collecting blood in one part of Australia in 1975, on percentage it should go down the next year but it does not.

Senator HUMPHRIES—I seek a clarification. The graph that I have does not show the blood collections in South Australia going up; it shows them going down. Can I ask what you are referring to, Senator Hutchins?

CHAIR—Senator Hutchins is referring to page 65 of the original submission. Is that correct?

Senator HUTCHINS—Yes.

Senator HUMPHRIES—Thank you.

Senator HUTCHINS—Then we go to the part of your submission where you make the very real observations about the effect of AIDS on donations. The Red Cross rightly takes a very proactive decision in that period to advise at-risk groups that they should no longer make donations to the Red Cross. That had an impact on your blood supply as well, not just from 1988 to 1990 but in the lead-up to that period, didn't it?

Dr Wylie—Yes.

Senator HUTCHINS—In fact, you say on page 66 of your submission: 'It could not be ruled out that fear of AIDS had contributed to the decline.'

Dr Wylie—That is true. To contextualise this for the committee's benefit, it is important to remember that non-A, non-B hepatitis was not the only issue that we were dealing with; there were a multitude of issues at the time. HIV had already impacted on the blood supply. In fact, one of the tables in our written submission makes it clear that the donation rate per head of population fell during that period of time. In New South Wales it took almost six years to recover from those donor losses.

Senator HUTCHINS—What was the really critical period? Was it from 1984 to 1988? Can you advise us if there a time when there was a considerable risk to the availability of blood?

Dr Wylie—The impact of HIV and the steps taken to counteract its potential impact commenced in Australia in May 1983. As I said, in New South Wales it took a long time to recover from that. But you raise a really important point, which I would like to speak to a bit further. The deferral of donors was one issue, but the other huge impact in the 1980s was the fear of the general public that they could acquire HIV simply through donating blood. Although there was enormous education from the time, from the level of the Prime Minister of the day down, huge numbers of people indicated when surveyed—this was also true in the United States—that they were fearful of getting HIV simply through being a blood donor, and they stopped donating blood.

Senator KNOWLES—They were worried about getting it from giving it as opposed to from receiving it.

Dr Wylie—Correct—even though there was never that risk in Australia and there is no risk of that today. In fact, if you surveyed the general public today there would still be a significant percentage of people with that concern.

Senator HUTCHINS—When do you think the community concern was allayed, not only for donors who were deferring but for people not donating because they thought they might get AIDS? Was it 1988, 1989, 1990?

Dr Wylie—There is no specific answer to that question; it was a gradual recovery over time.

Senator HUTCHINS—But would you say the crisis period was from about 1984, when you put the letter out?

Dr Wylie—As I have stated, the initial impact of AIDS and the initial deferrals took place in 1983.

Senator HUTCHINS—And you sent the letter out to donors in August 1984. How many donors do you think you lost as a result?

Dr Wylie—As a result of that letter? I would have to take that question on notice.

Senator HUTCHINS—In 1984 you were at Prince Alfred Hospital. Do you have an idea? Was it 10 per cent?

Dr Wylie—I am sorry, in 1984, as you state, I was training in internal medicine at Prince Alfred Hospital. I had no association with the blood bank so I would not speculate on an answer to that question.

Senator HUTCHINS—You put in your submission that in 1985 there was a six per cent drop in donations in New South Wales.

Dr Wylie—Yes.

Senator HUTCHINS—So I am assuming that probably gives us an idea. Then I think we get an idea from the *Courier Mail* report, which mentions a 15 per cent drop in donations in 1988.

Dr Wylie—Yes. Also, the overall donation rate per thousand head of population fell from a peak of around 60 to around 56 per thousand, which is a very considerable fall. So the impact was huge. There were significant shortages of blood and blood products at the time. One example that we have stated, and I take the opportunity to highlight again, is that factor VIII was only being produced and issued to people with haemophilia at a level of 1.2 international units per head of population. This was only 60 per cent of the level recommended by the World Health Organisation at the time for adequate care of haemophilia.

Senator LEES—While we are talking about factor VIII, recommendation 4 of what you presented to us today is that government facilitate access to the recombinant factor VIII and IX. Will that relieve some of the need you have?

Dr Wylie—We understand that the Haemophilia Foundation of Australia as a body wish to get greater access to recombinant factor VIII and factor IX. Our position is that we believe they should be able to get access to it where it is deemed appropriate and the best available therapy for them as patients.

Senator LEES—What is the difference between that and the usual factor VIII and IX?

Dr Wylie—The usual factor VIII that is produced from Australia is a plasma derived product.

Senator LEES—But in terms of treatment, what is the difference?

Dr Wylie—They are equally effective.

Senator LEES—As to your comments about where it is most appropriate, you would argue that the recombinant is just as effective or appropriate.

Dr Wylie—As a product. There are a couple of points to make here. Firstly, we are aware that there has been a working party looking at the policy for Australia on factor VIII and factor IX for some time. We welcome the outcome of that and the policy direction to be taken. Secondly, we have no fear as an organisation that our product will be replaced. In the short term, I believe there will be a continued need for the plasma derived product that we are able to produce and the recombinant product. It is certainly the case in developed countries that there is a trend towards replacement of the plasma derived product with the recombinant product. That is an international trend.

Senator LEES—What percentage of your blood donations would go over to factor VIII and factor IX products?

Dr Wylie—In the case of factor VIII, every possible plasma donation currently has factor VIII manufactured from it; in the case of factor IX, it is not limited by supply of plasma, so our ability to produce the plasma derived factor IX product is not constrained by supply. CSL make the amount of factor IX product that is required to be made in their agreement with the Commonwealth government, now the National Blood Authority.

Senator LEES—So if this material that you now produce was not used for this purpose, are there other uses for it?

Dr Wylie—You would not make the factor VIII from that portion of the plasma. Would we still need to send the same amount of plasma? The answer is yes. In spite of the need for factor VIII, which we are discussing now, the driver of real plasma growth in all developed countries including Australia is the need for another product, which is intravenous immunoglobulin. The Australian product is called Intragam P.

Senator LEES—Could what you have been using for this purpose be diverted to Intragam P?

Dr Wylie—No, they both come simultaneously from the same plasma.

CHAIR—On the question of factor VIII, we have asked CSL and others if they could give us an indication of the cost differential of both production of and actual cost to the purchaser. Can ARCBS throw any light on that question?

Dr Wylie—This is a very difficult question to answer. The reason it is so difficult is that we, as the Australian Red Cross Blood Service, do not have all the financial figures available to us to fully answer the question. The components that you need to know to answer that question are obviously the costs of running our service. You also need to know the cost to CSL to manufacture the factor VIII. That cost is unknown to the ARCBS. Then you need to compare that against the cost in the marketplace, so to speak, of the recombinant factor VIII product. The price of the recombinant factor VIII product in Australia is also unknown to the ARCBS.

The best light I can shed on it for the committee is to say that if you look at international markets you will see that the price of recombinant product generally runs at $A1 or more per international unit, whereas the price for plasma derived factor VIII products generally runs at around A40c per unit. I say that just in an endeavour to give more information than you may have had previously, but I recognise that unfortunately I am unable to completely answer the question in the Australian context.

CHAIR—So it is about two to five.

Dr Holland—If you look at the international markets.

CHAIR—That is actually the best answer we have had.

Senator HUMPHRIES—I want to pick up the point about people using the Red Cross Blood Service as a way of getting a free test for a number of conditions such as HIV and hep C. If you wanted to get a test done other than through the Red Cross, would you normally have to go to a doctor and get a referral to a pathologist for a test, or would you go straight to a pathologist?

Dr Wylie—Dr Rosenfeld may be able to give a more complete answer. It varied over the time that we are talking about. In 1985 the number of places where you could obtain an HIV test was extremely limited. That has obviously changed over time.

Dr Rosenfeld—You would need to go to a doctor to order the test and you would then need to go to a pathology practice to collect the blood and do the test. From my recollection, around that time the Red Cross was doing the tests before you could get them done elsewhere. You could not get them done outside privately, but they were available through the Red Cross.

Senator HUMPHRIES—What would it cost a person, approximately, to go to a doctor and a pathologist to get a blood test, assuming it was available?

Dr Rosenfeld—Most times it would be rebate only, so there is no direct cost to the patient; we all pay for it in our taxes. I do not know the actual cost. I think that back in those times you were not allowed to charge for the performance of an HIV test.

Dr Wylie—That is correct.

Senator KNOWLES—Have you estimated how much donations would need to fall before supplies generally and specifically—that is, factor VIII and factor IX—would be affected?

Dr Wylie—To answer the easy one first, supplies would have to fall a long way before factor IX became a problem, because it is not plasma supply constrained. In the case of factor VIII, unfortunately, any fall would have an immediate impact on the supply of plasma derived factor VIII in this country. The reason, as I related earlier, is that every single bag of available plasma that can be used to make factor VIII at CSL is used to do that.

Senator HUTCHINS—Coming back to the new donors graph, in Queensland you have a jump from 1989 and, as you can see from the figures, there is a jump in 1985. There is nothing for 1986; were there no new donors that year?

Dr Wylie—That would be because the figure, unfortunately, is not available.

Senator HUTCHINS—It is higher in 1987 than 1985. There is a big drop in 1988. Then in 1989 and 1990—1990 is when this new testing is introduced for HCV, isn't it?

Dr Wylie—Correct.

Senator HUTCHINS—But you still have high levels of new donors in Queensland. Is there any reason you can give to account for that?

Dr Wylie—That is because they are still trying to overcome the damage to their regular donor base. As I explained earlier, the recruitment of new donors is a very inefficient process, and only

50 per cent of new donors recruited come back. So you need to go through a considerable number of donations—as I mentioned, six is a number that can be used as an indicator—and that takes a number of years.

Senator HUTCHINS—If you look at the previous page, you can see that it does not look like that. It looks like there is some consistency in the figures, and in fact the figures for rates of donation per head of population decline in 1988. So you have the figures for everybody in 1985. In 1988 the figures drop, and you say that was the year that surrogate testing was introduced in Queensland, don't you?

Dr Wylie—Yes.

Senator HUTCHINS—In 1989 the figures climb, in 1990 they are consistent and in 1991 they are consistent, and they climb again in 1992-93. So one wonders whether the Queensland Red Cross had a pretty good marketing service rather than it being affected by anything to do with ALT testing.

Dr Wylie—It was affected by ALT testing because that is why the new donor rate rose. The table that I think you are referring to on page 65 simply represents Queensland maintaining its blood supply and holding its place. You will notice that it is within the HACC, so to speak, of the various jurisdictions. Of course Queensland, just like any other state or territory in Australia, had a need to grow its blood supply on top of these other issues so as to maintain an adequate blood supply for its community.

Senator HUTCHINS—I suppose we can go around in circles on this, if you would like. There is obviously a period there where the Queensland blood supply is affected by the AIDS epidemic and then it climbs again after 1989, in 1990 when you have this new test available. These are donations at a percentage, aren't they? Inevitably, the figure from 1971 has grown from the figure in 1993, hasn't it? The percentage as well has grown.

Dr Wylie—Queensland were unable to recruit significant numbers of new donors, and we have related to the committee that there was a 30 per cent increase in new donors compared with the rest of the country, so they were successful in that. But the key point is that relying on new donors with a higher risk, the great majority of whom never return, is not a good way to run a blood service. It is an incredibly inefficient way to maintain a donor base.

Senator HUTCHINS—I do not think anybody is questioning that, Dr Wylie. It is just that there may be other factors that we are not aware of that may have accounted for that increase in new donors and also an increase in donations, particularly after a period when there is a test in for hepatitis C.

Senator MOORE—I have a couple of questions on the donors, Dr Wylie. Regardless of this inquiry, it is the key point for the ongoing viability of the blood service and that four per cent of the population seems to be about the standard now. You cannot maintain service and growth with only four per cent of the population being regular blood donors. I know that during the 1980s there was a crisis and the figure dropped but, before then, was the percentage higher? Leading up to that period did more people willingly give blood? We know there was a crisis in 1987 and that there has been a marketing campaign since then, but from my reading of it that level has not

really changed much in the last five or six years, which is worrying. What happened before the 1980s?

Dr Wylie—That is a very interesting question because the reality is that the number grew each year per head of population, and the reason is that blood therapy as a technique was growing. You can go back decades but if you go back a long way, if you go back far enough, you find that blood transfusion was hardly used at all. It was a growing technology with a growing number of uses, and products were able to be stored longer so they were able to be used in higher numbers of clinical cases. It was an emerging technology.

The community responded and therefore there was an increase in donation rate per head of population during the 1950s, 1960s and 1970s. When we got to 1980, although there have been tremendous developments since, in a sense it was a much more mature technology and, having hit a donor rate per 1,000 population, it was a question of maintaining it. Senator Hutchins and others have noted the dips due to the various impacts, and I have described the shortages. During the 1990s, although the absolute number of donations we have collected has continued to rise—and we are very grateful to the donors who have supported us—it is a fact that in nearly all developed countries the actual donation rate was gradually sliding. That is a worldwide phenomenon as we have entered the new century.

Senator MOORE—As you have pointed out, the recruitment campaigns which all centres are running to try and encourage people to donate are catching up, so you are not keeping people as regular donors. The other aspect your submission raises is that as there are more preclusions being brought in people who have been regular donors are now having to stop. So you are having to catch up more. One of aspects we were talking about was the link with industries in terms of the relationship between the blood services and employers and encouraging employers to have their work force donate en masse and get large numbers of people that way. Has that been part of the ongoing recruitment processes?

Dr Wylie—It certainly has. We work, particularly in the major cities, very closely with large employers. In the main, we have had very good responses from the large companies in the capital cities. It is very much a feature of our program moving forwards. I take this opportunity to encourage industry again to get behind us—just as I would encourage the whole community. I think another endeavour that may be worth briefly pointing out, with the permission of the chair—one of the initiatives which has received worldwide acclaim in Australia—is the introduction of collecting blood from high school students, our 16- to 18-year-old donor program. It may be of interest to the committee to know that, by way of example, something in the order of seven to eight per cent of all of Sydney's blood supply actually comes from high school students.

Dr Holland—I would like to make a quick comment regarding the involvement of companies. There are two other things which have an effect on this. Firstly, there are no longer such huge concentrations of employees at big factories. We now have much smaller units so it is much more difficult to go there and get a sufficient number of donors. Secondly, with world competition as it is today, employers are less and less inclined to let their workers off for an hour or two to donate blood during the workday because it cuts down their competitiveness and their ability to be efficient. So there are lots of other competing things. It is not that they have not

been, in general, very supportive; but there are multiple things going into getting them to help us more.

Senator MOORE—I am really pleased you made that point, Dr Holland. It would have been too much if I had made that point about employers giving their employees time to make donations. You spoke about going to schools and encouraging donations there. It would seem to me that that is part of the education component about healthy lifestyles. So there is an advantage in terms of the education program with young people about the value of blood donation in having them discuss that at the same time as all the other issues about lifestyle, health and so on because they are so intrinsically linked. Certainly it would be useful, in terms of the recommendations that come out, to see how those things link together.

Dr Wylie—Often we go to primary schools as an educative exercise, and then we visit high school students when they are 16 to 18. As you say, it does educate them. It involves them in the experience. Most of them are very excited at the opportunity to do something, other than chasing their drivers licence, that represents a big step forward in their adolescence and going into adulthood. A lot of them do stay on as donors—having created that habit and with the education. It is certainly true that it is much more difficult to recruit adults who have never donated blood once they have reached their 20s and 30s.

CHAIR—It has been brought to our attention that it is important to maintain blood sugar levels as well, so I propose that we break very shortly for lunch. Colleagues, do we have any questions for Mr Pepper or Mrs Tozer, who have other commitments this afternoon?

Senator HUMPHRIES—I have a question for Mrs Tozer about the process. When you began to receive blood products, were you given warnings about the danger that blood products, no matter what care is taken with their preparation and supply, might still carry a risk of infection?

Mrs Tozer—That is a difficult question to answer because there were lots of risks with parts of the treatment. The medical team that was working with me certainly did go into all the risks, and I was prepared to accept them. It is difficult for me to answer that question because I have a science background and I was working in the educational field with 16- to 18-year-olds and had quite an extensive knowledge anyhow of the concerns with transfusions. I understand the biological nature of the products of blood. Yes, the medical team that worked with me certainly answered all the questions I asked and did furnish me with loads of information, and involved my family as well. My husband and children were invited in and we had roundtable discussions about all aspects of the procedure, not only the transfusions.

Senator MOORE—I will be asking this question to the wider group later but I have a particular interest in asking it of both of you as you have been the public face of the donors and the recipients for the Red Cross this morning. We have heard from people who believe they have acquired an illness as a result of the blood donation process. What would you say to them? You have spoken to us today from your points of view, as a long long-term donor and as someone who has received it. If you had the chance, and you may have already had that chance at some forum, what would you say to someone who thinks they have received an illness through the process?

Mr Pepper—That is difficult to answer. It is an emotional thing. I would put myself in that situation and know how emotional it would be. I can only relate my experience and that is that I have had faith in the system. I have given this story before. I signed up in 1967 when a doctor started up the particular program I am in. There was one chance in 2,000 of getting hepatitis at that stage. We knew that. Two hundred donors were asked to receive injections of Rh positive blood to produce antibodies. I went into that knowing that there was a risk. I had faith in the program. I am continuing now. I did not realise how important it really is. I have continued up to this point, and will continue.

Regarding the person who has got something, I would say that, at the time, the Red Cross did the best they could with the knowledge available. I am certain that everything that has been said here today has been said in good faith. I feel for those people. It is very tough getting on with life. But I would say: please do not blame the Red Cross and the people who come in and donate blood. These things happen in life. That is all I can say.

Mrs Tozer—I have a great deal of sympathy for people who have acquired hepatitis C through transfusions. I feel that I would know how they would react. With the condition that confronted me I would not be blaming anybody but I would react the same way. I am sure that for whatever reason those people received blood there had to be great risks attached to that. Although it is a very unfortunate thing, where would they be if they had not had that transfusion back then? I know that in the scientific world in the future things are going to be discovered that we do not know about now. As long we put in place procedures to give the very best results we can get at that time, I feel that is the best we can do.

The oncologist that looks after me has asked me on quite a few occasions to speak to individuals who were about to undergo the procedure that I went through, though not individuals who had contracted hepatitis C. I think that the human face—seeing someone who has gone through it and survived it, et cetera—does help people a tremendous amount. I can understand people having anger at having contracted hepatitis C. Emotions do come into it and that is understandable, but I think they have got to deal with it and move on as effectively as they can with all of the support and help that we can possibly give them.

Senator LEES—I have a question for Mr Pepper. As a long-term donor, what do you think is inhibiting work colleagues, friends or relatives of yours from donating? You are quite proud of being a donor and must have mentioned it, or perhaps you have run into them on your way to donate or after you have donated and raised the issue. What feedback are you getting from others as to why they do not want to be part of it?

Mr Pepper—With work colleagues, regular donors were coming all the time. The main thing was what Dr Wylie was saying. With the people I work with, when the AIDS epidemic went through—I can back up what he was saying—people had this feeling that the needles were re-used here to give a donation, and a lot of the information that came out was simply untrue. Whether that was an excuse not to go back, I do not know. The AIDS virus scared the daylights out of the people that I spoke to.

CHAIR—Thank you. We will take a break now.

Committee suspended from 1.32 p.m. to 2.08 p.m.

CHAIR—I call the committee to order.

Senator KNOWLES—Gentlemen, I would like to canvass some of the issues that were put to the committee yesterday. One was the continuing donations of hep C blood. Could you explain why that continued?

Dr Wylie—I think the most crucial point in answering that question is to understand that, as at the introduction of the specific test for hepatitis C in February 1990, no hepatitis C positive fresh components—packed cells, platelets, plasma—were sent to any hospital or other institution for the purposes of transfusion. Did we continue to collect blood from some donors who had been found to have hepatitis C? The answer is yes because they were enrolled in a study to evaluate the disease, the test kits and in some cases to provide plasma so that we could make test kits or prepare samples for quality assurance testing. I think the most important point—I will repeat it once more because it is crucial—is that from February 1990 no hepatitis C infected components were sent as fresh products to any hospitals for transfusion.

Senator KNOWLES—There seems to be some degree of confusion regarding that because we had a witness yesterday who was most critical that he was continuing to be sought as a donor. What was the process under which that was done at that stage in the nineties? Was it explained to people that it was not going to be used for transfusion purposes?

Dr Wylie—Obviously I cannot comment on individual cases but I can assure the committee that the only purposes for which donations continued to be collected was for investigation—for studies—and, as I have explained, for the preparation of material for quality assurance testing. Donors enrolled in those studies. We enrolled donors who we felt had hepatitis C and also donors who we felt did not have hepatitis C, because we were looking for a control group. They were informed about what they were entering into.

Senator KNOWLES—We had a further witness yesterday who claimed that blood from herpes infected people was being collected as recently as September 2003. Are you aware of any such claims?

Dr Wylie—I sense there may be some confusion in the terminology. I will take a moment to explain. The only herpes blood we collect is herpes zoster, which is the virus that causes chickenpox. We deliberately collect donations from people with high levels of antibody—people who have recently had chickenpox and people who have had shingles, which is the other manifestation of herpes zoster—for the specific purpose of sending that plasma to CSL so that they can make from the plasma a product called zoster immune globulin, which is then sent back and distributed to hospitals where it is given to people for whom chickenpox would be a fatal infection. It is used primarily in immunosuppressed people—people with leukaemia and people undergoing chemotherapy—and people who are severely immune depleted for whatever reason and people who are pregnant. So for a long time we have deliberately collected blood from people with high levels of herpes zoster antibody. That is the only herpes virus we collect blood for. I may not have answered what was behind the original question. The question was about herpes and that is the answer for herpes zoster.

Senator KNOWLES—Would you like to run through for the committee the methods of testing for new viruses? We have talked about SARS and so forth in the last few days. Would

you be kind enough to explain to the committee how you deal with new and emerging viruses as quickly as possible?

Dr Wylie—A lot has changed over the last two decades. First of all we have a national blood transfusion service, formed in 1996, which gives us centralised, coordinated, standardised decision making. We have a strong, powerful and effective regulator in the Therapeutic Good Administration—since 1991 for plasma products and since 2000 for fresh products. We engage constantly with the National Blood Authority and the regulator, TGA, and we continue to monitor—as do those other bodies—anything that is happening overseas. Recent examples include a very rapid institution of deferral for 14 days of anyone who has been in the SARS affected area. We have twice in the last year instigated very rapid deferral regimes in Cairns, with the dengue outbreaks that have occurred in Far North Queensland. Similarly we have instituted deferrals, where appropriate, for West Nile virus, which has been a huge problem for Dr Holland and further north in Canada. On each occasion these deferrals have occurred rapidly in consultation with the National Blood Authority and the regulator. It is always difficult to predict what is coming but I believe Australia now has extremely strong mechanisms in place not only for early detection but also for early response.

Senator KNOWLES—In section 4 of the submission you presented to the committee today, on page 19 you say:

We recommend that personal, social and medical support should be provided to anyone with hepatitis C.

From whom, and at whose cost, are you making that recommendation?

Dr Wylie—We believe it should be optimised within the capabilities and policy-making positions and decisions of all the stakeholders involved in delivering these services in Australia. One cannot help but be struck by some of the issues that the people infected with non-A, non-B hepatitis, now hepatitis C, face— in particular things like discrimination. We look to the committee, on behalf of everyone involved, to consider some of the issues that that discrimination raises, because no-one should be in a position of being discriminated against. As a humanitarian organisation, we want these people to be looked after. Again as a humanitarian organisation, we are trying to consider everyone with hepatitis C. We are an impartial organisation, although of course we have a particular interest in, and focus on, people who have acquired hepatitis C through a blood transfusion. We understand that there are also issues with access to treatment. I simply point that out and put on the record that we have noted that in the submissions. I think it is an important issue for this committee to consider and make deliberations on in due course.

Senator KNOWLES—But you go further than that in what you are suggesting in your recommendation, where you go to personal and social support as well as medical support. What types of personal and social support are you suggesting, and at whose cost?

Dr Wylie—The bodies that could completely address this are the hepatitis C councils. However, again, we were struck by people stating in the submissions that they were having trouble accessing support and that their needs were not being met and, equally, by the position of some of the providers—and I speak particularly of the TRAIDS submission—that their services were not being completely accessed or accessed as much as they might be able to provide for. I

think there are two issues here. There is the extent of the support and there is also, perhaps, whether there is currently some disconnect between what is available in the health system and the extent to which it is being accessed. But I have no further comment than that.

CHAIR—Have ARCBS any comment to make on the effectiveness of the hepatitis C strategy? I know it is somewhat outside your direct work but, given your association with this issue, do you have any comment to make on how the strategy has worked, the review process and the development of the next strategy?

Dr Wylie—I would have to restrict my comments to the blood transfusion side of things. I can only say that I think we as a nation should be gratified that in 2004 we have a risk of less than one in 3 million units of donated blood and that the risk of hepatitis C, whilst never being possible to completely eliminate, has been very largely eliminated in this country. We have had continued liaison and cooperation with all relevant agencies, but it would be inappropriate for me to comment beyond that.

CHAIR—For the record, it is important to recognise that the infection rates are increasing at quite concerning levels. I make it very clear that that is outside blood transfusion issues—I want to make that point.

Dr Wylie—We recognise—and I think a number of witnesses would have tabled figures similar to this—that, of the total number of people infected with hepatitis C in Australia, only five per cent have acquired their infection through transfusion. So clearly there is a large problem with hepatitis C outside the particular area on which we focus.

Senator KNOWLES—Would you care to expand on the statement that you make, also on page 19 of your submission, about the confidentiality issues when litigation is resolved? You say:

Given the issues canvassed by this Inquiry regarding discrimination, confidentiality agreements can also act to the benefit of plaintiffs.

Are you simply referring to their being able to conceal their identity and status, or are there further things that could be to their benefit?

Dr Wylie—To their benefit in any aspect of whatever led to and whatever the terms were of whatever settlement or resolution may have been reached in their case. We make that as a general statement; it could refer to any aspect.

Senator KNOWLES—I have some more questions on your recommendations. I think I have covered recommendation 1 about appropriate personal, medical and social support. In recommendation 4 you say:

Those governments facilitate access to recombinant Factor VIII and ... IX as recommended by the Commonwealth Working Party and by Haemophilia Foundation ... in its submission.

You have gone into quite a degree of depth today in talking about the ability to have the recombinant factor or the plasma derived factor VIII or IX. Are there any other issues which the

committee should be familiar with in either of those two scenarios that have not thus been covered? That is, in our consideration of the either/or or both options.

Dr Wylie—Only to reiterate that Australia currently definitely needs both, that there is equally a definite international trend in developing countries. I think there is debate which is probably better addressed by an expert in treating haemophilia as to some technical aspects of the products. However, in the Australian context I would reiterate that the plasma derived product and the recombinant product appear to be equally effective. I have already outlined to the committee the low risks of donors with infectious diseases entering our blood supply.

Senator KNOWLES—Furthermore, in your suggestion 3 on page 21 you say:

In agreement with many of the submissions, support for an educational program for the medical community about hepatitis C generally, including transfusion acquired hepatitis.

At first blush one would almost shake the head at the prospect of that even being necessary today. Why do you believe that it is still necessary to basically carry out an educational program with the medical community?

Dr Wylie—If I could first go back to 1990, when the test was first developed we were in a sense thrust into the front of knowledge at the time because we had the test and just about everyone else did not. There was clearly a need for education at that time. In fact at that time many people used us as a source of education. A lot of good things have obviously happened since then, but you cannot escape, from reading the submissions that have been made to this inquiry, that there are still issues out there in our hospital system regarding how some of these patients have their diagnoses explained to them. Again I return to the discrimination that comes through and some of the submissions with regard to some of the insinuations, for want of a better word. From our point of view, that is an inescapable message coming through from the submissions. That is not to say that many people are not treated very well, but at the end of the day the submissions have enough stories in them for us to feel compelled that this is an issue which the committee should take on board and look at.

Senator KNOWLES—Given that there is much documentation distributed in the medical community now which, as we had evidence the other day, is sometimes not read purely and simply because of the demands of people within the community proper, how would you suggest the tack be changed so that people do read the material that is provided or do read and understand any more material that is provided?

Dr Wylie—I might refer that question to Dr Rosenfeld, as he would be a receiver of that information.

Dr Rosenfeld—Thanks!

Senator KNOWLES—Is that what you call a hospital handpass?

Dr Rosenfeld—With a handshake! It is a problem. We are constantly buried in literature, in journals, in information. It is hard to summarise and it is hard to pull out the information that you need from the avalanche of stuff that comes through the mail, through the Internet and through

all the other sorts of venues. So you basically have to review what you have and pick the eyes out of what comes in. There is really not enough time to do all the reading that we all need to do.

Senator KNOWLES—What would this proposal do that is not already being done?

Dr Rosenfeld—It could emphasise specific knowledge about hepatitis C testing, about the validity of finding an antibody, whether you need to do hepatitis C RNA testing and where you need to go from there. Not everyone who has a hepatitis C antibody has hepatitis C. There is a lot of ignorance out there. I think the way to get that information across is through the colleges and the professional organisations that people belong to.

CHAIR—Could you explain further your suggestion 2, which calls for mandatory reporting to the ARCBS by medical practitioners and health care professionals of suspected transfusion transmitted cases? How would that assist?

Dr Wylie—We see this as crucial. There are two really important factors here. The first is that we feel that the great majority of cases are not being reported to us. Therefore, we cannot investigate them and, in particular, we cannot find donors in those cases where the suspected transmission is in fact from blood. So there is the axis of resolving that for the clinician and the patient. Equally importantly, if we find through the investigation of further cases a new donor previously unknown to us then that gives us the opportunity to start looking back on that donor's previous donations and then find out about however many other people who may have been infected by that donor with hepatitis C that we previously did not know about. So it is an important public health issue in terms of ascertaining the cause for the particular case that is referred. But it is also a critical public health issue to assist us in finding other people who have been infected with hepatitis C. We have said today that it is a concern that we have not been able to find everyone.

CHAIR—What is the reason that medical practitioners are not reporting? To go back to Dr Rosenfeld's comments, is it that they are just too busy?

Dr Wylie—It is not mandatory.

Dr Rosenfeld—If it was mandated I am sure people would report them. There are notifiable diseases which have to be reported, and if it became one of those then I am sure they would be.

CHAIR—Would there be resistance from the medical profession to that sort of mandatory reporting regime?

Dr Rosenfeld—I would not expect so. A lot of diseases are notifiable today. I would not see it as an issue.

Senator MOORE—Recommendation 6 really interests me. It is the one about the haemovigilant system. Is that a real word?

Dr Wylie—It is a real word, but it is difficult to achieve.

Senator MOORE—There are a very straightforward three sentences in the recommendation, but they seem to me to get to the heart of the whole issue about which we are talking. Would you mind expanding a little bit on how that may work and what cost would be involved in it—because I am sure that people want to know. The second point is what happens now. We know that there are records kept about where products are sent, but this kind of recommendation seems to sum up exactly where we need to be.

Dr Wylie—The problem with what happens now is that because there is no formalised system and we do not have interconnecting systems between the collection of the hospital blood bank level awards and ultimately the patients themselves, the information that is passed back is ad hoc at best and only a very tiny fraction of incidents that occur are ever reported. At the end of the day, the things that do get reported are often major things, but equally they come to attention in a very ad hoc way. We think it would be much better for the community as a whole to have a haemovigilant system which really would be built upon what we call a vein-to-vein tracking system. So not only would we have the donor side identified and connected but also we would have a seamless connection with the hospital which, in turn, would have a seamless connection further within the hospital to the wards et cetera. It can then be tracked and traced quickly, effectively and correctly so that action can be taken.

We in the Red Cross have done some preliminary work on this, but currently it is with the government agencies. They are further examining which way Australia will go on this. I believe that Professor Bruce Barraclough reported to the committee yesterday. He is quite involved in assisting government in how the next step should be taken. So it is something that, in three sentences, looks straightforward. It is highly desirable. It will be complex to achieve and will require significant resources, but we believe the outcome will be of tremendous benefit to the community.

Senator MOORE—So this system—and we will be asking questions about the Lookback program—and the whole concept of being able to trace who gets what and when would be fixed by such a system being in place and operating, wouldn't it?

Dr Wylie—Yes, but it would go further than that. When something happens—for example, someone believes they have had a transfusion reaction or infection—there would be a formal mechanism for reporting that. That would obviously go a long way to helping us solve some of our inability and our frustration to date in tracing all people who have received infections through blood transfusions.

Senator MOORE—My understanding is that that would be a very expensive process to put in place.

Dr Wylie—It is expensive and it is complex—and it would need to be taken, in our view, in a staged process. The Australian Red Cross Blood Service is very keen to continue working with the National Blood Authority and other bodies within government to try and progress this over a period of time because we see that it would have tremendous benefits.

Senator MOORE—And now that we have the national system in place, it would be all-in, wouldn't it? There would be no option for individual areas not to be part of such a system.

Dr Wylie—When you say we have one system, what do you mean?

Senator MOORE—We now have the national system structure in Australia with the National Blood Authority and that process. So if it were accepted and put in place, it would be a genuine national system.

Dr Wylie—It would, but the real trick, I believe, to getting this in is that it is going to require tremendous cooperation and resources at the state and territory government level because they are the primary providers of health in this country at the operational level.

Senator HUTCHINS—I cannot expect Dr Holland to come all this way and enjoy our sunshine without asking him a question or two. Dr Holland, I see that you are the Chief Executive Officer of BloodSource, Sacramento. Would you have used ALT testing yourself in your area or would that not be appropriate?

Dr Holland—Are you asking what my views are about the testing in my area?

Senator HUTCHINS—No, would you have been responsible for using ALT testing at your laboratory or clinic?

Dr Holland—Yes.

Senator HUTCHINS—So you did use it in that period from 1983 onwards?

Dr Holland—That is correct—because we were an accredited member of the American Association of Blood Banks and had no choice if we wanted to remain a member in good standing. We had to do it. Furthermore, about that same time, in the latter part of the eighties, because of a requirement in Germany, all blood or plasma for further manufacture had to be ALT tested. That applied to all plasma fractionation companies. So if we wanted to sell our plasma, it had to be ALT tested.

Senator HUTCHINS—So you were using that program even though you were publishing papers that did not agree with it?

Dr Holland—That is correct.

Senator HUTCHINS—I want to talk about the introduction of the first generation test for HCV—and this question may be more appropriately directed to you, Dr Wylie. In your submission on page 68 you say:

Many of the donors identified as hepatitis C reactive in the first few years of screening from 1990, turned out to be false positives.

We heard evidence this morning quoting a number of academics who said that there were a number of people who were false positives in that period. Do you have any idea how many people were incorrectly identified as having hepatitis C as a result of those tests that were introduced from February 1990?

Dr Wylie—In the first phase, 70 per cent of the people who reacted on the test were false positive; so they did not have hepatitis C at all. I do not have the exact figure with me, but over time a very substantial number of donors had to be managed.

Senator HUTCHINS—Does that mean they went back into the scheme as donors?

Dr Wylie—Unless these donors were enrolled in the study that I referred to earlier, they were basically put in limbo until we could resolve the situation for them.

Senator HUTCHINS—I imagine that would be reflected in the graphs on pages 65 and 66. I am assuming it would be, particularly the high level in Queensland.

Dr Wylie—It is certainly true that in Australia the loss of donors for any reason—and this was a perpetual problem through the 1990s—can only be met through the increased recruitment of new donors. At the end of the day, it is a risk-benefit. We had a test that could find 85 per cent of people with hepatitis C. It has continued to be a risk-benefit as we have had increasing deferrals through the 1990s for the virus that I mentioned a short time ago and for new variant CJD, which had a very major impact.

Senator HUTCHINS—In your contribution—I cannot recall the exact words; I suppose we can go to the document you read out—you said that costs were definitely not a factor in commercial decisions. Yet, the second last paragraph on page 52 of your submission states:

Costs were a factor but did not play a major role in decisions relating to the use of surrogate tests for NANBH in Australia.

Would you like to expand on that? The submission states that costs were a factor, yet you said earlier that commercial costs were not a factor. It is contradictory.

Dr Wylie—The implementation of every test has a cost. However, the answer to your question is: did that cost or any cost influence the decision to introduce or not introduce surrogate testing in Australia? And the answer is no.

Senator HUTCHINS—What were the actual costs? You may not be able to give us a direct answer now, but you may be able to advise us later.

Dr Wylie—I will take that question on notice. But I think the crucial point is that, whatever the costs, the key factor here was there was no evidence that these tests had any value in the Australian blood supply. Even in retrospect, the United States, which had five times the incidence, were also unable to demonstrate any benefit. The only thing that we could have achieved by introducing them was to damage the donor base and create shortages.

Senator HUTCHINS—In almost every submission we have received, there is reference to the controversy and the debate surrounding the ALT testing. Judging by the meeting of the American Association of Blood Banks in January 1981 and the decisions that were made subsequent to that, I do not think there is any doubt that there is a difference of opinion there. Were you involved in the decision making in 1987 Were you a member of the Blood Transfusion Committee?

Dr Wylie—No, I was not.

Senator HUTCHINS—Obviously the New South Wales representatives would have been.

Dr Wylie—Yes, that is correct.

Senator HUTCHINS—Do you know who that would have been at that time?

Dr Wylie—The New South Wales representatives of the National Blood Transfusion Committee were the director at the time, Dr Archer, and the chairman of the technical and advisory committee in New South Wales, Dr Kronenberg.

Senator HUTCHINS—Can you tell us when the decision was made to go from heating plasma at 60 degrees Centigrade for 72 hours to 80 degrees?

Dr Wylie—I think I understand the question. CSL advised, as a member of the National Blood Transfusion Committee in the 1980s, that it was endeavouring to move towards heat treatment of both factor VIII and factor IX products—moving from 60 degrees to 80 degrees. It kept the National Blood Transfusion Committee informed. The actual process—the steps that it had to take—and the timing of it is a matter that CSL would need to address, in conjunction with the regulator, the Therapeutic Goods Administration.

Senator HUTCHINS—We had a chance to talk to CSL the other day. One of the things they mentioned was that by heating it to 80 degrees Centigrade it affected between 10 and 15 per cent of the yield, which obviously at that time would have affected the amount of product available to put into the system. Regarding the Gosford incident—you have probably heard of the Barraclough report and also some questions to the minister—there are a number of bottles of Prothrombinex that have still not been accounted for. Is that correct?

Dr Wylie—With regard to the Gosford problem, I can perhaps assist the committee in the following way: first of all, the Gosford blood bank was not run by the Red Cross at the time. The New South Wales health department have indicated that in relation to what happened at Gosford and the issues that arose from it, they are the body that wishes to speak. They have indicated to us that they would be happy to come and speak, if required, on that issue. The other aspect of the Gosford incident is that CSL at the time initiated and carried out a recall which ultimately resulted in a final report being made to the regulator, the Therapeutic Goods Administration.

Senator HUTCHINS—The last sentence of the answer the minister gave me in response to a question on notices reads:

The ARCBS advised that following notification to hospitals by state and territory Blood Transfusion Services it was the hospitals'/treating physicians responsibility to notify relevant patients.

There was an attachment containing something like 15 pages which listed the hospitals involved. It appears to me, and you may wish to comment on it—not just on this incident but on how it might affect the future—that no-one took responsibility to make sure that Bill Boggs, who may have had this plasma, was advised of it. There was no authentication that that occurred down the line. Could that happen now?

Dr Wylie—As I have stated, the recall in that instance was carried out by CSL. As you are referring to your notes and answers there, there was a very complete recall and a very large number of institutions were contacted. We are aware that CSL wrote to all those institutions and physicians involved regarding the recall and the reason for it.

Senator HUTCHINS—But not all of that has been accounted for, has it?

Dr Wylie—As I understand it, the final report provided by CSL to the regulator gives a list, if you like, of the outcome of that recall.

Senator HUTCHINS—I am advised there are something like 1,800 bottles that have not been retrieved.

Dr Wylie—That would be because a number of those bottles would have been transfused or used prior to the initiation of the recall.

Senator HUTCHINS—When I was reading your first submission—I did not have a chance to read the one you presented to us before we started this morning—I noticed you mention on at least 14 or 15 different occasions the potential for a dwindling donor base. At page 66 of your submission you state:

It was against the backdrop of such sufficiency of supply concerns that the risk/benefit decisions relating to surrogate testing had to be taken.

Is that what influenced, in your opinion, the decision in 1987 not to introduce surrogate testing?

Dr Wylie—In my opinion, as I think the records clearly show, the decision not to introduce surrogate testing in Australia was because there was no evidence that it would be effective. The overwhelming evidence both from the United States and in the advice from the Council of Europe, which I quoted directly in my oral presentation today, indicated that the incidence of non-A, non-B hepatitis could vary enormously between countries. The value of ALT screening and core antibody testing was not proven in any environment. Dr Holland has spoken of a correlation. We had five times less incidence of non-A, non-B hepatitis in Australia. There was no evidence that those tests would have been of any benefit in the prevention of non-A, non-B hepatitis in Australia. There was evidence that it would have further eroded a donor base and therefore a blood supply which was already struggling. I repeat the example I used briefly before lunch: we were only running at 60 per cent of the amount of factor VIII recommended by the World Health Organisation for the adequate treatment of haemophilia.

Senator HUTCHINS—But neither the Queenslanders nor the Americans agree with your position.

Dr Wylie—I will refer the American position to Dr Holland. The Queenslanders made a decision which was different from the National Blood Transfusion Committee's policy. But I would point out that at the time that decision was taken the incidence of non-A, non-B hepatitis had not been studied prior to the introduction of surrogate testing in Queensland or subsequently.

Dr Holland—We had two studies from America which appeared to have a correlative effect and therefore a prediction that there might be some good. We had a big problem—certainly bigger than that of Australia and many other countries. We did think about the effect on the supply because that was going to knock out anywhere from three to eight per cent of our supply. As I mentioned, we had an out, which you did not have. We were already importing into New York State hundreds of thousands of units of blood a year.

Senator HUTCHINS—We were importing blood, but not to that degree.

Dr Holland—This is fresh blood components—red cells—for direct transfusion.

Dr Wylie—Can I interrupt you there. It is very important that the record shows that Australia has not imported fresh blood products.

Dr Holland—These were phased in over a period of about a year and a half. Basically, we had our own data and we did not think there was going to be anything specific for hepatitis C, despite a lot of false starts over the years. By that time it was perceived by enough people that non-A, non-B hepatitis was much more significant than we originally thought. All those effects came together in our country to mandate—voluntarily by our organisation; it was not by the government—that that testing be done. But if you did not belong to that organisation you did not have to do the testing.

Senator HUTCHINS—One of the submissions—and it may be the Red Cross one—mentions that New York State had for some time been importing fresh blood from Europe. What about the state you are from? Where it did it get its blood from—Europe as well?

Dr Holland—Very little blood in California came from Europe. None can now because of mad cow disease. Most of the blood imported into California came from the middle part of our country. So basically blood came in on the east coast and then blood was shipped further west. But the blood from Europe did not come all the way to California.

Senator HUTCHINS—I wonder whether it came from Europe.

Dr Holland—No. California imported its excess blood needs from other states that had an excess in the mid-west part of our country.

Senator HUTCHINS—New York did not import it from the mid-west because the mid-west could not keep up the supply?

Dr Holland—That is correct. They only had a limited amount. America had been since the 1950s, and was until November 2002, an importer of blood.

Senator HUTCHINS—Dr Wylie, when did we stop importing plasma?

Dr Wylie—We have never imported plasma. Australia has on several occasions had a need to import specific plasma derived products. One example of that was an Rh anti-D product in the 1990s. There has been a small amount of importation of an intravenous haemoglobin, which goes under the trade name of Sandoglobulin. But, in the main, Australia has pursued, and

continues to have, a policy of self-sufficiency, and the policy aim goes right back to 1975 with the World Health Organisation. I would note that Europe in particular has reiterated that the countries should attempt to remain self-sufficient for both fresh and plasma derived products. That is from the EU directive from 1989, so it is an important national policy.

CHAIR—I want to go back over the decision-making process that led to the decision not to introduce surrogate testing. Dr Wylie, you said earlier that 'the records show'. Were you referring to the record of the meeting of the National Blood Transfusion Committee?

Dr Wylie—Yes.

CHAIR—And that is where the decision was made?

Dr Wylie—Also records at the divisional level. It may be of benefit to explain where the National Blood Transfusion Committee fits in and how the system worked at the time. The National Blood Transfusion Committee was an advisory body to the Australian Red Cross executive and council. At the time, the primary operating responsibility and a lot of the local policy decision making was made in the divisions of the Red Cross in consultation with the state and territory governments; hence the decision in Queensland regarding ALT screening. It is important to point out that the National Blood Transfusion Committee comprised experts in haematology and people with expertise in surgery as well as representatives from CSL and from the Commonwealth government. It was chaired generally by an eminent haematologist, it had a deputy chair, and two members from each state and territory, one being the director of the state or territory and the other the chair of the division.

It is also important to point out that there was a huge amount of longstanding expertise and that many of these eminent professors and experts did all this voluntarily. The chairmen of the divisions and the chairman of the committee were all Red Cross volunteers as well as being experts. Within the state and territory divisions there were committees, which again comprised people who were giving up their time—professors of anaesthetics, professors of haematology, professors of surgery—that assisted the state and territory divisions to make local operating decisions. And then, at the end of the day, nothing of major import or change could happen without further consultation with the state or territory governments as the funding bodies at the time.

CHAIR—I still do not understand how we have a national body that makes a decision to recommend against surrogate testing and Queensland goes ahead and makes its own decision. It seems that there was no connect between those two entities. I am trying to understand its purpose.

Dr Wylie—The National Blood Transfusion Committee was an advisory body. One of its roles was to set policy and advise. In the main, when decisions were made and policies were set, with regard to implementation they were generally carried out in the state and territory divisions. On the issue of surrogate testing, the reason that we are here today largely is the controversy that surrounded it at the time. Queensland, in conjunction with their local committee and with the support of the state health department, felt strongly enough that they should introduce surrogate testing in that state.

CHAIR—Does the ARCBS have an understanding of the basis on which Queensland made that decision?

Dr Wylie—There were two factors that I believe influenced their decision: firstly, that it was technically possible—although ALT tests are imprecise and difficult to get accurate, reproducible results—and, secondly, as a medico-legal step to protect themselves and the concerns they had about future consequences. The problem that we all had was that there was no scientific evidence, as you have heard from Dr Holland and me, that the surrogate test was going to be of benefit.

CHAIR—It has been put to us that the Queensland decision was made basically on legal grounds not on medical grounds.

Dr Wylie—There was no scientific evidence—there were no studies—available to them or anyone else in Australia or internationally which would have enabled a scientifically based decision to introduce surrogate testing for either ALT or hepatitis B core antibody. The evidence was not available.

Senator KNOWLES—Just on that issue: you said that Queensland made the decision partly on medico-legal grounds, but I do not quite understand how that then sits retrospectively with the fact that 75 per cent of the positive hep C was missed. If they did it to protect themselves legally and yet 75 per cent was missed then, once again, that did not really protect them, did it?

Dr Wylie—I would reiterate that the national policy was not to introduce surrogate testing. Unfortunately, we have no scientific evidence, equally, of the effectiveness or otherwise of surrogate testing in Queensland. We do know from the evidence that the ALT test which they used was a very imprecise test with an enormously high false positive rate and also a very high false negative rate. It missed a lot of the truly infected people, and the great majority of people—91 per cent, in fact—who had a high level of ALT were not infected with non-A, non-B or hepatitis C.

Senator KNOWLES—I would have thought that people who got a transfusion in Queensland, believing it to be safe because the surrogate testing was in place, and contracted hepatitis C would have more cause to be angry than others who were not involved and received a transfusion.

Dr Wylie—I think ARCBS can only say that we have sympathy for anyone who has acquired non-A, non-B hepatitis—or, as we now know it, hepatitis C—regardless of the circumstances and regardless of the testing mechanisms that were in place anywhere.

Senator MOORE—You have seen in the submissions and heard in the evidence this issue of the way that Queensland did their own thing—which we have quite a strong record of doing in lots of areas. On this particular issue there was limited data that we could find published anywhere about the basis for this decision, but then it was clear that they had done it. The thing that surprises me—and Senator Knowles was touching on this—is that there was an advisory body which went down one track with all the evidence they had and one significantly large segment of the organisation went a different way. Isn't that a perfect pilot? If you have an argument about whether one thing is going to be effective or not and you have one group who,

for whatever reason, have gone that other way, then shouldn't we be able to find some specific scientific evaluation of the Queensland decision?

We have not been able to find anything that comes under the heading 'Paper to group 1988 results of Queensland surrogate testing process'. We have been searching for that, because it would seem to me that, in the scientific process, there we have a pilot. It is standard scientific practice to test what is going on. The first figures that we have seen up until now that even says what happened in Queensland are in your paper we received today. On page 14 there is a paragraph there that actually gives us some information about what happened in Queensland. That is worrying. Can you shed any light on why it was not studied more closely? The other thing we have heard consistently is that this was a major debate—and the word 'debate' is used all the time in the literature. People must have been interested. So Catherine Hyland and her group in Queensland make this decision: wouldn't that have been closely watched?

Dr Wylie—I would like to touch on one point right at the end of your question. It was not Catherine Hyland's decision. I think it is important to clarify that Catherine Hyland was a scientist running a laboratory; she was not a policymaker or a decision maker on any of these issues.

Senator MOORE—Why, then, is her name consistently used? That is an error I have followed through from the data that we have seen. We have seen writing about Dr Catherine Hyland.

Dr Wylie—Her name is consistently used because of the paper—and I have the paper with me—which was published in July 1988 in *Pathology* of which she was the principal author.

Senator MOORE—That was referred to in CSL evidence.

Dr Wylie—There has been some degree of confusion as to the purpose of that paper. I think it is important that the committee notes that this is not a paper about the effectiveness or otherwise of surrogate testing; this is a paper that describes a method for doing ALT screening—no less, no more.

Senator MOORE—Yes, we were told that was the case, and we are just waiting to see a copy of that paper. Given that that was her methodology—and I would imagine that that was part of the process of making the decision to go that way in Queensland—why wasn't that scientifically evaluated and made public?

Dr Wylie—It is a very complex issue but I think I can step through it and give the committee some assistance. The first problem was that there had been no prior assessment of the level of non-A, non-B post-transfusion hepatitis in Queensland. So they had no base on which to assess the effect of the test. Secondly, it was less than a year into the use of the surrogate test in Queensland that Enzell, in May 1988, reported the cloning of the hepatitis C virus. This changed everything. Within a year of that, in 1989, we had a real test for hepatitis C as a research tool. I think the committee has heard the rest of the story a number of times.

The other critical thing which I think may assist in sorting out the complexity of this is that the National Blood Transfusion Committee did not just decide not to implement surrogate testing as

a policy; it took the trouble, for the second time in a decade, to do a prospective post-transfusion hepatitis study specifically evaluating both the surrogate tests—hepatitis B core antibody and ALT. They had done the first study in 1979, and the second study was commissioned in 1987. So whilst a study was not done in Queensland—and, remember, they had no base to work from, to begin with, as an incidence—there was a national study, run as a national project through the National Blood Transfusion Committee, that looked at the incidence of post-transfusion hepatitis in a number of Australian hospitals and the effectiveness or otherwise of both the ALT test and the hepatitis B core antibody test.

Senator MOORE—Yes, that was a national study, but I am still at a loss to understand why, when the Queensland situation was a ready-made pilot—with the process being used consistently in that area using the donors that were going through—that it was not more effectively evaluated, even for a 12-month period.

Dr Wylie—They did not have an incidence; they did not do a study before or after. As I have said, events swept everything away from May 1988 onwards. To set up a study such as the one that was being done nationally required planning, logistics and resources. It was not something that could suddenly be switched on in Queensland, it having embarked on surrogate testing. We had a national study going on here and we had events, particularly the cloning of the hepatitis C virus, happening almost simultaneously, and there had not been a prior assessment of the incidence of non-A, non-B hepatitis after transfusion in Queensland.

Senator MOORE—So how do we know the data that you have printed in your report, that 92 per cent of the blood Queensland rejected was good? How do we know that 75 per cent of infectious donors were not detected? How did we get that data?

Dr Wylie—When the specific hepatitis C test came in they were able to look at samples that they had stored from donors with raised or otherwise ALTs and see how successful the correlation was.

Senator KNOWLES—They retested them?

Dr Wylie—Yes. That does not mean they knew anything about the effectiveness of it as a surrogate test in a transfused population or that that was a study looking at a transfused population. It simply confirmed what we knew from the US and from other data that the core antibody test was hopelessly ineffective as a surrogate marker and, as you have cited with ALT, that 91 per cent of people whom they recorded as having a raised ALT did not have viral hepatitis.

Senator MOORE—It does not follow the normal scientific process, though, of testing while you go. It worries me as a Queenslander that the Queensland process has taken on a life of its own through this inquiry—it has been referred to consistently—and the appropriate assessment of that seems to be after the event as opposed to the process—

Dr Wylie—I repeat that they were not in a position to test its effectiveness at the transfusion end.

Senator MOORE—I understand; it was not set up to be tested.

Dr Wylie—It was not set up that way. They could only in retrospect assess—

Senator MOORE—Retest the samples they had.

Dr Wylie—Correct.

Dr Holland—I would like to comment in two respects on your question. First of all, we were not there; we cannot put ourselves in their place as to why they did not organise some kind of study to see whether they had accomplished anything. However, if they had done that after the fact, all they would know would be the rate of hepatitis they then had, and they would not know whether they had made the rate lower, left it unchanged or it had actually gone higher, because they did not have a comparison. So it was almost not appropriate to do that study without the prestudy Dr Wylie was talking about so that you would know where you had come from and whether you had made an impact. But why they did not even try to do the first study, just to see what happened, we do not know because we were not there.

CHAIR—At the same time, though, as being able to ascertain the number of false positives, that same data could advise the Red Cross of how many donations were not used that were positive.

Dr Wylie—I am sorry, would you repeat the question.

CHAIR—The data that you have described in your submission here today tell us the number of donations that were false positives.

Dr Wylie—Yes.

CHAIR—The same data, surely, could tell us the number of donations that were not used that were actually positive. Therefore, you could extrapolate to say that the infection levels were reduced by this percentage.

Dr Wylie—I understand the question, thank you for repeating it. It shows a correlation, as all these studies have shown, including the US studies that Dr Holland has referred to—there is a correlation of between 20 to 30 per cent, but the key point is that their new-donor rate had increased and they were only finding a fraction of the people with hepatitis C. If you have introduced increased levels of hepatitis C and you are only finding 30 per cent of it, then at best you may have tread water and at worst you may have increased the risk to the blood supply. Hence Dr Holland's comment that, without knowing the base from which they started, it was impossible to work out whether they had gone forwards, backwards or stayed the same.

Dr Holland—Let me answer it another way, too. Almost no patient gets a single transfusion, period. Whether it is for cardiac surgery or chemotherapy for cancer, you get five, 10 or 20—you may get a multiple. Even if you were lucky enough, because of this 90 per cent rate, to pick up one out of 10, you still have the other nine. In the study in America where they actually checked that out it was shown that, because you do get multiple transfusions, even if you were able to pull out occasional ones with those tests you miss most of them. So the net effect on patients was that the rate of hepatitis transmission was no different because you could not get the majority of them out of the system and because most people do not get just one transfusion.

CHAIR—Senator Moore's point is well made, though: we had a perfect opportunity to do a comparison, which was missed.

Dr Holland—Except that they should have done the study before they started, to see where they were, and then put that into place and then measured it afterwards in exactly the same way, very carefully, otherwise they would have had no idea of what they had done.

Senator HUTCHINS—Dr Wylie, a number of the people who have appeared before us who have been infected with hepatitis C have been very critical of the Red Cross's Lookback program. A lady from Tasmania appeared before us yesterday who said she essentially had to do her own looking back herself and had to do a lot of the finding out about when she contracted her illness and what to do. Is there a difference in the way some state services of the Red Cross approach dealing with Lookback? Is there a problem?

Dr Wylie—I think the first important point to make is that Lookback, at its best, is an imperfect process. There is no form of Lookback available that will ever find all people who received or acquired non-A, non-B hepatitis or hepatitis C post transfusion. The Lookback that can achieve that does not exist. There are limitations with every form of Lookback that you undertake. We hear the criticisms and I have expressed to the committee this morning our frustrations at not being able to find everyone. While following a common theme, there are differences between the states and territories in the Lookback processes. This is a necessity as a result of different state and territory legislation and different policies of state and territory health departments. That is a fact. However, the real problems that make Lookback so difficult for us are there and would be there regardless of these differences.

We have used two principal types of Lookback. The first is donor triggered Lookback. The first problem that donor triggered Lookback suffers from is that we can only look back on a donor if we know about them. Either we have to have retested the donor and found them to be positive, after the introduction of screening, or the donor needs to have contacted us to say: 'Look, I'm hepatitis C positive now and I know I was a blood donor. You may choose to look back.' Then we need to be able to track that donor's previous donations to the hospital level, which we can do in the great majority of circumstances. Then the difficulties begin at the hospitals end with finding records, finding who the transfusion was given to and ultimately with locating the patients themselves. Patients may have died and will obviously not be able to be tested. Patients may have moved. Patients may be otherwise not contactable. There may be elderly patients who do not want to know, who do not want to be tested. They may not want to know about something late in their life. Doctors, out of respect, may not contact patients who are terminally ill. There are tremendous difficulties in and limitations on going in that forwards direction.

The second type of Lookback is recipient triggered Lookback, and I have already made comment on that. Because there is not mandatory reporting of suspected cases, we have a difficulty immediately because not all cases are being reported to us and therefore we cannot investigate them all. Cases that are reported to us are investigated, but we may have difficulty in resolving the case in the affirmative or in the negative if a unit of blood can be identified as the cause or if there was no unit involved. If there are many units involved, regrettably the exercise of finding all the donors—as in some cases hundreds of units of blood have been transfused to particular individuals—is a very difficult logistical exercise. It may not be possible to find all

those 200 donors for the same sorts of reasons I outlined earlier that it was difficult to find all the recipients. In those cases the Lookback cannot be completed and resolved. This explains why it is incomplete, and this explains why we cannot make it complete. I have shared our frustration with our inability to make it a complete program, but there is no Lookback system available which will find every single person that is involved.

Dr Rosenfeld—Can I make some comments as a user at the coalface. We have been involved in the Lookback program because we receive notifications from the Red Cross to chase X number of units, and they give us the numbers. On those occasions, we have gone through our records, we have found out the record number of the patient who has received the blood and we have notified the medical superintendent to then notify the patients and/or their doctors. That is one aspect.

The second aspect is that I have instigated the recipient Lookback. I have had a patient who has come to see me who has been hepatitis C positive with no drug history et cetera but admitted to having had a blood transfusion X years in the past, and I have started a Lookback for that unit. On those occasions I have had no success finding a donor, so the feedback I have got is that that was unsuccessful.

The third aspect I have been involved in is when a notification comes in and I find these units of blood have been give to one or more of my patients. In nearly all of these cases the patients have actually died in that time, mostly because patients who are multiply transfused are the very high risk population. An awful lot of these people will have died from other causes—leukaemias, lymphomas et cetera. Most of these patients for whom we end up getting a notification about as the treating doctor have died not from the hepatitis but from their other illnesses.

Dr Wylie—I think it is very important to resolve any confusion there may be about our ability to quickly identify recipients of blood or blood products once we know the donor. We do not have that capacity. We can identify the unit. We can then notify the hospital, but the Australian Red Cross Blood Service does not have the ability to instantly or even quickly identify once we know of a possible infective donor unit who the recipients of that unit were. I get back to the haemovigilance point I made before: in a vein-to-vein system of transfusion how much better off we would all be if such a system was in place that, whilst we would still not instantly know who the recipients were of a particular unit that we were trying to trace, it could very rapidly find the recipients and test them.

Senator HUTCHINS—Have you or the service had any dealings with a group called the tainted action blood group?

Dr Wylie—I think the name is the Tainted Blood Product Action Group. Is that the body you are referring to?

Senator HUTCHINS—You might have had dealings with them then.

Dr Wylie—I am aware of the organisation.

Senator HUTCHINS—Have you had any dealings with them or their representatives?

Dr Wylie—I have personally never been approached by any of the people who made the presentation yesterday. I presume they are the only people who have come forward as members of this body. None of them have ever approached me.

Senator HUTCHINS—That doesn't mean that they may not have approached representatives of the service elsewhere, or do you know that they haven't?

Dr Wylie—I do not know the membership of the Tainted Blood Product Action Group. I can only make statements about those people who I know are members or who represent people who are members. I can advise, and it would be inappropriate to go into personal details, that a number of those people have had substantial dealings—telephone conversations—with members of the Australian Red Cross Blood Service and particularly the Lookback councillors and Lookback coordinators.

CHAIR—A number of people who have given evidence have talked about the fact that Red Cross had denied to them that a blood transfusion had occurred. There seemed to be a mismatch of information, with what the person with hepatitis C remembered as the experience that they had had not concurring with the advice from the Red Cross. Do you have any comments about the mismatch of experiences that a patient thinks they had and what Red Cross thinks they had? It goes to the question of: did you or did you not have a transfusion? It seems to me fairly straightforward that if the patient thought they had then they must have. Why is this happening?

Dr Wylie—I think this is a distressing issue for the recipients involved. It is a fact, however, that the incidence of hepatitis C in our community is reasonably prevalent, as we have discussed, but also equally prevalent is the incidence of transfusion. There will be a number of people out there who have hepatitis C and who have had a transfusion but did not get their hepatitis C through transfusion. That is simply a fact. That makes no statement at all about the source of anyone's infection with hepatitis C, but it does not categorically follow that a person with hepatitis C who has been transfused definitely got their infection through that transfusion.

CHAIR—That would be a fairly small cohort, though, one would imagine.

Dr Wylie—I would prefer to take that on notice, if I may, and perhaps provide further detail.

CHAIR—Thank you.

Dr Rosenfeld—There are many occasions when patients come to see us after a hospital admission, for various reasons, and they often say, 'I've had a blood transfusion.' I go back and look through their records, either the blood bank's or their own, and find they have not. Conversely, I have found that when they say, 'No, I didn't have any blood,' I go back and find they had two units here and four units of platelets there. Blood transfusions are sometimes given overnight. Nursing staff may have told the patient, 'Yes, we gave you blood,' or, 'No, we didn't give you blood.' People forget. Getting the history from patients is not always that accurate, even when you go back and chase through the records. Sometimes we can find no evidence of it, and sometimes we can find evidence and they deny it.

CHAIR—Thank you.

Senator HUTCHINS—Yesterday we had the Medical Error Action Group give us a copy of a letter from Slater and Gordon. Also today we had Mrs Lewis give us a copy of a letter of Slater and Gordon's. I wonder, unless it is not appropriate, Madam Chair, if we could try to discuss that now.

CHAIR—Ask some questions, but witnesses might remember the comments at the opening of the inquiry.

Senator HUTCHINS—Am I right in understanding that Slater and Gordon have at some point put advertisements in the newspaper asking people who believe that they contracted hepatitis C from a blood transfusion to contact them?

Dr Wylie—I think you would have to refer that question to Slater and Gordon.

Senator HUTCHINS—Have you had any dealings with Slater and Gordon over the settlements of hepatitis C claims?

Dr Wylie—The issue you are alluding to I would wish to take on notice and deal with subsequently.

Senator HUTCHINS—Subsequently in terms of what—you will write back to us?

Dr Wylie—At a later date subsequent to this presentation.

Senator HUTCHINS—I would like to ask some questions about your confidential submission.

CHAIR—We can do that in a moment. Senator Humphries has some questions. We might try and complete questions on this part of the proceedings and then move on.

Senator HUMPHRIES—Before I ask my questions I think I should just put a matter on the record for the sake of completeness. It is a possible conflict of interest. I was a member of a fundraising committee in Canberra in 2002 for the Red Cross. It was raising money for a range of Red Cross services in 2002. I just want to put that on the record for the sake of declaring all interests before I ask questions. Could we discuss, for confirmation, a couple of things you said earlier on. What did the figures of 91 per cent false positives in surrogate testing and 80 per cent of actual hep C infected donations being missed relate to? What test or study did that relate to?

Dr Wylie—ALT testing.

Senator HUMPHRIES—But in what study or paper was that particular outcome found to be the case?

Dr Wylie—Dr Holland can almost certainly add to this, but the figure of 90 or 91 per cent has been repeatedly identified in multiple studies. The effectiveness at the other end—of missing 80 per cent or 70 per cent—again is a figure that correlates with our experience and multiple studies performed throughout the world.

Dr Holland—You can look at it two ways. First, you can say that if you take 100 people with an elevated ALT what percentage of them have hepatitis C when you test them for it. Only about six or seven per cent, in other words, 93 per cent of them—

Senator HUMPHRIES—It is not so much the process by which you arrive at that figure that I am interested in. I am interested in a source for it. Is there a documentary source we can look at to underline what you are saying to us today?

Dr Wylie—We can provide further information on that from our data. That is not a problem.

Senator HUMPHRIES—That would be fine. I also want to clarify what Dr Holland was saying before about ALT testing in the United States. Dr Holland, were you saying, with the benefit of hindsight, that the use of ALT testing in the US between 1987 and 1990 was appropriate for US circumstances but not appropriate for Australian circumstances, or were you saying that it was a mistake even in the US context?

Dr Holland—What I was saying was that in '86, when we proposed putting it into place in the USA, we thought it was appropriate for America, based upon paid donors, the amount of hepatitis we had and the fact that we did not think a test for hepatitis was coming along the way. It was not an inappropriate choice at the time, and so it was done. In retrospect, looking at the only two studies which bear out what Senator Moore asked—what evidence do you have that it did anything?—the evidence we have was that it did nothing and that it was absolutely useless. So, in retrospect, it was not a good choice either.

Senator HUMPHRIES—Even in the United States?

Dr Holland—Even in the United States.

Senator HUMPHRIES—With a high post transfusion hepatitis occurrence?

Dr Holland—That is correct.

Senator HUMPHRIES—I am trying to track down some information about the transmission of hep C in the period after 1990. Dr Wylie, you said earlier that no fresh blood products with hepatitis C were sent for transfusions from February of 1990.

Dr Wylie—That is correct.

Senator HUMPHRIES—CSL has previously advised us that neither albumin nor immunoglobulin products have ever been associated with virus transmission. We heard evidence this morning, though, about there being some transmission of hepatitis C through blood products in the period between 1990 and 1992-93. This was referred to in an NHMRC paper in 1993. Can you give us any clues about that? Are you aware of the NHMRC paper discussing hepatitis C infection from blood in that period?

Dr Wylie—I am not personally aware. Obviously, it would be tremendously helpful if the paper could be provided. Then I could provide a response. It is important to understand that the first generation test that we put in place in February 1990 was not perfect. It found 85 per cent or

thereabouts of the infected donors; therefore, it still missed some donors. As I said in our oral presentation earlier today, it will never be zero. It is a question of making it sequentially safer as these various generations of tests come along. It was 85 per cent; then, with the second generation test in 1991-92, it was better; and then, in 1994, we moved to third generation tests and it was better again.

Although that got us into a tremendous position, the thing that has really made the final difference in getting us down to less than one in three million units was the introduction of NAT testing in 2000. I reported this morning that there were 13 transmissions that we know about of hepatitis C after the introduction of even the first generation test. That is because it was imperfect. But there have been no transmissions that we know about of hepatitis C through blood transfusion in this country since the introduction of NAT testing in 2000.

Senator HUMPHRIES—So it is possible that the NHMRC paper—and I understand that it is coming to us—is referring to those 13 cases you mentioned that were effectively let through because of the imperfections in the first generation test.

Dr Wylie—It could be. It is difficult for me to comment without having the paper. With the chair's permission, if the paper could be made available then I would obviously be very willing to provide comment.

CHAIR—We will pass that on.

Dr Wylie—Thank you.

Senator HUMPHRIES—Thank you. Today there was criticism of the Red Cross for using the first generation antibody testing that was used from 1990 until 1991 and the suggestion that it should have been using a different and less imperfect test. What opportunity was there for the Red Cross to use a different test?

Dr Wylie—None.

Senator HUMPHRIES—So you had only one test that you could have used.

Dr Wylie—In February 1990 there was only one test from one company available and ready to roll to the Australian blood banking community on that date. I guess it is an interesting historical fact that we had thought there would be a choice of two but the other company was not able to get its product satisfactorily to market so we were left with a single choice as at February 1990.

Senator HUMPHRIES—Was that true of the second generation test as well that came in in 1991?

Dr Wylie—No, by the time the successive generations of tests came along there were a number of providers in the market. The salient point there is that the Australian Red Cross Blood Service will use the best test available to it but it can only use those tests which have been assessed by the national reference laboratory and registered by the Therapeutic Goods Administration as marketable in Australia. That is what limits our choice.

Senator HUMPHRIES—Can I go back to the sort of decentralised approach that was taken by the Red Cross to making decisions about whether to adopt a surrogate testing model from the mid-1980s onwards. You said that state and territory branches of the Red Cross were able to make their own decisions about that. You also said that state and territory governments were involved in decisions made by the different divisions because they were the funding agents of those divisions. Do you know if any state or territory governments were involved in the decisions in around 1987 or so about whether to respectively introduce or not introduce surrogate testing?

Dr Wylie—State and territory governments would have been informed through liaison with the blood service. They would have been aware of the debate and they would have been aware of the policy developed by the National Blood Transfusion Committee and the decision to do a study.

Senator HUMPHRIES—So, presumably, state and territory governments could have come forward and said, 'We think it is quite wrong not to have surrogate testing. We think you should do surrogate testing'—they could have put that point of view—to the Red Cross divisions.

Dr Wylie—I think in the liaison between the two organisations such a debate could have taken place, but again I would emphasise that there was no scientific evidence to point to such a position being taken.

Senator HUMPHRIES—You do not know whether there was any consultation with, or involvement by, the Queensland government in the decision to introduce surrogate testing in 1987 in that state?

Dr Wylie—I would have to take the detail of that question on notice, but it is my understanding that that would have been with the knowledge of the health department.

Senator HUMPHRIES—And with their support, do you think?

Dr Wylie—I would have to take the detail of that question on notice.

CHAIR—While you are doing that, Dr Wylie, could you also provide us with an understanding of the legal relationship between each of the divisions of the Red Cross and the state government. I am trying to understand the legal relationship between the two bodies.

Dr Wylie—We can provide information on that.

CHAIR—And across Australia. That would be useful.

Dr Wylie—Certainly.

Senator HUMPHRIES—I have one other question at this stage, which I ask with some embarrassment. It was put to us yesterday by one of the groups that a number of members of what I call this victims group had been harassed in a number of ways after they made claims against the Red Cross. That included, according to this evidence, anonymous phone calls, people being followed and mail being intercepted.

Senator KNOWLES—And medical records being removed from hospital records.

Senator HUMPHRIES—So, for the sake of completeness in the record, could you respond to that claim. Is there any basis for that claim being made in your knowledge?

Dr Wylie—I am not aware of any basis on which such a claim could be made. I have no evidence, as a senior member of the Australian Red Cross Blood Service, that anything of that nature has ever occurred. I have worked closely with the people involved in this process for a long time. I hold them in high regard—they are hardworking people trying to do the right thing in terms of the Lookback program et cetera for the benefit of the community; that is why they work for the Red Cross.

Senator HUMPHRIES—I suppose after the HIV problem being dealt with in the early part of the eighties Red Cross would have some understanding of the problem of people making claims and the emotion that goes with making claims and coming back to the Red Cross in circumstances where they feel infections might have been contracted or transmitted through Red Cross blood products.

Dr Wylie—We have come to this committee today looking for constructive solutions to move forward. We have sympathy for these people and we want them to get the best care that the health delivery system in Australia can provide.

CHAIR—That concludes today's public hearing. I would like to thank everyone for their contributions today, the Australian Red Cross Blood Service and also others who have been with us today.

Evidence was then taken in camera—

Committee adjourned at 4.33 p.m.