# COMMITTEES
## Community Affairs Committee
## Report

**Senator MOORE** (Queensland) (9.51 a.m.)—I present the report of the Senate Standing Committee on Community Affairs, *A matter relating to the Positron Emission Tomography (PET) Review 2000*, together with the *Hansard* record of proceedings and documents presented to the committee.

I will speak very briefly to allow some other senators to make comments, and I know there will be some interest in this report. When my friend Kay Denman asked me to ask questions on this issue in Senate estimates in 2003, I did not realise just how much of an interest I would be taking in the issues around PET in Australia. In respect of this report, we have received complaints from a number of people, particularly to Dr Ware and Professor Hicks, who are particularly concerned about the process that went on around the introduction and the assessment of PET during the MSAC process in 2000. You may ask why we are taking note of this issue in 2008. The reason is that there was never a formal completion of the discussion around this process, and it should have happened much earlier.

The committee became immersed in correspondence going backwards and forwards between a range of people. The key element that came out for some of us on the committee was that there was genuine confusion, lack of closure, lack of openness in communication and also deep hurt caused, I do not believe deliberately, to a couple of people who had dedicated their lives to developing PET and making sure that it was valued not just in Australia but also internationally.

People had a range of views, and I think one of the real issues we struggled with was that all this went on in 2000 and we were trying to come to grips with a trail of communication that was clouded, at best, and made worse by the fact that all the officers in the Department of Health and Ageing who were originally dealing with this issue were no longer in the employ of the department. We received information at several hearings from a series of officers who were reliant on documents which were not up to scratch.

One of the issues that has come out of this particular report is that we must do better. There is no doubt about that. I think the department has accepted that. There have already been changes made to the way the MSAC process operates and the way documentation is maintained. I think Dr Ware and Professor Hicks particularly deserve an apology and I am giving that now, even though it is not a formal recommendation from our committee. I am sorry that they have gone through the last seven to eight years of concern, legal expenses, doubt and, I believe, ill health as a result of this process. This may well apply to other people but I particularly wanted to name those two gentlemen.

We believe that the system has been flawed. We believe it can do better. One of the good things to come out of this is that PET, the technology to which so many people are dedicated, particularly Dr Ware and Professor Hicks, has been strongly vindicated through the years of testing and exploration. This is a great technology. It provides services to many people. We should be proud of it. The way this process went ahead was a blot. Our committee became deeply involved. I do not think a single member of the committee was untouched after working

through this process. I want to leave it to other senators to make their contributions.

**Senator HUMPHRIES** (Australian Capital Territory) (9.55 a.m.)—The Chair of the Senate Standing Committee on Community Affairs indicated that there were a range of views on the evidence that the committee was presented with on this matter. I have to say that my view will be very different to that of other senators who sat through that inquiry. I want to bring closure to a very long inquiry that the committee engaged in on this matter. This inquiry took two years. It conducted three public hearings. There were at least eight private meetings of the committee that I counted to do with this matter. There were hundreds of documents. The Department of Health and Ageing received well over 100 pieces of correspondence on the issue. There were questions at the estimates committee. There was enormous vexation about this issue.

The issue, in my view, boils down to a single word that appeared in a report prepared by what was called an inferior committee in a process designed by the department of health to answer a question about whether Australian medicine should be allowed to have access to this new technology—positron emission tomography. The question is why that one word had been added to a report of the committee charged with a professional review by the department of health in 2000. I should point out that this was not the drafting of a recommendation about to go to the minister for health. The process was much more attenuated than that. It started with a consultancy and then went through a supporting committee, a steering committee and the Medical Services Advisory Committee process and then it went to the minister for health to see whether this particular technology should be approved for general use.

The stage we are talking about was a fairly early one in this review process—the report of the so-called supporting committee, which was making recommendations to the so-called steering committee. The chair of that supporting committee, Professor Richard King, a respected academic and clinician, had the task of preparing the report of his supporting committee to present to the next committee up the line, which was the steering committee. The issue was whether positron emission tomography should be funded by the taxpayer for general or restricted use in Australian medicine.

The meetings, I gather, had been difficult. Members of the committee took different views about this particular technology and there were some arguments in the course of the committee. Eventually Professor King, as the chair of the committee, had to prepare a report. The report, I should say, was not the minutes of this committee; it was a draft of a report which was to be handed up to the next stages until it finally reached the minister. The minister, on the basis of the recommendation from that process, makes a determination.

Professor King felt that he needed to present a report which was cohesive, which logically hung together and which would be useful to the superior stages of the review process. Professor King made a number of editorial changes to the document that he was charged with editing. He did it, as he put it, to make 'the document read logically'. He made quite a number of changes. Some of these changes were to rearrange the order of sentences, to restructure recommendations and to make the flow of the text read generally better than it had previously. One change he made, however, was to attract in due course the furious ire of one doctor who was not a member of the committee, Dr Robert Ware, and an only slightly less vociferous objection from someone on the committee, Professor Rodney Hicks.

What was the change that was made? I want to read to the Senate the version which was seen by the supporting committee and the version of the relevant paragraph which was handed up to the steering committee. The first version reads:

> While the Committee agree that unrestricted funding is unwarranted at this time, the evidence suggests that PET is safe, clinically effective, and potentially cost effective in the indications reviewed.

This was changed to read:

> While the Committee agree that unrestricted funding is unwarranted at this time, the evidence suggests that PET is safe, potentially clinically effective and potentially cost effective in the indications reviewed.

I am sure most senators listening to the debate today, and most other people listening, would have failed to grasp the difference between those two paragraphs. The difference is that the word 'potentially' has been inserted before the words 'clinically effective'. Professor King made that addition because he felt that the version that was being handed up did not logically hang together unless that change was made. He went back to another section of the report, which was agreed on by all the parties to the supporting committee, and it read:

> Based on the results of the NHMRC Clinical Trials Centre's evaluation and the clinical experience of committee members, the MSAC Supporting Committee concludes that there is insufficient evidence of PET's clinical or cost effectiveness with respect to the six indications reviewed to warrant unrestricted MBS funding.

Those words were modified in being passed over to the next stage—the steering committee—in ways which I invite members to read and to try and understand. I would suggest to them that they will find very little difference in the meaning of the way the words are used from one version to another.

I come back to this central issue about the insertion of the word 'potentially'. Professor King's point was that it was very difficult to justify proceeding with the text as it stood without the insertion of the word 'potentially'. He said, in the agreed text, that the committee 'has concluded that there is insufficient evidence of PET's clinical effectiveness'.

If the committee concludes that there is insufficient evidence of PET's clinical effectiveness, how could it go on to say that the evidence suggests that PET is clinically effective? He said that you cannot do that; that it is a contradiction. 'If we say that there is insufficient evidence of PET's clinical effectiveness, we cannot in turn say that it is clinically effective.' He decided that, to make this document clear and logical, the word 'potentially' should be inserted.

That unleashed a storm of protest. He was accused of being corrupt, of trashing the reputation on an international level of the scientists involved in this process, of engaging in scientific fraud and of pursuing a political objective. Incidentally, Professor Brendon Kearney was also caught in this flack. He was also a member of both the steering committee and the supporting committee, which handed up these amended recommendations. The fact is on any objective reading of these two versions there is very little difference indeed. The change that Professor King made to the earlier document is an entirely logical and understandable change made by a person who wanted to do a competent job as the chair of that committee to deliver to the next stage of this review process a document which stood on its own strengths and was logical and coherent.

In asking some of the members of those committees to reflect on differences between the two versions, a number of academics and clinicians had different points of view. Professor Brendon Kearney saw no substantive difference between the two versions, for example. Dr John Primrose said:

> I can see no difference in meaning between the two versions of the recommendations contained in appendix A of Senator Humphries' letter. The second is merely an expanded and clearer version of the first.

Although it is different to those of other members of the committee—some took a more harsh view about the differences between the two—I think that comment reflects an accurate and fair reading of what occurred in this matter.

I will not have time today to make comments about other allegations that were made, particularly a hysterical comment about criminal fraud alleged about Professor King. I will use an adjournment speech in the future to make comments about that and set the record straight. I think this has been an enormous fuss about nothing. It has been a storm in a test tube.

**Senator MILNE** (Tasmania) (10.05 a.m.)—I could not disagree more with Senator Humphries. Frankly, I find it offensive that he should stand here and say it is a storm in a test tube. We are talking about the treatment of cancer patients around Australia and their ability to access a technology which gives more accurate diagnosis and is a more focused diagnostic tool than anything that was available at that time or since. As Senator Moore, the chair of the committee has said, we have had evidence and have concluded as a committee that over the years PET technology has come into its own more and more. In fact, it has been demonstrated not only to be safe and clinically effective but also to be cost effective because it avoids unnecessary and costly treatments and, in many cases, operations.

I went to the Peter MacCallum clinic with Senator Moore and Senator Polley, and we saw for ourselves exactly how good this is as a diagnostic tool. In part, our Senate committee inquiry was to look at whether the Department of Health and Ageing had obfuscated or misled the Senate committee and the Senate over time in relation to information on this. The inquiry was also to look at the significance of what occurred. I think it has been highly significant. The impact of the changed supporting committee report—and I will come to that—has been that this technology has not been rolled out around Australia as fast as it would otherwise have been. That means the long delay in getting the best information to vulnerable cancer patients has, in my view, been likely to have diminished their ability to help themselves and has caused a great deal of needless suffering, irrespective of the Medicare funding decision. That sort of outcome is the opposite of what was promised with MSAC.

Let me go back to how it happened. The former Minister for Health and Family Services, Dr Michael Wooldridge, had been involved in a massive scandal in the late 1990s—a scandal known as 'scan scam'. It was around the magnetic imaging machines. At the time they were being rolled out there was a massive scandal as a result of a budget leak and as a result of alleged links between Dr Wooldridge, people in the industry and so on. So when, shortly after the scan scam, an approach was made to the government of the day to assess the PET technology, what the minister of the day did was to add into the MSAC a special committee. They had set up a process by then to assess new technologies so that the minister would not be involved in apparent scandals like that in the future and to try to set up an arms-length process. What happened with this one, though, was

that there was a special committee added in, which had not happened before. It was a unique event in the history of MSAC assessment. It was a steering committee, and this process was established at the request of the minister because of concerns over the potential expense of PET to the Commonwealth.

So this committee was added in with the significant purpose of looking at the cost to the Commonwealth, because the implications were that, if this had been found to have been safe and clinically effective, it would have had to have been rolled out and a Medicare rebate would have had to have been provided. These scans cost somewhere between $800 and $1,000 per scan, so you can imagine the cost to the Commonwealth if a finding had come out saying that they warranted unlimited Medicare funding. That would have been a massive hit on the health budget at the time, especially because at that time there was agreement—and everyone agreed—that it was only potentially cost-effective. It certainly would be helpful to cancer patients, but would it be cost-effective? We now know that it is more than cost-effective because it saves money, as it saves unnecessary treatments and things, but at the time that was not as clear as it has become since.

So this special steering committee was inserted. It was ministerially appointed. Its chair, Professor Kearney, in October 1999, at the first meeting of the steering committee, noted:

> ... should the technical evaluation of PET prove inconclusive, some sort of data collection regime would be a reasonable condition for wider introduction of PET.

So he was already saying that the technical evaluation might prove inconclusive. Then, at the second meeting of the steering committee in January 2001, he was minuted as saying:

> The committee should prepare itself for the possibility that the MSAC supporting committee report would find that the evidence for PET is not sufficient to warrant widespread dissemination of the technology, in which case it is likely that the status quo would be retained or a very minimal rollout may be recommended.

He was already saying that before the expert doctors committee, the supporting committee, had even met. So here was the chair of the ministerially appointed steering committee to oversee how much money, effectively, the Commonwealth would wear already warning what the likely result would be, before the experts could meet. Then the supporting committee met and it found that PET was safe, clinically effective and potentially cost-effective.

That is what the experts found. However, their report was changed and not only was the word 'potentially' inserted before 'clinically effective'—therefore implying that it was unproven, which was certainly not found—but an additional primary finding, which Senator Humphries chose not to mention, was inserted at the front of the report, which took away the statement in connection to whether it warranted unlimited funding. That was removed and a straight-up statement was inserted to say: 'There is insufficient evidence at this time from which to draw definitive conclusions about the clinical effectiveness and cost-effectiveness of PET.'

That is completely wrong. That is not what the supporting committee found. That was inserted in there and the expert doctors, who had found something different, were never told that their report had been changed. The only people who knew it had been changed throughout the whole process were Professor

Kearney and Professor King. They were on every single committee. They were on the steering committee, ministerially appointed, they were on the expert doctors committee and they were on the MSAC itself and on the MSAC executive. So they knew through the process, but they never, ever told MSAC, when it made its decision about what to recommend on how much funding should go out there, that the experts had found something different.

As a result, those experts on that supporting committee for the past eight years have had to put up with the fact that they are out there advocating for this technology and people have been throwing in their face, 'Well, if you really think it's so good, why did you find all those years ago that it was only potentially clinically effective?' That is why they have fought so hard over these years to get the record put straight, to say that that is not what they found. They did find that it was clinically effective.

We have at least fixed that up. I am really pleased that the committee has recognised that the expert doctors report was changed, that it did matter, that it has compromised the reputation of people such as Professor Hicks and others who have advocated for it, such as Dr Ware. I am really pleased to endorse the apology to them because not only has Professor Hicks suffered because his name was on the report but also Dr Ware was insulted throughout by the health department, which in the end had instructed people not to continue with correspondence with him, not to provide FOI and to absolutely obfuscate and frustrate any attempts to get to the truth.

So does it matter? Does it matter that a finding came out in 2000 that justified the Commonwealth not rolling out the funding? Yes, it does, because what happened was, even though the doctors said it was safe and clinically effective, the result was that the Commonwealth funding was restricted and a few centres around Australia were designated as data collection centres. If you got the PET scan done at those centres, you got a Medicare rebate but, if you had the PET scan done in any other place in Australia that was not one of those contracted centres, you did not get a Medicare rebate—except for three indications of cancer, whereas the main data collection centres were collecting for 22. The result was that this technology was not made available to cancer patients around Australia and those expert centres were collecting data for something they already knew was effective.

I think there was a deliberate change to this report. I do not believe it was editorial, and I do believe that there is a case to answer from the people who changed it and who failed to tell people that it had been changed. If Senator Humphries wants to stand up and say that is not the case, I am happy to stand up to say quite the contrary. I think there was a political agenda to change the report with respect to funding, at the expense of cancer patients.

**Senator POLLEY** (Tasmania) (10.15 a.m.)—I seek leave to have incorporated in *Hansard* my speech on the Community Affairs Committee report entitled *A matter relating to the Positron Emission Tomography (PET) Review 2000*.

Mr Acting Deputy President, I rise today to speak on the report *A matter relating to Positron Emission Tomography (PET) Review 2000*.

Firstly though I should once again extend my thanks to Elton Humphery and all the members of the Community Affairs Secretariat. They must surely rank as one of the busiest Committees in the Senate—I think there are currently five inquiries

coming under their jurisdiction—and under that workload, the quality of their work is just staggering. They truly do an outstanding job.

PET is a technology that is widely used in the diagnosis of cancers and is now coming to also be used in investigating cardiac and other conditions. It has been in use in Australia for a number of years now, and during the course of this inquiry we visited the scanners at the Peter MacCallum Centre in Melbourne to see exactly how the technology works, and to meet patients for whom this technology has been extremely beneficial.

These stories were truly moving, and really gave those of us in the Committee an appreciation of the benefits of the technology.

Firstly I would like to commend the Rudd Government for listening to Tasmanians and setting aside $3.5 million in the Budget for the establishment of a PET scanner in Tasmania at the Royal Hobart Hospital.

This is something that I pushed for repeatedly while we were in Opposition—to no avail unfortunately as the previous Government was too busy pork barrelling in short term solutions like the Mersey takeover to look into the long term health of Tasmanians.

Thankfully this situation has been resolved and Kevin Rudd and the Minister for Health, Nicola Roxon have come through with a PET scanner, which will save Tasmanians from having to fly to Melbourne to use this incredible diagnostic tool.

Of course this is just one of many initiatives that were put forward under the Government's Tasmanian Health Plan before the last election—a plan that has been delivered in full, as has every other election promise. A stark contrast to other administrations.

For those in this chamber who are unfamiliar with PET, it is probably appropriate that I explain a little bit about it. The way PET works is by producing a three dimensional map of what's going on inside the body, user a radioactive tracer that is introduced into the body.

From scans of the body after the tracer has been introduced, a three dimensional representation is recreated that allows doctors to locate tumours and other medical problems within the body.

The uses of this are many and varied—as I stated earlier, initially it has been used to help find cancers throughout the body, but I understand that in more recent times the usefulness of PET has been extended to include diagnosis of cardiac and other conditions. So it should be obvious to all just how useful this technology can be for doctors.

The Community Affairs Committee report gave me a good understanding of just what is possible using PET scans, and how it can be superior to other diagnostic tools that are out there.

That's why I'm proud that the Rudd Labor Government has come through on its promise of a PET scanner for Tasmania and, as I understand it, work on rolling this out will start in August this year. It can't come soon enough for Tasmanians.

I also understand that work on the Launceston Integrated Care Centre is also expected to start reasonably soon—another example of how seriously the Rudd Labor Government is taking the health of Tasmanians. After 11 long years of neglect, it appears that we now have a Federal Government that is serious again about health care, and investing in the health system.

Moving on to the reasons behind this inquiry, and the recommendation put forward by the Committee: we recommended that the Department coordinate a disclaimer notice with the Medical Services Advisory Committee and then able to circulate that disclaimer to all those who hold copies of the MSAC Assessment Report: Positron Emission Tomography or the Report of the Review of Positron Emission Tomography.

It is hoped that this disclaimer will clearly indicate which members of the Supporting Committee did not agree with that final report.

By doing this it will allow those members to ensure that their views are noted on the public record—which is extremely important as it will show that they did not necessarily agree with the views in the original report.

While there were allegations of political interference in the process it must be noted that the Committee did not find any evidence of this.

The passage of time since the 2000 Review has resulted in very strongly held views being formed and these were expressed in evidence. Committee members accepted these views and interpretations of events to differing degrees.

Often we were not assisted in our deliberations by the extant records and minutes of meetings at the time not recording actual decisions and discussions. These procedural issues really should have been handled better at the time.

I do feel for Dr Ware who has spent such a long time on this issue, and who has at various points received unsatisfactory answers to his questions by the Department.

That's why I am glad that this inquiry has contributed in at least some small measure to ensuring that this situation will not happen again, and that those who do disagree with findings in the future will have a clear avenue to register that disagreement. Dr Ware has been exceedingly patient and I commend the determination of both him and Professor Hicks in this matter.

I think that we have all learned a lot during the course of this review—it has certainly been thorough and has been ongoing for two years.

I believe that it has been beneficial and that the issues raised by Dr Ware and Professor Hicks underline the importance of ensuring the independence of scientific and technical assessments of new medical technologies.

It's evident from the comments today the differing views of committee members.

I commend this report to the Senate.