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SENATE

COMMUNITY AFFAIRS LEGISLATION COMMITTEE

Reference: A matter relating to PET Review of 2000

FRIDAY, 28 APRIL 2006

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SENATE

COMMUNITY AFFAIRS LEGISLATION COMMITTEE

Friday, 28 April 2006

Members: Senator Humphries *(Chair)*, Senator Moore *(Deputy Chair)*, Senators Adams, Barnett, Nettle and Polley

Participating members: Senators Abetz, Allison, Mark Bishop, Boswell, Bob Brown, Carol Brown, George Campbell, Carr, Chapman, Colbeck, Coonan, Crossin, Eggleston, Chris Evans, Faulkner, Ferguson, Ferris, Fielding, Forshaw, Heffernan, Hogg, Hurley, Joyce, Lightfoot, Ludwig, Lundy, McEwen, McGauran, McLucas, Milne, Nash, O'Brien, Parry, Patterson, Payne, Robert Ray, Siewert, Stephens, Stott Despoja, Watson, Webber and Wong

Senators in attendance: Senators Adams, Allison, Humphries, McLucas, Moore, Nettle and Webber

Terms of reference for the inquiry:

Inquiry into matter relating to PET review of 2000

WITNESSES

Committee met at 9.08 am

WARE, Dr Robert Edward, Private capacity

HUTTON, Ms Bridget Theresa, Private capacity

READ, Mr Kenneth Eric, Private capacity

CHAIR (Senator Humphries)—I declare open this public hearing on a matter related to the positron emission tomography, commonly termed PET, review of 2000. The committee has received correspondence from Dr Robert Ware relating to this review. The review of PET technology was completed in August 2000. The issues surrounding the review process have been raised at previous estimates hearings of this committee. That correspondence has been circulated to members of the committee. Senator Moore has moved that the correspondence be published for the purposes of parliamentary privilege and the motion was agreed to. The committee agreed to hold a short public hearing today to allow evidence of this matter to be taken in public. For that purpose I welcome Dr Robert Ware and other colleagues of his and ask them to state the capacity in which they appear.

Dr Ware—I am appearing in relation to the correspondence I have had with the committee.

Ms Hutton—I am assisting Robert as his librarian.

Mr Read—I am Robert's barrister.

CHAIR—I understand information on parliamentary privilege and the protection of witnesses and evidence has been provided to you. The committee prefers evidence to be heard in public, but evidence may also be taken in camera if you consider such evidence to be of a confidential nature.

The committee has before it your detailed correspondence, dated 30 January and 18 April 2006. Obviously, it is therefore not necessary for you to repeat the information contained in that, except as necessary to draw our attention to particular things that you want to draw to the attention of the committee. I invite you now to make an opening statement. At the conclusion of your opening statement members of the committee will no doubt want to ask you questions. Dr Ware, we are in your hands.

Dr Ware—Thank you very much for giving me the opportunity to appear before this inquiry into matters related to the PET review of 2000. Senators, the most important clinical application for PET is cancer management. To quote the Treasurer:

> Cancer is a cruel disease. We all know someone who has it, or has died from it.

It is the largest single killer of Australians. Even survivors rarely avoid physical, emotional and economic trauma from their treatment experience. Cancer is the public's largest health-care concern by far.

The Medicare Services Advisory Committee should have been a huge advance for Australians with cancer. MSAC is Australia's foremost health technology assessment agency. It is a taxpayer funded committee with the explicit purpose of vetting new procedures based solely upon clinical and scientific grounds, free of politics. MSAC's explicit objective is to speed the introduction of new procedures that could be clinically demonstrated to be far more effective than the existing practice. In Dr Wooldridge's own words, the MSAC initiative is one of the 'most important and significant reforms' imaginable in the Australian health-care system, and I fully subscribe to his enthusiasm.

Dr Wooldridge was also emphatic in his opening address for MSAC that unnecessary human suffering, and even loss of life, resulted from slow uptake of beneficial new medical procedures. MSAC contributed to the 2000 review of PET conducted by the Department of Health and Ageing. That review of PET was to assess its role in Australian clinical practice on the basis of its safety, clinical effectiveness and cost effectiveness.

As was MSAC's usual process, a scientific supporting committee was also established. The supporting committee's role was to evaluate the scientific evidence and to make recommendations to MSAC itself. The report of the scientific supporting committee for the PET review found that, while the committee agreed that unrestricted funding under the MBS is unwarranted at this time, the evidence suggests that PET is safe, clinically effective and potentially cost effective in the indications reviewed. That is highlighted for the committee on the second page of the attachment to my submission. I would like you to note that on the first page it is headed as the MSAC supporting committee's report.

If I could take you now to the next document, what I am going to show you is that, before the scientific supporting committee's report was presented to MSAC for consideration, material alterations were made. If you go to the second page of that document, you will see highlighted the words 'the MSAC supporting

committee concludes that there is insufficient evidence at this time from which to do draw definitive conclusions about the clinical effectiveness and cost effectiveness of PET.'

You will also see a second alteration. There you will see that the word 'potentially' has been inserted before the words 'clinically effective'. So there has been a huge change in meaning from the supporting committee's report. I emphasise: there has been a huge change in meaning by those two alterations to what the supporting committee found in their report.

I will go to the next document. Dr King, the chair of the scientific supporting committee, who obviously knew the wording of his committee's recommendations, presented the altered report to MSAC as if it were the unaltered report of his committee. You can see at the top of the MSAC minutes that it says: 'The chair of this supporting committee, Dr King, spoke to this draft report.' In fact, what he was speaking to was the report that was altered.

The next document has now been handed out. Obviously, Senators, you will not have time to go through the text of those minutes and be sure of this but at no time was there any discussion that what they were looking at was not the report of the supporting committee, that it was the altered document. It simply was not disclosed to them. I hope as you have some time you might look through the document to verify that. As evidence that MSAC did not know that what they were looking at was an altered document, you can see the minutes of the MSAC executive from the 9 June 2000 meeting, which was the meeting following the MSAC meeting where that altered report was presented. I will quote from those minutes:

It was noted that a majority of MSAC members—9 members out of 14, with Dr Kitchener abstaining—endorsed the recommendations of MSAC supporting committee ...

The only conclusion is that a fraud has been committed on MSAC. They thought that what they had were the recommendations of the supporting committee. They thought that they were agreeing with those recommendations. They were not; they were adopting the altered version, but the fact of the alteration had been kept from them.

If you look at the last document, which I have now given to you, you can see that this is the final document which was actually published and is now in the public domain. It was accepted by the minister for health in August 2000. That report is still the basis of the government's current policy on PET. That report, I am saying, quite clearly misrepresents the real benefits of PET. Therefore, by virtue of the logic which justified MSAC's existence, this report must cause unnecessary misery to Australian cancer victims.

I have a brief summary of all of that, with the documents in order. It is there for you to have a look through. I have a copy for each of the senators on the Senate Community Affairs Legislation Committee. The last point I wanted to take you to is that the department of health has dishonestly concealed the alteration in Senate estimates and in a number of other public forums. I am saying that the harmful effects of the defective health care information contained in the MSAC's PET report could have been minimised if the department had allowed its processes and the process of the PET review to be properly scrutinised, but it did not. The department covered up the dishonesty-induced corruption in MSAC's PET report with more dishonesty. I draw your attention to the second last document in the folder that I gave you. It is a *Hansard* extract from the supplementary budgetary estimates 2003-04. It is question EO3-045.

CHAIR—Dr Ware, the last document in my folder is the minutes of a meeting with Dr Ware regarding—

Dr Ware—I said the second last document.

CHAIR—I am sorry.

Dr Ware—I think it is there. I may have got myself out of order. I am told that it is not there.

CHAIR—We have the other documents that you circulated to us previously. Is it in this folder?

Dr Ware—Yes, it is, but I cannot tell you off the top of my head where it is. With the documents you were given, it was included in attachment A, appendix A, I think.

CHAIR—We have seen that document.

Dr Ware—To continue, Senator Harradine asked a completely unambiguous question in relation to the PET review of 2000. He asked:

Did the Scientific Supporting Committee in its report find that PET scanning was clinically effective and possibly cost effective?

Do you all have a copy of that? Can I continue?

CHAIR—Yes. We certainly have the documents here in front of us.

Dr Ware—To my mind, the department's answer to Senator Harradine's question is also completely unambiguous. They said no. But, as you have already seen, the Scientific Supporting Committee did make a recommendation that PET was clinically effective. I think the second part of the answer to Senator Harradine's question is also a lie. The answer says:

Supporting Committees of the Medical Services Advisory Committee (MSAC) do not make findings. Neither do Supporting Committees make reports, this being the responsibility of MSAC.

However, I have already shown you a document that says 'MSAC Supporting Committee report', so they do make reports. You have it in front of you. I believe that these documents are proof that the department entered onto the public record false information about the 2000 PET review.

I brought this matter to the attention of the Australian Public Service Commissioner on 26 May 2005. Ms Briggs told me that it was a matter for the head of agency and provided my letter of complaint to the secretary of the Department of Health and Ageing as well as her own response to me. Yet in November 2005 advice from the secretariat of the community affairs committee indicated that the department had not requested modification of its answer to Senator Harradine, which I think I have just proved to you was false. So in full knowledge of its error the Department of Health and Ageing did not take the obligatory step of correcting that error.

Today in this opening address I think I have spoken about the tip of an iceberg of dishonesty. My letter to you of 26 January 2006, which I believe precipitated this process, contains many more examples. In essence, systematic corruption by public officials has cheated vulnerable Australians with cancer out of their right to access the best health care advice. This dishonesty has hindered rational health care financing decisions. Australian families throughout the country have suffered unnecessarily because of this misconduct. But the harmful effect is worse in rural and regional Australia. The 2000 PET review failed to consider many of the clinical indications for PET at that time. It failed to consider breast cancer entirely, it failed to consider those cancers which particularly affected children, and it failed to consider the use of PET in end treatment monitoring, which is probably the most important and, for the future, valuable and cost saving aspect of the technology.

Senators, I also believe this systematic corruption has prevented you from ensuring that public officials act in the public interest. Nobody can do their job if they make decisions based on false and misleading information. I trust that you will agree that these matters are of great public importance. I believe that an independent inquiry into these matters is required. This could force retraction of the faulty MSAC PET report. It could facilitate restructuring of MSAC so that this episode cannot be repeated. It could also make sure that persons responsible for the material abuses of the public trust which I believe have occurred are held properly accountable for their actions. I look forward to answering your questions. Thank you for giving me the chance to speak to you.

CHAIR—Thank you very much, Dr Ware, for that opening statement. Is there anything that your colleagues wish to add at this point?

Mr Read—It has been neatly summarised to you, but the scientific supporting committee found that PET was 'clinically effective'. Somewhere between that report and when it came to MSAC—the body responsible for making the major recommendations which Minister Wooldridge accepted—that report was altered. The alteration was obviously material. PET went from being 'clinically effective' to 'potentially clinically effective'. MSAC thought that when they read the recommendation 'potentially clinically effective' that was the result of a proper scientific review. It was not. It was the result of a fraudulent alteration. That rebounds in two areas: Medicare funding and, quite importantly, health care generally. If a member of the public goes into a GP's rooms and the GP says, 'You may or may not have cancer. There's a test. It'll cost you $1,000 or $1,500, but it is only potentially clinically effective,' the decision of that person who has the money may well be, 'No, I won't have this clinically effective treatment.' If they were told it was clinically effective, their decision might well be quite different. So it rebounds not only in the public arena in terms of public Medicare funding but also generally in health care.

CHAIR—Thank you. I will lead off with some questions. I see that you have given us some documents. One is labelled 'Draft MSAC Supporting Committee report'. The second document is called the 'Final assessment report'. The fifth document is called the 'MSAC assessment report'. Can you explain the difference between the second and the fifth documents?

Dr Ware—The way the MSAC process works is that the supporting committee basically do all the scientific work—they look at the evidence. MSAC meet only three times the year. They have a huge number of applications and issues in front of them. They do not have the time to look at the evidence themselves so they pick experts in the field to generate that information for them. The experts generate a report which is then formatted into an MSAC template which is called the 'draft report', which MSAC considers. When they have approved it, it becomes their final report that goes off to the minister. The first of those three documents says the 'MSAC Supporting Committee' and that is changed to 'MSAC' in the second document. Do you have that?

CHAIR—The second document is headed 'Commonwealth Review of Positron Emission Tomography, March 2000, MSAC application, Final assessment report'.

Dr Ware—That is correct.

CHAIR—The fifth document is headed 'Positron emissions tomography, March 2000, MSAC assessment report'. I take it that the second document is the draft of the final report and the fifth document is the final report.

Dr Ware—That is correct. The second document with the bright pink highlighting is the one that went into final MSAC meeting on 24 May 2000. That was the one that was represented to be the supporting committee's report. That was the one that was put up for their endorsement. I am showing you the final document to show you that those crucial recommendations were translated exactly as if they had been the supporting committee's recommendations.

CHAIR—You say the second document is the draft report of the supporting committee.

Dr Ware—It is not the draft report of the supporting committee.

CHAIR—It purported to be the draft.

Dr Ware—It ought to be, it was represented to be, MSAC believed it to be, but it was different.

CHAIR—I read the second document in fact as the first draft of the report that MSAC itself was proposing to make rather than the report of the supporting committee. It is not headed 'report of the supporting committee'; it is headed 'MSAC application, Final assessment report'. We do not have any other pages other than the one page and the covering page. It talks about the MSAC Supporting Committee in the third person—'the MSAC Supporting Committee concludes' blah, blah, blah and then makes approved recommendations. Can you show us anything that would demonstrate that this is actually meant to be the supporting committee's document rather than MSAC's document?

Dr Ware—The supporting committees do not publish information to the public domain; it always comes out under MSAC's banner. It has to be formatted into the MSAC format for MSAC to approve but it is always presented as if it were developed by the MSAC Supporting Committee itself—and you see that report. The other crucial issue there is that under general findings it says:

The MSAC Supporting Committee concludes that:

MSAC are being told that that was a conclusion of their scientific advisory committee. But if you go back to the previous document, which was the report that they approved, it was not there. It did not exist.

CHAIR—I can see in document 1, which is headed, as you say, 'Draft, MSAC Supporting Committee report', that whoever drafted this document believed that the committee was making two recommendations. The first one says:

... concludes that there is insufficient evidence on PET's clinical or cost effectiveness with respect to the six indications reviewed to warrant unrestricted MBS funding.

The second recommendation says:

... the evidence suggests that PET is safe, clinically effective and potentially cost effective in the indications reviewed.

Those two recommendations in the draft document are picked up almost word for word in the approved recommendations which appear in the second document, and pretty substantially again in the fifth document, which, as you say, is the final report—the published document—of MSAC.

With respect to those recommendations, there are only two differences between the first draft and the last draft that I can see. One is that the number 'six' has been omitted from the first recommendation. It said, 'with respect to the six indications reviewed' and in the last draft it just says 'with respect to the indications

reviewed'. In other words, 'six' has been omitted. The second difference is that in the second paragraph the word 'potentially' has been added before 'clinically effective'. You referred to the sentence:

The MSAC Supporting Committee concludes that:

. there is insufficient evidence at this time from which to draw definitive conclusions ...

That appears to me to be a summary or a paraphrasing of what the MSAC Supporting Committee was saying to MSAC. If this second document is indeed a creation of MSAC rather than the supporting committee, would that not be an appropriate thing for it to do, that is, to summarise what the supporting committee was saying to MSAC for the purposes of discussion on that higher body?

Dr Ware—I agree with you. As MSAC is structured it has the right to make any decision it wants and it does not have to accept the supporting committee's recommendations. It has the right to change the wording as it sees fit. But it does not look at any evidence itself and it has repeatedly been said that these conclusions are based on the best, most rigorous evaluation of the evidence. If you look at the words in the document labelled 'Draft, MSAC Supporting Committee report' you will see that there are two points. The first point says that there is insufficient evidence of clinical and cost effectiveness to warrant unrestricted Medicare funding. The second point says that while the committee accepts that there is not enough evidence for unrestricted Medicare funding, the evidence suggests that it is clinically effective. I think that is a definitive statement of what they thought of the evidence.

The whole crux of the PET review was to see if PET really helped patients. Everything else flowed from that. Was it of real benefit to patients? There is no point looking at distribution of resources, workforce issues or even cost effectiveness if the technology is not clinically effective. I am saying to you that they made a definitive statement about that and that was changed, but it was not changed within MSAC; it was changed before it went to MSAC. You are saying that MSAC might have changed or might have paraphrased that document; they might have done but they did not. It was done before they got it. I can table the FOI release from the department which says that that was the document that went into that meeting; it was not the document that was modified as a result of the discussions within MSAC.

CHAIR—Could I come to that? You have tabled at least, I assume, some of FOI documents.

Dr Ware—Yes.

CHAIR—There is a schedule of documents relevant to the FOI request and it is numbered. Five documents have been tabled, including the PET Review Steering Committee's third meeting agenda and the PET Review Steering Committee's agenda item 2, 'MSAC evaluation report'. I assume that the second item is, in fact, document 1. Is that right?

Dr Ware—Yes.

CHAIR—The document that you have tabled is headed 'draft'.

Dr Ware—Yes.

CHAIR—We are all familiar with the workings of committees. Like this committee, committees are often presented with drafts and the committees very frequently, if not almost inevitably, will change the draft before it is actually presented for report or publication. I cannot see any documents among those that were provided under the FOI request which amount to minutes of the supporting committee meeting that would demonstrate whether this document, as a draft, was adopted without amendment or whether the document was changed in some way and, if so, how before being presented to the MSAC.

Dr Ware—Your point is very well taken. One of the difficulties for us always with this process is actually getting access to the real documents that were presented to different people. For example, the last FOI release took me six months to get, because we figured that we did not have the absolute and concrete evidence of the final approved recommendation. That schedule says that that was presented to one of the other PET review committees as the authorised report of the MSAC supporting committee. So I am saying to you that, even though it says 'draft', the department gave it to me as that document. I believe we can accept that.

CHAIR—Where does it say that?

Dr Ware—I do not have the schedule in front of me. Am I able to have your document? It would be quicker.

CHAIR—Yes.

Mr Read—It is attachment A to the second letter.

Dr Ware—Yes, I agree with you. It was presented to that meeting of the steering committee as if it were the MSAC evaluation report. I could show you, by going through the minutes, that it in fact states that MSAC had not as yet looked at the document itself.

CHAIR—The minutes of the supporting committee?

Dr Ware—The minutes of the meeting of that steering committee on 6 April 2000.

CHAIR—Do you have those minutes?

Dr Ware—Yes, I do.

CHAIR—Could you table them for us, because that is fairly crucial.

Dr Ware—Yes. Would you like this handed over?

CHAIR—Yes, please.

Dr Ware—May I read from it before I hand it over?

CHAIR—Yes, certainly.

Dr Ware—It states:

Agenda item 2: MSAC evaluation report

The MSAS Supporting Committee met by teleconference on 23 March to finalise the evaluation report. See attachment A.

So it states that the MSAC supporting committee met. That is at attachment A, which you have. It continues:

The MSAC Executive gave approval for the report to be considered by the Steering Committee in formulating recommendations. The MSAC evaluation report will be presented at the next full meeting of MSAC in May, for formal endorsement.

There is a second piece of evidence I could give you. If you go to the supporting committee minutes of 23 March, you will see a document headed 'Draft Commonwealth review of positron emission tomography, MSAC supporting committee report'. If you look through that, you will see that that document is exactly the same as the document which I just handed up to you which was presented to the steering committee.

CHAIR—I need to clarify something here. The document you have given me is an agenda for the meeting of 6 April.

Dr Ware—That is correct.

CHAIR—And the next document that is attached to that is headed 'PET review steering committee, 3rd meeting, Sydney, 6 April 2000, agenda item 2'. This reads like an attachment to the agenda rather than the minutes of 6 April.

Dr Ware—They are the minutes of 6 April, as supplied to me.

CHAIR—Can you show us the document? You say that they are the minutes. How do you know that? This looks to me like an agenda for the meeting of 6 April and a set of proposed recommendations for the meeting of 6 April.

Dr Ware—Those are the documents that were supplied to me by the department under the FOI request. The front page is document 1, 'PET review steering committee, 3rd meeting agenda', and on the pages behind that is the 'PET review steering committee, agenda item 2'.

CHAIR—You are quite right: it is a document, the date of which is 6 April. But it is very unlikely that the minutes of the meeting of 6 April are also going to be dated 6 April. They are more likely to have been created a few days afterwards and produced some time later. That reinforces what seems to me to be the case—that this document you have given us is in fact the agenda for the meeting and the draft report. The crux of what you have put to the committee is that there was some alteration in the draft report that was presented to the committee and approved by the committee and the one that reached MSAC. To be sure of that, we need to see the minutes of the steering committee meeting of 6 April to see that there was no resolution at that meeting that the report be changed, or changed in the way that it finally appeared at the MSAC. We need a document that is headed 'Minutes of the meeting of 6 April'. You have not given us any indication that this document is in fact the minutes of the meeting, because it is actually headed 'Agenda'.

Dr Ware—The first page is the agenda. If you look at the schedule from the FOI request, page 1 is the agenda and page 2 is the minutes.

CHAIR—Where does it say that?

Dr Ware—If I could hand up the next document, which is again an FOI release, it is titled 'Minutes of the 3rd steering committee meeting'.

CHAIR—That is entitled 'Minutes'?

Dr Ware—It has 'minutes' on it. That was supplied to me from a previous FOI release. They were the minutes that were, as you say, typed up a couple of days later as the result of that meeting's deliberations.

CHAIR—This is a different document from the one you have just referred to. This one is headed 'Minutes'. On the second page it says:

However, members suggested some minor changes to the wording of certain recommendations.

Do we know what those minor changes were?

Dr Ware—I have taken you down a slightly confusing alley because of trying to verify that that document that was labelled 'draft' was in fact the final version approved by the supporting committee. So the steering committee was a committee that was solely asked to look at the policy decisions; it was not to do the science. That committee did ask for some modifications of that document to be done, but they had no justification for doing that whatsoever. They were not there to do the science. This is not MSAC itself; this is a separate committee that is—

CHAIR—This is the steering committee?

Dr Ware—This is the steering committee that is working alongside MSAC. So MSAC was to do the science and the steering committee was to put that science into a policy perspective. I will read from the published report of the PET review:

The Department of Health and Aged Care ... conducted the review with the guidance of a steering committee comprising representatives of the medical profession, State and Territory government and consumers. The steering committee was responsible for consideration of the broader policy issues associated with PET, and with the preparation of the review report and recommendations for presentation to the minister.

An integral part of the review was a technical and scientific evaluation of PET, conducted by a supporting committee of the Medicare Services Advisory Committee ...

So the steering committee should not have changed the supporting committee's document. If the steering committee had changed the supporting committee's document, it should have been identified to MSAC, because that committee has no role in the MSAC process at all.

CHAIR—What we have in front of us is the minutes of the steering committee meeting of 6 April.

Dr Ware—Yes.

CHAIR—The minutes say:

... members suggested some minor changes to the wording of certain recommendations. These changes have been incorporated in the revised draft approved indications and revised draft Steering Committee findings and recommendations at attachments A and B respectively.

The first two paragraphs of attachment A are headed 'Revised approved indications' and the second of those paragraphs reads:

While the committee agrees that unrestricted funding is unwarranted at this time, the evidence suggests that PET is safe, potentially clinically effective and potentially cost effective ...

The word 'potentially' in respect of 'clinically effective' does now appear in these minutes as what was adopted by the steering committee.

Dr Ware—Yes, it does.

CHAIR—Your contention before was that the steering committee report had been changed before it had reached MSAC.

Dr Ware—No, I have never made a contention that the steering committee report was changed before it went to MSAC. It was the supporting committee's report that was changed before it went to MSAC. So the steering committee, again, could make any decisions it wanted to, but the steering committee did not have the jurisdiction to change the supporting committee's report. It did not have the jurisdiction to change the supporting committee's report and not identify that to MSAC. What I have shown you in the documents was that the document that was presented to MSAC was represented to be the supporting committee's. It says that the MSAC supporting committee concludes that there is insufficient evidence of clinical and cost effectiveness at this time. That was not in the document that they ratified. I am not sure whether, in this forum, when I have

been struggling to get documents out of the department, that we can verify in a legal sense that these are the documents. You do have something in front of you that says, 'The MSAC supporting committee finds this,' and they did not find that.

CHAIR—Where are the minutes of the MSAC supporting committee that will demonstrate that to us?

Dr Ware—I have handed you the fourth MSAC supporting committee report, I think.

CHAIR—What is the number of that document? Is this draft 1?

Dr Ware—That is an extract from the 23 March fourth steering committee report, but I think I have handed you the whole minutes.

CHAIR—I do not believe I have seen them, so could you direct us to where this document is?

Dr Ware—It has come out of my file. I have handed it up. I do not know.

CHAIR—Is it in the folder that was given to us?

Dr Ware—No. I have just handed it up in this second round, during your questioning.

CHAIR—Okay: it is the fourth PET MSAC supporting committee meeting. You say this document does not support any changes or variations to the draft document, which is document 1. Is that what you are saying?

Dr Ware—That is correct.

CHAIR—Does the supporting committee report to the steering committee and then the steering committee to MSAC?

Dr Ware—Normally there are no steering committees in MSAC processes. The steering committee was because the original applications to MSAC, as it says in the issues statement there, were shelved in the interests of having a review of PET with a broader focus, and Dr Wooldridge did that. I assume the steering committee was there to make sure that, if the MSAC found that there was evidence that PET really helped patients, there was a smooth transition to rapid implementation of proper access for the public to PET technology in line with his original statement to MSAC. So the steering committee was only to look at the policy, but it was to be advised on scientific matters entirely by MSAC itself.

CHAIR—Can you tell us where, in the minutes, the report was adopted without variation? Having only just seen these, it is hard to read just where the adoption of the report was made. I see there was discussion in the meeting of extensive changes to the report.

Dr Ware—Yes.

CHAIR—It does not actually use the words that are necessarily going to be adopted in the final report, but it talks about the process of discussion of those changes. Where do we have a document that summarises the final outcome of the meeting?

Dr Ware—My understanding is that the document that summarises the final outcome of the meeting is the document which is entitled 'MSAC supporting committee report', which is appended to the back of those minutes. That is the same as attachment A, which subsequently went through the steering committee but never found its way to MSAC itself, because it was altered.

CHAIR—The minutes talk about rewording and redrafting of documents: 'funding mechanism should be reworded to remove specific reference to etc'. I am trying to see where it actually says that the attachment is the document that was to be forwarded to the steering committee.

Dr Ware—If in attachment A, which you were handed up, you go back to the schedule of documents for the FOI request, that was the document that the department supplied to me. I asked them for the document which was the report of the supporting committee, as authorised by their 23 March 2000 meeting. They gave that attachment A—not on that document; that was a document from a previous FOI release—and that was the report appended to those minutes that they gave me. That was the final meeting of the supporting committee. They never met again, so I believed that was the actual supporting committee's report, the final version. If you compare that to the one that went to the steering committee that the department released to me, they are word for word the same documents.

CHAIR—My eye has just been drawn to the last few paragraphs of the minutes of 23 March, which begin with some discussion about Associate Professor Scott seeking clarification of the funding of PET services following the finalisation of the review et cetera. Then there is a paragraph that says the chair advised that this was not a decision of the supporting committee to make. I assume that refers to funding.

Dr Ware—Yes.

CHAIR—It then says that the issue should be referred to the steering committee, who would make a recommendation to the minister on the issue.

Dr Ware—Yes.

CHAIR—Now, those words by themselves would suggest that the supporting committee was actually handing to the steering committee the decision to make on what recommendation should be handed up to MSAC.

Dr Ware—Senator, if those words suggest that to you, there is an abundance of evidence that says that that is not the way the process was structured. That was not the way it was represented to the public. Would you like me to read the words from the front of the PET review report which describe the process again?

CHAIR—The report of MSAC?

Dr Ware—The published report of the PET review. It has two sections. The front section is the report of the PET review, which is effectively the report that the steering committee put together and sent to the minister. At the back is the MSAC report on PET. They went to the minister together. The description of the process that was followed was as I have read to you. I can verify that by referring to estimates 2002, when the department supplied Senator West with some information about PET, if you like, to verify that it is exactly the same words.

The Department of Health conducted the review with the guidance of a steering committee. The steering committee was responsible for consideration of broader policy issues associated with PET and with the preparation of the review report and recommendations for presentation to the minister. An integral part of the review was a technical and scientific evaluation of PET conducted by a supporting committee of the Medicare Services Advisory Committee. So I do not believe that the steering committee had any right to change a supporting committee report. They certainly did not have any right to change it without identifying that to MSAC. And as you have seen, the document that went to MSAC for approval states that the MSAC supporting committee 'recommends', 'finds' or 'concludes' where they did not.

CHAIR—The supporting committee appears to be of the view that the steering committee could make changes or variations to what was being proposed to MSAC. That seems to be the view of the supporting committee. It would be interesting to get information that suggests that the process was defined in such a way that it was impossible for that to occur. It seems from the minutes as though it was the view of the supporting committee members that they could hand up to the steering committee some decisions to be made about this. If you can give us evidence—perhaps you can take this on notice—that would suggest that there was no power for the supporting committee to do that and that it was incumbent on the supporting committee to make all the scientific conclusions and not leave anything to the steering committee then I would be very happy to look at that.

Dr Ware—Senator, if I could just clarify that, the steering committee had the role of making recommendations to the minister. But it is clearly in the public domain that that was as a result of the information that was supplied to them by the supporting committee. You have the document that went to the steering committee and it says that, even though there is not enough evidence in the supporting committee's opinion to recommend full MBS funding, it was clinically effective. That is the core of the issue that the patients want to know, and that was changed.

CHAIR—We have only just been given this document. This was not amongst the documents you have previously tabled to the committee. This seems to be, with respect, a crucial document.

Dr Ware—Sure.

CHAIR—I have not exhaustively read these pages of minutes, so I cannot be sure what it says and we should not now detain the committee by sitting here and reading it all. But I do point out that the last few paragraphs of the minutes of the supporting committee do suggest that the chair of the supporting committee meeting was saying that it was not a decision for the supporting committee to make with respect to funding and that the issue would be referred to the steering committee, which would make a recommendation to the minister on the issue. That seems to leave that issue for the steering committee to resolve.

Dr Ware—That is an issue of funding. I am talking about the recommendation, based on scientific evidence, about whether or not PET helps patients. Something that is also quite relevant is that the minister is not bound to accept MSAC's recommendations, anyway. Even if MSAC says, 'This is the best technology we

have ever seen,' the minister does not have to adopt that. The funding issue is separate from the fact that there is deliberate effort in the public domain that is explicit: MSAC will do the best scientific evaluation of the evidence to let people know whether technology has really helped them. That is completely separate from the funding decision, whoever makes that decision or recommendation.

Senator POLLEY—Thank you, Dr Ware, for your evidence this morning. Do you have any evidence that the MSAC report has influence on patient care decisions?

Dr Ware—I do have evidence of that. This letter is from Professor Ray Lowenthal, who was the immediate past President of the Australian Cancer Council. He said that PET was one of the most important advances in the treatment of cancer for a considerable period. He said: 'At present, if patients require PET scanning, they need to be sent to Melbourne at considerable inconvenience and at significant government expense. Furthermore, a number of patients who could benefit from PET scanning are not sent to Melbourne either because they're too sick or because of inconvenience or difficulties with travel. Some of these patients no doubt are missing out on optimum treatment. The oncological community in Tasmania would welcome your support for provision of PET scanning facilities in this state.' He is saying we are not using this technology as well as we would like to, because it is not widely available to us. We can send patients to Melbourne, but there are some patients who just cannot get there.

Senator POLLEY—Would you be able to table that letter for us?

Dr Ware—Certainly.

Senator POLLEY—Also, do you have any evidence that also suggests that MSAC's report has influenced other governments besides the Commonwealth government that has been to the detriment of patients?

Dr Ware—I think the best evidence of that comes from the Tasmanian government. I have put forward my potential conflicts of interest: I used to work with a medical imaging group in Hobart that was interested in establishing a PET scanner there. Their proposition to the government was that they would put in the capital funding for the scanner, that the government's existing mechanisms for vetting patients for travel to the mainland would stay with the director of state-wide imaging and that the state government would not be committed to any minimum number of patients who would be serviced. What they asked for was that the average travel expense for patients going to the mainland to get their scans free under Medicare would be given as a fee-for-service for the patients who had PET scans locally, which was in the order of $750 at that time.

The response from the state government was: 'No, we are not going to talk to you. The MSAC findings say that we do not know that PET is clinically effective. There is an ongoing data evaluation process to assess this. It is prudent for us to send these patients to this trial until we know that PET is actually a service that Tasmanian patients should have access to at all.' When they refer to the issue of insufficient evidence of clinical effectiveness, what they are really saying is: 'We do not know whether this technology helps people or not. We do not know whether this technology causes more harm than good. It is not prudent for us to provide it locally until we have good scientific evidence.' That is an extremely defensible position by relying on the MSAC report.

Senator POLLEY—How many occasions have you tried to raise these issues with the department?

Dr Ware—It is difficult for me to count how many times I have tried to speak to the department about the issues. Very soon after the original report from the PET review came out, I wrote to them saying that, if the supporting committee was an integral part of the process, I simply could not understand how they could possibly have come to the conclusion that PET was not of definite benefit to patients. I have worked with the people who are on the supporting committees for 10 years. I am a co-author with them on scientific papers. I have heard them speak at meetings. They have written editorials in the *New England Journal of Medicine* and local Australian journals. There is absolutely no doubt that they believe that PET is clinically effective. I wrote to the chair of MSAC and I said: 'This can't be so. Can I have the minutes of the meeting?' And the answer was: I need legal advice on that. I said: 'This is supposed to be a transparent and open scientific process. Why can't I see the decision-making process of these people?' It has been like that every step of the way. It has been a case of: 'We know you're well meaning but you don't know the facts.' Then you get a document that proves that you are right and they will not write to you anymore.

Senator POLLEY—Would it be fair to say that, for at least five years, you have been raising these concerns? I was just wondering whether you could enlighten us as to how you perceive the department's handling of your concerns?

Dr Ware—They have been completely dishonest and completely obstructive. The one simple goal in the whole process is to let people know the truth about what technologies can improve their health care. All the issues of funding and implementation were their decisions to make; they did not have to obstruct me in finding out why this faulty health care information was in the public domain. It culminated in my being black-listed by the department in 2002. They said that they would not speak to me about PET anymore; that it was not good use of public money to keep talking to me.

Senator POLLEY—Have you tested this matter of being black-listed? It is a pretty significant thing to happen.

Dr Ware—I have tested it on a number of occasions. I thought they may have eased off just before Christmas last year. I rang Chris Sheedy, who was then the Assistant Secretary, diagnostics and technology branch, and said: 'Chris, over and over again you have said in estimates that it is the MSAC report that is guiding government policy and the government's actions. You've said over and over again that there is not enough evidence of PET's clinical efficacy. I'm telling you that that was a fraudulent finding. I need some more documents to get access to that so that I can prove it in black and white and relatively easily for people to digest.' He said, 'Sure,' and referred me to Samantha Robertson, who was then looking after MSAC.

We had a process that went through a number of iterations: 'Yes, we're getting the documents. No, I'm conferring with my superiors.' After eight weeks of this process I got a letter saying, 'Dr Ware, as you know, the department said we won't speak to you anymore.' More recently, I rang them to ask for the list of MSAC members who attended the 24 May 2000 meeting. The departmental, supposedly secretarial, adviser to MSAC said. 'The department said that we do not speak to you and neither does MSAC.' Here you have the department making decisions on the basis of a supposedly independent committee of MSAC.

Senator POLLEY—Obviously you have tried to deal with the department, but I can also see from your correspondence that you have raised your concerns directly with the Prime Minister. What did you put to him, and what was his response?

Dr Ware—I bumped into the Prime Minister before the last election, at the end of August 2004. He graciously gave me five minutes of his time while he walked around the Hobart waterfront. I said that I wanted to talk to him about PET, because there was a report from MSAC in the public domain that was wrong; that it was hurting patients; and that it needed to be retracted, irrespective of the funding decisions. I told him that I had credibility on the issue and that Mr Read, Hilton Francis and I had an article in a medical journal of Australia with an editorial associated with it, that it had been covered on the front page of the *Sydney Morning Herald* just recently and that I had been invited by MSAC to participate in a PET supporting committee process. I said: 'I have credibility. I would like you to look into this. It is hurting sick and desperate people and the department won't listen to me, the minister's office won't listen to me and, I want you to know, as the head of the country, that this terrible thing is happening.' He said that if I sent information to a particular person, whose name has just escaped me, he would be briefed on the matter. To my knowledge that has not happened.

Senator POLLEY—Have had any further response from the Prime Minister?

Dr Ware—I have had no further response from the Prime Minister. I wrote a letter in January 2005, with some extensive supporting documentation. The Department of Prime Minister and Cabinet claimed that they had never received it. I resubmitted it. They said that they would bring it to the Prime Minister's attention but that I should talk to Mr Abbott. I wrote to Mr Abbott in November 2003 when he became health minister. I put up my concerns, but I still have not got a reply from him.

Senator POLLEY—Would it be fair to say that, when Senator Patterson had the responsibility, she was aware of these issues?

Dr Ware—Yes. I communicated with Senator Patterson. I had a response from her noting my concerns. In September 2002, she facilitated a meeting with me and some MSAC people, and I put my concerns to them. Many of their responses to my concerns then were simply untrue. For instance, they said that all the supporting committee members had signed off on the document that went to MSAC. It is absolutely clear that that is not true. The chair of the supporting committee said that it was documented that he was the one who asked for the changes to the supporting committee's document to be 'potentially effective'. But, to this day, no-one has identified how the main finding that there was 'insufficient evidence of clinical and cost effectiveness'—the one that all government policies follow from—got into the document that was presented to MSAC.

Senator POLLEY—My final question, if I can have the indulgence of the committee, is: what do you want the committee to do, Dr Ware?

Dr Ware—As the exchange with Senator Humphries has shown, verifying the veracity of documents in a forum like this is extremely difficult. That is a thing that lawyers spend a lot of time doing—making sure whether this is the truth or that the truth—and once they decide on that they argue the case. What I am trying to do here is show you that I indeed have a case. I am not bitter and twisted because I have not got my own way over five years. I think that there needs to be a proper and independent inquiry. I think that it is of massive public importance of itself. If MSAC can behave like this and it is not changed, why won't it happen again? I think that an independent inquiry would let us verify that what we are seeing here is indeed true. It is very difficult for you here—and I am sorry that the process of distributing documents was a bit shambolic, but it is a complicated process. It took the years to work out what had actually happened. I knew that what came out was not right but to work out how it had actually happened took me years. We have got the documents there and in that process the department can be made to hand up the documents. What was the supporting committee's report? What was the final version? Why was this draft on it? Was it the draft? Was it the final version? I would like that because I am absolutely certain that fraud has occurred. I am absolutely certain that the fraud was on MSAC because the document they thought was the supporting committee's report was not the report at all. Ultimately I would like to see this document retracted from the public record. It has hurt people and it needs to go because it is dishonest.

Senator MILNE—I would like to follow up from Senator Polley's questions with regard to the supporting committee's report and what got to MSAC. That is the whole crux of this matter that Senator Humphries has been trying to get out and it is what we all need to get out. We are not here really to discuss the cost effectiveness. What I am really interested in is the conclusion about the clinical effectiveness and safety, and that was the responsibility of the supporting committee. Is my understanding correct?

Dr Ware—Yes.

Senator MOORE—On that basis you are saying that you have got a document which demonstrates that the chair of the supporting committee, Dr Richard King, inserted the word 'potentially' after the report left the supporting committee, or at least without the approval of all members of the supporting committee?

Dr Ware—Yes.

Senator MILNE—We do not know who inserted the additional words that turn up in the MSAC supporting committee document—and there is a whole paragraph of additional words there. We do not know who put that in or when it was put in?

Dr Ware—That is correct.

Senator MILNE—I also understand that a copy of a letter that was written by Rodney Hicks to Ms Halton—Rodney Hicks was a member of the supporting committee—says:

... I again request that the Report the Commonwealth Review of Positron Emission Tomography should be altered to correct the errors identified by myself and others and to reflect the true opinions of the majority of members of the original Supporting Committee, and that a similar approach should be taken to MSAC's Final PET Assessment Report.

He goes on to say:

If these documents are not amended to reflect the true findings of the committee of which I was a member, I again request that my name be removed from document. My international reputation has been sullied—

and all senators have a copy in the file. Professor Hicks was on that original supporting committee—is that correct?

Dr Ware—That is correct, yes.

Senator MILNE—Do you know of any other people on the steering committee who have also said in any way publicly, or let anyone know, that they also object to what went forward purporting to be the recommendation of the committee?

Dr Ware—It was a supporting committee—you said 'steering committee'. I do not know of anyone who has gone on the public record complaining about it. I do know that people are terrified of putting a foot wrong with the department or the government. The people who were experts on that committee were all people who had PET scanning facilities in existence and they were scared that if they said anything there would be retribution. The other important thing is that they all signed confidentiality agreements and that has certainly held back people from speaking out publicly. It certainly restricted what Professor Hicks might have said on the public record, I know for a fact. I asked the department at one stage whether the confidentiality agreements were permanent because previously the instructions to the participants were that when the report was in the

public domain the confidentiality agreements lapsed. Certainly with the PET review that information was changed and the department made it clear that they expected those confidentiality agreements to be observed.

Senator MILNE—How many people were on the supporting committee?

Dr Ware—I think that there were seven members.

Senator MILNE—So from what you have said, the only way we can get to the truth of this committee is to have all the minutes of this committee or, indeed, some of the other members of this committee, or all members of this committee, come and say what they know to the parliament?

Dr Ware—That is correct.

Senator MILNE—In relation to Ms Halton and the department, specifically when did you point out to the department that this material change—this very significant change—had been made between the supporting committee's report and what MSAC deliberated upon? When did you let them know that that had occurred?

Dr Ware—I believe I did that in a letter to Alan Keith, who was then assistant secretary for diagnostics and technology, when I got the first FOI release and that was in approximately May 2001.

Senator MILNE—So for the last five years we can confidently say that people in the department have known, that not only you but also Professor Hicks have pointed out that there has been a flawed and wrong basis on which MSAC made its final assessment report?

Dr Ware—That is correct. Senator, could I read to you from a 3 April 2002 response from Jane Halton?

Ms HALL—Please do.

Dr Ware—I wrote a number of questions over a period of time, which in fact the Ombudsman had to intervene to get an answer on from the department. Ms Halton sent me this letter as a consolidated series of answers to my questions, which I had actually posed as a whole thing to Mr Podger. I said:

Modification of the conclusion of the Supporting Committee for PET, that PET is 'clinically effective' by inserting the word 'potentially' was undertaken without any reference to those who were properly responsible to make this determination. Will MSAC be made aware that a major conclusion issued in their names was determined by the Steering Committee for the PET Review—

which I thought had occurred at that time—

a committee which has no jurisdiction in the deliberations of MSAC?

Part of the answer said:

The final wording of MSAC's findings and recommendations—and MSAC reports are ultimately products of MSAC, not supporting committees—was determined and approved by the full committee following the meeting of 24 May 2000. Modification referred to was made for the sake of consistency with MSAC's primary finding that 'there is insufficient evidence of this time from which to draw definitive conclusions about the political effectiveness and cost effectiveness of FDG PET'.

So this is the secretary of the department who has identified what the primary finding of this whole expensive process was, and it is that changes to one finding are justified on the basis of another finding, which I have shown you was not in the supporting committee's report, and MSAC did not know that.

Senator MILNE—I want to go back to the role of Richard King as chairman of the supporting committee and his insertion of the word 'potentially'. After the committee had concluded that in fact it was clinically effective, he inserted 'potentially'. That was the basis from which everything flowed, including those words being put in, and we do not know how they got there. Has Richard King ever explained on the record to anyone why he inserted that word after the deliberations of the committee, and has he ever said with whom he discussed inserting that word?

Dr Ware—No, not to my knowledge.

CHAIR—Can I follow that question up for clarification: Dr King has admitted to being the person who made the modification by inserting the word 'potentially'—is that what you are saying?

Dr Ware—There is a final document in the folders that I have given you. On the last page I think it says, 'The chair of the supporting committee requested that the change be made.'

Senator MOORE—That was the point I was getting out of Senator Milne's questions: where had the ownership come down to one person? Can you point me to the phrase? Which document has that sentence in it?

Dr Ware—It is in the last document.

Senator MOORE—Of the folder you sent in to us?

CHAIR—Is that the 'minutes of the meeting with Dr Robert Ware regarding the MSAC PET report'?

Dr Ware—Yes, that is correct—that document there.

CHAIR—So it is the last page of this document.

Dr Ware—It is the last page of that, and it is the top paragraph.

Senator MOORE—20 September 2002?

Dr Ware—It was September 2002.

CHAIR—The minutes say: 'The word "potentially" was inserted at the request of the SC chair'—I assume SC means supporting committee—'who is responsible for bringing draft recommendations to MSAC.' Who made that statement?

Dr Ware—These are the minutes, the summary of a meeting I held with MSAC members and the department on that date.

CHAIR—But who took these minutes?

Dr Ware—I do not know.

CHAIR—Was it the department?

Dr Ware—I do not know. The department submitted those to me as their official record of the meeting.

Senator MOORE—Dr Bernie Towler. It says on the front page who took the minutes: Dr Bernie Towler, medical adviser, MSAC. The way I would read that is that he or she took the minutes.

Dr Ware—That was what the department sent to me as the minutes of the meeting.

Senator POLLEY—So that is their record.

Senator MILNE—To come back to the context of this: you have alleged in your documents that there was ministerial interference in the process, and I note that the standard MSAC assessment process was changed particularly for this PET review. You said a moment ago that it could have been because there had been applications from the Wesley Hospital and others for the scanner prior to this. That was held up in the light of this assessment process. I am interested in thinking about the fact that at that time there was a political scandal around the MRI scanners. Clearly this PET scanner was going to be very expensive. The terms on which it was rolled out would be expensive for the government. That was the context. Can you give me a sense of why you are saying that there was political interference in the process?

Dr Ware—It is clear that MSAC's normal process was changed. It is documented in the *Medical Journal of Australia.* Professor Weedon said that MSAC asked for a deviation from its process because of the cost of the technology. That is outside its terms of reference, explicitly. MSAC started reviewing the applications. They chose a chairman on 10 May, 1999. Nine days later, at a full meeting of MSAC, they changed course completely. All of a sudden they needed ministerial advice. They needed to know about the cost of the technology, controlling its roll-out. I know from MSAC executive minutes that the applicants were told that their applications would not be looked at until the ministerial review was finalised before MSAC—which is notionally independent—had actually received the advice from the minister. So I know that those things were done. MSAC's process was changed. The department and the minister made active decisions on behalf of MSAC.

I do not have absolute or any sensible proof that the minister actively intervened to produce the outcome that occurred. I do not have information that the minister tried to make the people whom he said he was trying to protect through MSAC actually suffer by dint of this false information on the public record.

Senator MILNE—I note in this letter from Rodney Hicks that he says he was told by the chair that the bar had been raised as a result of the MRI scam and that it was highly unlikely that unrestricted funding for PET would be recommended—this before any consideration of the evidence had ever taken place. So clearly he was a member of the supporting committee and that was already being talked about before any assessment of the clinical effectiveness or cost-effectiveness had taken place. Who appointed the chair of the supporting committee? Was Dr King elected or chosen from his peers on that supporting committee or was he a government appointee as chair of that committee? Do you know?

Dr Ware—I don't know conclusively from the information. What I do know is that MSAC had started to process the initial application from Wesley, and they had chosen a chair. They had nominated Dr Terri Jackson—

Senator MILNE—As chair of which committee?

Dr Ware—As chair of the supporting committee. In the process of restructuring how PET was assessed, Dr King became the chair of the supporting committee. I don't know how that came about. It is not clear from the minutes that he was selected by MSAC itself.

Senator MILNE—Just as a conclusion, from your point of view, to establish this without any shadow of a doubt we need to know the process beyond the supporting committee and before MSAC and Dr King's role in inserting that word. Who else inserted that paragraph and who had been spoken to in regard to that? That is essentially what we need to get now.

Dr Ware—Yes, Senator.

Senator MILNE—I would like to thank you for all of the work you have done in trying to collate the documents. Clearly, it is now up to us to collate the rest of the documents. I appreciate the effort you have put in. I note here what Dr Hicks had to say on *The 7.30 Report:*

... the current review is an awful outcome, not for Rod Hicks, not for Peter McCallum, not for the Austin but for patients. I owe this to the one in three Australians who will die of cancer and who will potentially be denied access to this technology as a result of the current review...

which is a very powerful quote from a letter he had written. So I appreciate the work you have done in this regard.

Senator MOORE—I have a straightforward question on process. We receive so much documentation. In many ways sometimes that makes it more difficult because you are wading through so much.

Dr Ware—It has—I am sorry.

Senator MOORE—No—don't be. In terms of the information you put before us, my understanding is that a considerable amount of that has come through FOI requests.

Dr Ware—That is correct.

Senator MOORE—Can you let us know—and you can take this away—how many FOI requests you had to put in to get what you have here? Also, from your point of view, will that reflect the full history of the process? My understanding is that, as you have taken this on since 2000, there has been considerable interaction between various people and various departments. We have had a lot of questions from senators this morning about where it is, what it is and what those minutes say. It is not normally your responsibility to provide all that. In terms of process, I would like to know how many FOI requests you had to put in to come up with this process, how detailed those requests needed to be and whether there was ever a blanket exchange of information.

Dr Ware—Can I answer the question?

Senator MOORE—Sure.

Dr Ware—I cannot be completely accurate, but, as I said, I know what these people on that committee think. I work with them. I know the answer that came out could not possibly have reflected their views. I could not talk to them. MSAC would not talk to me. Mr Read said: 'You just have to get all the documents. Put in a request for all the documents.' I got an answer back saying: 'There are 5,000 pages. That will cost you $28,000. By the way, you are not going to get 2,000 of them anyway because they are privileged.'

Senator MOORE—So it cost less, then.

Dr Ware—I thought, 'There's not much point spending that money.' We then tried to focus on where we thought the details might be, and that information was supplied to me free of charge. Those documents led to other documents, which we then requested. Then the department said: 'Yes, you can have them. It is going to cost in the order of $800.' In the end I think I got about 30 photocopied pages for that $800. I challenged them in the AAT because I thought it was unfair. I asked them to consider revoking the charges because it was in the public interest. They said: 'No, it's all in the public domain. That won't happen.' And there were documents they said I could not have as well. So we went to the AAT. They stared us down, right to the line, and eventually they capitulated and handed over the documents and I got my money back. There were a number of FOI requests after that. Believe it or not, I am relatively articulate and organised. I know the guts of what

happened here and I know that it is wrong for patients. One of the things that concerns me about this is that there must be all sorts of things happening in the community where people think something has gone wrong but they just do not have the wherewithal. They are not sure enough about their facts, they do not have the financial resources to see it through. If I had not had Mr Read's help I would not have been able to sort through this. I simply would not have been able to do it.

Senator MOORE—Can I ask on notice—that is a term we use if you take it away—if we can get a summation of your document search, what you had to do, how many times you had to ask, the interaction you had? You must have put that together in one form for the AAT case. I do not want a large five-page explanation; I would just like to see what you had to do to seek the information.

Dr Ware—Do you mean letters to the department and those sorts of things?

Senator MOORE—And the response. From our point of view, we want to know what it entailed for you, as a citizen, seeking information over a period of time on one issue.

Dr Ware—I would be pleased to do that.

CHAIR—I want to just come back to the minutes of the supporting committee meeting on 23 March 2000. It is clear from looking at those minutes that the document headed 'MSAC supporting committee report' is in fact only the draft that went to the committee meeting, not the report that was adopted at the committee meeting. I draw that conclusion by looking at the various issues discussed at the committee meeting about the report. Decisions were made to change the report but the changes do not appear in this draft. I think it is reasonable to conclude therefore that this is the draft that went to the committee for consideration of that meeting rather than what came out of the other end of the committee.

For example, looking at the page on which those recommendations appear that have been the subject of so much debate, it says the committee decided:

- Item three of the *primary staging* section (absence of definite systemic disease on conventional staging) is to be removed

But that third item is still in that draft document that is in front of us. It was also said:

- The Committee agreed to removing the section entitled 'Assessment of clinically resectable metastatic disease'.

The draft of the report attached to the minutes still includes that section. I think what we can safely conclude from all of that is that this document, which is attachment A to the minutes, was, in fact, the draft of the document that went to the committee rather than the report that came from the committee up the line to the steering committee.

Dr Ware—I think you are in the wrong document. I think you are looking at the 6 April 2000 steering committee document.

CHAIR—No, I am looking at the document entitled 4th PET MSAC supporting committee meeting, Thursday 23 March 2000.

Dr Ware—I cannot deal with the question without looking at it and looking at the data but my understanding is that the document that is appended to that is the ratified report of the supporting committee.

CHAIR—I suggest you go back and have a look at the minutes. The minutes make it clear that that document was being amended by that meeting of 23 March. That document is not the final outcome of that meeting because there are changes agreed to by the supporting committee to the document which have not been reflected in the document itself.

Dr Ware—I do not think you will find in those minutes that they discuss adding the word 'potentially'. I do not think you will find in those minutes that they said that we should add the bit about insufficient evidence of clinical or cost effectiveness. Because that contradicts completely with what they did decide—that it was potentially clinically effective. They did agree to some changes, those changes were made, but they did not agree to the changes that are crucial to the issue that I am trying to draw your attention to.

CHAIR—I agree that they did not explicitly make those changes but there are a number of rather vague, I must say, sections of the minutes where they refer to changes being made subsequent to that meeting. For example, it says:

Dr Hicks will provide the Department with appropriate wording for the primary staging indication as soon as possible.

Presumably, that was to be some incorporation into the document that was going to occur after that meeting had occurred.

Dr Ware—Yes.

CHAIR—And the chair advised that the supporting committee was not to make decisions about funding of PET and that the issue would be referred to the steering committee which would made the recommendations. We do not have in front of us a document which summarises the view of the supporting committee. If it is available, it has not been presented to us.

Dr Ware—I think the thing that says MSAC Supporting Committee Report is the document that summarises the view of the supporting committee, the decisions of the supporting committee. I believe that is the document appended which you have there and I am not aware of that document not reflecting the changes. As I said to the department in the last FOI release, I would like to see the document that went to the steering committee which was represented to be the final report of the MSAC's supporting committee. That is one of those documents that I handed up that they gave to me. I believe that the documents are equivalent.

CHAIR—As I say if you read the minutes, it is clear that the attachment is not the final report. It cannot be the final report because there are changes made by the committee which have not been incorporated into the report. I will leave you to consider that. Perhaps I have misread it in some way.

Senator ALLISON—I want to understand the implications of what you are suggesting is 'fraudulent'. That is a very strong word to use in these circumstances. As I understand it, the recommendations of the supporting committee talk about cost effectiveness in the indications reviewed. In the final recommendation in the list that we have it says:

... FDG PET be funded on an interim basis in the following clinical conditions:

What is missing from that list of scenarios that might have been in the scenarios identified by the original supporting committee's report?

Dr Ware—In all of the indications that the supporting committee was allowed to look at in that process, they actually found evidence of clinical effectiveness. That is in that document that left the committee. I will read to you from the PET supporting committee review final report. It says: 'The current review has examined the role of PET in six distinct clinical indications. However, consultations with current PET providers suggests that the indications reviewed account for approximately 40 per cent of the clinical PET procedures conducted.' So they excluded 60 per cent, and they did it because they did not provide enough time to do the review to truly give a national perspective.

Senator ALLISON—But is the 40 per cent that they did look at reflected in the list of those which were given the go-ahead for interim funding?

Dr Ware—Yes, it was.

Senator ALLISON—So we are just talking about the difference between what was reviewed and what was not reviewed in terms of what PET might be used for under the new arrangements?

Dr Ware—If I understand your question correctly, that is not what we are looking at. The supporting committee found that PET was clinically effective in those indications it was allowed to review. But that was changed to an equivocal conclusion that said there was insufficient evidence of its clinical effectiveness and it was only potentially clinically effective. That is the guts of it. Even in those indications that were accepted for interim Medicare funding to get some more data, the supporting committee's assessment of the true benefits to patients was downgraded substantially.

Senator ALLISON—I am still not clear, I am sorry. There are nine dot-point indications. The report says:

On this basis the steering committee recommends that FDG PET be funded on an interim basis in the following clinical conditions:

And there are nine of them. Did that proceed?

Dr Ware—Yes, it did, on an interim basis.

Senator ALLISON—Does that represent the 40 per cent that were looked at by the supporting committee?

Dr Ware—Yes, it does.

Senator ALLISON—I have a question about the minutes of the MSAC meeting of 24 May. The chair, under item 3, commenced by advising members that there were a number of conflicts of interest among the supporting committee members. What are the implications of that? Why in your view does this minute begin with that? Is that a reason why these changes were made?

Dr Ware—As Senator Milne pointed out, I suspect that it was at the time that the whole thing about the MR scam was unfolding. It was well known that Dr Wooldridge was very upset. He called the radiologist untrustworthy over and over again in a *7.30 Report* transcript. So the issue of conflict of interest was absolutely paramount at this time. Everyone was completely paranoid about it. The conflicts of interest were declared by those members. It was decided and even minuted that, even though the people on the supporting committee had potential conflicts of interest, it did not matter because their role was to decide on the science. It is not in that minute you have. Their role was to decide on the science, whereas the funding issues were completely separate. It was decided that those conflicts of interest were not paramount. I do not know why that was put in as an explicit minute. My guess is that it was to discredit those people's opinions.

Senator ALLISON—Can you tell the committee who Dr King was? Was he the chair of MSAC at that time?

Dr Ware—No, the chair of MSAC was Professor David Weedon. The assistant chair was Brendon Kearney, who took over the role as chair of the steering committee. Dr King was a member of MSAC who took over the role of chair of the supporting committee.

Senator ALLISON—Dr King advised that the current evidence in support of PET was not strong?

Dr Ware—Yes.

Senator ALLISON—Thank you. I have one more question on the list of indications. Breast cancer was not able to be reviewed by the supporting committee—is that right? What reason would there be for that?

Dr Ware—The original applications to MSAC both included breast cancer and far-ranging indications for PET. By the time they had constituted all these committees, they had wasted three months of the six-month review process, so when it was presented to the first supporting committee meeting they said, 'We've time to do only six indications; you tell us the indications where the evidence is best.' At that time, the scientific evidence for breast cancer and other tumours was not as well developed, so they said, 'If we have to put our best foot forward, these are the indications where the scientific evidence is best developed.' They were thinking of clinical effectiveness and cost-effectiveness, and the feeling at the time was that we would get knocked over on cost-effectiveness. No-one remotely considered that anyone would claim that it was not clinically effective. It was completely out of left field that this would happen.

Senator ALLISON—There are criticisms throughout these documents that the cost-effectiveness study was not done, or was not proved. Whose fault was that?

Dr Ware—The decision was made that, because there was not enough evidence of clinical effectiveness, they should not do the cost-effectiveness evaluation. During the process there was evidence of cost-effectiveness documented in the clinical literature, particularly for people who have recurrent colorectal carcinoma being considered for liver resection. They actually note in the report that there was evidence showing that it was cost-effective, but it was never evaluated in that indication. It was really evaluated only in lung cancer, and it was evaluated badly.

Senator MOORE—The documentation we have provided naturally has come from your focus. Even the *Medical Journal of Australia* article has your name on it, although it has the names of other people as well. Has this issue caused outrage in other parts of the industry? I take the point you made earlier in evidence that on a whole range of things people are, understandably, a bit reluctant to speak out on against departmental and ministerial views. In the wider medical community, on the issue of PET, is there concern that, in all the stuff you have sent us, we just have not found—because it is not something we look at regularly, but I would be interested to know something that is quite well known and has been haunting Senate estimates committees for several years now—whether there are more people who are interested than just the usual suspects?

Dr Ware—There are more people who are interested. There are other people's names on the public record. In *The 7.30 Report*, which Senator Milne referred to, Dr Ball says that he thinks PET is one of the most important advances in lung cancer for many years. In 2000, he said that he thought we needed 18 to 20 scanners just to do with lung cancer. One of the scary things for me about this is that what has been created is a group that controls the knowledge that society runs by. Public money has been spent and there is a strong public representation that this process was going to give doctors, patients and governments the best information about clinical and scientific aspects and they could go off and do their own assessments of how that applied to their particular circumstances. That has been exploited ruthlessly to cut down anyone who stands up. It becomes, 'Here's another couple of doctors arguing the toss in the press,' and it has been exploited ruthlessly. In *The 7.30 Report* Professor King said, 'All may be very well but MSAC found X and

MSAC are the experts, not these people.' The fact that Dr Hicks was part of the supporting committee seems to escape the public record.

Senator MILNE—This is incredibly complex and there are so many documents, as my colleagues have said. We are running out of time. Is there anything critical to this that you think we have missed and that you would like to draw our attention to? It is entirely possible that in the bulk of this we have missed something really critical. You have come a long way, so please draw our attention to anything that you think is really critical in our deliberations.

Dr Ware—I think we have covered things very well. It comes down to the issue of deciding whether or not those documents prove my case. One thing that is absolutely inescapable is that the department's response to Senator Harradine's question in 2003 was wrong. It was completely wrong and it was misleading. Why would they do that if this was all above board? Surely, if the changes that were made were perfectly acceptable and in the public interest, why confuse the issue? That is one of the things that disturb me. Even if this were just some terrible mistake, we have to move on from our mistakes. We have to have a process whereby we can recognise that they occurred. I do not think that providing misleading information to estimates committees or in the public domain is the way to run that process.

CHAIR—That concludes the questions we have. Dr Ware, I thank you and your colleagues for appearing today. The committee will now hear from the Department of Health and Ageing and will explore with them the issues that you have raised. The committee's exercise here is to determine whether there is the basis on which to proceed to a more full inquiry into the issues that you have raised. Obviously, the committee will use the evidence it takes today to make that assessment. Thank you very much for your appearance here today.

Dr Ware—Thank you very much for the opportunity to speak to you.

CHAIR—That is fine.

[11.11 am]

HANNON, Ms Wynne, General Counsel, Legal Services Branch, Department of Health and Ageing

LEARMONTH, Mr David, First Assistant Secretary, Acute Care Division, Department of Health and Ageing

WOODLEY, Mr Peter Andrew, Acting Assistant Secretary, Diagnostics and Technology Branch, Department of Health and Ageing

CHAIR—We will resume this public hearing into the issue of positron emission tomography and the conduct of the review into that matter in 2000. I welcome David Learmonth, from the Department of Health and Ageing, and also Ms Wynne Hannon and Mr Peter Woodley. Thank you for appearing today and for waiting while we dealt with the earlier witnesses.

I remind you that, as departmental officers, the Senate has resolved that you should not be asked to give opinions on matters of policy. This resolution prohibits only questions asking for opinions on matters of policy and does not preclude questions asking for explanations of policy or factual questions about when or how policies were adopted.

I think you were present in the room for much of the earlier evidence that we took from Dr Ware and his colleagues. I do not know whether you heard the evidence given previous to that, perhaps remotely in the building or in some other way; we obviously have some questions to ask you about that evidence. Before we do that, I invite you to make an opening statement to the committee.

Mr Learmonth—Thanks very much. I am conscious of the committee's time but I would like to make a couple of brief points up front. Firstly, I would say that there is a lot of discussion around specific documents and quite a bit of detail that there was not meant to be. To start with I would like to, if I could, elevate the issues.

It seems to me that what is in contention is the nature of a change from a draft report to a final report and its significance. That there have been changes to a draft report in the preparation of a final report is of itself unremarkable. It is not contested that were changes made to a draft report in the preparation of a final. It seems to me, though, that there are certain questions that need to be asked about the nature of those changes. First of all, are the changes made supported in the text and the general discussion of the committees and the documents? I think the answer, on any cursory reading of the relevant documents, is that the changes and additions between draft and final were utterly consistent with the material in the remainder of the report and indeed in the discussions. So they are unremarkable in the sense that they attempt to summarise or draw out key points.

Secondly, were the changes made with the knowledge of those concerned? Clearly, as I think Senator Humphries was articulating earlier, the minutes of the last meeting indeed contemplate that changes will be made and the changes in question—as I think the evidence shows—were made at the request of the chair of the supporting committee. Clearly, they were known and contemplated. Clearly, they were consistent with the remainder of the report and the deliberations.

Finally—and I think this is a key one—were the changes somehow determinative of what followed or otherwise significant in terms of the government policy that flowed from it? I think the answer there quite clearly is that they were not. It is not the role of the supporting committee to make findings. It is the role of MSAC to make findings and recommendations, and MSAC, perhaps contrary to suggestions, is not a cipher or a rubber stamp of supporting committees. It would be remarkable in the extreme for MSAC to accept uncritically the report and work of a supporting committee. It takes its role seriously. It examines the full weight of evidence presented to it, and it makes its own decision. As to whether or not particular words or content that appeared in a document that went before MSAC are somehow automatically mechanically determinative of MSAC's view on what transpires, it is clearly wrong. Finally, ultimately the role of MSAC is not to decide on clinical effectiveness alone. It is to decide on the application for public funding through the MBS or related.

If you look at the whole train of material from supporting committee to MSAC to decisions there has been a consistent and constant theme, which is that there is mixed and inconclusive evidence as to the clinical and cost effectiveness of PET. It is borne out in the recommendations of MSAC in what was adopted by the government, in that what was adopted for public funding was a limited access regime, a limited number of

machines and a limited set of indications tied clearly and comprehensively to data collection which would enable subsequent review, monitoring and better understanding. That review process itself has been borne out in that subsequent to the original decision there have been government decisions to expand the range of indications for which PET is available on the basis of the data which emerges. Clearly, in our view, there have been changes. The changes are unremarkable in that (a) they were made, (b) they were consistent with the remainder of the report on any cursory reading, (c) they were made with the knowledge of the chair of the supporting committee and others, (d) they were not in any way determinative of what followed in some mechanistic fashion and (e) the whole theme is borne out throughout all of the decisions and reports.

The only other point I would make is that there have been some quite serious allegations—as you, Mr Chairman, pointed out—about the department, its officers and others in relation to fraudulent behaviour and other inappropriate behaviours, and I cannot let the record go uncontested. We would refute those allegations absolutely.

CHAIR—Thank you. Ms Hannon or Mr Woodley, do you wish to make any statement?

Mr Woodley—Not at this stage, thank you.

CHAIR—Could I start by clarifying one aspect of what we have been dealing with. There was a document provided to us headed up *Commonwealth review of positron emission tomography, March 2000, MSAC application, final assessment report*. I do not know if you have a copy of that document. It might or might not be part of that larger document. At the top of page IX is the heading 'Recommendations' and beneath that 'General findings'. The section reads:

The MSAC Supporting Committee concludes that:

- there is insufficient evidence at this time from which to draw definitive conclusions about the clinical effectiveness and cost effectiveness of PET ...

Do you have that document in front of you?

Mr Learmonth—I believe so, yes.

CHAIR—The question we are trying to determine is whether or not this is a document which is a creation of or the document of the MSAC supporting committee, the MSAC steering committee or MSAC itself. Can you clarify that matter for us?

Mr Learmonth—To the extent that it is possible to actually determine definitively which documents we are talking about—I guess from being in the audience, I am sorry—the document in question, I think, is the document that represents the final product from the supporting committee to MSAC. I think you characterised, from memory, the two documents in question well. One was a document that went to the final meeting of the supporting committee, at which it was determined that changes ought to be made.

CHAIR—Yes. This is not the same document that I was referring to; this is a different document.

Mr Learmonth—Yes. And the one in question, if it is the same one—and certainly my document has the same sentence as yours—represents the final report of the supporting committee as provided to MSAC.

CHAIR—It was put to the committee that those words—

- there is insufficient evidence at this time from which to draw definitive conclusions about the clinical effectiveness and cost effectiveness of PET—

purport to be words that were determined by and agreed to by the MSAC supporting committee but those words do not actually appear in any of the documents that the MSAC supporting committee actually considered or agreed to. Therefore the question was posed: how were those words, as it were, put into the mouth of the MSAC supporting committee when it did not actually use them or adopt them? It seemed to me, with respect, that this document is in fact not a document of the supporting committee; it is actually a document of MSAC itself in which it purports to summarise what it believes the supporting committee was putting to it. Obviously you have not got the document in front of you. Could you take on notice to determine whether those words are the words of the MSAC supporting committee or of MSAC itself. That is a fairly crucial question because that determines whether or not, as it were, the supporting committee has been verballed in what it was recommending to the committee.

Leaving that question to one side, the other question is the adoption of a single word in the approved recommendations, and that is the word 'potentially' before 'clinically effective'. As you have heard from previous evidence, there was discussion about a draft document at the 23 March meeting of the supporting committee. The supporting committee report then was presented to the MSAC steering committee. We do not

have in front of us any clear indication of the process whereby that document was changed, refined or developed for the purposes of presenting it to the steering committee. You have said to us in your opening remarks that it is possible for change to occur and that that is the way by which it occurs. Can you outline for the committee exactly how changes would be made to a document like that under usual rules dealing with the supporting committee's work and who would be authorised to make those changes?

Mr Woodley—It is on record that a change was made. That is not contested. I understand it is also on record that the chair of the supporting committee, also a member of MSAC, took responsibility for the insertion of the word 'potentially'. I think it is also material that two additional members of the supporting committee were members of MSAC.

CHAIR—Who were those two members?

Mr Woodley—Professor Brendon Kearney and Dr Michael Kitchener.

Mr Learmonth—The committees were not distinct. Three members of MSAC were on the supporting committee, and two members of the supporting committee were on the steering committee. There was necessarily visibility between them given the common membership.

CHAIR—The argument is that members of the supporting committee would not have approved or did not approve the insertion of the word 'potentially'. Dr Hicks particularly has taken umbrage at the suggestion that he approved the word 'potentially' when in fact there is no decision of the supporting committee to adopt that word. Can you enlighten us on how other members of the committee would be involved, if at all, in a process of adopting those sorts of words for the final committee report?

Mr Learmonth—We can see that the word 'potentially' was inserted by the chair of the supporting committee in discussion and is—in any event, again, we would contend, on a cursory reading—utterly consistent with the body of the report, which the entire supporting committee would have deliberated on.

CHAIR—As you understand it, was it contemplated in the work of the supporting committee that changes like that could be made before the report was to be presented?

Mr Woodley—I could not comment on that, Senator. I was not party to those meetings where those discussions occurred.

Mr Learmonth—It is probably difficult to articulate a hard set of rules about how change is to be made. It depends on the circumstances and the nature of the particular set of circumstances applying.

Mr Woodley—Certainly the chair of the supporting committee communicated to us recently that he felt a deep responsibility to present to MSAC a report and conclusions that were consistent. He felt obligated to present conclusions that would be consistent with the body of the report.

CHAIR—This is hearsay, of course, but did he feel that his capacity to make the change to reflect that consistency was within his brief as chair of the committee and was consistent with his responsibilities to the other members of the committee?

Mr Woodley—He advised that he felt that was his clear responsibility as chair.

CHAIR—Dr Hicks has asked for his name to be removed from association with what purports to be the views of the supporting committee with respect to that particular recommendation. Firstly, is there a capacity to do that and, secondly, has it been done?

Mr Learmonth—My advice is that all the users on the supporting committee signed off on the report that went to MSAC and that were offered the opportunity to put in a minority report and they did not take that opportunity.

Mr Woodley—I can add some further information to this: while it was not possible to remove the names of members of the committee who were part of this process, there is now a uniform disclaimer on the MSAC website and contained in MSAC reports that says that the views expressed are not necessarily those of any individual involved in the process.

CHAIR—That is there now; it was not there at the time this report came forward.

Mr Woodley—That is correct.

Senator MOORE—Postdated?

Mr Woodley—It applies as at the time it appeared on the MSAC website, and it now appears routinely in MSAC reports.

Senator MOORE—When did that appear? I want the exact date of when that appeared.

Mr Woodley—I will have to take that on notice.

Senator MILNE—But it does not name Dr Hicks.

Mr Woodley—No, it does not name anyone.

Mr Learmonth—But, again, I would reiterate that my advice is that members were offered the opportunity to make a minority report, and that was not taken.

CHAIR—That was done subsequent to the final meeting of the supporting committee.

Mr Learmonth—I am not sure when it was exactly done.

Senator MILNE—Can you follow up on that, please? This is really very important because, if I were a member of a supporting committee and I was given an opportunity to sign off on a final report and, if I did not want to, I was given the opportunity to make a minority report, and I did not do either, having been offered those opportunities, it does not follow logically to me and it would not be consistent—it would be fairly illogical, in fact—to then write very strongly afterwards asking to have my name deleted and go on the *7.30 Report*, because we are not talking about people without enormous credibility in the medical field. So I would like specifically the date and the minutes of the meting of the supporting committee at which all members of the supporting committee were given the final report of the supporting committee and signed off on it, and specifically the date and the minuting of where they were given the opportunity to submit a minority report. It is critical that we know in fact that that occurred.

CHAIR—We were told that the meeting of 23 March 2000 was the final meeting of the supporting committee. There were not any subsequent meetings to that. Is that correct?

Mr Woodley—That is probably correct.

CHAIR—So, presumably, any report that was signed off was circulated separately out of a committee meeting. It was sent to members independently of that meeting or at a different time.

Mr Learmonth—I am not sure what the actual process was.

CHAIR—Can you take that on notice and give us information about how that process you have suggested, of signing off and being offered the chance to write dissenting comments, was engineered? Was it done by correspondence? If so, can we see the correspondence?

Mr Learmonth—Sure.

Senator MOORE—Mr Learmonth, you can see that we have inches of paper on this particular issue. I know that the department must have a significant sized file on this issue; it has been pointed out in some of the correspondence how much correspondence the department has been involved in. The information you just gave us about the offer to members of the supporting committee to have a minority report: has that been corresponded in any document telling people that that occurred?

Mr Learmonth—The evidence I have before me in relation to minutes of a meeting was that that was made known to Dr Ware in a meeting with MSAC members and others on 26 September.

Senator MOORE—So the particular issue about the offer of a minority report—

Mr Learmonth—That appears in the minutes of this meeting.

Senator MOORE—So it was minuted?

Mr Learmonth—Yes.

Senator MOORE—We have just got to find that.

Mr Learmonth—I suspect it is in there.

Senator MOORE—It is just that we have to cross-reference all that document.

CHAIR—Perhaps we could find those while questions are being asked. Is there someone who can locate that for us?

Senator MILNE—Could you also table for us the final report of the supporting committee that was submitted to all members of the supporting committee for their sign-off and the offer of a minority report? There is some debate here as to whether what we have got before us is the draft final report of the steering committee or the final report. I would like to see the final report that was submitted to all members of that committee for their sign-off and for their minority report offer, so I would like to have that document.

CHAIR—That is what I have asked for as well.

Mr Learmonth—Yes, we will need to clarify that, and I think that is what the chair has requested on notice.

Senator ADAMS—In front of me I have a letter from Dr Hicks to Ms Halton on Wednesday, 2 April 2003. I am quite confused about what is contained within this. I will read the piece that I would like you to take note of and I also ask, with regard to the invitation to the reconvened supporting committee meeting, if I could have the agenda and any details pertaining to that. The letter says:

Dear Ms Halton

It has recently come to my attention that Ken Miles, Mike Fulham and myself have not been approached to participate in the reconvened MSAC Committee relating to PET. It is surely not a coincidence that the 3 co-opted experts in PET who were most critical of the process of the PET Review have now been excluded.

I do not have the date of that meeting, because I have got so much here, but this is a letter to Ms Halton on Wednesday, 2 April 2003. Further on in the letter he says:

I would have voted against the draft report if it had been made clear that this document was destined to be represented as a true reflection of Supporting Committee opinion. Yet, we did not have any opportunity to review the Final report until after the Minister had agreed to the findings and recommendations!

He then goes on to talk about the evidence and the potential that that completely misconstrued it. So I would like you to give me a copy of that agenda and notification of to whom it went and why these three members were missed.

Mr Woodley—The membership of supporting committees is determined by the chair of MSAC.

Senator ADAMS—These people were members of that committee and they were the only three who were not asked to go to the meeting.

Mr Learmonth—We will go back and find that information for you.

Senator ADAMS—I have the list here, in the documented evidence, of who is on that committee. Those are the three people—

Mr Learmonth—What is the name of the correspondent?

Senator ADAMS—The correspondence is a letter to Ms Halton on Wednesday, 2 April 2003, from Rodney Hicks, MB BS (Hons), MD, FRACP, Associate Professor of Medicine and Radiology.

Mr Learmonth—We will provide that to you.

Senator ADAMS—Thank you.

Senator ALLISON—Given the nature of this part of the inquiry, why wasn't that documentation brought? You must have been anticipating a question along these lines and a request for it, so why wasn't it brought?

Mr Woodley—Which document, Senator?

Senator ALLISON—The document we are referring to, the document that Senator Adams has asked for.

Mr Woodley—The agenda of a subsequent meeting of that subsequent committee?

Senator ALLISON—Yes.

Mr Learmonth—I suspect it is hard to predict which document out of thousands of documents might come up.

Senator MOORE—We believe about 5,000 pages, Mr Learmonth.

Mr Learmonth—I would hate to hazard a guess.

Senator MOORE—That is what we were led to believe that it could be, under an FOI request.

Senator MILNE—I would like to discuss the confidentiality agreement of members of the supporting committee. For how long does that confidentiality agreement stand?

Mr Woodley—I will need to check that.

Mr Learmonth—We will take that on notice.

Senator MILNE—It would be extremely helpful to this committee if members of the supporting committee at that time could speak freely about what occurred. What you said a while ago was that changes were made. We agree that there were changes—with the insertion of the word 'potentially' and the sentence

'There is insufficient evidence at this time from which to draw definitive conclusions about the clinical effectiveness and cost effectiveness of PET'. It has been alleged that that insertion occurred between the supporting committee report and the MSAC report. What you said a little while ago was that those changes were made with the knowledge of the chair and others. Richard King is obviously the chair. I would like to know who the 'others' were who signed off on those changes.

CHAIR—Before you answer that question, can I just clarify that the question I was asking earlier was in relation to the insertion of the word 'potentially', and you answered in respect of how changes occurred with respect to the insertion of the word 'potentially'. My question did not relate to those other words, because they related to what I suggested to you might not have been a report of the supporting committee at all but in fact a report of MSAC. You have taken on notice the question of whether this document, the one with those words that Senator Milne has just quoted, is a document of the supporting committee or a document of MSAC. I want to clarify that this is not necessarily a document which was purported to be a document of the supporting committee.

Senator MILNE—Regardless, I want to know how those words—both lots—got into this report, at what point they were inserted and who inserted them. In particular, you said that changes were made with the knowledge of the chair—and that is Richard King—and others. Who were the 'others' who were consulted and obviously agreed to these changes?

Mr Learmonth—Particularly given the chairman's comments and questions about the provenance of the document, I will take that on notice. The chair clearly was involved, and it would appear that the steering committee was also involved in some of the consideration of the changes. We will provide a definitive answer to you on notice.

Senator MILNE—Thank you.

CHAIR—If there are no further questions on this particular issue, I will move to another issue and we can come back to that other issue if necessary. Can I go to the question of the answer given to Senator Harradine in the estimates committee. Senator Harradine asked some questions on notice on 5 November 2003. The first question he asked was:

Did the Scientific Supporting Committee in its report find that PET scanning was clinically effective and possibly cost effective?

The answer that came back from the department at that stage was:

No. Supporting Committees of the Medical Services Advisory Committee (MSAC) do not make findings. Neither do Supporting Committees make reports, this being the responsibility of MSAC.

With respect, it does seem as if that is something of an overstatement, given that we have seen several documents from the supporting committee which are headed 'report'. Can you explain whether that therefore is consistent with the answer that has been given, and can you explain why it is suggested that they do not make findings, given that they were obviously making recommendations to the steering committee?

Mr Learmonth—I think what is clear is that supporting committees do not have a determinative role. They do not make findings per se or make determinations on matters in some sort of final way. They exist to provide support, as the name suggests, to MSAC, which is the deliberative body and will come up with recommendations for a minister. Clearly, they are not determinative bodies and they do not make findings; they support and assist the work of MSAC. Regarding the use of the word 'report', what I would say is that the question was taken in the context of the MSAC process generally. It appears to me that the answer is directed to the report proper which goes from MSAC to the minister—which, again, is the province of MSAC, not the supporting committee.

CHAIR—I would suggest that, with the benefit of hindsight, you might have reworded that answer to make that clear.

Mr Learmonth—With the wisdom of hindsight and the ability to apply the word 'report' to many pieces of paper, that may well be so.

Senator MILNE—What about with reference to the word 'no'? That is pretty clear. I do not find this a matter to take lightly. The specific question was:

Did the Scientific Supporting Committee in its report find that PET scanning was clinically effective and possibly cost effective?

And the department gave the answer 'no'. Yet we have a draft that says that is precisely what the supporting committee said. You can confuse that with what MSAC may have finally concluded and what other people might have said at another time, but this was specifically about the supporting committee—and we have asked for that final report of the supporting committee to be documented here. A lot of requests were made to have the department correct this answer, but there has never been an attempt to correct it. When we get that final supporting committee report we will find what they actually said, so we will be able to check that against this, but why has the department not corrected this answer previously?

Mr Learmonth—The question and the answer do not go to the content—in other words, whether something was clinically and cost effective or not. It went to a higher construction of the question, which is: does a supporting committee make findings? It does not and that is quite clear in the response. The supporting committee does not make findings one way or the other; it provides supporting material, evidence and views to MSAC. That is the nature of the question and the clear answer in response. It is not a question of whether or not something is cost effective; the question is: does it make a finding? It is not constituted to make a finding—that is not its role.

Senator MILNE—The question was: 'Did that committee, in its report, find that' etc. We know that a report exists from this committee because you just said that that report was given to the other members of the steering committee to sign off on and make a minority report on.

Mr Learmonth—Neither I nor the answer to the question disputes that there is a report or other piece of paper from the supporting committee which contains views about the clinical and cost effectiveness of PET. That is not an issue. The question is: is it a finding? The answer is, 'No, because the committee is not empowered to make a finding.' It is not the committee's role to make a finding. That was the precise question that was asked and the answer is quite clear: it did not make a finding; it is not its role. It certainly expressed views about those things—undoubtedly, you are quite right—but it is not a finding.

Senator MILNE—Don't you think it is reasonable that people reading this would interpret that differently? With respect, that is highly evasive. If every question that was asked by the parliament elicited this kind of pedantic response, we would never find out anything.

Mr Learmonth—I do not think anybody could really take a view one way or the other about the committee's views about clinical and cost effectiveness, because the answer does not go to that question; the answer goes to the question of whether it was the supporting committee's job to do that.

Senator MILNE—No, it does not.

Senator WEBBER—I would like to intervene. As someone who is not a health bureaucrat, when I read 'Did a committee make a finding of such and such?' and the answer is 'No,' I would interpret that, as I am sure 76 members of the Senate would interpret that, as 'No, they didn't make a finding.'

Senator MILNE—Exactly.

Senator WEBBER—Not 'No, they don't have the power to make a finding, but 'No, they didn't make that finding.'

Mr Learmonth—If the answer had been 'No, full stop,' I could understand the ambiguity, but the answer clearly does not go to the substantive issue of cost effectiveness or clinical effectiveness; it goes to the role of the committee. The answer is:

> No. Supporting Committees ... do not make findings. Neither do Supporting Committees make reports, this being the responsibility of MSAC.

That goes directly to the issue of process and who has responsibility to make findings. It is quite clearly not an answer about clinical or cost effectiveness and, therefore, I do not think it would give rise to any ambiguity about that question. It is very clearly answering something different.

Senator WEBBER—So neither do supporting committees make reports? It would seem to me that they do make reports, because they make recommendations.

Senator MILNE—Exactly.

Senator WEBBER—If that is not a report, I do not know what a report is.

Mr Learmonth—I acknowledge that there is probably some ambiguity about the word 'report', as the chairman alluded to earlier. This answer was probably couched in the context of the process, which is that the report proper on PET is a report made by MSAC to the minister.

CHAIR—If Senator Harradine had asked the question, 'Did the scientific supporting committee in its report conclude that PET scanning was clinically effective?' then presumably the answer would have been quite different.

Mr Learmonth—Or had asked, 'What did the supporting committee think about the cost effectiveness or clinical effectiveness of PET?' That clearly would have elicited a different answer.

Senator ALLISON—What additional evidence was provided to MSAC after the report or the recommendations, or whatever we are calling what came from the committee, in order for them to make a decision?

Mr Learmonth—Additional to the supporting committee's—

Senator ALLISON—Yes.

Mr Woodley—In accordance with MSAC's general routine, one of the members of MSAC was charged with the responsibility of formally critiquing the report. That was Dr Terri Jackson from Monash University's Health Economics Unit. She provided a detailed verbal and written critique of that report. MSAC members themselves routinely absorb all the material before them. As we said before—

Senator ALLISON—Is that report available? It does not seem to be amongst our documents. Can you provide that to the committee?

Mr Learmonth—It is available and we are certainly happy to table that document.

Senator ALLISON—Where did the extra evidence come from?

Mr Learmonth—Dr Jackson. She did not tender additional evidence; she drew out the evidence as it stood in the text of the document that was before MSAC.

CHAIR—I want to come back to the question about the words that appear on the pages headed 'General findings':

The MSAC Supporting Committee concludes that:

- there is insufficient evidence—

et cetera. The front page of that document is headed 'MSAC application final assessment report'. In the last paragraph on the inside cover of that document it says:

This report was prepared for the Medical Services Advisory Committee ... by ...

It mentions five people, at least one of whom was present at the supporting committee meeting—that is, John Symes, according to the minutes of that meeting—but at least some of whom were not apparently present at that meeting. It goes on to say:

... with recommendations made by the MSAC Supporting Committee for PET.

It then it goes on to say:

The report was endorsed by the Commonwealth Minister for Health and Aged Care on date.

I do not know whether or not that means that this is a draft, but the date is omitted. That would suggest to me that clearly this document is not the report of the supporting committee. This document, in fact, is the report of MSAC. The words that appear there state:

The MSAC Supporting Committee concludes that:

- there is insufficient evidence—

et cetera. That is MSAC's summary or paraphrasing of what they understood the supporting committee was saying. I put it to you that the words that are used there cannot be characterised as words that purport to be actual words minuted and agreed to by the members of the committee; it is only MSAC's assessment or summary of what they think the supporting committee was saying to them. I am sorry to be long-winded about that.

Mr Woodley—Without being entirely confident of which document you might have in front of you, if MSAC is putting its name to it, it is not necessarily an endorsement of the views of another body of people; they are the views that MSAC itself has arrived at after due consideration, not that that helps.

Mr Learmonth—I think that was 'yes' to your proposition.

CHAIR—That is good.

Senator ADAMS—Going back to this letter to Ms Halton, written by Dr Rodney Hicks. I do not have a copy of her response. Would I be able to have that?

Mr Learmonth—Certainly.

Senator ADAMS—It is a response to the letter written on 2 April 2003. There is a comment here, which really ties in with the MSAC report. Dr Hicks says:

I communicated my dissent regarding the final report to the Chair of MSAC, Dr David Weedon, who referred it to Dr Richard King, Chair of the Supporting Committee. I have had neither a formal response nor valid rebuttal of my arguments …

Would there be documentation to show that Dr Hicks communicated his dissent regarding the final report to both the chair of MSAC, Dr David Weedon and that he, in turn, referred it to Dr Richard King, and also that Dr Hicks has not had a formal response from either person? Would you be able to check on that correspondence?

Mr Learmonth—Certainly, and if there has been a response, we will provide you with copies.

Senator ADAMS—Thank you.

Senator MILNE—I would like to return to the role that Dr Richard King has played. It is a central role in all this. Who appointed Dr King as chair of the supporting committee?

Mr Woodley—We do not have documentation of that, but it is routine that the chair of MSAC appoints chairs and other members of supporting committees.

Senator MILNE—What you said is that recently Dr King had been in discussions with your department about his responsibilities of faithfully reporting the view of the supporting committee. Can you tell me who contacted him, what was the purpose of that contact and is there written documentation of that contact?

Mr Woodley—There is no written documentation of it. I spoke to him yesterday. I rang him in the context of going through the documentation we were preparing for today's discussion.

Senator MILNE—Can you reiterate what he said about his role in inserting the word 'potentially' and anything else that he might have done?

Mr Woodley—The conversation did not go to that level of detail. What he conveyed to me was that it was his strong view that any document he would have presented to MSAC as chair of the supporting committee would have been a document that he would have had to have been confident reflected the evidence and the views of that supporting committee.

Senator MILNE—When we get the documentation we will see of course whether the members of that supporting committee actually signed off on it. We will get the report and we will also know whether they were given that opportunity. Mr Learmonth, you also said that the changes that were made to the supporting committee's draft report were utterly consistent and you also said they were not determinative. I put to you that there is a substantial difference between saying that the evidence suggests that PET is safe, clinically effective and potentially cost effective and saying that it is potentially clinically effective. There was also the inclusion of another paragraph at some point, saying 'insufficient evidence'. Do you agree that there is a difference between saying something is safe, clinically effective and potentially cost effective and saying that something is potentially clinically effective?

Mr Learmonth—The question is: whether it would have made a difference to MSAC.

Senator MILNE—No. You said the changes were utterly consistent.

Mr Learmonth—With the body of the report.

Senator MILNE—I am asking you: regarding a change that says that something is safe and clinically effective and potentially cost-effective, by putting in the word 'potentially' are you saying that that is utterly consistent?

Mr Learmonth—I am saying to you that it is utterly consistent with a report which—if you read through the considerations of the evidence as to clinical and cost-effectiveness—is mixed, is inconclusive and shows that there is stronger evidence for some indications than others as to clinical effectiveness, and less so as to cost effectiveness. Clearly there is a sense of potential that more information would enable a better view to be formed about, hence the entire approach. The funding recommendation, which is to fund on a limited basis a limited number of machines for a limited set of indications tied to compulsory data collection in order to

evolve that view and test the potential, has been borne out in the subsequent decisions to expand the indications.

Senator MILNE—But I am not talking about the big picture and in the fullness of time and every report and consideration that ended up with an MSAC report. I am talking about one committee report, and you said that it was utterly consistent. I am asking you: is there a material change between saying something is clinically effective and saying something is potentially clinically effective? Yes or no?

Mr Learmonth—There are two questions there. Is it a material change? Yes. Is it consistent with the body of the report? Yes.

Senator MILNE—The body of the report from the supporting committee?

Mr Learmonth—Yes.

Senator ALLISON—Which one?

Mr Learmonth—Any one.

Senator MILNE—To me, there is a vast difference between reaching a conclusion that says something is clinically effective and a conclusion that says it is potentially clinically effective.

Mr Learmonth—I agree with you that of itself that is a material change. Is it a reasonable summary of the discussion which it purports to summarise? Yes.

Senator MILNE—That is your view, but you were not a member of the supporting committee. The supporting committee was asked to sign off on a report which it judged was a reasonable assessment of what it had decided, and I guess that is where we are going to have wait to see what they actually signed off on, because I think there has been a good deal of hindsight in determining what the committee actually thought. Let us actually see what it did sign off on. Finally, in terms of whether the change was determinative, would you not agree that, because this was found to be only potentially clinically effective and cost-effective, that has influenced the extent to which this technology is now available in, for example, my state of Tasmania?

Mr Learmonth—Let me be very clear about your question. That MSAC found that the potential clinical and cost effectiveness has certainly gone to the decision to make public funding available for PET. Was that view determined by the insertion of that word? No, it was not.

Senator MILNE—On what basis do you make that absolute assertion that MSAC was not influenced in that way by the insertion of the word 'potentially'?

Mr Learmonth—Because MSAC is not a cipher; it is not a rubber stamp of supporting committees. It looks at the substance of the evidence and the differing views—and there are always differing views regarding these things—and makes its own decision. It by no means simply accepts uncritically any view coming from a supporting committee.

Senator MILNE—Is MSAC a cipher or rubber stamp for the government?

Mr Learmonth—No, it is not.

Senator MILNE—Is it independent from the government?

Mr Learmonth—It is an independent group of clinical experts.

Senator MILNE—So why does some of its correspondence get written by the department?

Mr Learmonth—The department acts as a secretariat for MSAC.

Mr Woodley—And for many other committees. Could I bring to the committee's attention words which I understand to be contained in any version of the supporting committee's report that might be available. In respect of funding, the supporting committee noted that 'it is recommended that interim funding be made available for the above indications, subject to the provision of data'.

CHAIR—Is that from the minutes of the meeting of 23 March?

Mr Woodley—It is from a report headed *Commonwealth review of positron emission tomography: MSAC supporting committee report*. I will add one further quote:

... there is insufficient evidence on PET's clinical or cost effectiveness with respect to the indications reviewed to warrant unrestricted MBS funding.

Senator MILNE—That is right—and the next paragraph reads?

Mr Woodley—I am sorry, Senator?

Senator MILNE—Mr Woodley, you read out the first recommendation. Could you read out the second one, please?

CHAIR—I think you are reading from a different document.

Mr Woodley—My point is that one of the supporting committee's conclusions was that funding might be provided on an interim basis for a restricted number of indications, subject to the provision of data.

Senator MILNE—I understand your point. You read one of the recommendations and I am asking you to read from the same piece of paper the second recommendation.

Senator MOORE—Whichever one you have.

Mr Woodley—It reads that while the committee agrees 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.' That is not in dispute. That is contained in versions of the supporting committee's report.

Senator MILNE—So it is in versions of the supporting committee's report. Is it in the final version of the supporting committee's report—given that, as we heard earlier, it does not report?

Mr Learmonth—I guess the point Mr Woodley is trying to make is that, if you look at any of the documents in relation to this—the supporting committee's report or others—there is a constant theme which pervades all of them consistently, which is that the evidence is very mixed as to clinical and cost effectiveness for different indications. Certainly the group asserted that there should be open funding. The potential was recognised in the decision to recommend limited funding and data collection as a platform and a basis to take the issue forward. That pervades the documents generally.

Senator MILNE—Nobody is disputing that what pervades the documents is potentially cost effective. There is debate about the potential cost effectiveness—

Mr Learmonth—And its extent.

Senator MILNE—I would agree—but nevertheless it is there. I do not think you can argue that the same applies to the clinical effectiveness; that is, whether it is safe and clinically effective. That is the point. One is a matter of government policy and one is a matter of medical fact and evidence. That is what we are trying to tease out here—that is, the extent to which the medical evidence has come through MSAC to make its final finding, quite apart from cost effectiveness, which we have agreed earlier. The steering committee made a judgment about it and MSAC made a judgment.

Senator MOORE—I have two questions. I will go with the general question first. You heard me ask a previous witness about the FOI process—how many applications there were, at what cost and over what period of time. I do not know whether this is your particular area, Mr Learmonth, or whether it is Ms Hannon's area. It seems to me that there was considerable correspondence entered into. It would seem that the intent of the legislation was to allow an open exchange of information—not to make people agree, necessarily, but that, when people had a stated interest in an issue and they went to the department and said, 'I want to have this information,' it should be quite an easy process.

In terms of the department's records, I would like to find out from your area the number of contacts, the time and the interchange that it took for a person who was interested in this area to gather the information—which he did so that he could bring it to us. It seems to me that that is part of the communication process and the exchange. I am interested to know what the process was to request the information, how long it took and how many times the information had to be asked for.

Mr Learmonth—We can certainly provide that. There has been an awful lot of interchange.

Senator MOORE—I reckon there has.

Mr Learmonth—The department has engaged seriously in good faith to try to explore this as much as possible. My advice is that in the period March 2002 to October 2002, for example, there were 115 pieces of correspondence to and fro. This has been something that the department has devoted an enormous amount of resources to trying to resolve to Dr Ware's satisfaction.

Senator MOORE—Following on from that, in the evidence we had this morning, we were told that Dr Ware was advised that he was blacklisted and that there would be no further correspondence entered into between him and the department. That interested me, and I am just wondering whether that is a regular process. What actually leads to a department telling someone that they would receive no further information from the department—if in fact that was said?

Mr Learmonth—As a matter of general principle, I would not want to comment. I would not have a good view of that. I would suggest it would be not that common. It would arise on the basis that there had been a very substantial attempt to resolve an issue. A conclusion had been reached that it was unlikely that the issue was not being advanced at all—there was no new information, there was no new matter coming in, the issue was unlikely to be advanced any further and any further effort would not be an efficient and effective use of the department's resources.

Senator MOORE—Who makes that decision?

Mr Learmonth—Ultimately I imagine it would be a matter for the secretary, as it was in this case.

Senator MOORE—I have one question on documents. I could ask lots, but it is not timely. We were given a document this morning from the Medicare Services Advisory Committee, Executive Committee Teleconference, 9 June 2000, which is the only document I have seen that talks about a majority of MSAC members and refers to the supporting committee report. It specifically opens up by saying:

It was noted that a majority of MSAC members, nine members out of 14, with Dr Kitchener abstaining, endorsed the recommendations of the MSAC supporting committee for PET.

I am interested to know which supporting community report that refers to and—I have seen the guidelines for MSAC—when it says 'nine members out of 14', it particularly lists the one member who abstained. Is it process that you name the people and how they vote? Is that in something where you have needed as the executive committee to determine it wasn't a unanimous agreement? There was obviously significant discussion around this issue, which is evident from the controversy that happened later. What is the guideline about naming the people and how they voted, and could we find that out?

Mr Woodley—I am not aware that MSAC has specific guidelines on recording the views—

Senator MOORE—No, in the guidelines we have had they don't.

Mr Woodley—And in my personal experience MSAC does not record the views of individuals unless they explicitly wish that those views be recorded.

Senator MOORE—Do they always give the voting results—nine out of 14 in this case? I am just looking at standard practice, if this one were different.

Mr Woodley—I can only speak on the basis of personal experience, and the answer would be no.

CHAIR—I understand the issue of PET's clinical effectiveness and potential funding is being reconsidered at the moment. Is that the case?

Mr Learmonth—I think it is fair to say that the original decision was one which contemplated further review in that the limited availability of funding and limited circumstances in which it would be made available were tied explicitly to data collection and further monitoring. That has already resulted in additional indications being approved by government for funding. We would anticipate that process continuing at some point. I dare say there will be a review of the data on a more comprehensive basis and a further review.

Senator MOORE—Wasn't there a time frame to that review?

Mr Woodley—Yes. MSAC will begin to consider the data.

Senator MOORE—In 2006.

Mr Woodley—That is correct.

Senator MOORE—I suppose this is a standard question. At what stage? Has it begun? We are almost in May 2006.

Mr Woodley—I note that we are not actually directly responsible for the MSAC secretariat. I don't know exactly when this year it will commence. I don't believe it has at this stage. As Mr Learmonth indicated, it has been a continuing process. In May 2001 PET recommended funding for an additional four indications, and that was accepted by the minister in June of that year.

Senator MOORE—That was based on clinical effectiveness?

Mr Woodley—That was based on MSAC's assessment of the evidence in respect of those indications and a further nine indications were recommended by MSAC in August 2001. They were approved by the minister in September of that year. So it has been an expanding body of indications for which public funding has been available.

Senator MOORE—The MSAC report endorsed the data collection on clinical effectiveness and cost effectiveness.

Mr Woodley—The data will contribute to MSAC's reconsideration of the clinical effectiveness and cost effectiveness.

Senator MOORE—What are the headings for the data collection?

Mr Woodley—I cannot go to the detail.

Mr Learmonth—The data would be such as to be able to support the committee's consideration of those questions, yes.

Senator MOORE—If one agreed it was safe, the two issues that were being discussed were cost effectiveness and clinical effectiveness. I should know this after all the Senate estimates questions.

CHAIR—I think safety was there.

Senator MOORE—Safety was fine; it was the next two that were in question. The agreement was that there would be a number of things supported and that there would be ongoing data collection from the places that had been approved—that is paraphrasing. I am interested as to the data processes that were agreed. Did they follow-up both headings: the clinical trial aspect and the cost effectiveness aspect?

Mr Learmonth—The two are not inseparable. The data that is being collected will enable consideration of both.

Senator MILNE—In relation to these confidentiality agreements, in a letter to Ms Halton Dr Hicks said that Ms Halton had asserted that permanent confidentiality was a standard requirement of MSAC. Yet he said that was not the case because he had previously been on other committees where that confidentiality agreement was limited to two years. Can you provide the committee with the confidentiality agreement that was required to be signed by the supporting committee? If it was not limited to two years, can you also indicate why this was so and who made the decision to make it an unlimited, if you like, confidentiality agreement? Can you indicate whether that was explained to people on the steering committee? Was it spelt out that this was a permanent confidentiality agreement? This is critical because we need to have a clear understanding of what people agreed in relation to confidentiality and this particular agreement. Finally, Dr Hicks also indicated to Ms Halton that he had been contacted by a member of MSAC requesting that he request Dr Ware refrain from being critical of the PET review because it was making important people angry. Did Ms Halton follow-up on that as the secretariat to MSAC or did she take no action in relation to that?

Mr Learmonth—Ms Halton provided an answer.

Senator MILNE—Do we know which important people were being made angry?

Mr Learmonth—I am not aware of the basis of that and whether or not it is an accurate portrayal. We will investigate and provide the answers.

Senator MILNE—I would like all details referring to that and what follow-up was taken by Ms Halton at that time.

Mr Learmonth—Certainly.

Senator ALLISON—In regard to the additional nine reformations in 2001 for other indications, did that actually happen? Are those indications now agreed?

Mr Woodley—That is correct.

Senator ALLISON—How does that list of 13 compare with the original list on the MSAC report?

Mr Woodley—They would be all additional to the six which were original.

Senator ALLISON—All 13 are additional to the six?

Mr Woodley—Yes.

Senator ALLISON—What happens to the other indications? We heard this morning that only 40 per cent of indications were recommended in the first instance. How many remain? Is anybody else looking at the remainder of the indications?

Mr Learmonth—As the data unfolds and the evidence develops around PET, any of the indications previously considered but not approved, and potentially other indications that might not have been originally considered but might come to the fore, would also be considered.

Senator ALLISON—How do they come to the fore? How does that work?

Mr Woodley—My understanding is the data collection applies only to those indications which MSAC has considered.

Senator ALLISON—I think the original list had nine points under that, plus four, plus an additional nine. How many more are there? I am just trying to get an idea of the scope.

Mr Woodley—I will check this. I think that is it—that is the range of indications for which public funding is currently available.

Senator ALLISON—My question is that, with the ones that are not, is 20 per cent remaining that is not subject to public funding after these are taken into account or is it more than that?

Mr Woodley—The applications for which PET might be applied are probably much larger. That is really a clinical question that others would be better qualified to answer. However, it is probably relevant to note that any individual organisation can make an application to MSAC to consider a technology in respect of a particular—

Senator ALLISON—Anyone can put in an application such as you describe; that is what triggers MSAC to make another consideration of the indication—is that right?

Mr Woodley—Most often. Matters can also be referred to MSAC by the minister, the department or AHMAC.

Senator ALLISON—You said 'most often'. Does that mean that consideration is sometimes not made if an application is put in?

Mr Woodley—No, I meant that—

Mr Learmonth—There are other ways to raise it.

Senator ALLISON—So, tomorrow, if someone puts in an application for the remainder of conditions, indications, then MSAC would resume their study—

Mr Learmonth—Or new ones that were not previously contemplated. Equally MSAC would consider that.

Senator ALLISON—Thanks.

CHAIR—Thank you very much for providing your evidence to the committee today. You have taken a number of issues on notice which we look forward to seeing answers to.

Committee adjourned at 12.17 pm