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# Official Committee Hansard

## SENATE

STANDING COMMITTEE ON COMMUNITY AFFAIRS

**Reference: A matter relating to PET review of 2000**

THURSDAY, 14 JUNE 2007

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**SENATE STANDING COMMITTEE ON  
COMMUNITY AFFAIRS**

**Thursday, 14 June 2007**

**Members:** Senator Humphries (*Chair*), Senator Moore (*Deputy Chair*), Senators Adams, Allison, Carol Brown, Fierravanti-Wells, Patterson and Polley

**Participating members:** Senators Barnett, Bartlett, Bernardi, Mark Bishop, Boswell, Bob Brown, George Campbell, Carr, Chapman, Crossin, Eggleston, Chris Evans, Faulkner, Ferguson, Fielding, Forshaw, Heffernan, Hogg, Hurley, Hutchins, Joyce, Kirk, Lightfoot, Ludwig, Lundy, Marshall, Mason, McEwen, McGauran, McLucas, Milne, Nash, Nettle, O'Brien, Parry, Payne, Robert Ray, Siewert, Stephens, Stott Despoja, Watson, Webber, Wong and Wortley

**Senators in attendance:** Senators Adams, Allison, Boyce, Humphries, Milne, Moore, Patterson and Polley

**Terms of reference for the inquiry:**

To inquire into and report on:

A matter related to the PET review of 2000

**WITNESSES**

**HANNON, Ms Wynne, General Counsel, Department of Health and Ageing ..... 22**

**HICKS, Professor Rodney John, Director, Molecular Imaging and Co-Chair of Translational  
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**WOODLEY, Mr Peter, Assistant Secretary, Diagnostics and Technology Branch, Department of  
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**Committee met at 4.04 pm****HICKS, Professor Rodney John, Director, Molecular Imaging and Co-Chair of Translational Research, Peter MacCallum Cancer Institute**

**CHAIR (Senator Humphries)**—I declare open the public hearing of the committee's inquiry into the positron emission tomography (PET) review of 2000. As those in the room are aware, we have had a series of hearings into this matter, the last being on 30 March. On that occasion, we heard from a number of witnesses but we were unable to complete the evidence on that day and, as a result, it is our intention today to complete hearing the evidence of Professor Hicks and also to hear from the Department of Health and Ageing. Subject to the views of the committee, that should conclude the evidence that we take on that issue.

Before Professor Hicks continues with his evidence, I want to remind members of the issue which I raised at the beginning of the hearing on 30 March about the purview of this inquiry. This is not an inquiry into whether or not PET technology is a clinically efficacious technology in Australian medical settings. It is not even an inquiry into whether PET technology should have been viewed as a clinically appropriate and efficacious application in 2000. The issue for us is whether the processes used to make the decision, in 2000, on the use and the funding of PET in Australia was appropriate, and appropriately reflected the contribution by parties in various expert committees, to the making of that decision. I want to make that clear in order that we do not wander from the main point.

Professor Hicks, I welcome you back to the committee and thank you for coming again to help us with this matter. I think you are familiar with information on parliamentary privilege, having been here before. As you know, we prefer to take the evidence in public today, but if there is information of a confidential nature, you have the option of seeking to make that evidence available to us in camera. We have the evidence you presented on a previous occasion and you were in the process of being questioned about that on the last occasion. Is there any additional information of a written kind that you wish to formally put before the committee? We have the papers which you forwarded to us.

**Prof. Hicks**—I propose not to speak to those papers directly today. I think they were issues in response to the previous *Hansard*. I have other matters that I wish to raise at this particular meeting.

**CHAIR**—The committee authorises publication of the extra information which Professor Hicks has given to us. I invite you to make a statement, if you wish, to add to what you said before, or if you want to briefly restate what you said before, or make any other comments and then we will proceed to ask you further questions.

**Prof. Hicks**—I would like to thank the senators. This has been a marathon exercise for you all and I think it is a very important issue and I thank you for giving me the opportunity to finish my testimony here today. The product of the Australian PET review was published with the imprimatur of the Australian government in March 2001. This report was lent credibility by the fact that it involved experts in PET such as me, Professors Scott and Fulham, and representatives of the major stakeholders, such as Professor Michael Millward a medical oncologist, and a representative of the College of Surgeons, Professor Rob Thomas.

MSAC is charged with the responsibility for providing syntheses of the best possible evidence to inform the Minister for Health and Ageing, the medical profession and the public regarding the safety, clinical and cost effectiveness of new technologies. As such, these kinds of reports have national and international impact. They are cited as being systematic reviews at the forefront of evidence-based medicine. The body charged with the responsibility for the synthesis of that scientific evidence in the case of the PET review was a scientific supporting committee on which I and other experts sat. MSAC endorsed the report of our committee, believing this to be the true product of our deliberations and the steering committee, in turn, endorsed MSAC's report, again believing this to be the opinions of the experts who sat on our committee.

I will read from a document from October 2000 which was sent to me by the secretariat of MSAC. It states:

I am pleased to advise that the review steering committee accepted the findings and recommendations of the Supporting Committee and incorporated these into the steering committee's own report and recommendations presented to the Minister for Health and Aged Care, the Hon Michael Wooldridge.

It is clear that they believed that that report came from the experts in our committee. There is no doubt that our report was changed. Richard King admitted that in the last Senate hearing. It is also beyond doubt that we were not informed of that change. Richard King told you that he did not inform us that that change was made. What remains in doubt is whether these changes were material or merely editorial in nature. That is the suggestion that Richard King has made.

I wish to again state on the public record that the changes were material and remain so. However, because Richard King has sought to impugn my integrity, based on allegations that I have a conflict of interest and that I have behaved in a consistently illogical manner during the course of this review and subsequent to it, I want to present evidence to you that shows that my opinions were not held only by me but were shared by my colleagues.

After the Senate committee, I forwarded the *Hansard* record to two key colleagues on our committee—Professor Michael Millward, a medical oncologist who represented the College of Physicians, and Professor Bob Thomas, a surgical oncologist who represented the College of Surgeons. Neither can be claimed to have had, or to now have, a conflict of interest as they are end users, not providers of PET technology. They also both worked and continue to work in centres that have funded PET centres.

You may remember at the last meeting that Richard King quoted Michael Millward in support of his contention that we agreed that the evidence was poor with respect to the clinical and cost effectiveness of PET. Consequently I asked Professor Millward to provide me with responses to the key assertions made by Richard King at that meeting. I will quote from his response to me:

My own distillation of the term 'clinically effective' at the time reflected a combination of diagnostic accuracy, and the findings of the PET scan leading to a change in patient management that would be reasonable to infer would be beneficial to the patient ... even if there was no direct evidence from randomized trials that such a change in management affected survival or other outcome. Therefore, in response to your questions:

Did the addition of the "General Findings" to our ratified recommendations cast greater doubt on the clinical effectiveness of PET than encapsulated in our approved recommendations?

His response was an unequivocal ‘yes’. He continued:

Did our recommendations require alteration because they lacked sense or logic?

His response was no, they did not lack logic or sense. He went on:

Was the characterisation of PET as only “potentially” clinically effective contained in the altered recommendations an appropriate assessment of the evidence that we reviewed at the time?

He replied:

The addition of the word ‘potentially’ alters the meaning from ‘... suggests ... clinically effective’ to ‘... suggests ... potentially clinically-effective’ and is not as accurate.

Do you agree with Dr King’s assertion that our committee held the firm view that there was insufficient evidence of PET’s clinical-effectiveness per se? In other words, is “potentially clinically effective” the same as “clinically effective”?

His response was:

No, I do not agree with Dr King’s claim, nor with the statement that “There was no clinical effectiveness in those things agreed to by the PET subcommittee ...” (if he is referring to our committee). I think our recommendation regarding funding for the 6 scenarios reflects the view that in those indications, we considered the evidence suggested PET was safe, clinically effective, and potentially cost effective.

I also approached Professor Rob Thomas—as I said, a surgical oncologist and representative of the college of surgeons. He wrote:

I am happy for you to take to the Hearing my view that the committee did agree (from my memory of the matter) that PET was clinically advantageous in the assessment of tumour stage in selected situations and that this view was encapsulated in the committee’s final report. There was no consideration given to modifying the committee’s findings at any meeting which I attended.

Professor Ken Miles, who at the time was a PET provider but no longer resides in Australia and cannot be considered to have an ongoing conflict of interest, wrote:

My recollection of the time of the review was that, in my view, the evidence for the clinical effectiveness of PET in the 6 indications was better than that for almost any other application of any imaging modality.

I remind you that he is both a radiologist and a nuclear medicine specialist and is internationally recognised as a leading authority in both those areas. So here we have three people with, I think, unimpeachable international credentials and no conflict of interest who support my contention that we found that PET was safe, clinically effective and potentially cost effective and that the changes in the report that Richard King has attested to were not valid.

This, the *Report of the review of positron emission tomography August 2000*, is the document that arose supposedly from our deliberations and is in the public domain. It has been published by the government. I will read from the first page, the executive summary. It makes clear who is responsible for the evidence included in this:

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 (MSAC). The membership of the committees involved in the review is given in Appendix 1.

My name is there. We go to the first page of findings and recommendations:

These have been informed by MSAC's report on its evaluation of PET ...

Under 'General findings: term of reference 1'—term of reference 1 is 'Does PET work?'—the findings were couched in such terms:

To assess, in conjunction with MSAC and the profession—

and I will come back to that—

and with reference to available sources of evidence, the cost-effectiveness, clinical effectiveness and safety of PET, especially in relation to other diagnostic modalities.

The primary finding is:

1. The review steering committee accepts MSAC's conclusions that:

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

I believe that casts unequivocal doubt on the clinical efficacy of this modality. I want to turn to the issue of 'in consultation with the profession'. As part of this review, submissions were sought. Indeed, 49 submissions were ultimately received from stakeholders, including professional organisations, current and potential PET providers, state health departments and individuals with a range of views on PET. In relation to term of reference 1, a synopsis in appendix 3, hidden at the back of this report, says:

There was general consensus among the submissions addressing this term of reference in detail that PET is a valuable tool in guiding treatment decisions in a range of indications in oncology (by far the primary application), neurology and cardiology, and can be beneficial with regard to patient outcomes and costs.

Among the claims made were:

- PET often demonstrates superior diagnostic accuracy over other modalities, including CT and/or MRI, and provides information not obtainable by other means ...

This is a unique technology; the profession said so.

- PET results in significant changes in patient management, primarily through the identification of patients who will not benefit from expensive further treatment, leading to a reduction in morbidity and/or costs.

If you avoid morbidity and you avoid costs, it cannot help but be cost-effective. The profession was asked to comment. They commented in unanimous terms saying that this technology works. Many submissions noted that PET's potentially most beneficial application was in oncology, particularly in the staging of primary disease, especially lung cancer, and the detection of recurrent tumours and monitoring the effects of therapy.

So I come back to that primary finding—is it true to suggest that the primary finding, the synopsis, of this report, the view of MSAC—my committee, the view of the profession was that there is insufficient evidence at this time to draw definitive conclusions about the clinical and cost-effectiveness of PET? If this product represents the process, then it is the fruit of a poisoned tree; it is rotten to the core. It does not reflect the process that we went through; the process went wrong. We need to understand how and why it went wrong.

The next issue, I think, is whether it matters. Does it matter? The report has, I know, misinformed patients, doctors, health policy makers, and the government, not only in Australia but throughout the world, as I emphasised last time. This review has been used to justify, what I believe to have been, an unnecessary and wasteful data collection process where the resources, both fiscal and intellectual, of the PET community could have been directed far more efficiently and appropriately to establishing and growing the database in areas where there was not already firm evidence of efficacy.

To put it in context—what does this mean to the care of patients? Each day in the United States, the equivalent number of people die from cancer as died in the collapse of the twin towers on September 11.

At the recent American Association of Cancer Research meeting, the American Cancer Society was trumpeting evidence that a great potential victory in the war over cancer was starting to occur. For the first time, they were able to show that fewer people died in the last year of data collection of cancer than had died in the previous year. The number of patients fewer who died of cancer was 3,014. This occurred in a denominator of 557,000 people who died in the United States in that year of 2004. That is ignoring the suffering of the people who survived cancer and who continued to live with cancer; the loss of productivity in the parents, the children, the spouses and the friends who look after those people; the mental illness, the depression and the anxiety that this disease causes. This is a national and international tragedy.

We have shown, and the PET data collection has confirmed, that this technique changes the status of disease in up to 50 per cent of patients. It improves the care in a similar number of patients by better selection and delivery of therapy. The fact that this review has limited, in this country and in other countries, access to this technology on the bogus contention that this technique does not work, or the evidence that it works is weak is a tragedy. It is a national disgrace, I believe, that we are now six years into this process. We have now a consensus, I think, amongst the health departments. We have amongst the politicians a recognition that this technique works, but it should have been there in 2000. It was there in 2000 and, somehow, the process obscured that vision and obscured that information being disseminated to people throughout the world. And there I finish my impassioned display.

**CHAIR**—Thank you very much indeed for that. Professors Millward and Thomas were on the supporting committee.

**Prof. Hicks**—They were.

**CHAIR**—Who was the third person that you mentioned?

**Prof. Hicks**—Professor Ken Miles, who was a provider at the Wesley Hospital in Brisbane. Along with me, he was also one of the initial applicants to MSAC with a review of the PET literature.

**CHAIR**—Was he on the supporting committee as well?

**Prof. Hicks**—He was on the supporting committee, yes.

**CHAIR**—Is it possible to table the views that they expressed to you?

**Prof. Hicks**—Certainly.

**CHAIR**—Did they send you a letter to that effect?

**Prof. Hicks**—They sent emails, which I am happy to provide.

**CHAIR**—Thank you very much. Perhaps you can confirm whether or not it is the case, but it appears to me that there were some divisions on the supporting committee about the extent of effectiveness of PET technology. Some took the view that it was not appropriate to allow unrestricted MBS funding of PET at that time and others took the view that it should be allowed greater access to that funding.

**Prof. Hicks**—I do not think that there was any contention amongst the members with respect to the issue of unrestricted funding. We are aware—and all the members of the committee were aware—that no new technology, particularly an expensive and high-technology one, is ever given unrestricted Medicare funding. We do not think it is appropriate and we said so in our conclusions.

**CHAIR**—What was the issue that divided the committee in that respect? What was the critical divide on which there was such contention?

**Prof. Hicks**—There was consistent effort by the chairman, Richard King, and the literature review chair, Professor John Simes, to cast doubt on the validity of the evidence that we looked at and to apply what we, the clinicians, believe were inappropriate and unachievable benchmarks for a diagnostic test. It was contingent on the chair to record that dissent and to give us the opportunity to express that dissent but, at every step that we tried to do that, we were coerced to agree to this.

**CHAIR**—When you say ‘dissent’, this committee is meant to operate on a majority basis. If the majority of the parties and the clinicians and so on say a certain thing, that is what is meant to be in the report.

**Prof. Hicks**—The issue that I am alleging that we had disagreement with was never in our report. We never had an opportunity to comment on the general findings. They were never in any document that we saw. We never would have agreed to them, so how could we have dissented with that view when we never saw it.

**CHAIR**—The committee has been supplied with the draft of the report.

**Prof. Hicks**—I think we went through that last time.

**CHAIR**—That is right.

**Prof. Hicks**—We said the evidence is insufficiently strong to warrant unrestricted funding given the caveat that I have just given you, recognising we knew that unrestricted funding was not on the table. But we said unequivocally, despite that recognition, PET works; it is safe, clinically effective and cost effective.

**CHAIR**—Sure. But you said on the last occasions that you did not agree with the version that the committee saw and that, as you say, was understood by the committee as what was in the draft of that report, notwithstanding that that was the view that seemed to be distilled by the committee. There are variations between what was in the draft and what was finally presented to MSAC. We can come back to this question of the differences between the two versions, but what was in the first draft, which you all accepted and agreed reflected the outcome of the process?

**Prof. Hicks**—We accepted.

**CHAIR**—Accepted. It was a view you did not agree with and you still do not agree with.

**Prof. Hicks**—I still do not agree with it; that is correct. But that is not the issue here. If that was the only point of this discussion I would not be here. It is the contention—the international publication of a report that casts doubt on the clinical efficacy of this modality. That is why we are here. That is why I am here.

**CHAIR**—I put it to you that what is in this draft casts doubt, that is, the draft that you saw which reflected what you discussed.

**Prof. Hicks**—I disagree with that vehemently and my colleagues disagree with it. We put that question to them—did it cast greater doubt? The insertion of the primary finding that, ‘there is insufficient evidence at this time to allow definitive conclusions on the clinical cost-effectiveness of this data,’ all my colleagues disagreed with that statement. They concur with me.

**CHAIR**—It seems to me that in both drafts of the report, the phrase to the effect that the committee 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,’ is consistent between both versions of the document. The one substantial difference between the two versions of this document is the use of that word, ‘potentially’ before the phrase ‘clinically effective.’ I put it to you that that is the only substantial difference between these two documents.

**Prof. Hicks**—It is a very substantive difference. The primary finding was inserted without our knowledge or our consent and cast an on-going doubt. Our conclusion was unequivocally linked to the issue of funding. I have not challenged terms of reference 3 in this report which goes to the issue of funding. We agree that PET should not have unrestricted funding. I do not disagree with it. What I disagree with, and we will have to agree to disagree, I think, because you have pressed me on this a number of times, is that there is a fundamental difference between saying, ‘this doesn’t work well enough to warrant unrestricted funding,’ and saying, ‘this technique

doesn't work,' and that was the implication of inserting 'potentially' and also what Richard King alleged at the last meeting.

**Senator ALLISON**—Can I suggest not just implication, but the outcome?

**Prof. Hicks**—The outcome?

**Senator ALLISON**—This would not be funded because of that phrase.

**Prof. Hicks**—We know that this has influenced state governments, possible administrators and indeed the former Minister for Health and Ageing was challenged on this. I have here a letter where he said, 'Given the largely inconclusive findings of the review, this evaluation is still in process to be put in place,' and it is signed by Michael Wooldridge.

**CHAIR**—My contention to you is that both versions of the report said the same thing and I want to pin that down. You said the primary finding that 'There is insufficient evidence at this time from which to draw definitive conclusions about the clinical effectiveness and cost-effectiveness of PET' was inserted as a primary finding when that was not the view of the supporting committee.

**Prof. Hicks**—That is right.

**CHAIR**—What you call the primary finding is not headed in the report that was handed up. It happens to be the first dot point under the heading Recommendations and I assume that is the basis upon which you say it was the primary finding of the committee.

**Prof. Hicks**—No. The primary finding I have referred to is that which appears as a primary finding and has been identified by the Secretary of the Department of Health and Ageing as the primary finding identified by the minister as the primary finding of the PET review that there is insufficient evidence of PET's clinical and cost effectiveness. No issue of funding; no mention of funding. A categorical statement about the evidence.

**CHAIR**—With respect, what the secretary of the department says about this process is a different issue to the one that the committee is examining. The committee is examining the changes that were made between the supporting committee meeting and the MSAC consideration of those outcomes. That is the issue we are looking at.

**Prof. Hicks**—I think the question has been asked and answered.

**Senator ALLISON**—Can I interrupt on that point? I challenge that statement. Whether we like it or not, we are talking about the implications of certain wording being changed and what that means for the outcome. I think it is appropriate for that report and for subsequent documents that have come from that changed wording to be referred to.

**CHAIR**—I accept that is your view, but I am trying to pin down the fundamental question facing the committee is that there has been a change in the nature of the agreement or the decisions that were made by the supporting committee. These were modified in a way which was criminal—that is the allegation. They were criminally changed in order to effect some different

outcome. I am trying to identify how that occurred. I accept that, based on what was finally handed up by MSAC, there might be questions about the wording that should appear in these documents and how it might be characterised by the minister in his statement and by the department's secretary in her statements about this matter. The question we are looking at is—what happened between the supporting committee and the steering committee? That is what we are looking at.

**Prof. Hicks**—That has been established. Professor King told you that he had changed our report.

**CHAIR**—That is right. Indeed, that is clear.

**Prof. Hicks**—He told you that he had not informed us of that change and therefore we had no opportunity to give a dissenting view. As soon as I saw this report, I wrote to the chair of MSAC, to Richard King and to the Secretary of the Department of Health and Ageing challenging this finding in this report—the validity of it as being unrepresentative, although purporting to reflect our views. I challenged it and I have continued to challenge it. I have asked for my name to be removed from it and it has not been done.

**CHAIR**—I put it to you, Professor Hicks, that you would have challenged the findings of the report on either version. You disagreed with both.

**Prof. Hicks**—Absolutely not. I disagree. I have said that the issue of funding is completely within the bailiwick of the Department of Health and Ageing and the minister to determine what gets funded and how it should be funded. It is not their role to interfere in scientific process. They should not and cannot misinform the public about the efficacy of a medical technology.

**CHAIR**—On the previous occasion you appeared here, I put to you that you did not agree with that statement about funding, and you agreed with me that you did not agree with it. I am sorry to put that in a convoluted way, but you agreed that you had dissented from that view taken by the majority of the committee.

**Prof. Hicks**—I think you will remember that my reputation had been severely impugned by Professor King in his testimony. He accused me—

**CHAIR**—As Professor King's, in turn, by other witnesses. There were a lot of accusations flying around.

**Prof. Hicks**—Yes, I agree. He was peeved and I was peeved at being called illogical, irrational and overly passionate.

**CHAIR**—But not a criminal.

**Prof. Hicks**—No, not a criminal. In a sense, all you have as a professional and academic is your intellectual and academic reputation and he had severely impugned mine by his comments at that time. You are also aware that many of the senators were trying to get onto planes. It was a very difficult time for all of them. I felt a great pressure at the time to answer the questions and to convey the message that I have given you today in a very short period of time. The documents

are complex and I was not as well across them as my colleague, Dr Ware. I agree with you, and if I misled the senators, I apologise for it—I did not mean to. I agreed that we did agree that the evidence was not strong enough for unrestricted funding. I did not agree—and I still do not agree, never did, never will—that we cast doubt on the clinical efficacy of this technology. I put it to you that that is what you are trying to suggest to me.

**CHAIR**—I come back to the statement in the draft which you say reflected the discussion in the committee. You did not agree with the outcome, but you agreed that the draft of the committee's report that you saw, which has been tabled in this committee and which was subsequently altered by Professor King—he admits he altered it—you can live with. You say that you accept that this was an accurate reflection of what the committee found.

**Prof. Hicks**—With respect to the issue of funding. As I said, I think, this has been asked and answered. I only have an hour to give evidence, so I think there are many other important issues.

**CHAIR**—That may be the case, but with respect, we have to ask these questions. That is our job in this process. I still do not understand the difference between the two phrases that have been used in the draft report and the final report. I will read those two phrases to you. The first one says:

Based on the results of the NHMRC Clinical Trial Centre's evaluation and the clinical experience of committee members, the MSAC Supporting Committee 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.

That was the view that you could sign up to. I do not say you agree with it, but you agree it reflected what the committee had decided.

**Prof. Hicks**—You are quoting out of context. While we agreed that there was insufficient evidence, the committee found that PET was safe, clinically effective and potentially cost-effective.

**CHAIR**—That is the second dot point. I am quoting from the first one.

**Prof. Hicks**—They go together. It is like being quoted out of context. You, as a politician, would not want to be quoted out of context. I could say to you, 'A Mercedes-Benz is a wonderful car, but it is very, very expensive and it will put off potential buyers.' If you only said, 'This is a very expensive car and will put off potential buyers,' and ignore the issue that this is a wonderful car, you are misquoting, you are misrepresenting the position of the person making that statement. That report misrepresents our opinion, our statement—categorically.

**CHAIR**—It seems to me that there are two phrases that have been drawn to our attention as being issues where an alteration was made which did not reflect the will of the committee.

**Prof. Hicks**—It is not only that. The primary finding has been inserted.

**CHAIR**—Sorry, what primary finding has been inserted?

**Prof. Hicks**—The primary finding that appears as the primary finding in the PET review.

**CHAIR**—Can you read what that primary finding is?

**Prof. Hicks**—I read it out earlier.

**CHAIR**—I would ask that you indulge me.

**Prof. Hicks**—Terms of reference 1:

The review steering committee accepts MSAC's conclusions.

Not their conclusions, MSAC's conclusions—

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

It has no statement—

**CHAIR**—How is that different to saying:

MSAC 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.

**Prof. Hicks**—Because terms of reference 1 has nothing to do with funding. It is about whether the technology works. If you go to terms of reference 3:

To clarify the role of PET in Australian clinical practice: ... determining which indications/applications should be eligible for funding; and where funding is appropriate, determining suitable funding models.

Terms of reference 3 is clear and I have made no contention about that. I have not challenged that contention on any of the documentation that any of the senators have seen.

**CHAIR**—Neither the steering committee nor MSAC altered anything to do with the question of funding. That is a subsequent iteration for which MSAC is not responsible—surely.

**Prof. Hicks**—They altered the strength of our statement regarding the clinical efficacy by adding 'potentially'.

**CHAIR**—That is another part of this. That is a second paragraph—a different paragraph to this one. In the changes to this paragraph, there is no substantial difference between the draft that was considered by the committee and the draft that finally went up to MSAC.

**Prof. Hicks**—With respect, I think we are arguing in circles. I do not think we are going to resolve this.

**Senator ALLISON**—Chair, I raise a point of order, I think it is an argument that you are putting and not questions and I suggest we move on.

**CHAIR**—I am putting it to the witness and asking him to respond.

**Senator ALLISON**—You have done that several times and I think the witness has answered satisfactorily.

**CHAIR**—Well, that is your opinion.

**Senator ALLISON**—You referred to the impact this had internationally and you mentioned the United States and gave an example. Can you expand on that? Which countries have read this report and have not done their own studies on it, and would regard it as authoritative and influenced their practices and funding decisions?

**Prof. Hicks**—At the last meeting, Richard King pointed out that MSAC is a member of a group of health technology assessment agencies called INAHTA, the International Network of Agencies for Health Technology Assessment, who represent many of the industrialised countries in the world. They performed a number of these reviews under the auspices of INAHTA. Subsequent to the Australian review, Danish, Scottish and Canadian reviews were performed. They all based and justified their opinions on the conclusions in the Australian review. In fact, in several of them, the primary finding has been quoted almost verbatim in their reports.

In methodologies applied to those reviews, they use the justification that, as the Australian review has already looked at the data up to 2000, they only need to consider new data that has come since that time. Unless there is compelling evidence that the situation has changed since the Australian review then we can, like them, find that there is no compelling evidence for introducing PET into our health care systems.

The Danish review has had the effect of significantly restricting the availability of PET in the country. An editorial by one of the leading PET providers in Denmark criticises vehemently the process of the Danish health technology assessment and its outcomes. The Canadian health technology review, similarly. My Canadian colleagues had very limited access to PET. The Scottish review found that PET was clinically effective in lung cancer but said, ‘Because the evidence in other areas of application were weak as found by the Australian and other health reviews,’ that they should not widely introduce PET. In New Zealand, no patient has access to PET because their government tells their clinicians that the Australian health review found that the evidence was weak. Patients pay to get on a plane and pay for their own PET scans when they come to Australia.

**Senator ALLISON**—In your opinion, has this been helpful to governments who might not want to be funding such expensive diagnostics?

**Prof. Hicks**—Of course. The appeal of this kind of report to funding bodies around the world is self-evident. I said so when we saw the first draft of the MSAC review by the literature reviewer. It is easy to be a critic and find weaknesses in the evidence. If you are genuine in recognising the problem that cancer poses, it would be intendant, I think, on anyone who was doing this dispassionately with patients’ best interests in mind, to look at where the evidence is to improve the care of patients, and that is there in spades—even in the existing report, despite the primary finding.

**Senator ALLISON**—Professor King said—you have provided us with the *Hansard* of his statement:

There was insufficient evidence to warrant unrestricted funding, which means that the evidence was poor.

**Prof. Hicks**—I have read out the emails from my colleagues who sat on that committee. I have read the synopsis of the submissions to the PET review from the professional groups who all agreed that the evidence was stronger than it was for any other currently funded technique or any technologies that have subsequently been funded through the MSAC process.

**Senator ALLISON**—Just to be clear, all the members on your steering committee object to that interpretation of the report that the evidence was poor?

**Prof. Hicks**—Yes.

**CHAIR**—All the members? Or the ones that you consulted?

**Prof. Hicks**—All the ones that I consulted who I consider to be experts either in oncology, neurology, cardiology or PET.

**CHAIR**—There are others, presumably, who might take a different view?

**Prof. Hicks**—The chairman of the committee and the leader of the contracted literature reviewers are the two people, I believe, who had the major influence on this and I have expressed that view to the chair of MSAC.

**CHAIR**—Were there others on the committee who have another view?

**Prof. Hicks**—No, there were no others.

**CHAIR**—Only five?

**Prof. Hicks**—No. The list is there. There is a representative of the Cardiac Society of Australia and New Zealand, Richmond Jeremy; the Australian Association of Neurologists, Mike Fulham who is also a PET provider; the Royal Australasian College of Surgeons, Professor Thomas; the Royal Australasian College of Physicians, Professor Millward; the Australian and New Zealand Association of Physicians in Nuclear Medicine, myself; the Australian and New Zealand Association of Physicians in Nuclear Medicine, Andrew Scott; Michael Kitchener as a member of MSAC; Richard King a member of MSAC and the chair of our committee; and John Simes, a member of MSAC and the chair of the contracted literature reviewer.

**CHAIR**—Do we know whether the other members share the views of Professor Millward, Professor Thomas and you, or whether they share the views of Professor King and Professor Simes?

**Prof. Hicks**—Richard King said of Andrew Scott that if he had expressed a concern about the findings of the review—that the evidence was weak—he would have acted on it. Andrew wrote an article in 2001—he submitted it in 2000—that said:

The methods for evaluating the evidence for PET remain complex, particularly as the standard evidence-based approach of randomized controlled trials is not generally applicable to imaging technologies. PET has the potential to dramatically improve our ability to manage patients with cancer and is also making major contributions to the development of new therapies.

Do you think that he would not have agreed with me that PET is an effective technology? He wrote it before the publication of this report and between our committee's sittings. And this report—

**CHAIR**—I do not know. But he used the word 'potential' there, didn't he?

**Senator ALLISON**—He said 'dramatic' though—'dramatic' and 'potential'.

**Prof. Hicks**—The words were 'to dramatically improve.'

**CHAIR**—'The potential to dramatically improve.' We seem to be rather obsessed by the word 'potentially', but it depends where it is used.

**Senator PATTERSON**—Professor Hicks, I have a question that you do not have to answer if you do not want to. Why do you think it was changed?

**Prof. Hicks**—I have no evidence to support this, but my suggestion to the committee is that there was a political objective in the PET review. I submitted an application to Michael Wooldridge in 1998 suggesting that we had a model of PET that was fundamentally different and potentially much more cost effective than the academic models of PET practice that were established and funded by the federal government at that stage. He wrote back to me to say that until there was compelling evidence of clinical and cost effectiveness from the two funded centres, he would not consider any additional extension of funding. He also said that the only way that I could get funding for my centre was to make a formal application to MSAC, which I duly did. I spent three months of my life looking at the primary evidence, searching the literature, reading the articles and synthesising the literature regarding clinical and cost effectiveness. I submitted to MSAC a document about two centimetres thick in which I made the case that PET was clinically and cost effective. So I did not come to this review without any background of having looked at the evidence.

Ken Miles, who was in a similar position to me, did a similar report. He did it independently of me but came up with very similar conclusions. They were submitted to MSAC. At the first meeting, where those applications were due to be considered, the minister was minuted as being in attendance but not minuted as having said anything. As an outcome of that meeting, the chair of MSAC, David Weedon, wrote to Michael Wooldridge to say that we were aware that the minister had a view about PET and, because of the implications of the technology, we suggested that the minister have the department conduct a formal review into this new technology.

A unique process was set up—as my colleague has demonstrated through documentary evidence—which had never been done before and has not been done since. Under this process, there was a separate steering committee—MSAC and the supporting committee. It was a very complex organisational structure with certain people represented on multiple committees and some on only one. There was very little interaction between those committees.

At the very first steering committee meeting Brendon Kearney was minuted as informing the steering committee that they should prepare themselves that the evidence for PET might be insufficient to warrant unrestricted funding. That is a clear statement, at least in my mind, that there was a political outcome that was desirable here. We have evidence at the very first committee meeting where I challenged—

**Senator PATTERSON**—That would have been said about unlimited access to MRI too. I do not think anybody has unlimited access to almost any technique.

**Prof. Hicks**—That's right.

**Senator PATTERSON**—So I think anybody would have said that to a group. I would have said that to a group.

**Prof. Hicks**—Sure, that is fair enough. At the very first meeting I challenged Richard King on the levels of evidence that he put in our terms of reference. I said, 'These have not been applied previously to MRI.' I had the MRI report, which had recently been released. I said: 'It wasn't applied here. Why not?' And he said: 'The minister has determined that the levels of evidence have to change. The bar has been raised because of what happened with MRI.' So we were asked to provide a different level of evidence than had ever been applied before.

That would be fine if those levels of evidence were freely disseminated, they were transparent, they were consistent and, as well as that, they went on being applied to new technologies—and we know that they have not, because subsequent diagnostic tests have been approved for Medicare funding without those same benchmarks being applied. In fact, at one of MSAC's committee meetings John Primrose, who was the government's adviser, said, 'The evidence for PET is greater than has been available for any of the other technologies we've looked at, including CT and MRI'—and I think Rob has the actual documentation there; I do not want to misquote John—'but a decision is required on this very point.' That was the one steering committee meeting, I believe, that Richard King was not at and did not speak to. I think there is a continuous thread through this that there was an agenda to restrict the availability of PET and not to have an increase in PET funding.

**Senator PATTERSON**—But that does not explain the change.

**Prof. Hicks**—Unless you believed that it was the only way that you could get rid of what was a politically unpalatable decision of saying, 'We're not going to fund this.' It is easy to say, 'We're not going to fund this because it doesn't work,' or, 'There's not enough evidence that it works.' That is much more politically palatable than saying, 'This works really, really well, but we're not going to fund it.' That is my own synthesis on it.

**Senator MILNE**—I just want to take you back to this process of what was signed off on, since that has been a matter of contention here. I have heard you say and have read in your evidence previously that the reason that you did not dissent was that you were not given a final report from the supporting committee to dissent from. Since then we have had the department give several versions of events, and I have looked through the evidence there. One version of events is that the department says, 'Yes, changes were made, but all the supporting committee members signed off on it.' That was one version.

Another version, given in 2000, was that the document that was sent to the supporting committee members to sign off on did not include the subsequent changes that were made et cetera. Can you take me through what it is that the supporting committee actually put their name to. Did you ever sign anything? Where is it documented on who voted about what? Can you explain that, because I think it is pretty critical here. There seems to be a lot of contention about what the supporting committee agreed or did not agree to. There is also the issue of the primary finding. Ms Halton in her evidence said, 'The reason the word "potentially" was later inserted was to make it consistent with the primary finding.' But there is no evidence anywhere. It is not minuted anywhere—there is no evidence anywhere of where that came from. So I would like you to comment on those two things.

**Prof. Hicks**—The first I saw of the primary finding was in the final report; it never appeared in any of our documentation. We never signed a document, we never signed off on any documents. In my recollection, no voting forms were ever put to us. I put that question to Michael Millward as well and he says, 'I do not recall our committee ever being put any question that required a formal vote or that it was expected our final report would be unanimously endorsed by committee members.' He said that we did not have to sign it and we didn't.

**Senator MILNE**—You did not see the primary finding that Ms Halton says was the reason 'potentially' was inserted. Dr King says he agreed to its insertion—he has not said who actually put it in there. He said he agreed to it being in there for consistency and so on, but you have no idea where it came from and, therefore, in your view it cannot be attributed to your supporting committee.

**Prof. Hicks**—No, and there was no inconsistency in our report. And again Michael Millward has said, 'Did our recommendations require alteration because they lacked sense or logic?' and his response was, 'no.'

**Senator MILNE**—Is the department wrong in saying the document was sent to you and you signed off on it?

**Prof. Hicks**—Yes, I believe that they are.

**Senator MILNE**—They were completely wrong about that. Given that you did not ever sign off on it, and the first you saw of it was the final report, and given that you responded immediately saying, 'I do not agree with that and it was not what was concluded and my name is on it,' do you think that you have been afforded natural justice in this process?

**Prof. Hicks**—I do not believe so. If this is, as it is purported to be, a scientific process, this is about evidence and evidenced based medicine. When you write an article all the authors sign a document saying that they have read the document, they agree with its findings and they endorse its publication. If they disagree, they will either take their name off or they will ask for it to be changed. That then goes to a journal for publication and the reviewers will come back with criticism, and if it is a valid criticism those changes will be made or the criticism will be rebutted. I have made substantial criticisms of the evidence and the conclusions and the statements in this—they have neither been rebutted nor corrected. It is not only me. The primary authors of papers that have been misquoted in this paper have written to MSAC pointing out that

their primary data has been misrepresented, that conclusions that they never made have been presented. They have gone to MSAC and yet they remain unchanged in this document. To me that constitutes scientific fraud. This document is on the public record as a synthesis of evidence which the authors, the department of health, and the other contributors know to be incorrect.

**CHAIR**—I am sure we have got that document that has been tabled in the many documents we have already had presented to us before.

**Prof. Hicks**—It is on the government website. It is freely available.

**CHAIR**—We have not got it here. Could we have that document passed over to this side of the table for a few minutes.

**Senator MILNE**—Professor Hicks, given how strongly you feel about this document and the effort that you have gone to, I ask you: is it still your request that you have your name taken off this document?

**Prof. Hicks**—Absolutely.

**Senator MILNE**—And that it be corrected on the website and any other—

**Prof. Hicks**—Yes, and I would like that same privilege to be extended to my colleagues, who I am sure would like the opportunity to have their name distanced from this report.

**Senator MILNE**—What you are saying is all members of that supporting committee should be afforded the opportunity to make their view known in relation to being associated with the document?

**Prof. Hicks**—Yes.

**Senator MILNE**—Have you any sense at all of where that primary finding came from, since it is my assertion that I have not seen it anywhere on any minutes, on any meeting record, on anything? You have no idea?

**CHAIR**—Could I butt in with a question here. The *Report of the review of positron emission tomography August 2000*, I note that what this report says—and you quoted from it before—is that the review steering committee accepts MSAC's conclusions that there is insufficient evidence at this time from which to draw definitive conclusions about the clinical effectiveness and cost effectiveness of PET.

**Prof. Hicks**—Yes.

**CHAIR**—What this describes is the views of the steering committee, not of the supporting committee?

**Prof. Hicks**—Yes. I have also entered into my testimony the letter that I received from Eliza, the secretary, to the Medicare Services Committee saying to me—written to me, 'I am pleased to advise the steering committee accepted the findings and recommendations of the supporting

committee and incorporated these into the steering committee's own report and recommendations presented to the Minister of Health and Aged Care, the Honourable Michael Wooldridge.' It is clear that they believed that those statements were our views.

**CHAIR**—That is a private communication—

**Prof. Hicks**—It is on MSAC letterhead by a member of the health department. I think that is—I am happy to enter it into the public record.

**CHAIR**—In fact it is already evidence before us but the statement in this report is as to the finding of the steering committee and that is a different body to the supporting committee, isn't it? There is nothing to suggest to us that the steering committee did not take the view that there is insufficient evidence at this time from which to draw definitive conclusions about—

**Prof. Hicks**—But it has been presented to this committee on several occasions that the steering committee looked at no evidence per se. They did not review the literature. They did not discuss with the experts in the field. They did not look at the submissions. The submissions that went to the steering committee were precised by Professors Kearney and King. They were never tabled at the steering committee. I believe that important works from the Thoracic Society, the Medical Oncology Group of Australia, the Clinical Oncology Society, the Epilepsy Society and various other august groups or craft groups in the area, that if this was a genuine, open and scientific process that their views would not have been consigned to an appendix at the end of the report as a synopsis—they would have been made available within the body of the report; potentially unless there was a confidentiality agreement included as part of the process of publication available on the website. That is what I would have liked to have seen. That is what I think should be there if this was a genuine scientific process. Because those opinions ought to, in the terms of reference of MSAC, influence the decisions of the steering committee. They were charged with responsibility to not only look at the evidence that we provided them from the supporting committee but also the submissions that came from the profession.

As I said, the profession spoke with one voice, loudly, clearly: PET is effective technology and by current standards of care is a cost-effective technology because it stops people having things that they should not have. Remember at the last meeting I pointed out what they are: they stop surgeons doing unnecessary operations on people who either cannot be cured or have already been cured of their disease. It stops us missing areas of tumour in a radiation treatment field because we know that although we do not cure everyone who we give radiotherapy to, we cure no-one when we miss areas of tumour, and we stop using ineffective chemotherapy drugs which are a major problem throughout our health economy. We are spending tens of thousands of dollars in drugs which improve the health care of 10 or 20 per cent of all patients. If we can identify them earlier and more robustly that they are not responding, we save the patient the toxicity of that drug, we save the community the cost of that drug and we give the patient the opportunity to start a better or alternative therapy, or to make plans about what is left of the rest of their life.

**Senator MILNE**—Can I just ask for clarification on those submissions? Are you saying that the submissions were never made available, that they just went to Professor King and somebody else and there was a synopsis made? Firstly, were the submissions ever made fully available?

Secondly, in your professional view, did the synopsis that was provided accurately reflect the submissions?

**Prof. Hicks**—I have the evidence second-hand from what Dr Ware has told me because he has sought this information and got it through freedom of information, and I have read it but not in the detail and not across it as well as he has. But my understanding is, and I will ask Rob to correct me if I am wrong, that there is no minuted discussion that those submissions were ever tabled or discussed within the steering committee. In terms of whether it adequately reflects their views, they said it worked. That is reasonable, but there are a number of riders on it which I think, in my view, are somewhat pejorative—the claims that are made instead of the statements. I think there is a continual theme in this document. There is always an implied doubt that is put on every statement—every positive statement that is made there is some rider —‘but we don’t know if this is going to do that; this looks really great, but—’; there is always that ‘but’ there.

**Senator POLLEY**—Thank you for your evidence. You have made the assertion that you believe that there was political interference from the minister down. You also state in the letter to Jane Halton that an MSAC member had actually phoned you and tried to suppress your dissent on this report. Is that normal practice and wouldn’t that also lead to some sort of political interference?

**Prof. Hicks**—I was very shocked by receiving that phone call and one of my other colleagues is willing to sign an affidavit to the effect that he was also called. We were asked to pull this guy behind me off because it was making very important people very unhappy. It’s Dr Michael Kitchener who is a member of MSAC and also a member of the Association of Physicians in Nuclear Medicine. My reply was why should a scientific process make anyone unhappy—we are looking at the evidence. We are not making any statements about whether it should be funded or not. That is the prerogative of the government. We have never challenged that. We have never said that the department could not have decided to do exactly what they have done. Personally I think it was a stupid decision, but they are entitled to make stupid decisions; they are government. The issue was if this was science, it should be free of political interference and if we are stating our opinions based on scientific facts, our analysis of the data, it should be free from political interference. That has been my contention throughout this process. I have everything to lose from this process. We are just at the point in the cycle of funding where funding is going to be re-evaluated, how is the government going to refund this technology? My program, everything I have spent over the last 15 years building up, is potentially jeopardised by coming out, putting the department officials offside, putting the government potentially offside by saying these things. My colleagues, as I said last time, are sitting on their hands because they are scared of losing funding. They do not want to rock the boat. They think that this is too important to what is going to happen with funding in Australia. My perspective, and it has always been my perspective, is that this goes beyond Australia. This goes to the whole world of cancer patients. One in three people in the world die of cancer.

I lecture internationally and I go to the Third World, to India, to Malaysia, to China and give lectures on PET. They are racing to embrace this technology because they have got an epidemic of cancer as they westernise. This process of scientific review has global implications and that is where I feel my moral responsibility is. If it kills my program and I do not get refunded in the review or the funding streams hurt, so be it. I feel a moral obligation to patients with cancer to have fought this fight. I have the utmost respect for Rob for doing this for so long. He has been

accused of a vendetta against King. This is not about Richard King. It is not about the department even. It is about what the message is that is given to cancer patients. That is what matters. I do not care what you decide to do with Richard King—whether you decide he committed fraud or not, whether you think the department lied to you. I do not care about that. But what I do want you to put aside is this report that says that in 2000 there was insufficient evidence. This and the reports like it I liken to six colour-blind men asked to comment on what the colour of a woman's frock is like and they say, 'It is very dull, isn't it?' They are coming from completely the wrong perspective. It is easy to be critical if you do not apply appropriate yardsticks and benchmarks to evaluate any evidence. We looked at the evidence. I have looked at the evidence. My colleagues have looked at the evidence. The profession has looked at the evidence. It worked and the process—I know you want to come back to the process—that has got this so fundamentally wrong has to be a flawed process. It was.

**Senator MOORE**—I apologise for being late. There was some legislation in the chamber I wanted to get kicked off. I had read so much and it is all going around and around in my head. I think most of us are feeling the same way. I only have one question and that is: when did you know that it was Professor King that made the change? We had been going through so many discussions about was it changed, wasn't it changed, who changed it, how was it changed? Professor King, as you saw at our last sitting, I think almost in his opening statement said, 'It was me. I made the change.' It was very quick.

**Senator MILNE**—No, he agreed to the change. He refused to say he did it.

**Senator MOORE**—But he took absolute responsibility for the change. I thought we had sat through several hours of evidence before that without that clarity. I am wanting to know from your perspective when did you know that Professor King took that—

**Prof. Hicks**—In this place.

**Senator MOORE**—When that evidence was given?

**Prof. Hicks**—I suspected—it looked like a duck, it smelt like a duck, it probably was a duck.

**Senator MOORE**—PET might have been able to tell you.

**Prof. Hicks**—I had my suspicions, but that was the first time.

**Senator MOORE**—That was the first time. In terms of the process, the amount of interaction that you have been having over years around this, what were you told before that? Everyone kind of knew there was a change even though people talked around it with that word 'potentially', and where the adverb was put in the phrase seems to be critical. People have been talking backwards and forwards for a long time. Were you in previous discussions and/or emails and/or letters? It just wasn't agreed that that was what happened? Or it wasn't responded to or what?

**Prof. Hicks**—Senator Adams, I think it was, asked a question in an earlier hearing regarding whether my correspondence had been answered or not—and the department supplied the first letter of response. I wrote to David Weedon as the chair of MSAC. He forwarded it to Richard

King who responded on his behalf and that was sent back to you as the response. I subsequently wrote to him on 7 March 2001 and said, ‘Thank you for your response to my letter to David Weedon. I am surprised that you appear to have taken such exception to my comments as I am not expressing any other opinion to David Weedon that my colleagues and I have openly expressed to both you and John Simes during our meeting, namely, that we perceive major problems in the interpretation of the value of the evidence regarding PET arrived at.’

I go through chapter and verse supporting that argument. I say:

You accuse me of being ungenerous to MSAC and those people who have been supportive to PET—

and in parentheses a suggestion that Richard King made at the last meeting as well that he had been very supportive of PET—

I didn’t and I don’t expect people to be generous to PET. I have only asked that the process by which PET is evaluated be consistent with that applied to other diagnostic technologies and that MSAC sets consistent and realistically-achieved benchmarks for scientific evidence, particularly when it applies to clinical and cost-effectiveness.

I wrote:

You and David Weedon have both conceded in meetings of our subcommittee that the standards of evidence required for PET had changed in the context of the introduction of MRI.

I concluded, and I think that this had been quoted before in this place, with the words:

I thank you for your thinly veiled invitation for me to resign from my role in the MSAC Supporting Committee but I am sorry that I cannot accept. I will go on arguing the case for PET where there is evidence of its superior diagnostic accuracy and impact on patient management. I will continue to press for appropriate evidence-based medicine evaluations and benchmarks for diagnostic test assessments. I will advocate in the press and elsewhere, the need and urgency for adequate clinical PET funding and suitable resources for data gathering. I will speak to Government or Opposition representatives about the issues within the bounds of my confidentiality agreement. 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.

I have been pretty consistent in this.

**CHAIR**—Thank you very much for your evidence today, Professor Hicks. You are going to table some more documents for us—the emails to you from Professors Millward and Thomas, thank you.

[5.23 pm]

**HANNON, Ms Wynne, General Counsel, Department of Health and Ageing**

**LEARMONTH, Mr David Andrew, Deputy Secretary, Department of Health and Ageing**

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

**CHAIR**—Welcome. Thank you for waiting today. I understand you were waiting on the previous occasion we had these hearings without having the chance to give evidence so I do appreciate your patience. I think you are familiar with the rules about you not being asked to give opinions on matters of policy and so forth. We can take evidence in camera if you apply to do so. You have heard the evidence given previously, not just today but on the previous occasions. We obviously want to ask you questions about that, but do you have an opening statement that you would like to make about these matters?

**Mr Learmonth**—No, to allow the maximum time for senators to ask questions. I would like once more for the record, in light of the testimony at the last hearing, to put on record the department's complete repudiation of the suggestions of improper behaviour on its behalf.

**CHAIR**—Thank you for that. Can I get you to outline clearly to the committee what the usual process is for an expert committee like a supporting committee—and I assume supporting committees are used all the time in MSAC type processes for making recommendations on new technology to the minister—to build up recommendations that eventually reach the minister. Can you comment, in describing that process, on the responsibility that each stage in that process has for assessing, refining, changing any of the outcomes of the earlier stages of that process?

**Mr Learmonth**—I will do our best. I might make an opening remark and pass to Mr Woodley. There is something of a before and after answer to this. My colleague will correct me if I am wrong, but when this matter went through MSAC it was very early days. I think it was the second application that MSAC had ever considered and it was the first one where it had this particular structure of three committees essentially in the main MSAC, a supporting committee and a steering committee. The steering committee, as I say, I think was the first example and it had a particular role which you would not normally find associated with MSAC. That was essentially because it was considering higher order things associated with implementation and not mere cost-effectiveness of a particular technology. So it was concerned with such matters as population distribution, workforce, infrastructure and so on, in other words, matters that would be associated with a rollout of these machines should a positive recommendation be made. While there was some overlap, it had a particular function. Now my recollection, and Mr Woodley will clarify, is that, as I say, this was very early days and I think there has subsequently been a review of how MSAC works, and a lot of the processes strengthened, clarified, improved about how the various committees work and so on. I am not sure whether you want the before or after.

**CHAIR**—I think we need the before.

**Senator MOORE**—And the after.

**Mr Learmonth**—Perhaps Mr Woodley can give you the history and you can delve where it would suit you.

**Mr Woodley**—I will do my best. If I could just make one comment first: that I think this was the second reference to MSAC rather than the second application—the difference being that the source of MSAC’s work applications generally comes from beyond the department—from beyond government. References I think at that time could come either from the minister or from the department.

**Senator MOORE**—What was the first one? I would like that information. Could you take that on notice?

**Mr Woodley**—Absolutely. I am speaking from my own experience. I was involved in the review of the MSAC process, therefore I was involved in some of the processes that occurred before then. However, I was not directly involved or in any way involved in the PET reference. On that basis, I first refer senators to I think Ms Murnane’s letter to this committee that followed the first hearing of this committee on this matter. I recall that that included a broad outline of the processes that are generally undertaken in the context of MSAC assessment. Senators may wish to refer to that afterwards. There are a range of parties with responsibilities through the process. The department provides secretariat support. There is a panel of independent and professional health technology assessing agencies, one of which is assigned to each reference for assessment. Their job is to assemble and analyse the evidence that relates to references generically. They are guided by a body formerly known as supporting committees, now known as advisory panels. That is put together generally on the advice of the MSAC executive and generally consisting of people with clinical expertise in the field that relates to the technology under review. These might be people who provide the service that relates to the technology or refer for that particular medical service. Health economics expertise is sometimes brought into these committees. They are generally chaired by a member of MSAC and there is generally a second member of MSAC sitting on the committee as well.

Again just speaking in general terms, that supporting committee or advisory panel would consider the scope of the review, they would consider what the applicant or what source the reference came forward with and basically ensure that the research question was appropriately scoped that took into account—making sure everyone understood what the technology under review is, what it is being compared with, what would be used as standard clinical practice in the absence of this particular technology. This gives guidance to the professional and independent health technology assessing agency to go away and then thoroughly consider the whole range of evidence that might bear on this question.

In my experience, the advisory panel or supporting committee meets two to three times in the course of any particular assessment. That would vary, but I would think two to three times is the mean. They will meet first to basically scope the research question. They will meet again perhaps at an interim phase of that process to consider the evidence that is coming forward and how it is being analysed by the health assessment agency, and generally they come together towards the end to basically review what the conclusions have been. That documentation goes to the next scheduled meeting of MSAC. MSAC routinely appoints an individual member to

critique the material that comes to the committee. In this particular case it was Professor Jackson. That is always a member who has had no previous involvement in that particular assessment.

Generally the chair of the supporting committee who is a member of MSAC will speak to that particular item on the agenda as well. In my experience, there is a robust discussion amongst MSAC members. They are, again in my experience, very diligent and take their role on MSAC very seriously. They routinely read all of the documentation very thoroughly. In my experience, it would be unusual for MSAC to accept the material that is put before them without comment or without requesting further information or clarification or amendment. They are particularly mindful of presenting to the government a consistent document that is internally consistent. On the basis of their assessment, they will frame a recommendation.

**CHAIR**—To the minister.

**Mr Woodley**—To the minister. It is also not unusual in my experience that the committee may choose not to make a final decision the first time it considers a particular application or reference. It may in fact send it back for further work to be done or further clarification to be provided, in which case it will come back to the next scheduled meeting of MSAC.

**CHAIR**—I am interested in the relationship between the supporting committee and MSAC—I am using the old terminology here. Do you understand that relationship to be one of there having to be agreement between the two bodies?

**Mr Woodley**—No.

**CHAIR**—Or is the one body, the supporting committee, an advisory body to MSAC so that if the supporting committee says a certain thing, is it open to MSAC to say ‘We disagree. We take a different view and we will recommend something different to the minister’?

**Mr Woodley**—Yes, it is.

**Mr Learmonth**—The subcommittee is essentially there to pre-digest through MSAC. It is not binding. MSAC looks throughout the entire evidence and forms their own view on it.

**Senator POLLEY**—So they can discredit any scientific evidence that has come forward, discriminate—

**Mr Learmonth**—They can form their own view of the evidence.

**Senator MILNE**—Surely the point is—

**CHAIR**—One at a time. Senator Polley?

**Senator POLLEY**—I just asked for them to answer the—

**Mr Learmonth**—I feel the common model, say for example with the Pharmaceutical Benefits Advisory Committee there are two subcommittees—the drug utilisation subcommittee and the

economic subcommittee—that essentially pre-digest all the detail within their particular remit and provide substantial material to the Pharmaceutical Benefits Advisory Committee proper and the entire committee will then go through the material. So the subcommittees are about commissioning work and—if you will excuse the term—pre-digesting those bits in order to serve up a considered piece of advice evidence and so on to the principal committee. So it is quite common.

**Senator PATTERSON**—They could recommend that the drug was cost-effective but the PBAC might decide—

**Mr Learmonth**—They wouldn't make a recommendation. They would come to certain conclusions based on what they saw—

**Senator PATTERSON**—But the PBAC might make a different decision.

**Mr Learmonth**—Their decision holds no particular weight. The principal committee looks at all the evidence and forms their own view. I do not know how else to characterise it.

**Senator PATTERSON**—Why would a report be changed, then? That is the implication.

**Mr Learmonth**—It is, and if I could refer you to both Mr Woodley's and Professor King's testimony, they are keen for their report to be essentially logical. I recall Professor King testifying before—I have got the quote here—that the changes are made to ensure internal consistency with the report so that what is reflected, for example, in conclusions or a summary at the front is consistent and a fair summary with what is throughout. It is internally consistent and logical. That was precisely Professor King's testimony.

**Senator ALLISON**—That is in the very least arguable.

**Mr Learmonth**—Not in the testimony of Professor King in this particular case. As a general proposition I would suggest that that is why amendments might be made: in order to ensure we have got a logical and internally consistent document. In this particular case, that is certainly Professor King's view.

**Senator PATTERSON**—Given that, would you expect that the participants, the members of the committee, would be shown any changes and either have a chance to put an alternate view—

**Mr Learmonth**—I think what we are trying to say is that the members of the committee go back to the actual evidence and form their own view. They will look at the recommendations and I am sure they will note the recommendations. They will look at the conclusions and I am sure they will note them. As I think Professor King and Mr Woodley and others have testified, they take their job seriously. They go back through all of it. They all come to their own conclusions about what the evidence says and argue that.

**Senator POLLEY**—They can make their own recommendations based on their evidence and their judgement but they don't change minutes.

**Mr Learmonth**—Quite so.

**Senator PATTERSON**—And their name is on it and if they do not agree you would imagine they would be able to say that.

**Mr Learmonth**—That's right. I think there are two cross-purposes here.

**CHAIR**—That is looking at the process.

**Senator MILNE**—That is what I will come to.

**CHAIR**—Senator Adams had a question about process.

**Senator ADAMS**—I do have a question about the process with the supporting committee. They were there gathering scientific evidence; was that part of their role?

**Mr Woodley**—The health technology assessment body, the CTC, the University of Sydney, that would have been their primary responsibility.

**Senator ADAMS**—On the role that Dr Hicks was playing as a member of the supporting committee, he was there to look at scientific evidence as to whether the PET machine was scientifically suitable for the job it had to do—that is putting it in very basic language. He has already said that was part of his role. As a professional and an expert in this particular area, this evidence was then taken on to the next committee, which was the steering committee, and that evidence, as far as I am concerned, was changed. I have sat through all these hearings and I have read quite a lot about what has gone on, but I have sat on a number of committees like this that have been advisory and then they have gone on to another committee that has pulled the whole thing together. A report has come out and I have been given a draft report to read and then, if I have agreed with the content of it of the area I was involved in, I have signed it. This is where I find it very difficult with this process that something has gone horribly wrong that a person who has international following and is considered by their peers to be very esteemed or—I am trying to think of the word they used for their scientific committee—eminent; that his name has appeared on a report and it has gone everywhere. He has been out as a proponent of supporting this technology only to have a report being published and released with his name as part of the group that has approved it. The process is wrong. There is something very wrong.

**CHAIR**—What is the question?

**Senator ADAMS**—That is the question. I asked about the scientific evidence; was that what they were doing?

**CHAIR**—Were you gathering scientific evidence in the supporting committee is the question.

**Mr Woodley**—Speaking in general, supporting committees make a contribution to the process which is largely undertaken by the health technology assessment agency of gathering clinical and economic evidence that relates to the research question.

**Senator ADAMS**—How did it go so wrong and how did Dr Hicks's name appear on the final document when he had not actually read and approved of his name being put forward?

**Senator MILNE**—Was he allowed to remove it?

**Senator MOORE**—Do you agree that that is accurate? We are putting this forward: do you agree that someone's name has appeared in a report that they have not actually seen fully and accepted, and their name appears in it? Do you agree that that has happened?

**Mr Learmonth**—I think I want to take that one on notice, and I will tell you why. There were many documents floating around seven years ago and I would like to have a good look at who saw what and who had what opportunity to say what in that context at the various meetings before I would provide a concluded view on that. I do not necessarily accept it at all on face value and I would like to have a look.

**Senator MOORE**—That is very central because I think that Senator Adams and I am sure others have been tracing through what has occurred and, Mr Woodley, you have given us the kind of whiteboard picture of how all the boxes fit together and I know Ms Murnane's letter did as well. What we are trying to find out is: when people come on those bodies, do they understand exactly how much ownership at each stage and what the responsibilities are? Secondly, does each person who is on each of the bits have rights to actually say yes, I agree/no, I don't and sign off at each step. That is the kind of process point that we are trying to find out, because there are so many models of how these bodies work in MSAC. Considering the sensitivities of the issues that people are looking at and the professional expertise which very often probably don't agree but if you don't agree, if something moves forward for minutes or from decisions or recommendations knowing they are not directional recommendation, they are recommendations about what happens, just that ownership at each level to say Claire Moore was part of this group and I do not agree with what goes forward. Or Claire Moore was part of this group and I actually agree with that and sign off on it. If I do not agree, the responsibility I have to say Claire Moore does not agree with this bit because—and have that actually in the processing document.

**Senator ADAMS**—It is a consenting to that report.

**Senator MOORE**—Is that what we are trying to—

**CHAIR**—Could we have an answer to that question.

**Mr Woodley**—I think I heard a few different questions. I will have a go at one and if there are others.

**Senator MOORE**—And then we will sign off on that one.

**Mr Woodley**—I preface the answer again with in my experience—

**Senator MOORE**—That is all you can give.

**Mr Woodley**—members of supporting committees come to the process with a range of different understandings of the role of the supporting committee. Some individuals participate in these processes a number of times and benefit from that experience. From my recollection, one of the outcomes of the review of MSAC's process is that the internal view was that MSAC itself

formed a view that it might more routinely advise or inform new members of the supporting committees what their specific role is.

**Senator MOORE**—Expectations and responsibilities.

**Mr Woodley**—Yes, indeed.

**CHAIR**—So the threshold question we have not yet answered. Putting aside the understanding that members have of those processes, what is the actual process? Is it the case that the members of the committee need to agree with the recommendations that are taken to the next level and if those recommendations are changed, is there a process for the committee members of the lower stage to distance themselves from those changed recommendations.

**Mr Woodley**—MSAC often takes a different view to the advice it is receiving from a supporting committee. I think I referred earlier to the process whereby sometimes MSAC will refer the matter back to that committee if it considers that a substantial amount of work needs to be done or redone but not always. In my experience, there is not a routine closing of that loop if you like if MSAC amends—reshapes a report to a point where it is comfortable with it, it does not formally, in my experience, communicate that back to the supporting committee.

**Senator ALLISON**—What is laid down in the process or is there none?

**Mr Woodley**—I would have to take that on notice. There are procedures written down. I am not aware that they come at that issue.

**Senator ALLISON**—Mr Woodley, you did a review of MSAC and presumably you recommended some changes. Was this question of process in terms of whether or not steering committees or advisory committees or whoever they are get to see the final report and tick it off before their name is attached to that report? Was this an issue that you discovered when you did your review and did you make any changes following that review?

**Mr Woodley**—Not that I recall.

**Senator ALLISON**—You did this review and you cannot recall whether or not there was a recommendation along those lines or whether you discovered there was a problem process-wise?

**Mr Woodley**—MSAC came to a whole range of conclusions. I do not recall that the process of feeding back to advisory panels was—

**Senator ALLISON**—I am asking about your review.

**Mr Woodley**—It was MSAC's, I am sorry.

**Senator ALLISON**—I thought you conducted it.

**Mr Woodley**—I gave them a hand as an administrator.

**Senator MILNE**—We heard evidence before that there were guidelines at the time that governed this process that said the supporting committee was entitled to be told that they were able to make a dissenting report and that there was provision for that report. That is in the guidelines. In all this discussion of feedback and so on it was in the guidelines at the time. We know that. Did that steering committee—

**CHAIR**—Were there guidelines?

**Mr Woodley**—I understand there were guidelines but I am not convinced that they came to the issue of feeding back from MSAC.

**Senator MILNE**—No, I did not say that. What I am saying is there were guidelines at the time covering participation and rights of people in the supporting committee and one of those was that they be given the opportunity to dissent. Were all the members of that supporting committee informed of it and given the opportunity to do it? We have heard today from Professor Hicks to say that he was never informed that he could make a dissenting report and in fact could not have done so because he was not given the final report on which to be able to make a judgement to dissent. So that is the first question. My second question: nobody on this committee has ever doubted the capacity of the steering committee or MSAC itself to change recommendations. The question is whether they were told that changes had been made, because throughout this whole process they all say, ‘We accept the findings of the supporting committee’ and that goes right up through the system. But they were not given the findings. This whole inquiry is about how those findings got changed and how they were misrepresented as ‘the findings’ further on. Everybody made judgements based on that, so I want to come back to that in a minute because it is not about whether anybody else could change it. It is whether they made judgements based on what was a true representation of the supporting committee’s report. Can I just go back to my first question about the dissenting report.

**Mr Woodley**—There were guidelines.

**Senator MILNE**—Yes, and what did they say about the rights of the supporting member to dissent?

**Mr Woodley**—I will read from the documentation I have got in front of me. Section 7.5 of MSAC’s operating guidelines state:

In reporting to MSAC on its evaluation of an application, the supporting committee’s report should note whether or not all supporting committee members were in agreement with the supporting committee’s report. If not, the name of the supporting committee member(s) and the nature and extent of the dissenting view, should be included in the supporting committee’s report. Areas of agreement/disagreement amongst supporting committee members and by whom those views are held, should be stated.

**Senator MILNE**—Did that occur?

**Mr Woodley**—We provided documentation around this—

**Senator MILNE**—You have provided thousands of pages and I have looked at thousands of pages and no evidence has been provided that the committee was given that opportunity and in

fact we have heard from Professor Hicks, who was a member of that committee, that it was not given to him and that he did not see the final report in order to be able to take up the option even if there is some dispute about whether he was offered it.

**Mr Woodley**—Without personal experience of this I can only refer to the documentation and I would rather we provide you with further documentation or pointed you towards documentation that has already been provided. There has been an extent of evidence around this.

**Senator MILNE**—There has been extensive evidence but it takes a lot to get it. Can I ask specifically that the response to that be provided. What was the supporting committee offered and who was offered the opportunity to make that response? Where is the report of the supporting committee about who agreed, didn't agree, what their points of difference were et cetera? Does it exist?

**Senator PATTERSON**—On a final document, Senator Milne.

**Senator MILNE**—Yes, on the final document on which they then—

**CHAIR**—This is the final document from the steering committee to MSAC.

**Senator MILNE**—From the supporting committee on—

**Senator PATTERSON**—We are not talking about drafts. We are talking about the final document.

**Senator MILNE**—The supporting committee members to—

**CHAIR**—To the steering committee.

**Senator MILNE**—Yes. Their report that they signed off on or did not sign off on and given this opportunity to dissent or whatever else they wanted to say.

**Senator ALLISON**—Just before you go on, can I also ask why is it that we have seven high-level members of the department here, this is a central issue to our inquiry, and why it is that not one of you are able to answer this question? I find that extraordinary—

**Senator MILNE**—It is a pretty simple question.

**Senator ALLISON**—when this is so core to the issue that we are discussing that you would come along today not prepared, not having the information that we are requesting.

**Mr Learmonth**—This happened seven years ago. I do not think any of us were there at the time.

**Senator ALLISON**—This inquiry has been going for some years in this committee and if I can suggest if this committee had been given a more honest appraisal of the situation at the time, we would not be wasting our time either with yet another hearing. So I think, if I might say so,

we have had a fairly poor response from the department in answer to some of the issues and questions that have been raised.

**Senator MILNE**—If I can just continue, when Senator Harradine put a question on notice about this very issue some years ago there was an opportunity for the department to be very straightforward about this. He asked specifically: ‘Did the Scientific Reporting Committee in its report find that PET scanning was clinically effective and possibly cost-effective?’ He meant ‘potentially cost-effective’ but that is what he asked. The answer was ‘No.’ When we fleshed that out last year, the excuse for saying no that the department gave was that the supporting committee didn’t make findings and reports and therefore technically you could say no. Since then we have seen lots of documents, including one referred to by Professor Hicks earlier where the MSAC review steering committee has written a letter saying that the steering committee accepted the report and findings of the supporting committee. So right through the documents, everybody else accepts that the supporting committee makes findings and reports and recommendations or whatever else. Yet, the excuse for saying you answered no to Senator Harradine all those years ago was on that basis. Do you now agree that you were disingenuous and actually not particularly truthful in answering that question?

**Mr Learmonth**—No, I do not agree with that.

**Senator MILNE**—Why not?

**Mr Learmonth**—I refer you to my previous testimony about that and the strict interpretation of what role the supporting committee has versus MSAC. I did acknowledge, as I think the chairman pointed out at the time, that there is some ambiguity and looseness about words that he used and that has undoubtedly contributed to the perception.

**Senator MILNE**—That is your view. I have a different one. Can you also explain to me who inserted and when was the primary finding inserted? It is not minuted and not referred to anywhere, but Ms Halton says that the word ‘potentially’ was inserted and Dr King agreed to that insertion based on the primary finding, which was not the primary finding.

**CHAIR**—I think there is some confusion about what the primary finding was. The primary finding did not use the word ‘potentially’, as I recall. It was that earlier paragraph we were talking about which was about another phrase: ‘insufficient evidence at this time from which to draw definitive conclusions about the clinical effectiveness and cost-effectiveness of PET.’

**Senator MILNE**—I have not actually got the exact sentence of the primary finding that we are talking about.

**CHAIR**—That describes the primary finding of the steering committees. I am not sure that—supporting committee.

**Senator MILNE**—I am talking about the supporting committee. Ms Halton’s evidence to this committee was the reason why ‘potential’ was inserted was to make the whole thing consistent with the primary finding of the supporting committee. We have had evidence to say it was not the primary finding of the supporting committee. There is no evidence anywhere to say that this finding was—if I could ask Dr Ware because I do not have it in front of me.

**CHAIR**—Could I clarify this: what is the primary finding is not especially clear. What is in the final document that went from the supporting committee to the steering committee has a number of general findings and there are four dots under that heading. The first of those says: ‘There is insufficient evidence at this time from which to draw definitive conclusions about the clinical effectiveness and cost-effectiveness of PET.’ The word ‘potential’ does not appear there so that has not been entered there. Three paragraphs later there is a phrase where the word ‘potentially’ appears twice, but I would not describe that as the primary finding because it is not the first of the findings under that heading ‘General findings.’ Can we clarify what we are saying? Are you asking about the changing of the word in that paragraph where the word ‘potentially’ was inserted before clinical effectiveness.

**Senator MILNE**—The whole sentence was inserted as a primary finding.

**CHAIR**—That is the first dot point under the heading ‘General findings’ I take it.

**Senator MILNE**—Yes.

**CHAIR**—That sentence is certainly different to the one that was in the earlier draft.

**Senator MILNE**—That was inserted as the primary finding and it was on that basis that Ms Halton said the word ‘potentially’ was inserted.

**CHAIR**—Sorry, the word potentially was not inserted in that primary finding. It does not appear in that primary finding.

**Senator MILNE**—But the logic for inserting it later—

**CHAIR**—Later in the document, not later in time.

**Senator MILNE**—The potentially clinically effective, the potentially was inserted later.

**CHAIR**—That is not the primary finding. That is a point that comes further down the page. We want to make it clear what we are were talking about. There were two bits that were changed in the report: one was a paragraph that began the section under the word recommendations, it talked about insufficient evidence from which to draw definitive conclusions. There is another paragraph further down the page which talks about evidence that PET is safe, potentially clinically effective and potentially cost-effective. There are two different parts of the report. I am trying to clarify what we are talking about here. Are you talking about that first—that is what went up eventually from—that is what they finally produced and what was finally given to the—

**Senator MILNE**—‘There is insufficient evidence at this time from which to draw definitive conclusions about the clinical effectiveness and cost-effectiveness of PET.’ That was the primary finding that was suddenly inserted and in order to make the rest of the report consistent with that primary finding at a later time ‘potentially’ was inserted to make it consistent with that. What I am saying is, there is no evidence anywhere to say that that is the primary finding that the supporting committee ever arrived at but Ms Halton’s justification was that that was the primary finding. What I am saying is where did it come from? Who put it in there and when?

**Mr Learmonth**—So I understand could I rephrase your question and see if it is what you are after? When you are talking about inserting primary finding do you mean insertion of the word ‘potentially’ in something which is inconsistent with the body of the report? Is that the concern?

**Senator MILNE**—No, I am saying—

**Senator ALLISON**—Who wrote the primary finding?

**Senator MILNE**—Who wrote the primary finding that there is insufficient evidence at this time from which to draw definitive conclusions about the clinical effectiveness and cost-effectiveness of PET? That is the primary finding to which Ms Halton referred and that is why later in the document it was put that it was justified to be consistent with that to put ‘potentially’ in front of safe and clinically effective. If the primary finding was not the primary finding, then there was no justification to insert anything to be consistent with it. What we have done throughout thousands of pages and many FOIs and goodness knows what, nobody anywhere who actually was on any of these committees or minuted on any of these committees or any meetings can actually say who wrote that and when it was put in and the fact that it was never represented to the steering committee, to MSAC, to anybody else that was inserted after the supporting committee concluded its deliberations. That is why there is this accusation of scientific fraud, because nobody knows where it came from and it changed everything.

**Mr Learmonth**—If I can refer you to the testimony from Professor King last time, he said that the issue of the word ‘potentially’ is not one with the primary finding or summary. It is with the body of the report, which you would hope and expect the primary finding or summary would reflect and be based on. I will make two quotes from Professor King, who was on all three committees. He said: ‘I did not make that change. I agreed to the change being made by the superior committee. It was not made by anyone in the health department; it was not made overnight; it was not a fly-by-night decision. It was made purely and simply so that the document read logically.’ He goes on to say—superior committee is what his testimony says—that the primary finding was not inserted. There were editorial changes made to that primary finding which did not change the meaning of the primary finding at all and which did not change the outcome of the review at all. By saying that there is insufficient evidence at this time to draw definite conclusions about the clinical effectiveness and cost-effectiveness of PET reads to me as the same but somewhat better worded than saying that the MSAC Supporting Committee 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.

**Senator MILNE**—From that I take it that the department’s position is now the position of Professor King? Because the department’s position has changed several times—the evidence shows at one point there were no changes, then there were changes, they were agreed to, they were not agreed to. Now Professor King that said that there were changes made and that he agreed to them but he cannot remember who actually proposed the changes but nevertheless he took responsibility for them. Now the department is referring me to Professor King. I am actually interested in Ms Halton’s interpretation of events because as in her role in the department the capacity for Dr Ware to get documents was blocked, in every way the public were being denied evidence to a whole range of documents and so on and it is Ms Halton here that kept this out of the public arena for a very long time. What she has said is that that primary finding was the basis for all the changes, everything that happened. I want to know how that

primary finding was arrived at and why the change was not relayed to the other levels of assessment, because all this would have been different. If they had decided to make a different recommendation in spite of the evidence given to the supporting committee, so be it. The supporting committee's report would have been on the public record and people would see it was a political decision or whatever decision it was. That is why we are getting very frustrated and people on the supporting committee are frustrated that, as the chair of the committee says, they feel they have been verbally.

**Mr Learmonth**—Could I say two things: one, neither the secretary nor anyone else in the department has prevented Dr Ware or anybody else getting access to documents on this. There is a substantial list of FOI requests and thousands of documents having been provided. So, contrary to suggestion, there is no restriction whatsoever on information being provided by the department or anyone else that I am aware of. I do not accept that at all.

**Senator MILNE**—You just qualified it by saying, 'Unless there is a history.'

**Mr Learmonth**—No, I take issue with the point you made twice, which was that the secretary had impeded access to documents by Dr Ware. I am suggesting to you there is a very substantial history of documents having been provided under FOI, thousands of pages. There has been no impeding of that access whatsoever.

**Senator ALLISON**—There was no refusal for any documents?

**Mr Learmonth**—The documents were provided in accordance with the FOI Act.

**Senator MILNE**—There was no recommendation from anyone in the department to desist?

**Senator ALLISON**—How many documents were—

**Mr Learmonth**—I am sorry?

**CHAIR**—One at a time. Senator Milne.

**Senator MILNE**—I understand that there was a recommendation made from people in the department to disengage and not facilitate Dr Ware; is that not the case?

**Mr Learmonth**—That is entirely separate to FOI and that is a matter about entering into further correspondence. That is entirely different and does not affect in any way whatsoever Dr Ware's statutory right to refer to FOI access material.

**Senator MILNE**—And under FOI, not all the documents that were asked for were provided; isn't that the case? Until we started this hearing and started asking for them—then more documents were forthcoming.

**Senator PATTERSON**—There are often documents—and I asked Ms Hannon to correct me if I am wrong, there are documents which may not be eligible—FOIable, but the Senate has more power to get them and that may be the case.

**Senator ALLISON**—Perhaps if we could have a list of documents refused on FOI application.

**Senator PATTERSON**—I have to say I do take some objection to the claim that any departmental officer would have impeded access to FOI documents. There are documents which are not FOIable, if they can go on to cabinet for some other reason. I do not know that these would have gone to cabinet; I do not think they would have. But there may have been legitimate reasons. I do not always agree with public servants but I would take objection to that.

**CHAIR**—Can I understand the evidence that you are giving to be that all the documents which were required to be supplied under FOI have been supplied.

**Mr Learmonth**—That is correct.

**CHAIR**—And a decision by the department to limit continued correspondence with Dr Ware as a result of a very large amount of correspondence with Dr Ware was a decision which was separate to that question of whether he would have access.

**Mr Learmonth**—We cannot in any way constrain Dr Ware's or anybody's right to access under FOI. It would be taken very seriously. We have got no ability to constrain that.

**Senator POLLEY**—Can we then have tabled the list of documents that we requested that were not able to be supplied according to you under FOI.

**Mr Learmonth**—Certainly.

**Senator POLLEY**—And why.

**Mr Learmonth**—Yes, that is something that is provided to the applicant.

**CHAIR**—Just on this question of the primary finding, do I understand the primary finding—if we mean it to be the one that says, 'There is insufficient evidence at this time from which to draw definitive conclusions' et cetera—derives from the first dot point in the draft of the supporting committee report which the members saw which read, 'The MSAC Supporting Committee concludes that there is insufficient evidence on PET's clinical or cost-effectiveness.' That is essentially the same recommendation.

**Mr Woodley**—I have those words in front of me as part of the record of the supporting committee's meeting of 23 March 2000, if that helps.

**CHAIR**—The one set of words derived from the other; is that fair?

**Mr Woodley**—I can read them if you wish.

**CHAIR**—I have read them several times. I do not think we need to read them again.

**Mr Woodley**—Okay.

**CHAIR**—We need to try and wrap it up. Senator Adams?

**Senator ADAMS**—Coming back to supplying of documents, I would like to ask the department why originally we were sent one letter that was written by Professor Hicks to MSAC and the second letter was never mentioned. That has finally come to light now; we have actually been given a copy of that with this last lot of papers that we have received on this. I just wonder why the department did not mention that. This was a question that I did ask of the department in April in what must have been our Senate committee looking into PET at that stage in April 2006. I think if that letter had been supplied at that time we probably would not be sitting here today. These are the sort of things that have frustrated me as a committee member when something like this turns up this week and the department could have supplied it to us a year ago. Why did we not receive it?

**Mr Woodley**—I think it needs to be established that the department actually had possession of that most recently received. We will certainly look into that, but I think that remains a question.

It was sent to the chair of MSAC in 2001 and it has just now come to light.

**CHAIR**—I thought it was in the earlier documents.

**Senator ADAMS**—No, it was not. We have never seen the second letter, Gary. We had the first letter.

**CHAIR**—Can you show me which letter you are talking about?

**Senator ADAMS**—Yes, I can. It is in here. I have never seen it. I have gone through all my things. It was 7 March 2001. I just feel with the evidence in this that we would not be here today.

**CHAIR**—All right, if you take on notice the question of why that document was not provided.

**Mr Learmonth**—Do we know which one it is?

**CHAIR**—Are there further questions, Senator Allison?

**Senator ALLISON**—Can the department explain what is the process for a member of an advisory committee or a support committee that develops the basis for a report in wishing to withdraw their name from that report?

**Mr Learmonth**—Then or now?

**Senator ALLISON**—Then and now.

**Mr Woodley**—The best I can do is a response we provided on notice to a question from Senator Moore dated 28 April. A disclaimer first appeared on the MSAC web site in July 2004.

**Senator ALLISON**—A disclaimer for what?

**Mr Woodley**—It appears and I think is now routinely published in MSAC reports. It appears if someone attempts to open an MSAC report electronically.

**Senator ALLISON**—A routine disclaimer; you are not talking about a specific—

**Mr Woodley**—Yes, and I will come to that. It reads, ‘MSAC recommendations do not necessarily reflect the reviews of all individuals who participated in the MSAC evaluation.’ I think it is also routine that members of supporting committees are identified in the appendixes of MSAC reports as well as members of MSAC. It is also clear that the report is of MSAC.

**Senator ALLISON**—So there is no capacity for someone to have their name completely removed from that report?

**Mr Learmonth**—I am not sure the guidelines actually deal with it explicitly and perhaps part of the reason is that the experience of people here there has not been any other occasion where someone has asked for that to happen, so I am not sure the guidelines contemplate it. Perhaps they should.

**Senator ALLISON**—If there is no guideline and someone asks for that to happen, what happens then?

**Mr Learmonth**—So far that is a hypothetical. That is not something apart from this that the committee has had to contemplate.

**Senator ALLISON**—Mr Learmonth, this is not hypothetical. We are dealing with the actual case here.

**Mr Learmonth**—I am saying apart from this. This has arisen.

**Senator ALLISON**—And arose some time ago. What has been the process of dealing with this request by at least one member of this supporting committee to have his name removed from the report?

**Mr Learmonth**—I will take that on notice.

**Senator ALLISON**—Mr Learmonth, I find it extraordinary that you are not able to answer that question.

**Mr Learmonth**—I am sorry.

**Senator ALLISON**—I will have to ask you why you cannot answer it.

**Mr Learmonth**—I am not sure I can give you an explanation that will satisfy you. I do not know the answer to that question.

**Senator ALLISON**—You do not know why it is you cannot answer the question.

**Mr Learmonth**—No, I do not know what the answer is.

**Senator ALLISON**—I asked you why you thought you could not answer the question.

**Mr Learmonth**—Because I do not know the answer. I am sorry.

**Senator ALLISON**—Is this because you have had no involvement in the request for a name to be removed from the report?

**Mr Learmonth**—Correct—that the least of that—

**Senator ALLISON**—Who present has been involved with the receipt of correspondence or that request who can answer the committee's question?

**Mr Woodley**—I do not think there is anyone on this side of the table who was involved when correspondence was received. I could check that. I do not think anyone was. My understanding though is that the procedure that is described in our response to Senator Moore's question arose as a consequence of Professor Hicks's approach.

**Senator ALLISON**—Should such a letter arrive for this or another report, where would it go?

**Mr Woodley**—Those sorts of correspondence would most routinely be directed—it would depend who it was addressed to.

**Senator ALLISON**—To you?

**Mr Woodley**—No, not to me. To the MSAC secretary.

**Senator ALLISON**—Who is the MSAC secretary?

**Mr Woodley**—The MSAC executive, I am advised.

**Senator ALLISON**—If that happened in this instance, what would then be the process?

**Mr Woodley**—The MSAC executive would consider it, the MSAC executive consisting of the chair and deputy chair generally and often one other member. What process they would follow—

**Senator ALLISON**—If we assume that this might have happened, what is the process for appeal against a decision that this would not happen?

**Mr Woodley**—I do not believe there is—

**Mr Learmonth**—I do not think there are processes outlined and I would not want to speak for the MSAC chair as to how he might choose to handle this. I would imagine there would be discussion within the committee—the independent committee how it ought to be handled. But the guidelines are not explicit on this matter.

**Senator POLLEY**—If you are expecting people to participate in these committees wouldn't there be a logical process whereby a person's professional integrity was going to be protected? That is not unreasonable and surely the whole reason we are here is because potentially many people in our community have been denied access to something that could have been life saving.

**Mr Learmonth**—These matters are handled differently in different committees. Not all of them require unanimity. These are committee decisions that are reached and it would not be I dare say usual, whether it be MSAC or PBAC, for there to be unanimity of view. People accept a committee puts forward a response.

**Senator POLLEY**—We are talking about individual professional integrity and you are now saying that if a report is produced and they question that and they want their name reviewed, you cannot tell us what the process is and that there is no protection for them. We are talking about a federal government department.

**CHAIR**—We need to be asking questions so we can move on.

**Senator PATTERSON**—I do not think it is right to say that it changes the course of whether the treatment is available or not. I think that is drawing a long bow because a committee may say it is effective but a decision might be made that there are five other things lined up that are more effective and it may not be funded. I do not think that is the issue that you can say because of this. I have to clarify something because a member of the committee has made a statement. I happen to have a bit of experience and it is not the case that if the committee recommended and said yes, maybe it should be funded on a limited basis or whatever, that it would necessarily be funded. I cannot think we can say that.

**CHAIR**—I take your point. We are not at the stage of making statements.

**Senator PATTERSON**—I am sorry, I am going to finish. I have been very constrained.

**CHAIR**—Senator Patterson, I know you have, but we have an opportunity—

**Senator PATTERSON**—I have one more point to make and I will make it.

**CHAIR**—Senator Patterson—

**Senator PATTERSON**—I have one more point to make, Mr Chairman, and I will make it. The last point is that I do agree with what has been said, that there should be a process if people disagree that they have the opportunity for that to be recorded in the final report, and that seems to be the issue that that has not been done.

**Senator ALLISON**—I just want to continue that line of question before about process, Mr Learmonth. I am sorry to do this to you, you appear to be in terrible pain and I wish you would go home. On this question of process, you have been aware of this issue because of the fact that the committee has been inquiring into this matter for some time now. Did you, at any point, make contact with the MSAC executive manager—

**Mr Woodley**—Executive.

**Senator ALLISON**—to ask them the question that I raised earlier about process and about what happens when a member of a supporting committee wishes to have his name removed from the report?

**Mr Learmonth**—I have not, but I will now do so and provide you with a response.

**Senator ALLISON**—I ask you why it was not done before.

**Mr Learmonth**—It was not something that I contemplated at that point. As I say, this is something that does not happen routinely. In anyone's experience there has not been another occasion when anyone has done it.

**Senator ALLISON**—I realise it does not happen routinely; however, as has been said several times already, this committee has been considering this matter for probably two years. Again I ask you why this committee was treated with such contempt that you thought it not necessary to ask the question that would inevitably be raised at this hearing.

**Mr Learmonth**—I am sorry that I did not. It was certainly not an expression of contempt—far from it. I guess not everything can be contemplated and in this we did not speak to the MSAC committee or executive but we will certainly do so. If the guidelines ought to be amended to provide for an explicit process for people to note their dissatisfaction or withdraw their association, we ought to do that.

**Senator ALLISON**—So that is the process. Now let's take the current situation with this report and the witness we have just heard from. Can the committee have similar undertakings from you that there will be a review of this request for a name and possibly names to be removed from that report?

**Mr Learmonth**—I will absolutely take it up with MSAC.

**CHAIR**—Senator Polley?

**Senator POLLEY**—I just want to clarify some comments that you made at the last committee hearing that we had, Mr Learmonth: 'My advice is that all the users on the supporting committee signed off on the report that went to MSAC and that they were offered the opportunity to put a minority report and they did not take that opportunity.' You have heard the evidence today. Are you standing by your comments? Can I further ask where you got that advice from, because that has been disputed today in evidence.

**Mr Learmonth**—That was my advice at the time and I think that was reflected in the minutes of a particular meeting, but I will go back on notice and provide you the reference.

**Senator POLLEY**—Can I just make a point that, by having information now given to us on notice, it then denies us the opportunity to further ask questions. That is what has led to the frustration today. We want to try and end this. I am actually now going to put on record that I, in discussions when we finish this, am going to propose that if necessary we recall the department.

**CHAIR**—Okay, that is your prerogative. Are there any other questions, Senator Milne?

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**Senator MILNE**—At the last hearing the department gave evidence—and this is in relation to the changes made from the supporting committee’s report. The department said, ‘Yes, the changes were made, but all the supporting committee members signed off on it.’ On 12 April 2000, in answer to a question on notice, the answer was, ‘The document that was sent to the supporting committee members to sign off on did not include the subsequent changes that were not minuted at their final meeting. There is nothing minuted in any final meeting about the changes that were being made.’ The department has given both those answers. They are contradictory and I would like to know which one is true. Given this issue about the guidelines and so on, the dissenting report, it goes to that as well. Which one of those answers is true because you felt able to answer which one is true and which one is not?

**Mr Learmonth**—I am sorry, would you mind reading the two answers?

**Senator MILNE**—At the last hearing the department said, ‘Yes, the changes were made, but all the supporting committee members signed off on it.’ Assuming that somewhere that is minuted or there is a document with their signatures on it or something—

**Mr Learmonth**—And is consistent with Professor King’s testimony.

**Senator MILNE**—Contrary to that, on 12 April 2000, in answer to a question on notice, the answer was, ‘The document that was sent to the supporting committee members to sign off on did not include the subsequent changes that were not minuted at their final meeting.’ Implying that the changes minuted were there, but not the ones that were not minuted. If they were not minuted, there is no record of them, it is a matter of opinion. I want to know which of these answers is correct.

**CHAIR**—Isn’t this the same question that Senator Polley has asked and is being taken on notice.

**Senator POLLEY**—Yes, similar.

**Senator MILNE**—Okay, I will leave it with you on notice but I would like to know which one is correct. Finally, I would just like to know: do you still stand by the answer that you gave to Senator Harradine when Senator Harradine asked particularly about whether the supporting committee found that this technology was safe and clinically effective, and potentially cost-effective, and you answered no, you do not believe that is what they said? Do you stand by ‘no’ or do you want to reconsider?

**Mr Learmonth**—I can only refer you to my previous testimony on this. I recall that bit of it quite well. There are a couple of things here. The answer to the question ‘No’ was an answer that reflected the formality of the process and the roles of the committee. You then asked me if that could provide a misleading impression as to whether or not PET was. I went on to say that if all we had said was no, I would agree you would have a point. But we didn’t. My recollection is that the answer was not just ‘no.’ It was no and then a process based explanation. It made it quite clear in doing so that the answer was nothing to do with the substance of whether or not PET was clinically cost-effective and everything to do with whether or not the supporting committee made findings and recommendations.

**Senator MILNE**—Which begs the other question, since there is correspondence now from MSAC and so on saying that the supporting committee can—in fact they refer to the report of the supporting committee and the findings of the supporting committee, which would seem to make your answer even technically in terms of process wrong.

**Mr Learmonth**—I agreed with the chairman's suggestion at the time that there is some loose use of wording and ambiguity. But in terms of formal roles, no, the supporting committee is not empowered to make findings and recommendations. That is the province of MSAC.

**Senator MILNE**—Even though—

**Mr Learmonth**—However bits of paper are labelled—that on reflection could be labelled differently.

**Senator MILNE**—Given everything that has been said, do you now agree that the supporting committee did find that PET was safe, clinically effective and potentially cost effective?

**Mr Learmonth**—Potentially so.

**Senator MILNE**—Potentially.

**Mr Learmonth**—The supporting committee talked about insufficient evidence to draw definitive conclusions. It talked about potential cost effectiveness.

**Senator MILNE**—Do you agree now that the supporting committee concluded that PET is safe, clinically effective and potentially cost-effective? Do you agree now, after all this time, that that is what they concluded?

**Mr Learmonth**—It is not my place to agree with what the supporting committee found. The supporting committee found what it found. What it found is in its report.

**Senator MILNE**—What is in the report is not what it has found. That is what they have said.

**Mr Learmonth**—It is not what the chair of the supporting committee has said at all.

**Senator MOORE**—Professor King?

**Mr Learmonth**—Professor King.

**CHAIR**—Do you believe that if the form of the words that had reached MSAC was as originally drafted by the committee, as opposed to what actually reached MSAC, this would in any way have changed the decision that the minister was asked to make about the funding of PET under Medicare at that time?

**Mr Learmonth**—I do not believe so.

**Senator MOORE**—Can you answer that, Mr Learmonth? It is an opinion.

**Mr Learmonth**—It is.

**CHAIR**—A lot more questions have been asked this afternoon and I thought one more would not make any difference. One very last question because I am about to draw it to a close.

**Senator MOORE**—I am trying to establish I think that this particular case is fairly unusual.

**Mr Learmonth**—One-off.

**Senator MOORE**—In terms of the statement that both you and I think Ms Halton made about the decision that there would be no correspondence with Dr Ware, and we have had that previously, how many other cases in the department are so designated?

**Mr Learmonth**—I would not know. I think one of your colleagues asked me that. I am not sure we ever recorded that in a systemic way to be able to provide an answer.

**Senator MOORE**—Can you have a look at that?

**Mr Learmonth**—I can certainly look for you.

**Senator MOORE**—It was one of the things in the very first hearing we were trying to trawl over and find out. You have made it really clear about statutory responsibilities and other parts of the act, which is fine, but one of the things we were sussing out was the sheer volume of correspondence, the time, all those things which you explained, and Dr Ware explained as well. But I am trying to get my head around whether—I think Ms Halton actually even said it was not the only one. They are rare, but it was not the only one—

**Mr Learmonth**—I would characterise it—

**Senator MOORE**—I am just trying to put this in the context, the whole environmental process.

**Mr Learmonth**—I will certainly ask.

**CHAIR**—We are going to draw to a close at this point. I thank you for the evidence that you presented today under difficult circumstances, I think. I understand you have taken a number of questions on notice and I would appreciate having the answers to those things provided as soon as you can, please.

**Mr Learmonth**—We will get them to you as soon as possible.

**CHAIR**—The committee needs to have a private meeting now to talk about a few issues. I thank Hansard for today's proceedings. Could I ask those not involved in the committee to leave the room?

**Committee adjourned at 6.30 pm**

