COMMONWEALTH OF AUSTRALIA

Official Committee Hansard

SENATE

COMMUNITY AFFAIRS REFERENCES COMMITTEE

Reference: Hepatitis C and blood supply in Australia

THURSDAY, 1 APRIL 2004

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SENATE

COMMUNITY AFFAIRS REFERENCES COMMITTEE

Thursday, 1 April 2004

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

Participating members: Senators Abetz, Allison, 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: Senators 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 the 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 3.20 p.m.

BURRELL, Professor Christopher John, Chairman, Australian Centre for Hepatitis Virology Inc.

CHAIR—I declare open this public hearing. This is the first hearing of the Senate Community Affairs References Committee inquiry into hepatitis C and blood supply in Australia. There has been a high level of interest in this inquiry, and I welcome everyone who is with us today. Our first witness is Professor Chris Burrell, who is on the telephone from Adelaide. Professor Burrell is from the Australian Centre for Hepatitis Virology.

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

Prof. Burrell—I think we could say that this story began in 1974-75, when two key publications identified a percentage of cases of hepatitis after blood transfusion not caused by hepatitis A or hepatitis B—a paper from Feinstone and a paper from Prince. These helped focus the mind of the scientific community on this additional problem that had not been solved as a result of tests for hepatitis A and B.

The condition was first recognised as jaundice or abnormal liver function tests after blood transfusion, an acute disease that appeared to resolve. It was then studied extensively from that time, and it became evident that the causative agent was not related to known viruses. There is a very extensive list of candidate agents from 1976 through to 1989 that proved to be not the cause of the condition. It was also clear that this was the commonest form of post-transfusion hepatitis in the United States, with 65 per cent to 90 per cent of cases of post-transfusion hepatitis falling into this category.

The acute disease was very mild and mostly there was no jaundice. So, unless the blood recipients were tested for liver function, it would not be evident that they had become infected. It was known that chronic infection occurred in a percentage of these, though the exact rate was not known. It was also known that some of these people remained infectious for a long time. It was also known that there was a link to chronic active hepatitis and to cirrhosis. The proportion of individuals was not known and the time frame was not known. There was still some scepticism about how significant chronic disease was in this infection.

At the same time, there was a significant amount of chronic hepatitis appearing in gastroenterology clinics, where the cause was not known—possibly auto-immune drug reactions and other causes—and it was assumed that some of these cases could be due to this infective agent, though there was no way to estimate. I actually wrote in 1992: ‘an unknown proportion of these chronic liver disease cases are likely to be due to this infective agent’. It was also possible there was more than one agent. On the basis of incubation period, there was evidence that there were perhaps two or more distinct agents..

If we look at transmission of this infection, we see that it was clearly transmitted by blood. It first became recognised because of blood transfusion. It was also known to be a problem in renal dialysis and in drug users. The extent of patient-to-patient spread through surgery and use of endoscopes was not known. There was also some suspicion of non-blood routes, but these were not defined at all. In summary, we knew that transmission was occurring continually with the use of blood. In different parts of the world, from two per cent to 20 per cent of transfusion recipients became infected with this agent. There was debate about the seriousness. The acute infection was usually minor. Persistence occurred, leading to some disease in some patients. We did not know how large the burden of disease was.

To prevent this, in theory, we expected there would be some degree of overlap between donors who were infective and donors who had had prior infection with hepatitis B. We thought that, to some extent, the transmission routes would be the same. We also thought that there would be overlap between infective donors and donors with abnormal liver function. But, again, the extent of the overlap was very difficult to get hard numbers on. The only practical way to measure this was to do cumbersome studies of post-transfusion and look at the recipients of blood. By the time these studies were completed, we were in a climate of improving the safety of blood all the time.

There was a strong move to reduce the number of units that were transfused per patient, because it was quite clear that, the fewer number of units used, the less risk each patient was at. Secondly, there was a move from commercial donors to volunteer donors. It was quite clear that the risk of transmission from commercial blood donors was five to 20 times more than the risk of transmission from volunteer donors. A lot of the initial studies of attempts to prevent this were done in populations with commercial blood donors. The third measure that came in all through the 1980s was self-exclusion of donors on their history. This was the period in the mid-1980s where blood donors were given an extensive questionnaire. Donors who admitted to risk practices self-excluded. It was also the time of the introduction of screening for HIV.

All of these measures came in sequentially from the late 1970s at different rates in different parts of the world. By the time evaluations of attempts to introduce a particular measure to lower the rate of transmission were done, there had been other measures introduced and the target was moving and improving all the time. There was also a sense that specific screening tests were around the comer and, if measures were attempted to try to reduce this a little bit, these might be supplanted by a screening test before the measures were up and running.

This is the background to the very extensive discussion about the use of surrogate markers that carried through from the late 1970s to 1990, when a specific test was introduced. The principle of the surrogate markers was that it was assumed that infective blood units for this infection—which was still known as non-A, non-B hepatitis—could partly be identified by a marker of past hepatitis B because of the presumed overlap of patient groups and, secondly, that they could also be detected by testing for abnormal liver function, because it was presumed, quite sensibly, that some liver disease in the community would be caused by this agent.

Tests for abnormal liver function were first extensively evaluated in the United States in the late 1970s and early 1980s. These tests led to evidence that, depending on the height of the abnormality of liver function, those units, if they were used, transmitted a higher percentage of non-A, non-B hepatitis. There was also evaluation of blood units positive for past infection of

hepatitis B. Again, those blood units that had antibody indicating past hepatitis B had a twofold to 2½-fold increased rate of transmission of non-A, non-B compared to blood units that did not have past evidence. So there was some foundation for looking at these markers as a way to identify a fraction of the infective units.

How this led to policy is that in the United States the blood banks adopted screening for liver function—ALT screening—and also anticore screening, which is the test for hepatitis B, on the basis of the types of studies I have talked about and some anecdotal evidence of significant liver disease occurring in some patients after they had acquired this post-transfusion hepatitis B. There was a lot of discussion and ambiguity about what percentage of these patients actually developed trouble, which has only become clarified in the last five years, really.

An opinion that was quite influential was an opinion of Harvey Alter, who agreed with the policy of the United States blood banks but stressed that it was a predicted efficacy, it was not proven and it needed further study to properly demonstrate if these measures were truly indicated or not. At the same time, the FDA never proceeded to the point of requiring tests for liver function. This was a voluntary move by the United States blood banks, not by the FDA. This was also based on evidence from the United States where the rate of post-transfusion hepatitis was 10 per cent or more of transfusion recipients. Some of the centres still had commercial donors. It was a high rate and emphasised the unreliability of extrapolating from one region of the world to another.

The first solid piece of information we had in Australia was a study of cardiac surgery patients after blood transfusion done by Yvonne Cossart in 1982. All the blood donors were volunteer donors. She found that two per cent acquired post-transfusion hepatitis compared to the 10-plus per cent occurring in the United States. During the 1980s we then introduced HIV screening and donor exclusion in 1984-85, and this reduced our rate measured of non-A, non-B to 1.1 per cent in 1987 to 1990. In Australia we were able to drop the rate from two per cent to 1.1 per cent, based on these two studies. At the same time, the Americans were succeeding in reducing it from 10 per cent to six per cent of their recipients. So, clearly, the problem was smaller in Australia. With respect to the gains that were estimated to have been achieved in the United States—but it was not proven that they were the cause—to bring the rate from 10 per cent to six per cent, we had already brought the rate down from two per cent to 1.1 per cent, and there was no way of knowing whether the measures that were assumed to be responsible in the States would play that same kind of role in reducing our incidence even further.

Looking at what we know now, since the advent of specific testing for hepatitis C, we have been able to pin down much more clearly the true sequelae of this infection. I am sure the committee has seen papers that have been published which have outlined these sequelae. We now have fairly reliable information, based on a lot of difficult studies, that, maybe in 65 per cent to 85 per cent of those who acquire acute hepatitis C, the infection persists and maybe 10 per cent to 20 per cent of such infections will progress to chronic hepatitis or cirrhosis after 20 to 40 years. We also have a much better idea of the prevalence of hepatitis C infection in different community groups. The extent of infection has been really surprising. I think people in the 1970s and 1980s would not have imagined the extent of infection that has been shown by these tests. This is largely because, with most infections being very mild or asymptomatic, the true pool of infected people in the community could be picked up only by those who had disease. We now have a much better handle on that.

With respect to the issue of surrogate tests for blood donations in Australia, I do not have all the information on the discussions that went on there. There was a very good series of international symposia on hepatitis every three years from the 1970s to the present time. These volumes are a very good source of discussion of what people were thinking at the time and how they were arguing. It is quite informative to leaf back through these volumes to read the arguments for and against different measures to try to reduce the rate of infection. I know there is a large number of Australians who go to these conferences who would have been aware of all of this knowledge at the time.

As I am sure you know, some surrogate testing was introduced in Australia in Queensland. There is a publication in the 1990 symposium where the correlation is drawn between the extent of abnormal liver function and the percentage of blood units with abnormal liver function that were subsequently shown to be positive for hepatitis C. As you would expect, there is a correlation. The higher the liver function abnormality, the higher the percentage of units that were positive for anti-hepatitis C and would then have been withdrawn once we had the specific test. These still contributed a minor percentage of the total number of infective units that would have gone through.

Armed with this knowledge, in retrospect, we would seriously have had to weigh up the risks and benefits, but here was a clearly measured number of cases that could have been prevented. Prior to that, everybody was working in the dark. People were working on hunches. The virus had not been seen and there was no way to identify with any reliability people who were infected. People just had to act according to the best information at the time, on which there was a significant degree of disagreement around the world.

CHAIR—That has been a very good introduction, and it has given us a good overview of the history, which I think is very important to this inquiry. I have a question that goes to item 7 in your submission. You talk about first generation tests being used and you say, 'there was reservation about the true diagnostic accuracy of a single result in an individual patient' and there were 'false positive and false negative results'. That was in the first generation tests that occurred around 1990. Is that correct?

Prof. Burrell—That is correct.

CHAIR—Can you explain that a little more for us, please?

Prof. Burrell—The first screening test used used a very small area of the antigens of the virus and the technology was not as good at dealing with cross-reactions or non-specific binding patients antibody. So some patients in whom the antibodies that had developed did not happen to match up with the narrow range of antigens in the test would have had true antibody but it would not have come up in the test, and that would have given a false negative result. Then there would be other patients in whom the screening test would give a positive reaction. The reason would not be that they had the hep C antibody; the reason would be that they had some other kind of reactivity, that the plasma was sticky or some other unrelated reason.

The first generation of tests had some problems like this. The second and third generation tests improved the range of antibodies they could detect. They detected closer to 100 per cent of the true infections and they got much better at avoiding the false positive reactions. But the problem

with all of this is to know what yardstick to use. Early on we did not really have any other yardstick. Subsequently, what has become more and more available is a means to detect the virus rather than the antibody. The presence of the antibody usually would be a reflection that the patient had been infected. If infection invariably leads to persistence, as it does with HIV, you can take the presence of antibody as proving the patient is now infected. But, with hepatitis C, we believe that only 65 per cent to 85 per cent of people with antibody are truly infected still and the rest have their antibody but have cleared the virus.

More and more, we have used the PCR test for the RNA of the virus itself to pick out those people who are truly carrying the virus. There are still problems with that test because that only has a certain sensitivity and, if a patient has a fluctuating level of virus, there may be times when the level goes under the sensitivity level and then comes up again. So they may appear negative and then be positive a week later.

There has been a lot made about the inaccuracy of the first generation tests. I do not have the percentages in front of me as to what we think their performance was compared to the best standard now, but I am fairly sure that even the first generation tests would have been well in the range of 75 per cent to 95 per cent reliable compared to what we have got now, which is just an extraordinarily large improvement on anything that surrogate markers were attempting to do. The introduction of the first generation test in 1990 was an absolute watershed, moving from being in the dark blindfolded to having a fairly reliable window on what was going on.

CHAIR—How long did we use the first generation test before tests detecting the virus were implemented?

Prof. Burrell—I think we carried on the first generation antibody test till about '92 and the second generation maybe till about '93 or '94. Then we continued on with the third generation antibody tests, which were carried right through. Then we introduced nucleic acid testing—which is a test for the virus itself—in blood screening several years ago. I do not have the exact date. That was almost a belt and braces decision, because the calculated number of infective units that escaped through the third generation antibody was really very small. I have the figures somewhere. It is something like one in 200,000 or one in 500,000 that would have escaped through the third generation antibody. But then, moving to the nucleic acid test—the PCR test—we got even better at that.

Senator HUMPHRIES—Professor Burrell, I would like to clarify a couple of things. You said that in some people the virus persists—I think that was the word you used—but for other people the virus is sort of flushed out or effectively disappears.

Prof. Burrell—That is correct, yes.

Senator HUMPHRIES—Is it the case that it fully disappears, or is it possible that it is simply at a level in the body that cannot be picked up by testing?

Prof. Burrell—It is very hard to be absolutely sure, but you might have a patient who has antibody and who shows the virus and then the virus is undetectable, and you can repeatedly test that patient over years and never find evidence of the virus. Then their antibody begins to decline, suggesting that there is not the continued presence of the antigen to keep that antibody

there. That is the kind of evidence that makes us treat that individual as having cleared the infection. We could never say that there is not one virus particle lurking somewhere in the bone marrow or somewhere in some unsuspected organ but, if we observe the patient like that over a period of years, we do not ever find the virus and their presence of antibody starts decaying with time, then we can treat that patient as though the virus has cleared—and it probably has.

Senator HUMPHRIES—I ask you to explain the very last point that you make in your submission on the last page after (ii). I am not quite sure what you mean by what you say there. Are you suggesting that there is a different standard at work today in the community that would have led, had this problem occurred today, to a demand for tests like the surrogate testing you talked about before to be put in place, whereas a different level of tolerance—you put it as 'society's tolerance of risk'—in the late eighties and early nineties led to a different preparedness to accept that test?

Prof. Burrell—That is a very interesting point. I think the history starts with the observed rate of 10 to 15 per cent or more of all transfusion recipients becoming infected in the 1970s in the States, and then measures were introduced to get this down to six per cent of all recipients. People knew this was occurring quite frequently. There was no firm evidence to suggest that it was causing serious incapacity to the majority of people who became infected.

Some of the measures that were talked about, for example, would reduce the transmission. There was one study in the States that looked at the role of screening for hepatitis B core. In this particular study, 5.6 per cent of people were becoming infected. The calculation was made that, if they screened for anticore as well, they would drop this by 0.4 per cent to 5.2 per cent. People had to accept the fact that around five per cent were becoming infected. There was absolutely nothing we could do about it. One measure to drop that from 5.6 to 5.2 would have been weighed in a cost-benefit situation. In the present time, where we have very low rates of transmission and a very high level of community expectation and community indignation if someone becomes infected through blood transfusion, I think the arguments would be weighted a bit differently. Have I explained that?

Senator HUMPHRIES—Yes, you have. Could I clarify it? You are saying that one of the factors that led to the approach taken at the time was that there was a lesser understanding of the effect of hepatitis C.

Prof. Burrell—Yes.

Senator HUMPHRIES—People did not realise it was going to lead to permanent liver damage, at that stage. Is that what you are saying?

Prof. Burrell—Yes. The proportion of people in whom it might lead to permanent liver damage was just not known at all. There had been some studies looking at a group of 20 people—that sort of number—who had developed infection by blood transfusion, and two or three of those might have gone on to cirrhosis over a period, but one would never know what that meant on a large scale and whether there were other factors. Because we did not seem to be seeing a large amount of unexplained liver disease in the community that could be due to this, it was not clear in any way that this was as extensive a problem as we now recognise.

There was also the real uncertainty of working in the dark with these markers that may indicate a number of infectious people and may not. We had no easy way to test it. We really could not be sure in any way whether we could extrapolate from a country with a 10 to 12 per cent rate of post-transfusion hepatitis—with commercial donors, with different policies on HIV, with different numbers of drug users in the community and with different questionnaires in the Red Cross—to a country like Australia, which had much lower rates before we started because of the way that the blood transfusion service was run and had then been particularly rigorous in the mid-1980s in the policy of donor exclusion and the screening for HIV. So to some extent it was really not at all clear whether Australia had already made all the gains that the Americans needed to make by using the approach of surrogate testing. That is just one argument that was going around.

Senator HUMPHRIES—Thank you for that.

Senator HUTCHINS—Professor Burrell, you said there were a lot of symposia on the debate about surrogate testing.

Prof. Burrell—Yes.

Senator HUTCHINS—There must have been a lot of debate about it. The debate in the 1980s would have been difficult and controversial.

Prof. Burrell—Yes. At each of these triennial symposia there is a section on non-A, non-B hepatitis. A lot of it is filled with the frustrating attempts to find a virus. This field was a graveyard of many virologists' academic careers because of all the failures that went on. But also in this there are debates looking at the benefits of ALT screening and anticore screening in different populations and some discussion and analysis of what it all meant. That record is quite a useful source.

Senator HUTCHINS—In some form or another, non-A, non-B was recognised in the seventies, wasn't it?

Prof. Burrell—Yes, absolutely.

Senator HUTCHINS—As AIDS developed, it was something out there that could not be identified and named until 1989, wasn't it?

Prof. Burrell—That is correct. In the 1970s, it was not even clear how much this was just an artefact of blood transfusion—if we did not do blood transfusion, did the disease actually exist? It only became evident later just how much it is maintained in drug users.

Senator HUTCHINS—I have read some minutes of a meeting that the American Red Cross held in January 1981 where they specifically discussed how to deal with non-A, non-B. It would appear that that starts the debate in North America. Would that be a correct view?

Prof. Burrell—I think that is right. There were some transfusion-transmitted virus studies that Blaine Hollinger and others got going in the 1970s. That was partly in response to the hep B screening and also the identification of non-A, non-B in 1974 and 1975. It was about 1980 that a

lot of these started to come to fruition. There were some presentations from Hollinger, AACH and one or two other people in the 1981 symposium, where they looked at a lot of this information. So I think that is right: that is the time when this first got quite a detailed analysis in North America. This was the time Yvonne Cossart did her study of cardiac surgery patients in Sydney to try to get some local data. Our data showed that there was at least a five times lower rate of transmission.

Senator HUTCHINS—There are a number of factors for that, which you mentioned in your presentation. During that period in North America, there was correspondence between various individuals that they should prepare to introduce surrogate testing and then it did not occur. This debate went on, as you said, throughout the world, and it was difficult and controversial. In your recollection, when did we first start to identify a problem and sit down and discuss it in whatever form?

Prof. Burrell—I cannot really answer that because I was not involved in the blood transfusion area specifically at that point. I know that prior to the Cossart study we assumed there would be something like the American findings here. I was not quite exact in my submission in saying that the Cossart study was consistent with overseas studies. In fact, the Cossart study indicated that, during the same period, our rate of this infection being transmitted appeared to be quite a bit lower than the North American rate. I would assume that, with that first evidence, the Australian debates would have started at about the same time as the American ones.

Senator HUTCHINS—I suppose the major factor in that is that we still have volunteer donors, as opposed to people who get paid for it.

Prof. Burrell—Yes. We were also generally trying to use less blood per patient. I do not know how much of a difference there was between us and the United States at that point, but certainly it has been recognised that fewer blood units is a way to reduce the risk quite substantially.

Senator HUTCHINS—I imagine that, at the same time, AIDS was having a significant impact on using blood as well.

Prof. Burrell—I do not know about that. I think the principle of less blood was very strong, even independently of HIV. There is a wonderful quotation by Bob Beale, who was the director of the South Australian blood transfusion service, that a blood transfusion should be treated like marriage: it should not be entered into wantonly, unadvisedly or without proper caution and it should be entered into as infrequently as possible. I think he made the comment in the 1970s that you should try to reduce the number of blood units.

Senator HUTCHINS—You mentioned disagreements about surrogate testing. Do you recall the for and against debate on surrogate testing in Australia?

Prof. Burrell—I do not have specific memories of the arguments that were raised in Australia either for or against. I know that the general sorts of arguments that were raised against it related to the blunt nature of it—that, if you withdrew, say, 2½ per cent of the blood donations, you would need to make those up from other donors or you would possibly have supply shortages. It was the cost and the tooling up versus the uncertain number of true infections that you might prevent by doing that.

Senator HUTCHINS—Was it a situation where, if you did this screening, testing, surrogate testing or whatever, you would probably pick up a number of people who would test positive, but they were not necessarily going to infect people with their blood?

Prof. Burrell—That is absolutely true. An example is the anticore screen for hepatitis B. Two studies were done on that in North America and one was done in Germany. The results were that 14 per cent of the blood units containing anticore—past hepatitis B infection—would transmit non-A, non-B, and 5.6 per cent of the blood that was negative for anticore would transmit infection. So only 14 per cent of even the anticore positive samples would be infectious, and 5.6 per cent of the anticore negative ones would still transmit.

If you then multiply that percentage difference by the relative numbers of each, you find that about 97 per cent would be anticore negative and three per cent would be anticore positive. Then the actual number of transmissions you would stop would be a very small fraction of the total still occurring. By that calculation, introducing anticore screening would prevent 0.4 per cent of recipients receiving blood, but 5.2 per cent would still become infected from the anticore negative units. That very slight difference and the crudeness of it would have made people wonder whether the numbers were actually right and whether the gain was really significant in the overall scheme of things. I imagine that that is the kind of argument that would have been used, although I do not recall the spokesmen for and against in Australia.

Senator HUTCHINS—Fair enough. Some of the submissions we have read have suggested that, if this type of screening or testing had occurred, a number of people would not have transmitted this disease to people through their blood because they would have been deferred from donating ever again.

Prof. Burrell—Yes.

Senator HUTCHINS—That was one of the concerns of people at that stage.

Prof. Burrell—Absolutely, yes.

Senator HUTCHINS—One would have to conclude then that whoever they were made calculated risks on these transmissions.

Prof. Burrell—I guess what we are talking about is based on the American data, preventing a small fraction of the total donating population at the expense of losing two or three per cent of all the donated blood and wiping out those donors. In the Australian situation we did not have anything like the same prospective data at all. We had two studies from Sydney. The other study that I am aware of, apart from Cathy Hyland's, was done after hepatitis C testing become available. It then became possible, for the first time, to measure exactly what might have been achieved by it. Prior to that it was very hard in Australia because our situation looked different and, as I said, we may have already made the gains that the Americans were showing might be done. It is possible that we had already made these gains through the other measures we were using. We might not have gained anything at all. I think that is an important point: there was not any real basis for extrapolating American figures to Australia and dividing by five and saying it must be the same.

Senator HUTCHINS—You mentioned Dr Hyland. Queensland introduced surrogate testing two years before the rest of Australia, didn't it?

Prof. Burrell—Yes, that is right.

Senator HUTCHINS—It was based on her work, the name of which I forget but which is mentioned in the Department of Health and Ageing's submission, that it was contested or that she contested it.

Prof. Burrell—I have not seen the case that Cathy used in 1987 or 1988 to introduce it, but I have seen her publication in 1990 when she was able to look at the types of units they were excluding and test them specifically for hep C. That makes interesting reading because, as you would expect, it shows that the units with abnormal liver function had a higher percentage of the hepatitis C antibody. But I have not read the case that she, or whoever, used in 1988. I do not quite know what the arguments were.

Senator HUTCHINS—I have one final question. When I talked about risk earlier, the Haemophilia Foundation Australia submission quotes a judgment made by Mr Justice Krever from Canada, where he says that hepatitis C was 'seen as a manageable complication of effective haemophilia treatment'. I suppose haemophiliacs had less chance than anybody else in getting non-A, non-B hepatitis transmitted to them in that period, by whatever means they had the blood or blood product, didn't they?

Prof. Burrell—There has always been a problem with haemophiliacs that the product they receive is made from pools, and the larger the pool, the more risk there is that there will be infected units included in that. There is also the difference of heat treatments and various other measures available that have been used to try and activate viruses from their products. But, again, I am not sure how the debate would have gone in relation to haemophiliacs.

Senator KNOWLES—Thank you very much for a very comprehensive submission. I really only have one question for you: what do you believe is the current risk of infection from whole blood or blood products today?

Prof. Burrell—I have got some figures on this. There is some very good work from people in the TGA and the National Reference Laboratory. I actually used this in a lecture but I do not have it in front of me at the moment. For the three major transmissible agents—hepatitis B, hepatitis C and HIV—in Australia, from memory, the figures are extraordinarily good. I think for HIV it is one in two million or one in five million—or something like that. For hepatitis B and hepatitis C it is a bit more often. I could send the table but I just cannot remember the numbers.

Senator KNOWLES—Would you be able to provide that to the committee in due course, Professor?

Prof. Burrell—Yes, I could send that. It is dated. It has been derived from TGA, I think, who have looked at this quite well, but I could certainly send that.

Senator KNOWLES—Thank you very much, Professor.

Senator MOORE—I only have one question and it is to do with the role of people who actually have contracted the disease. Your paper has said that over the last 30 years there have been various researching processes and meetings looking at this issue. From your point of view and observation, when did people who actually have the disease begin to be public in the process and start having their voice heard in the various debates about what should happen?

Prof. Burrell—Not really until the specific testing was introduced. Prior to that it was diagnosis by exclusion and we really had no idea of the size of the burden. But fairly quickly in the early 1990s this became apparent. I was involved in the South Australian Health Commission from '96 to '98 and by that time the community groups were well formed. There was an enormous problem in the fact that patients with hepatitis C were not succeeding in mobilising the support that HIV patients had succeeded in mobilising a decade earlier. Hepatitis C patients, quite rightly, felt that this was not getting the attention that it should. In answer to your question about the timing, I do not think there was much awareness in community groups prior to 1990 but, from my experience, by 1995 there was quite a lot of awareness.

Senator MOORE—I read in your submission that the focus of your organisation is very much on research and giving advice to the process. Has the growing awareness within the community and also in the wider group had any impact on the success of getting research and advice to different places heard more effectively?

Prof. Burrell—That is a very long and good question. It is improving all the time. I think that the community support groups and the government support groups for HIV have been excellent from '85-86 onwards. Early on with hepatitis C in the 1990s it was quite an uphill battle, partly because people did not quite know what to do and there were not the appropriate structures. It has very much helped since hepatitis C has come under the umbrella of the old ANCARD, which has now been reformulated, as you know. I think that it has been slower than we would have liked to have seen in terms of gaining community support but the government structures are improving all the time.

As far as research support goes, again, it has been very slow and the funding for basic research for hepatitis C has come from NHMRC and conventional sources like that. It has been hard to get enough good people into the field to have the kind of success rate that we would have liked to have seen in NHMRC. In the case of HIV this was done with some pump priming, establishment of the HIV national centres and that sort of thing, and this has been slower to happen with hepatitis C. It is happening with inclusion of hepatitis C in the current structure of national centres. I would have liked to have seen it happen faster. I would have also liked to see more awareness of hepatitis B, which is still numerically a very large infection in Australia and a very large infection globally. It has never had anything like the same awareness. I could talk all day about this, but it is probably not the time.

CHAIR—Senator Knowles asked about the satisfaction level with the quality of testing that they are currently using. Are we also able to ascertain levels of hepatitis C in blood that might have been donated through all levels and all stages of the disease? I think that you referred to it earlier but, in terms of testing now using current testing methodology, are we able to ascertain levels of hepatitis C in blood?

Prof. Burrell—This is an area that has had a lot of attention. As you know, there is a window period after the time a patient becomes infected before a particular marker becomes positive. If the marker you use is antibody then there is a discrete period—eight to 12 weeks often—before the antibody becomes positive, and the patient may be infectious before that. When you go to nucleic acid testing the patient is identified earlier so that window gets shortened. The window period between becoming infectious and becoming detectable is a lot shorter. These have all been calculated for the different infections.

There has been a lot made of this window period and I think it has been overplayed. The actual number of new infections is extremely low in the clean-living population of donors, who are not allowed to inject drugs or anything. If we are looking at shortening the window period by a week and a half in the life of an infected person, it is numerically very small. But it has gained a lot of attention, and obviously there is the potential for a case to slip through. That is the basis of the calculations now on how many infective units may still get through the current screening process.

In a way I do think with safety records of one in half one million or one in one million donations, depending on the virus, that needs to be put into perspective against the risk of an anaesthetic, the risk of complications from routine surgical procedures and all the other types of medical risks that people undergo where people accept that a certain procedure may carry a half a per cent risk of a complication. In the case of blood transfusion, the risk of one complication in half a million is a different order of figure. You could perhaps argue that a different standard is being applied to blood transfusion as opposed to a lot of other accepted medical practices. Obviously we can debate that, but a part of this is the community perception that there is a very high indignation rate—and you can understand why—if someone becomes infected by a blood transfusion. If someone has complications from other accepted medical procedures, the indignation factor is not as great sometimes.

CHAIR—Thank you, Professor Burrell. From Senator Knowles' question, could you provide us with those current rates? They would be very useful to the committee. It is always very hard to go first in any inquiry, and your evidence has been very useful to us. Thank you very much.

[4.19 p.m.]

PATERSON, Ms Kerry, National Strategic Development Officer, Australian Hepatitis Council

CHAIR—Welcome. Information on parliamentary privilege and the protection of witnesses and evidence has been provided to you. The committee prefers all evidence to be heard in public, but evidence may be taken in camera if you think that certain evidence should be of a confidential nature. We have before us your submission. Thank you very much for that. It is a very good submission. I invite you to make an opening presentation, and we will follow that with questions.

Ms Paterson—The Australian Hepatitis Council is a national community based organisation representing the interests of people with hepatitis C through our member organisations: the state and territory hepatitis councils. Hepatitis councils began to be formed in the early 1990s by people with hepatitis C and interested health care workers who were concerned about the lack of information and support available for people infected with the virus. Hepatitis councils are now established in each jurisdiction and provide a range of information and support services for all people with and affected by hepatitis C. They also provide hepatitis C education services for health and community workers and the general community.

The membership base of hepatitis councils is predominantly people with or affected by hepatitis C, and people with hepatitis C are involved on the boards of management and in the range of services provided by the councils. The Australian Hepatitis Council and our members work in partnership with a range of community based agencies, the medical community, researchers and all levels of government. Our organisations form a fundamental part of the national partnership response to hepatitis C.

In responding to the terms of reference for this inquiry, the Australian Hepatitis Council will address those terms of reference where we have specific expertise. While the Australian Hepatitis Council support the principle that, where negligence is established by proper legal process, compensation for that negligence should be made available to those individuals who have been harmed, we do not have the expertise or the resources to offer an informed view about negligence in this matter. Thus our focus is on the final two terms of reference, which concern the impact of hepatitis C and the services needed to improve outcomes.

I would like to highlight that the Australian Hepatitis Council and our members advocate that governments should recognise and address the needs of all people with hepatitis C, regardless of mode of infection, and to improve the prevention, care, treatment and support services for all people affected. It is our experience that there is little difference in the impact of hepatitis C on people's lives, or the services needed to address these impacts, according to how hepatitis C infection is acquired.

Hepatitis C is Australia's most commonly notifiable infection. Approximately 242,000 Australians are currently infected and an additional 16,000 people are estimated to be infected annually. Up to 75 per cent of the people infected with hepatitis C experience the virus as a long-

term, chronic condition that can have substantial impacts on their health and quality of life. Hepatitis C has a slow disease progression and physically affects people differently. There is little evidence that the natural history or disease outcomes of hepatitis C infection differ as a result of mode of transmission.

Some people with hepatitis C will remain healthy; some will develop liver disease, with a small percentage developing liver cancer and liver failure; and some will develop debilitating physical symptoms, such as lethargy, nausea, abdominal discomfort, sleep disturbance, joint pain and liver pain. The most common psychological symptoms reported by people with hepatitis C are depression, mood swings, panic attacks, confusion and memory loss. Dealing with the physical impacts of hepatitis C of debilitating symptoms and serious liver disease can devastate many people's lives in terms of their capacity to work and to participate in family life and social activities.

The other major impact that all people with hepatitis C have to deal with is the stigma associated with the virus. Discrimination against people with hepatitis C remains pervasive in our community. The most commonly reported context for discrimination is the health care system, which is not surprising, as this is where most people with hepatitis C disclose their status. Discrimination is also commonly reported in the workplace and it occurs in many other areas of public life. Many people have experienced rejection by family and friends following disclosure of their hepatitis C infection. For people with hepatitis C who have experienced stigma and discrimination, there is a sense of alienation from the rest of the community, and this can lead to social isolation and a lack of adequate support in managing their condition, as they are reluctant to access health care services or talk to family and friends about their concerns related to hepatitis C.

Given the stigma related to hepatitis C among the broader community, it is vital to avoid reinforcing notions of stigma about mode of infection by providing equitable and nondiscriminatory services to the diverse range of people affected by hepatitis C. The first National Hepatitis C Strategy launched in 2000 identified three priority areas for action to address the needs of all people with hepatitis C: treatment; health maintenance care and support; and preventing discrimination and reducing stigma and isolation. People with hepatitis C need: access to correct current information so that they can make informed choices about their health; access to supportive, non-judgmental health care services to assist them to manage the physical and psychological impacts of hepatitis C; and access to the best available treatments to give them the optimal chance of clearing the virus, as well as a society that is much better informed and less fearful about hepatitis C. Obviously, there are many challenges in achieving these outcomes.

The National Hepatitis C Strategy was reviewed in October 2002. The review concluded that the strategy has established a good foundation for action for the development of good collaborative partnerships at all levels within the sector and has raised awareness of hepatitis C as a serious public health concern, but that implementation was largely constrained by insufficient resourcing, absence of an implementation plan and performance indicators and governance structures that have not allowed hepatitis C to attract sufficient public attention or resources.

In conclusion, I would like to acknowledge that for the Australian Hepatitis Council, whose role it is to advocate for the interests of all people with hepatitis C, the issue of compensation for people who have acquired hepatitis C infection via the blood supply is highly emotive and divisive. While not denying the right of people to seek compensation, the Australian Hepatitis Council is greatly concerned that this approach—which divides those infected with hepatitis C into innocent victims deserving of compensation and the rest, who, by default, are undeserving—only serves to feed the stigma and discrimination that is felt by all who are infected with hepatitis C.

Senator LEES—Thank you very much for your submission. In the submission, you talk about the lack of knowledge in or understanding by the medical profession. Is there anything that your organisation is able to do? Are there any education processes or support for particularly those doctors who are likely to have patients who have hepatitis C?

Ms Paterson—Yes, particularly through our hepatitis councils. The Australian Hepatitis Council provides national resources and nationally consistent information on hepatitis C. We are specifically there to assist people with hepatitis C. There are other organisations that have specific projects around education for GPs, and we also work with those organisations on that. Hepatitis councils do a lot of work with general practitioners around improving the knowledge. A lot of hepatitis councils keep GP-friendly lists, so they try to have available those doctors who have got a good knowledge about hepatitis C and who are willing to see people with hepatitis C and deal with those issues.

Senator LEES—Excuse my ignorance, but is this issue handled in medical school and training? Wouldn't it be a normal part of a doctor's education to recognise hepatitis C and understand the risks, as well as support those who have hepatitis C?

Ms Paterson—I think it is getting a lot more attention at the moment in medical schools. We would probably still say not enough, particularly in terms of the broader aspects around hepatitis C—around the discrimination areas. You have to realise that there are a lot of doctors who did their training a long time ago. Doctors, like anyone, reflect community values, and there has been general misinformation about hepatitis C. Certainly, a lot of work on the Hepatitis Council phone lines is around correcting misinformation that people have. There are a number of horror stories about what people have been advised in terms of getting a diagnosis. So there are still very poor practices around pre and post test counselling for people with hepatitis C when they are diagnosed.

Senator LEES—You mentioned in your submission and just now that there are about 16,000 new infections annually. What are the most common causes of infection now?

Ms Paterson—The most common cause in Australia now is unsafe injecting practices. A lot of younger people are being infected at the moment. They are typically those people more at risk of those kinds of behaviours.

Senator KNOWLES—I am interested in your statement in both your written and oral submission that people, regardless of the way in which they contracted hepatitis C, should be able to claim compensation. Is that what you said?

Ms Paterson—No, that is not.

Senator KNOWLES—I wanted to clarify that. That is the way I interpreted what you said. Is that correct or not?

Ms Paterson—No, it is not correct. I was saying that I can understand why people would seek compensation for acquiring hepatitis C in this way and that, in terms of our role at the Australian Hepatitis Council, it can be quite divisive. We represent the interests of all people with hepatitis C. Because discrimination is such a huge issue, the way this is played out—particularly in the media—feeds the discrimination that occurs around hepatitis C. People perceive that you are a poor, innocent person if you got it through the blood supply, whereas there are a whole range of ways people have contracted hepatitis C. Therefore, the blame goes back to the individual, even for those people who, at the time they were injecting drugs and were infected, knew nothing about hepatitis C. How can we say that they were guilty when they knew nothing about it?

Senator KNOWLES—But that could be argued for a whole range of illnesses where one puts oneself at risk.

Ms Paterson—Yes, it could be.

Senator KNOWLES—Thank you for clarifying that. Be that as it may, how would you overcome that discrimination? How would you propose that it be overcome as a barrier?

Ms Paterson—If good services were provided to everyone, people would feel less aggrieved when dealing with the impacts of hepatitis C in their lives. Treatments are a lot better now. I feel that even people who have acquired it through the blood supply still suffer discrimination. Discrimination is a huge issue with this condition, whereas it may not be with other conditions.

Senator KNOWLES—You say that good service should be provided to everyone—I do not think you would get an argument from anyone on that—but I am a little unsure as to how you see the service provision being able to discriminate against those who have acquired it one way or the other. That is where I am a little unclear. Is there a situation where someone—or collective people—is sitting in judgment and saying, 'You got it that way, so you're okay; you got it that way, so you're not'? That seems a little far-fetched in this day and age.

Ms Paterson—Unfortunately, it is not. I did a national needs assessment of people with hepatitis C last year. Certainly a lot of people said that when they go into hospital the main question they are asked is, 'How did you get it?' not 'What do we need to do to look after your health?' There seems to be quite an interest in how a person got it, whereas it is much more important in terms of how you manage hepatitis C to know when you got it so you can have a look at disease progression and where someone is up to with hepatitis C. It is not far-fetched at all, in my view.

Senator KNOWLES—When someone has established how they got it, what discrimination in their treatment are they reporting to you?

Ms Paterson—There is a focus of: 'This is for people who may have injected 20 years ago, so it is no longer now part of their lifestyle.' It affects all people with hepatitis C. It seems as though

people are more interested in the fact that they may have been involved in illegal behaviour than the fact that they may be now quite ill from hepatitis C—whether they acquired it through the blood supply or whether they acquired it through what is commonly associated with hepatitis C, which is injecting drug use. Does that answer your question? I am sorry—I do not know if I missed your point.

Senator KNOWLES—No. I am trying to flesh out what is different in the treatment of people. Regardless of how they get hepatitis C, is there a difference in the way in which people are treated? Once all those million questions of 'How did you get it?' and everything else have been gone through, is there a discernible prejudicial difference in the way in which people receive their treatment?

Ms Paterson—If you are talking about pharmaceutical treatment, that now occurs in liver units and most people who are involved in those units are very well aware of the discrimination issues and take them into account. Therefore, the people who I guess are attracted to that kind of work are quite nondiscriminatory in the way they deal with these issues. However, if you are talking about health care and maintenance for people who might just go along to their GP or who, say, have to go into hospital for some other reason and somehow their hepatitis C status is disclosed, there have been many reports that those people have been treated differently. People get a sense that they are being treated differently, that people are backing off from them. I am not explaining that terribly well, I am sorry.

Senator KNOWLES—I know where you are coming from. I am just not sure that we are getting to where I am trying to get to, if you understand, and that is the actual treatment. The perception of an individual is one thing that is harmful to that individual, but I suppose the reality of the treatment is where I am trying to get to. While one might perceive they are being discriminated against because of the way in which they were infected, what is the reality of the difference in the administering of the actual treatment, whether it be in hospitals or by psychologists, psychiatrists, pharmacists or by whomever it might be that they come in contact with?

Ms Paterson—If the treatment in the hospitals and in the liver units is actually about hepatitis C, that last statement I made goes for that. One of the big issues is that, if you have a negative experience within the hospital system or when you are first diagnosed by your GP, it actually discourages you from going back. So I guess an issue is that you may not actually seek treatment and you may not seek to have your condition monitored well, because you do not like being treated in that kind of negative way. I think that has quite an impact for a number of people, particularly people from marginalised groups who are affected by hepatitis C. They traditionally do not access health care services well, so again they do not access them around these issues too.

Senator KNOWLES—I would have thought it was a breach of the Hippocratic oath if people are administering a treatment one way to one person and in a different or inferior way to another. That is why I am trying to get to the bottom of that and being a little bit pedantic. I hope you do not take offence to it, because I think that it is a very important question. I just do not know how it is manifested, that is all.

Senator MOORE—I am following on from Senator Knowles' question about the focus your submission gives to the discrimination that the people suffer. For the record, can you indicate the

forms that that discrimination takes? You have given an overview in the submission—and Senator Knowles has followed through on the health aspects—but you also talk about family, workplace and those areas. For the record, can you tell us about the kinds of things people have told you that are now part of their life because they have identified with hepatitis C?

Ms Paterson—I have probably talked about the things around the health care services and the problems with those. In the workplace there are certainly a number of cases where people have reported that they have been treated differently.

Senator MOORE—In terms of isolation?

Ms Paterson—Yes, very much in terms of isolation. Because people in the general community do not understand the mechanism of blood-borne virus transmission, they fear that normal social contact will lead to their being infected as well. They will do things like give them their sandwiches on a different plate or some very obvious things like that. In the workplace I am certainly aware that a whole range of things have happened, even with things like funeral services with people being able to view bodies. At a period when people are in grief, they are not allowed to view the body simply because that person had hep C. So there is a range of discrimination issues around all walks of life.

I think the issue of individuals and their family and friends is possibly one of the most difficult. Public life is one thing but, when you have trust in your family and friends, you think you have those relationships and that they will support you through thick and thin. People who end up with this diagnosis talk about family members not speaking to them; grandmothers talk about their children keeping their grandchildren away from them because they are worried about their grandchildren getting hep C. It is understandable to a certain extent because if they are not well informed they will have some fear around that.

It is interesting that a lot of people with hep C basically take on an education role that I think the health scene really should be taking on. They need to become well informed about hep C themselves before they disclose to others so they can manage other people's reactions to being told about it.

Senator MOORE—Leading on from that, you heard my question to the previous witness about the face and role of people like your organisation actually being the face of the condition. Can you give some indication of how you see that that face, or that role, has operated in Australia over the last few years and how you think it will operate into the future? In the overall discussion about the condition it is the voice of people who have it. What impact has it had or not had on the issues around research and awareness in the community?

Ms Paterson—Obviously the formation of the hepatitis councils was the first kind of organisation of the consumer voice in all of this. Our organisation has been going since '98. That voice is now being represented more at the national level. We have a representation role on a number of national committees for research and government policy—that kind of thing. That happens at the state level, as well, with hepatitis councils.

People are becoming more involved at the service delivery level. They have been involved on boards of councils. There are a number of initiatives where people are involved in the education

services within those councils, particularly around discrimination issues. I do not know if people know that there are 'positive speaker programs' where people with hep C do training in public speaking to feel more comfortable about telling their stories. They go out and tell their personal stories when the educators from the councils go out to educate health care workers about these issues. We feel that has quite an impact in terms of discrimination issues. So they are becoming more involved. Of course we would like to see people involved more and more in the response.

Senator MOORE—Is the consumer voice seen as a legitimate voice in the debate?

Ms Paterson—Certainly it is a legitimate voice. The national strategy is really based on the partnership approach and sees it as a guiding principle that the affected community is involved in the response.

Senator HUMPHRIES—I assume that the Hepatitis Council advocates for people with hepatitis A and B as well.

Ms Paterson—Yes, but really most of our work is involved with people with hepatitis C.

Senator HUMPHRIES—How many people are affected with hepatitis A and B in Australia at the present time? Do you know?

Ms Paterson—I would have to get back to you on that. I do not have those figures at the top of my head.

Senator HUMPHRIES—It would be a small number, I assume, compared with the 242,000 affected by hep C.

Ms Paterson—No, hepatitis B is a growing problem. We are hearing a lot more about it, particularly from the specialist physicians who are looking at treatment issues for people with hep B. It is certainly also an area that needs a lot more resourcing, in my view.

Senator HUMPHRIES—Do you know whether the rate of growth of hep C is a straight line, whether it is growing faster than the population or whether it is plateauing? Do you know what the trend is at the moment?

Ms Paterson—I know there are 16,000 new infections a year. I do not know that I am very good at terms—'plateauing' and all the rest of it—but to me it sounds as though it is going up at quite a significant rate. If you look at the Hepatitis C Virus Projections Working Group Report from 2002, the projections as to the number of people who may be affected in the future if current trends in injecting drug use continue are very worrying indeed.

Senator HUMPHRIES—Are you convinced that with a lot more spending on public education, particularly about unsafe practices with needles and things like that, we could reduce that rate of infection significantly?

Ms Paterson—It is not only a matter of spending more money. I think it is also about diversifying, as needed, some of the services of the needle and syringe program in order to bring down those kinds of figures. It is about the context of injecting. It is possible to inject safely but,

because of the context in which people inject and because of social policy and how we view drugs in our society, people will do it on the run and they will not take care about how they inject. In that context, the numbers will keep going up.

Senator HUTCHINS—On your web site you say that you suspect that five per cent of hepatitis C sufferers contracted the illness through blood transfusion. Is that a guesstimate or is that from facts?

Ms Paterson—It is a guesstimate, yes. It is between five and 10 per cent. I think that is fairly standard, as far as I am aware.

Senator HUTCHINS—The 16,000 a year is straight-out statistics, isn't it, irrespective of how they acquired the hepatitis C?

Ms Paterson—Yes. That would be all new infections.

Senator HUTCHINS—Overwhelmingly those infections are from people who used needles.

Ms Paterson—Yes.

Senator HUTCHINS—That does not necessarily mean that the people who use needles used them two months ago in Manuka mall or somewhere like that. Someone was telling me that a solicitor in Melbourne has written an article in the *Medical Journal of Australia* telling how, 20 years ago, she used a needle twice while she was a student and she has just been diagnosed with hepatitis C. Is that the sort of window through which people sometimes acquire this disease?

Ms Paterson—She would have acquired it 20 years ago but would not have known about it. She would not have been diagnosed until now. That is very typical of a lot of people who are diagnosed. They have actually been living with it for 15- or 20-odd years and then, suddenly, they experience symptoms or they have to have a blood test for some other reason and it comes back positive to hepatitis C. It is often quite a shock for people to have been diagnosed.

Senator HUTCHINS—So these 16,000 people are not just young people; they could be well into middle age.

Ms Paterson—The 16,000 we were referring to were new infections.

Senator MOORE—Not newly diagnosed.

Ms Paterson—Not newly diagnosed.

Senator HUTCHINS—Does that mean there are more than 16,000 people a year who could be diagnosed?

Ms Paterson—Sorry, the 16,000 is an estimate of the number of people with new infections each year.

Senator HUTCHINS—Is the figure of 242,000 accurate?

Ms Paterson—They have to be guesstimates, in a sense. I think the figure for known diagnoses to date is 130,000 or something like that—I would have to get back to you on that, too. Obviously, there are a lot of people still out there who do not know that they have hepatitis C. That is what I am saying those figures show.

Senator HUTCHINS—You talked about the capacity to work. In your experience, when people get hepatitis C, how does it affect their capacity to work?

Ms Paterson—People often talk about attacks of symptoms, where they will get severe lethargy, nausea and things like that. So it is that overwhelming fatigue that will sometimes make it difficult just to get up and start the day, let alone go to work. Once again, it is very different for different people—the disease progression is different in different people. It is those kinds of issues.

Senator HUTCHINS—Do they lose their jobs in that case?

Ms Paterson—Sometimes people give up their jobs because they cannot manage the work, yes.

Senator HUTCHINS—So you would find that a number of the people who get counselling from you are on some form of government assistance.

Ms Paterson—Yes, they would be.

Senator HUTCHINS—Are the drugs that people need to use to treat this illness covered by Medicare or the Pharmaceutical Benefits Scheme? Are they subsidised in one form or another? Are they free? Is that too broad a question?

Ms Paterson—Are you talking about pharmaceutical treatments?

Senator HUTCHINS—Yes.

Ms Paterson—S100 criteria apply, so that is covered by the Pharmaceutical Benefits Scheme. However, there are fairly strict eligibility criteria on that. Obviously, the government are trying to target those people who will go on to have serious liver disease and they are trying to target those quite expensive treatments to those people. Basically, S100 criteria mean that you have to have a fibrosis score of one or two on a scale of one to four before you can access those treatments. A lot of people would like to access treatment for reasons apart from liver disease. Also, if you are suffering debilitating symptoms you may not have a high fibrosis score but you are still suffering significant effects from having the virus.

CHAIR—Thank you very much, Ms Paterson. If you have further information you would like to provide to us, please feel encouraged to do that. I understand that you will follow the deliberations of the committee through the rest of our hearings, so please do not hesitate to give us any further information that you think would be relevant.

[4.54 p.m.]

DAVIES, Mr Philip, Deputy Secretary, Department of Health and Ageing

HORVATH, Professor John Stephen, AO, Chief Medical Officer, Department of Health and Ageing

MORAUTA, Dr Louise Helen Margaret, First Assistant Secretary, Acute Care Division, Department of Health and Ageing

SLATER, Mr Terry, National Manager, Therapeutic Goods Administration

STUART, Mr Andrew Jonathan, First Assistant Secretary, Population Health Division, Department of Health and Ageing

WITCHARD, Ms Nola, Acting Assistant Secretary, Acute Care Development Branch, Acute Care Division, Department of Health and Ageing

CHAIR—I welcome representatives from the Department of Health and Ageing. 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 such evidence is considered by you to be of a confidential nature. As you are public servants, you will not be required to answer questions on advice that you may have given in the formulation of policy or to express a personal opinion on matters of policy. We thank you for your very comprehensive submission. I now invite you to make an opening presentation to be followed by questions from the committee.

Mr Davies—I would like to make a brief opening statement on behalf of the department. I thank the committee for the opportunity to speak today. It is very clear that the issues we have been asked to address are, indeed, very complex ones. We have read and studied all the submissions to the inquiry. At the outset, we wish to acknowledge the suffering and the courage of those Australians who have acquired hepatitis C through transfused blood or blood products. It is impossible not to be moved by their stories.

You have our submission, in which we have provided information on each of the terms of reference, insofar as they are within the remit of the department. However, as we have noted, we believe that some of the terms of reference are more appropriately addressed by others. We have also attempted to provide additional assistance to the committee by supplementing our own information with expert scientific advice on technical issues from acknowledged specialists in the field. Those of us who are here today representing the department may not be able to provide full answers to all of the detailed clinical questions that the committee may wish to ask. If that is the case, I would like to suggest to the committee that the department would be happy to assist by identifying the relevant expertise from independent sources and by arranging for that to be made available to the committee at the earliest appropriate opportunity.

In considering the matters before us today we must not forget that, during the 30 years covered by the terms of reference of this inquiry, Australia has consistently had one of the safest blood supply systems in the world and that is still undoubtedly the case today. Australia can be justifiably proud of its blood system and Australians can continue to have confidence in the blood supply. The impacts of blood-borne viruses are devastating, but blood and blood products save many lives every day. By introducing as early as possible and constantly refining techniques for donor screening, blood testing and viral inactivation in plasma fractionation, Australia has been among the world leaders in maintaining its safe blood supply.

The other thing to remember is how much the whole environment has changed over the past 30 years not only in scientific knowledge and understanding but also in administrative efficiency and organisation. Indeed, our submission highlights the intense scientific debate on the nature, causes, detection and prevention of hepatitis C infection that took place in the last quarter of the 20th century. It also reveals how, frustratingly, new questions arose just when people thought they had reached certainty. In that context, it is important to note that the decisions taken in the past were based on the best available scientific evidence at the time, but even science is sometimes ambiguous. At the same time as these scientific developments, a rather uncoordinated blood system was slowly being transformed into the nationally managed system that we have today. For much of the period covered by the inquiry, crucial decisions on blood related matters were made with little or no involvement on the part of the Commonwealth government of the day. They were essentially the responsibility of state and territory based organisations.

In the seventies and eighties, each state acted with a high degree of autonomy in collecting and controlling its own blood supplies. There was, at that time, minimal central direction or regulation. The Red Cross collected and distributed blood, but that was carried out through transfusion services in each state, which made their own decisions and decided on their own procedures. At that time there were also some state blood banks, which operated outside the framework of the Red Cross system. There was a national blood transfusion committee, which could make recommendations, but it was not until 1996 that the Australian Red Cross Blood Service was created to bring a coordinated national focus to that part of the system. In addition, until the Therapeutic Goods Administration began to operate in 1991, states were also largely responsible for regulating many aspects of their blood sectors. Since that time, we have gradually developed a comprehensive and effective central regulatory system, but it was, in fact, only in 2000 that the TGA gained the power to regulate fresh blood components manufactured by the Red Cross Blood Service.

So for most, if not all, of the period under consideration by the committee, the states and territories played a central role in blood matters. State based arrangements meant that blood supplies were considered from a state based rather than a national perspective. Now, however, we have a much better coordinated national system in which the Australian government joins with the states and territories in planning, managing and funding the blood supply through the Australian Health Ministers Conference. The Jurisdictional Blood Committee, which is a subcommittee of the Australian Health Ministers Conference, sees the Commonwealth government and the states providing joint advice to ministers, and the National Blood Authority is the new key operational arm of governments within the system. The third major player in the blood sector, in addition to governments and the Red Cross, is CSL Ltd—the national producer of plasma products. CSL has been transformed from the government owned Commonwealth

Serum Laboratories into a private sector company operating on commercial lines as a fractionator of products from the plasma collected by the Red Cross.

What stands out throughout the period the committee is looking at is how well the various players did, in fact, manage to work together, albeit without a national framework, to address and handle issues which in many other countries led to major breakdowns. This professional commitment and this focus on positive outcomes for the community have allowed us to develop the new cooperative system which we have now, with all governments, the ARCBS and CSL each playing their own well-defined and well-understood role in the system.

At the same time we have also developed a more national strategic approach to dealing with hepatitis C and its consequences. Hepatitis C is a big problem for our community, and the National Hepatitis C Strategy is further evidence of the cooperation between the Australian government and the states. The strategy provides, amongst other things, funding for states to implement the services which they identify as most appropriate to the needs of those people with hepatitis C for whom they care. I would like to end by again acknowledging the distress suffered by those who have contracted hepatitis C through the blood supply and by their friends and families. That suffering makes it all the more imperative that we do everything we can to protect and maintain the mechanisms we have in place to ensure that our blood supply is as safe as we can make it.

CHAIR—Thank you, Mr Davies. As none of the other officers wish to make a comment at this time, we will go first of all to term of reference (m), which goes to the number of people that we are talking about, and to page 16 of your submission. There seems to be, across the submissions we have received, an accepted level of infection and I think these figures tend to reflect that. I want to discuss the last two dot points on page 16. Essentially what you are saying, I think, is that currently the infection rate through blood is very, very low—in fact, it is not occurring—and infection rates in other ways are diminishing. Is that because infection rates through intravenous drug use are increasing?

Mr Stuart—There are differing sources of information. I will go to the most authoritative source of information. Because hepatitis C is a notifiable disease, states and territories collect information on it. The 2003 annual surveillance report based on that information identified that the number of newly identified diagnoses of hepatitis C are declining. There was a peak of 20,465 in 2000 and 15,953 in 2002. Because people with hepatitis C are often very healthy for a long time and can carry hepatitis C for a long time, although the number of new infections is apparently declining they are continuing to enlarge the existing pool of infection in the community. There is an estimate of about 225,000 people living with hepatitis C in 2002.

In relation to sources of infection over the last decade—in fact, since the tests were introduced in the early 1990s—infection through blood transfusion has become negligible, so other issues have become a lot more important. With regard to sources of infection, we think about 90 per cent are related to injecting. The other sources are people who have come from overseas countries where there is less effective sterilisation of surgical equipment and so on who have come to Australia carrying hepatitis C. More recently there has been some possible growth—although I do not think we are quite certain about the dimensions of it—as a result of tattooing and body piercing in nonsterile environments.

CHAIR—You refer to that on the next page. I was going to ask that question. Are you suggesting that tattooing and body piercing are increasing the rates of infection?

Mr Stuart—I do not have separate information on that.

CHAIR—It is probably outside the scope of the inquiry anyway. You make the point in your submission that mother-to-infant transmission during pregnancy or delivery occurs but is unusual. Do we know at what rate that transmission can occur?

Mr Stuart—No.

CHAIR—Is that because we do not have it or we do not know?

Dr Morauta—We can take it on notice and see if we can find out for you.

CHAIR—Thank you.

Senator HUTCHINS—In your submission you refer to how the state and territory governments, along with the Red Cross, initially used to control their own blood supply and make determinations on that. You trace it back for us to about 1994. Is that when the Commonwealth started to effectively get involved in decisions? Earlier in the submission you talk about the national blood transfusion committee. You say that you are a member of an advisory body more than anything else. Could you tell us what the Commonwealth's involvements were from, say, 1970 onwards? There was a period in 1987 where a decision was made to not proceed with surrogate testing. I would like to know who was on that committee or what bodies comprised it. Was there a health ministerial council then?

Senator KNOWLES—Could you also do the state involvement and what their commitments were simultaneously?

Senator HUTCHINS—They would have been on the committee, I imagine.

Senator KNOWLES—No, not necessarily.

Mr Davies—We will take the chronology of the Commonwealth involvement first and then come back to the issue of the specific role of the committee. I think Ms Witchard is best placed to run us through the chronology.

Dr Morauta—We did put a chronology of some events on page A2. Nola, you might just want to talk about the governance arrangements.

Ms Witchard—The governance arrangements were really not changed in a major way until ARCBS was created in 1996, because the blood transfusion committee was a Red Cross committee and was made up of representatives of the blood transfusion service. There were Commonwealth representatives. There was a representative of the Commonwealth department of health, or whatever name it had, at varying stages. I believe there was also a representative of the Defence Force, and the Commonwealth Serum Laboratories was also represented at that stage.

Senator HUTCHINS—Is this the national blood transfusion committee?

Ms Witchard—That is right. The other major change was the creation of the Therapeutic Goods Administration. That did not make a difference to this governance arrangement, but it obviously created a new regulatory body.

Senator HUTCHINS—If I am right in what you were putting, in that period up until the TGA it was Red Cross decision about blood. Were the department, the state governments, the Defence Force or CSL in a position to say no on issues? Is that an appropriate question?

Dr Morauta—It might be better to ask the Red Cross that, unless anybody from our team knows. I am not sure how it got constituted, but I think it was an advisory committee.

Ms Witchard—It was an advisory committee. In fact, the blood transfusion services actually did make their own decisions. They could be recommended by this general committee. As Dr Morauta says, we have no information at the moment as to how or why Commonwealth representatives were on that committee.

Dr Morauta—It seems nobody in our team knows how it got to be the shape it was.

Mr Davies—I think the point is, as Ms Witchard observed, it was a committee set up by the Red Cross to advise Red Cross, and the Commonwealth occupied a couple of seats on the committee. But in terms of how and why this committee was constituted, I think that is probably a matter that rests with the ARCBS. We were just occupying chairs on that committee as the Commonwealth government.

Senator HUTCHINS—So the Red Cross at the time in the various states made their own decisions?

Mr Davies—Our understanding—again, this would need to be confirmed by the ARCBS or the Red Cross—was that, yes, the committee was an advisory committee and each state and territory Red Cross society or service made its own decisions within the framework of the advice from that committee.

Dr Morauta—I think in some states they were not Red Cross services; they were actually state services.

Senator HUTCHINS—Was this national blood transfusion committee just for hepatitis C?

Dr Morauta—No, I do not think so. I think it was a broader remit than that.

Mr Davies—Again, the Red Cross would have the terms of reference. Our understanding is that it was a broader advisory role.

Ms Witchard—Basically it was the blood transfusion committee. It was not specifically related to viruses; it was about how the blood transfusion system worked.

Senator HUTCHINS—I am assuming that at this period AIDS would have been dealt with by this committee as well.

Ms Witchard—Insofar as it was an issue about blood transfusion and policies for developing better procedures for that, yes.

Senator HUTCHINS—So the control of our blood transfusions in the eighties, until the Commonwealth got a handle on it, was really in the hands of voluntary organisations?

Mr Davies—Voluntary organisations and/or state and territory governments. It was not even consistent across those governments.

Senator HUTCHINS—Are you aware of whether there was any reporting mechanism back to any federal minister or state ministerial council during that period?

Mr Davies—We could look through the records to see whether there was any reporting to the Health Ministers Conference.

Senator HUTCHINS—If you would not mind. You put in your chronology that in 1987 the national blood transfusion committee did not support routine surrogate testing. Commonwealth representatives were observers or members of the committee at the time. Are you in a position to comment on the fact that, say, the Queensland government decided to surrogate test in 1988?

Mr Davies—That was the decision of the Queensland government and therefore one that we probably cannot comment on.

Senator HUTCHINS—Fair enough. As you are probably aware, I put a series of questions on notice to the minister in relation to compensation, and the minister has replied that there has been a $5.47 million financial contribution to compensation settlements. Why would you be making contributions to financial settlements through the Red Cross?

Dr Morauta—In the time we are talking about, the Commonwealth basically was assisting the states and the Red Cross with money for the services that they were running—roughly in the proportion of 40 per cent to 60 per cent, with the Commonwealth putting in about 40 per cent. We were not running the services but we were making a contribution from the national level. When the states entered into these compensation arrangements, the proposition—as we understand it—came forward that, if we had been contributing around 40 per cent of the money to what was going on without being directly involved in it, we should contribute to the compensation arrangements. We did it on that basis. But the arrangements were set up by the states and then we made a financial contribution.

Senator HUTCHINS—Why?

Dr Morauta—I am not sure that I have more to add to what I said.

Senator HUMPHRIES—Why would you pay the compensation? A number of these people have taken legal action against the Red Cross because of infected blood, and the Commonwealth is making a contribution to their settlements.

Mr Davies—We have made contributions to the states and territories that are parties to any settlements.

Senator HUTCHINS—Is this because of some agreement you had with the national blood transfusion committee, or a subsequent agreement?

Dr Morauta—I do not think it is as formal as that. We would have to try to dig it up. My understanding is that the schemes are relatively recent and the Commonwealth made a contribution.

Mr Davies—I do not think there was any prospective agreement, if you like, that should a claim arise it would be split. I think it was more post-hoc that we agreed to make that proportionate contribution. Again, we can look for any details.

Senator HUTCHINS—Has the contribution been made to the Red Cross or the various state governments?

Dr Morauta—I would rather take on notice where we would pay it. I am not dead certain.

Senator HUTCHINS—As I recall the questions on notice that have been answered by the department for the minister, a number of them have been to the Red Cross, because my questions were specifically about the Red Cross, and the minister does admit that a number of payments were made to the Red Cross.

Dr Morauta—That must be the case.

Senator HUTCHINS—So you are not aware of what the arrangement was between the Commonwealth and the Red Cross in that period?

Mr Davies—Do you have a note of the question number? We do have most of them here.

Senator HUTCHINS—It is question No. 1352. Minister Patterson states:

These settlements are not funded by the Australian Red Cross Blood Service ... Whilst the ARCBS (or its representative) is a party to some of the settlements, the costs in each jurisdiction are met jointly by the Commonwealth and the State or Territory involved under established indemnity arrangements.

Mr Davies—Having read through your questions and our responses, I am not aware that we actually go to the specific, as Dr Morauta said, of who we write the cheque to. Certainly question No. 1352 just refers to the Commonwealth making payments. It does not—

Senator HUTCHINS—You would be aware that, in later questions to the minister, I have asked about a particular incident and whether the individuals involved had received any compensation from the Commonwealth. The minister said that she is not in a position to answer that question, or words to that effect, and, if I recall correctly, that I should talk to certain other people about the issue. So you are not aware of the terms of the settlements that made? Effectively someone signs a cheque and they go somewhere, and you do not know what happens to the money after that?

Dr Morauta—I am sure there is a proper acquittal arrangement connected with the process. I just do not have the details of the practice here.

Senator HUTCHINS—In one of the minister's answers she specifically talks about administrative and legal costs. The answer states:

The Commonwealth has provided $5.47m (including legal and administration costs) in funding as its contribution to settlements;

I would be interested to know how much of that $5.47 million went to a hepatitis C sufferer rather than to Slater and Gordon or Taylor, Taylor and Smith or someone like that.

Dr Morauta—We will take that one on notice and see if we have that information for you.

Senator HUTCHINS—I have one or two more questions, then I will finish. Are you aware of any cases where haemophiliacs have been covered specifically in any settlements by the states or the Red Cross?

Dr Morauta—My understanding is that the schemes are not built around compensating people who receive plasma derived or plasma based products. As you know, people with haemophilia largely depend on such products.

Senator HUTCHINS—So none of this money has gone to them?

Dr Morauta—There may be some cases but the general drift of it is not in that direction.

Senator HUTCHINS—You may wish to take this question on notice and come back to us. There is a blood management system called Progesa that would benefit the Australian blood system. Could you tell us about this scheme? I read somewhere that it was originally estimated to cost $4 million, and it has blown out to $38 million. I do not know whether you have seen that information in any of the submissions. When will the system be available?

Dr Morauta—Governments have allocated $38 million for this project—that is, Commonwealth and state governments jointly. Can you nail where it is at in its process at the moment, Terry?

Mr Slater—This system will not be available until it passes the TGA's code of good manufacturing practice requirements.

Senator HUTCHINS—Do you know how long that will take?

Mr Slater—When the system is robust enough and when the tests are met that are required to prove that the system meets the code of manufacturing practice.

Senator HUTCHINS—Maybe that is a question for another place at another time. Finally, in your submission you quoted Professor Cossart as stating in her appendix 4 that, essentially, someone has more chance of getting hepatitis C 'on the basis of an arbitrary marker such as the initial of their surname'. You talk about 0.091 per cent. I think that is an incorrect figure because,

from what I understand, four out of 10 people who get hepatitis C get an illness. If you donate blood or have blood given to you by one of those four people, it will be a higher percentage than 0.091, particularly if you are a haemophiliac. You talk about people using people's initials. If your initials are, say, NR—Nicholas Romanov—you will get hepatitis C, won't you, because you are a haemophiliac?

Mr Davies—I think the point we make in the submission—Professor Horvath will fill in some of the technical detail—is that the accuracy of identifying a contaminated batch using the surrogate testing is only marginally different from the probability of doing so at random.

Prof. Horvath—I hesitate to try to interpret Professor Cossart's paper because she is one of the most well read, well researched people in the area. I think the point she makes is that, in an environment where there is such a low level of infectivity, as occurs in our community, the predictable rates are different. I will take you to another scenario. In my former life I was head of the largest dialysis transplant service in the country. It was predicted that, like the United States, we would have something like 30 per cent to maybe even 70 per cent of dialysis patients over a period of time being hepatitis C positive, with very serious consequences. Up to the time when I joined the Commonwealth in August last year the rate was running at under the general population, and that break-out of infectivity did not occur. In fact, when we consulted Professor Cossart and others, the explanation was that our relatively low baseline rate of hepatitis C infectivity made those predictions different.

Senator HUTCHINS—My point is that those predictions are based on patients. I would argue that you need to base them on batches of blood. I could have the argument about that with Professor Cossart, but it seems to me that, if you can identify people who have the disease or the illness, the result is quite different to the amount of blood out there that they may have unwillingly contributed to the system.

Prof. Horvath—You would have to ask Professor Cossart and others, such as Rawlinson, who have reviewed her paper and who support the line she has taken. I would hesitate to try to interpret it. It is outside my skill base.

Senator HUTCHINS—When we were talking to Professor Burrell earlier I asked a question in relation to the decision making on whether to introduce surrogate testing. I wonder whether you, or any of you, were involved in or aware of that decision making at that period.

Prof. Horvath—No, I could not help you.

Senator HUTCHINS—One thing that people who received the infection or illness in that period ask us is: if there was a measure or a test that could have been conducted, why was it not conducted? I suppose you cannot answer that.

Prof. Horvath—No, I cannot answer that. I think that would be better addressed to the people who made the Red Cross blood transfusions at the time.

Senator HUTCHINS—Was hepatitis C, or non-A, non-B hepatitis, a notifiable disease back in the 1980s? If the answer is not available now, perhaps you could advise us.

Prof. Horvath—We will take that on notice.

Mr Davies—We are informed that it became notifiable in 1991.

Senator HUTCHINS—Thank you.

Senator HUMPHRIES—Perhaps I could clarify something. I asked the question before of the Hepatitis Council and they were not sure. Is the rate of hepatitis C infection stabilised at the moment, or is it declining?

Mr Stuart—The figures I outlined earlier were for newly identified diagnoses in each of those years, which seem to have become less. It does appear that new infections have stabilised and may be declining since 2000. We are divining that from looking at the number of newly identified infections. We cannot measure specifically when the infection first occurred, because of the long lead time in identification. Nevertheless, the size of the pool of people who have infection in Australia is still growing, because of the long-lived nature of people with the hepatitis C infection.

Senator HUMPHRIES—This is a problem which is presumably not going to get any better, because the causes of hepatitis continue to occur, particularly with intravenous drug use. As testing occurs within a short period of time, it is just not possible to know how long before a person is identified with hepatitis C they were actually infected.

Mr Stuart—Yes, that is right.

Senator HUMPHRIES—Returning to the decision made by Queensland in 1988 to use the surrogate testing method of screening, are there any figures available for hep C rates in Queensland after that decision was taken, compared with Australian rates? I am talking about through blood transfusions.

Dr Morauta—We think not. I might also add that, although that was a decision by Queensland, it was implemented more or less fully in different parts of Queensland. I do not think it was a uniform response within Queensland—that was our information.

Senator HUMPHRIES—You said that the figures are not available.

Dr Morauta—That is right.

Mr Davies—We can check through our files but I am not sure we have that level of disaggregation.

Senator HUMPHRIES—As I recall—and I confess an interest in this; I was a member of a government that implemented a look-back program in the late 1990s—the reasons given at the time for putting such a program in place were that there was a concern that, without a measure to maintain confidence in the ARCBS, there was a danger that these services might not continue to be available in Australia, that they might be so weighed down with legal action that they might be put at risk of not operating any longer. Are you aware of that argument when it comes to the Commonwealth making a contribution to these compensation schemes?

Mr Davies—As we said earlier, we are not, as we sit here now, fully across the arguments behind the rationale for the Commonwealth contribution to the compensation arrangements, but your basic principle is very important. In all these matters, maintaining the public's confidence in the safety of the blood supply is a very important consideration, both as donors and as potential recipients of blood and blood products. It is essential that people know that the system is working as well as it possibly can. Whether you could have a chain of logic that went from there and ended up with the Commonwealth contributing to compensation arrangements, I would not like to answer here and now. But certainly your initial premise that public confidence is important is undeniably true.

Senator MOORE—I apologise; I had to leave so I am not quite sure what has been asked. I have a question about the education component and the role your department has in education in the community.

Mr Stuart—I hope to be able to help you with that.

Senator MOORE—You heard evidence from the Hepatitis Council that they have identified, through the various reviews of the strategies, that education and raising awareness in the community is a key issue and also their concern that there continues to be major ignorance not just in the health area, which they particularly identified, but also in the wider community about the impact of this condition, how people should behave and how they should be treated. Could you give us some indication about what role the department has in the community education process?

Mr Stuart—The Australian government does two things. In this area it primarily funds the state and territory effort but it also manages some programs itself. The programs that the Commonwealth more directly manages are, for example, drug diversion measures relating to needle and syringe programs, which have proven to be very effective in combating the spread of both HIV and hepatitis C—there is a report on return on investment on that program—and the retractable needle and syringe technology initiative, which is a pilot program. The government also funds a number of national peak bodies, such as the Haemophilia Foundation and the Hepatitis C Council, and it also funds the states and territories to undertake education efforts in their states and territories. I will talk about the numbers there in a moment. It also funds the Australasian Society for HIV Medicine, which I think is one of interest to you. The society provides education programs specifically for medical personnel, including general practitioners.

In the early days—in February 1998—$1 million was spent on social and behavioural research. About $700,000 was spent in 1998 for national hepatitis C education and prevention. In 1999-2000, the federal budget included $12.4 million over four years for the hepatitis C education and prevention initiative, of which about $6.6 million was allocated to states and territories to develop and implement hepatitis C education and prevention programs. I have already mentioned the supporting measures for needle and syringe programs. The 1999-2000 budget initiative reached its four-year revision date and has been continued in the 2003-04 budget at $15.9 million over four years to continue that initiative, with a substantial proportion of that funding again going to the states and territories.

Senator MOORE—I remember seeing, during the HIV education program, a particularly effective group of advertisements which were put out through schools and Indigenous

communities. The advertisements were trying to educate people about the worries and the potential for HIV transmission. I am interested that one of the points that come out in a lot of the submissions is culturally appropriate education programs, particularly around the issues of needles and needle exchange. I wonder whether any of the programs you have mentioned—and there are a lot—pick up those issues about Indigenous education. You can take that on notice; it is difficult.

Mr Stuart—From where I sit, I cannot speak in detail about what the states and territories are doing. We have a very substantial 2002 review of these strategies, which I have revised in preparing to come and talk to you. It says, amongst other things, that the effort in targeting specific subgroups within the hepatitis C affected community has not been all that good. That is a criticism of the impact of the strategy to date. It does not mention, for example, the haemophilia community or those impacted through the blood supply but it does mention non-English-speaking background communities, Indigenous communities and those in prisons. It will be a burden of work for the newly formed advisory committee to the minister to take on board that discussion about a range of groups who have perhaps been missed in the broad brush of the program—as is often the case when you first commence programs. The review also finds that the source of continuing infection in Australia, which is obviously of critical importance to the health departments, is the considerable pool of people who already have hepatitis C, most often through injecting drug use, often undiagnosed. So it is understandable when education initiatives are targeted at that group.

Mr Davies—If you go to the foot of page 23 in our submission—

Senator MOORE—I think that is where the question came from, Mr Davies.

Mr Davies—There is a specific reference to the ethnic media campaign. I understand last year's federal budget gave $16 million to continue funding that.

Senator MOORE—That is right.

Mr Davies—That is one example of an initiative. On page 21 of the submission we talk about the broad range of service providers—including Aboriginal and Torres Strait Island primary health services—who are engaged in these sorts of initiatives. It is quite broad but I think Mr Stuart is right: it is a job that I suspect we will never finish.

Prof. Horvath—Part of the difficulty is that there is a very large hepatitis C pool in the prison population. I think that in New South Wales—I may be corrected on this—the prison health service is managed by the health department, so there is some access by cooperative arrangement whereas most other prison health services are managed by the justice departments, which makes it very difficult to have some impact. So there are some real issues that we are aware of. Those problems are very difficult.

Senator MOORE—I have one more question. It is along the lines of the question Senator Knowles asked earlier to the person from the Hepatitis Council about the issues surrounding claims of medical discrimination and lack of awareness in treating patients with hepatitis C. Does the department become involved in discussions in terms of advising medical schools about the curricula? Do the issues that come up in, for example, the round tables you have about

contagious diseases and hep C get fed back by any focus of the department to the medical schools?

Prof. Horvath—I cannot speak so much from the department's point of view; I might leave that to Mr Stuart.

Senator MOORE—But in your previous life?

Prof. Horvath—But, on the basis of my experience in my previous life as a professor of medicine, hepatitis C is treated like everything else. My renal transplant ward, with lots of immunosuppressed patients, in fact was shared with the gastroenterology ward, with hepatitis C patients. It is a part of the normal teaching of all infectious diseases. Again, I can only speak for New South Wales and from personal experience. Patients are not labelled with armbands and stickers. All of those things that were a feature in the eighties are no longer. It is assumed that every patient is potentially an infectious risk to all the people managing them. Universal infection control procedures are the teaching in all medical schools and vocational training, because you do not know who has known current disease—and, again, what unknowns we have not yet found. We got rid of our tuberculosis wards in the 1960s, and now people say that we might have to build them again. So that is the current teaching. For the department's response, I will pass over to Andrew.

Mr Stuart—I have already mentioned the funding provided through the Australasian Society for HIV Medicine and their work in providing a comprehensive education program for GPs. Also, I am advised that Professor Bob Batey, who is the chair of our new hepatitis C advisory committee, has been doing quite a lot of work with medical schools to stimulate their interest in hepatitis C. He has been quite effective in that.

Senator MOORE—Thank you.

Senator KNOWLES—I want to try to clarify the issue of responsibility. This is a federal inquiry into what I perceive as primarily a state responsibility in conjunction with the Red Cross. What were the practices of the states in the critical time period? Where were the responsibilities sheeted home? As far as you know—and I know that I am asking you a whole lot of questions about matters with which you might not be familiar—what were the communications between the state governments and the blood service? The reason I ask these questions is that I want to see where there was an awareness of practice and an awareness of what should and should not be done. I want to see whether we can look at that with hindsight and see where the problems lay.

Mr Davies—That is a very difficult question for us to answer. I think I am right in saying that no-one sitting around this table was working in the system during the period you are referring to. Clearly, what passed between state and territory governments and the Red Cross in the 1980s and early 1990s would have been, effectively, invisible to people working in the Commonwealth health department at the time. As I mentioned earlier, I think we could look through any existing records of health ministers' meetings, which would have been a potential forum. We do not have that information with us here today. You are really looking for an impression of the level of dialogue that took place, and the quality and nature of that dialogue. We can certainly try to paint that picture from our records, but there would be a whole level of dialogue which we would not have been party to at all.

Senator KNOWLES—From where I sit there seems to be a huge degree of sensitivity on the part of all the states to providing much information to this inquiry. We have not got anything from them and they have not put their hands up to offer information. Given their level of responsibility at that time, I am intrigued to know what their role was. I know that it is a difficult question from a federal perspective, but I suppose as much as anything else I want to put on the record again what you have put in your submission. Equally, we need to look at the question of compensation because I think it is perceived that the federal government is liable for some compensation. In fact, I think the compensation liabilities rest with the states, and yet to this point we have not been able to get from the states their process of compensating. Is there any information that you might have that could shed some light on that?

Mr Davies—On the specific issue of compensation, I think Louise might answer.

Dr Morauta—I need to go back a step. When you ask who was responsible, maybe it is in these compensation arrangements, where you can see that the state governments are the primary funders and that the potential litigation is occurring at the state and Red Cross level. That suggests that when people have looked into this in a legal sense that is where they found the responsibility lying. That might be some pointer to add to the picture we have been painting. It is a kind of inference rather than anything else, because I do not think we have a lot to add. The compensation scheme documents are state documents; they legally do not belong to the Commonwealth. We get to see these documents, but we could not release them without another party agreeing to it, because they are not our documents.

Senator KNOWLES—So we need to approach the state governments for the release of any information that is pertinent?

Dr Morauta—Or any details or anything like that, yes. That would be my view on it. We cannot release them unilaterally. We could write to them and ask if we could, but I do not know that we would be entirely successful.

Senator KNOWLES—It remains to be seen whether we are entirely successful either.

Mr Davies—It is not to say that you would necessarily be successful either.

Senator KNOWLES—Thank you.

CHAIR—I want to traverse similar ground that Senator Knowles has traversed about the blood transfusion committee. Mr Davies, you said the Commonwealth was a member of that committee and had one or two seats on it. Who established the committee?

Mr Davies—We believe it was the Red Cross.

CHAIR—Can you confirm that? It needs to be made very clear.

Mr Davies—We can try to confirm it; it might be a bit difficult.

Dr Morauta—I suspect what we will do is ask the Red Cross, as we have done in answering some of Senator Hutchins's questions. We do not necessarily have the background.

Mr Davies—But we are happy to ask them if we cannot get an answer from our own records.

Dr Morauta—We believe that our people on there were observers, is that right?

Prof. Horvath—That is right.

Mr Davies—So the suggestion is that the Commonwealth members were not members as such but only had observer status. I think we need to take that on notice and come back to you with more details.

Dr Morauta—Why don't we try and get a list of the members of it at different times?

CHAIR—Can you also provide us with your understanding of what the role of the committee was? You referred to it in your submission, but can you expand on that? What was the purpose of the committee? What were its objectives? Who did the committee report to? Did it report to the Red Cross or to the states?

Mr Davies—Again we can certainly try to do that, but if you are speaking to the Red Cross you may get that information in a more timely manner by asking them. We will certainly pursue it in the meantime.

CHAIR—We will certainly ask those questions of the Red Cross, but if you could go back through your files there will be reports, minutes and all sorts of things.

Mr Davies—We will see what it looks like from our side.

CHAIR—If you could provide us with those minutes, it would be very handy. They would enunciate the role, the purpose and the reporting of it.

Dr Morauta—We will try to get you the details of the role—anything we have got which bears on the question of the role and the responsibilities of the committee, to whom it reported and that kind of thing.

Mr Davies—Our understanding, though, is that it was primarily an advisory body as opposed to a more rigorous regulatory function, but again the terms of reference should confirm that.

CHAIR—An advisory to whom is the other query I have in my mind.

Dr Morauta—I will make a cautionary comment: nowadays we expect everything to have terms of reference and to have something it is reporting to and to be very neat and tidy. Sometimes when you go back a bit, like when Sir Ninian Stephen went back in his report and looked at these structures, it does not come out that way. We will take it on notice and see what we find.

CHAIR—Thank you for that. Can I now go back to the issue Senator Hutchins raised about compensation. It is $5.47 million that the Commonwealth has contributed.

Dr Morauta—I think that answer was given last April and it is probably not the most up-to-date figure, but that was the right figure at that time.

CHAIR—I think Senator Hutchins has asked this question, but can you give advice to us—

Senator HUTCHINS—It is in the submission.

CHAIR—That is 2002-03.

Dr Morauta—I think the answer was given in April 2003, so that would not necessarily take us to the end of the 2002-03 year. My view is that that number is not the most up-to-date number but that it was the most up-to-date number at the time we answered the question. I think the question might have been asked in March and we answered in April.

Mr Davies—The answer was published in *Hansard* on 25 April, so that suggests it would not have included even the whole of that financial year.

CHAIR—I understand your point, Doctor.

Dr Morauta—We have taken on notice the question of that amount and whether we can distinguish between it going to administrative and legal and to the recipient of the compensation. I think that is something we will take on notice and see if we can answer.

CHAIR—The other question I would like to add to that list is: how much has gone to the Red Cross—which is the point Mr Davies was making—and how much has gone to the states?

Dr Morauta—We need to check exactly where those payments go to, and we will answer that at the same time. If we can put all of that together in an answer on the arrangement, we will do that.

CHAIR—The other question that you may or may not be able to answer is: how much have the various states and territories provided to that compensation pool?

Dr Morauta—It is roughly 60-40 in some states, but I understand for example that we do not contribute to Victoria. They meet all their costs themselves. There are slightly different arrangements in different cases. So, let us ask ourselves if, from our own records, we can give an aggregate figure on the equivalent state contribution.

Senator HUTCHINS—And how those arrangements were entered into.

Dr Morauta—Yes, I think that is something we have agreed to look at, because it is not clear to me.

CHAIR—The other thing I need to understand is the basis for those arrangements being entered into.

Mr Davies—I think we have taken that on notice as well.

CHAIR—That is the point of Senator Hutchins's question: on what basis has the Commonwealth committed that amount of money?

Senator KNOWLES—Mr Slater, I asked Professor Burrell earlier this afternoon a question about the rate of current risk of infection, and he dobbed you in. He said the TGA had some figures but he did not happen to have them with him. I wonder whether you have them available.

Mr Slater—Since the introduction of nucleic acid testing, we are not aware of any cases of transmission of hepatitis C through the blood transfusion system.

CHAIR—I have another question which goes to the relationship between the Commonwealth Department of Health and Ageing and local governments, which monitor and license tattoo shops and those sorts of places. What role does the Commonwealth have in ensuring that local authorities are in fact complying with the level of hygiene and whatever as part of doing what they do?

Mr Stuart—I think you are going to a state and territory government role as part of their health inspection role.

CHAIR—In my state, tattoo parlours and ear-piercing places are licensed by local authorities.

Mr Stuart—But that would be under state government regulation and oversight.

CHAIR—And there is no Commonwealth role in ensuring that those principles are being adhered to on a national basis?

Mr Stuart—We do not have any inspection or compliance role. We do participate in devising infection control guidelines which are at a higher level and operate nationally.

Mr Davies—I think this is one where the buck stops at the state level.

CHAIR—So the guidelines that we have developed at a Commonwealth level do not go to the minutiae of what should be occurring in a tattoo parlour?

Mr Stuart—No, they do not.

CHAIR—Can you see any role for ensuring that we do have a standard across Australia?

Mr Stuart—I think states and territories do take a strong interest and a strong role here. I do not immediately see a role for the Commonwealth.

CHAIR—I suppose my concern comes out of the figures that show that we are still getting very high infection rates—nine per cent—out of intravenous drug use. It troubles me that that is still occurring. We have raised a lot of questions in our minds this afternoon, and we have come to the end of our time.

Senator HUTCHINS—I just have one more question.

CHAIR—Certainly.

Senator HUTCHINS—Before Canberra got self-government, was the blood supply regulated by the Canberra Red Cross or the Commonwealth department of health? Were you on the advisory body as a result of that?

Dr Morauta—We will have to take that one on notice.

Senator HUTCHINS—You might have been running your own blood service, for all I know; that is why you have been paying their compensation.

Dr Morauta—I do not know how the ACT health system was managed pre self-government.

Senator HUMPHRIES—The Red Cross has run the ACT blood service for a long time, long before self-government.

Mr Davies—We will see what we can find out for you on that one.

CHAIR—I hope you will not mind if we send you some questions on notice.

Dr Morauta—Additional ones to the ones we have taken on notice already? That is fine.

Senator HUTCHINS—Or we could get you to come back.

CHAIR—If it seems that the work we do in the hearings next week requires you meeting with us again, we will pursue that if it is okay.

Mr Davies—We would be more than happy to do that. If you decide to go down that route and have some indication of the specific areas to explore, we could probably make sure we have the relevant people lined up in advance. That would be very helpful.

CHAIR—Thank you very much, and thanks to all the officers of the department for your cooperation.

Committee adjourned at 6.02 p.m.