ADDITIONAL COMMENTS
By Senator Milne

The Committee's Inquiry into the PET Matter has ascertained that;

- the report agreed to by the expert medical Supporting Committee for the 2000 PET review contained the recommendation that PET was clinically effective:
- A majority of the Supporting Committee members when asked by the Senate Committee confirmed they had decided at the time that PET was "clinically effective";
- The report of the Supporting was altered without their agreement by insertion of the words;

The MSAC Supporting Committee concludes that:

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

and

"potentially"

downgrading the Supporting Committee's conclusion to "potentially clinically effective";

- MSAC was not provided with the original Supporting Committee report, instead it was provided with the altered document, but was not told or given any indication the document *was not the genuine report* of the Supporting Committee;
- MSAC adopted the altered document in the belief it had adopted the true conclusions, report and recommendations of its Supporting Committee;
- The Minister accepted and authorised the publication of the report of MSAC along with the names of the Supporting Committee members;
- The MSAC report is represented as a "systematic review" or "level 1" knowledge about the patient benefits of PET
- The Commonwealth and at least one State Government has used the MSAC report as the basis for healthcare policy;
- The MSAC Report has been used as evidence by Government's in several countries including New Zealand and Canada;
- The finding that

there is insufficient evidence at this time from which to draw definitive conclusions about the clinical effectiveness and cost effectiveness of PET
has been dubbed the "primary finding"

- The "primary finding" has been used by the Australian government to cast doubt on the clinical value of PET, calling it an "unproven technology";

- All attempts to have the MSAC report corrected to reflect the fact that the Supporting Committee were never told of the changes and never agreed to them have been rejected by MSAC and the Government.

Does it matter to cancer patients or the Australian community that the Supporting Committee report was changed and that MSAC accepted an altered report? Has it affected medical treatment?

The impact of the MSAC report has been that:

- cancer patients around Australia have been denied knowledge that PET is safe and clinically effective.
- governments around Australia have not provided adequate resources to give patients the access they need to PET's treatment benefits. Because the report deemed that PET was not clinically effective then the federal government set about collecting data to assess that effectiveness. Evidence which the Supporting Committee argued was available in 2000.A small number of centres were contracted to do the data collection and the work at those centres qualified for a Medicare rebate. PET scans in other centres not contracted for data collection were only eligible for the rebate for three indications until recently when the number was increased to six. This has made the provision of PET scans in those centres and regions uneconomic forcing patients to go to capital city centres or in the case of Tasmania to Melbourne. The data collection covered only about 40% of the indications that PET was thought to be valuable for in 2000 and the subsequent "open" Medicare rebate is provided for a small fraction of that 40%.
- It has mattered to the experts in the Supporting Committee as well as they have not been able to have their names removed from a report which they did not agree to. I am pleased that at last that has been remedied with the erratum.
- The delay in acceptance that PET is safe and clinically effective thus requiring data collection long after clinical effectiveness was proven has slowed down the roll out of this technology across Australia and its availability to patients. This can only be seen a complete failure of government to respond to the urgent and compelling needs of cancer patients and has resulted in greater suffering.

Could it have been avoided?

The process and procedures for deciding the clinical value of PET

It should be noted that Professor Kearney and Professor King were common members to all Committees including the MSAC Committee. They, together with Dr Primrose (Secretariat) are the people who throughout the process saw the documents and reports and would have therefore been aware of the altered Supporting Committee report.

Steering Committee members

Professor Brendon Kearney, Chair

Dr Geoff Bower, Australian and New Zealand Association of Physicians in Nuclear Medicine

Dr George Klempfner, Royal Australian and New Zealand College of Radiologists

Dr Gabrielle Cehic, Royal Australasian College of Physicians

Mr Clive Deverall, Consumers' Health Forum

Dr Richard King, Ex officio member—Medicare Services Advisory Committee

Associate Professor Stephen Boyages, States and Territories representative

Professor Michael Quinlan, States and Territories representative

Mr Alan Keith, Department of Health and Aged Care

Dr John Primrose, Department of Health and Aged Care.

Supporting Committee to assess PET

Dr Richard King, Chair

Professor Brendon Kearney, Ex officio member—Chair of Review Steering Committee

Dr Rodney Hicks, Australian and New Zealand Association of Physicians in Nuclear Medicine

Dr Ken Miles, Royal Australian and New Zealand College of Radiologists

Associate Professor Andrew Scott, Australian and New Zealand Association of Physicians in Nuclear Medicine

Associate Professor Michael Fulham, Australian Association of Neurologists

Professor Robert Thomas, Royal Australasian College of Surgeons

Dr Michael Millward, Royal Australasian College of Physicians

Dr Michael Kitchener, Medicare Services Advisory Committee

Associate Professor Richmond Jeremy, Cardiac Society of Australia and New Zealand

Dr John Primrose, Department of Health and Aged Care

MSAC Committee

Member	**Expertise**
Professor David Weedon (Chair)	pathology
Ms Hilda Bastian	consumer health issues
Dr Ross Blair	vascular surgery (New Zealand)
Mr Stephen Blamey	general surgery
Dr Paul Hemming	general practice
Dr Terri Jackson	health economics
Professor Brendon Kearney	health administration and planning
Dr Richard King	gastroenterology
Dr Michael Kitchener	nuclear medicine
Professor Peter Phelan	paediatrics
Dr David Robinson	plastic surgery
Mr Alan Keith	Assistant Secretary of the Diagnostics and Technology Branch of the Commonwealth Department of Health and Aged Care
Associate Professor John Simes	clinical epidemiology and clinical trials
Professor Bryant Stokes	neurological surgery, representing the Australian Health Ministers' Advisory Council (from 1/1/99)

In October 1999 at the first Steering Committee meeting minutes indicate that:

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

At the second Steering Committee Meeting 27 January 2000 Kearney was minuted as saying that the Committee:

> "prepare itself for the possibility that the MSAC Supporting Committee report [would find] that the evidence for PET is not sufficient to warrant widespread dissemination of the technology. In which case, it was likely that the status quo would be retained, or a very minimal roll-out may be recommended".

This statement was made before the Supporting Committee had even begun to discuss the evidence, which occurred 14 February 2000.

Thus the Chair of the Ministerially appointed Steering Committee was already warning of what the acceptable outcomes might be before evidence was considered.

What followed was a process for deciding the clinical value of PET , known as the PET Review 2000 and it was fundamentally flawed.

MSAC believed it had adopted the true recommendation of its Supporting Committee.

In fact, MSAC adopted a recommendation about PET that conflicted fundamentally with the decision of the experts it had asked to examine the evidence and to provide advice on the value of PET in the context of contemporary Australian medical practice.

This failure could have been avoided if MSAC's operating guidelines had been observed. If the dissent provisions had been followed, the altered report could not have been sent to MSAC without the approval of the Supporting Committee members, and the right to dissent would have been afforded.

Several of the Supporting Committee members have indicated that they may have, or would have, dissented with respect to the altered report that was presented to MSAC in their names, if they had known about the alterations and had been offered the opportunity to dissent.

The failure could have been avoided if the MSAC members who were party to the altering the Supporting Committee's report and then presenting it to other MSAC members as if were the genuine article had alerted MSAC. MSAC should have been told that alterations had been made, identified the author(s) of the alterations and the logic for making those alterations. That action would have ensured compliance with the honest, open and transparent process that MSAC assures the public is followed. That action would have given MSAC members opportunity to seek further clarification from the Supporting Committee members, before making their own decision on the merits of the information provided.

The failure to alert Supporting Committee and MSAC members to the alterations could only be justified if the alterations were not material. Associate Professor King argued that the alterations were merely editorial to make the document read more logically and to clarify the true decisions and intent of the Supporting Committee.

Friday, 30 March 2007 Senate CA 39

Prof. King—Their firm view was that there was insufficient evidence on PET's clinical or cost effectiveness. How can you then have a firm view that PET is clinically effective?

CA 42 Senate Friday, 30 March 2007

Senator POLLEY—Is it possible for you to advise us as to who made the recommendation to change the wording of the supporting committee's report?
Prof. King—I have already said that. It was made by agreement with the ministerial review committee.
Senator PATTERSON—Let me ask a hypothetical question. If the two recommendations that the supporting committee had in their report had appeared in the PET review as is, would the outcome have been any different?
Prof. King—No.

The majority conclusions appear to accept the evidence of the Department and Associate Professor King that the alterations would not have influenced MSAC's decision making as follows; *"there has been no evidence presented that would indicate that the MSAC decision regarding PET turned on any amendments made to the Supporting Committee's report."*
However, the Standing Committee does have evidence that invalidates their conclusion. Associate Professor Richard King and Professor Brendon have made clear their belief that the MSAC decision regarding PET "turned on" the amendments to the Supporting Committee's report.

Associate Professor King wrote: *" I am proud of what I did to help PET scanning through the MSAC process as has been reinforced by Professor Kearney, without the changes made by the Steering Committee to the Supporting Committee's report it almost certainly would not have got up in MSAC at that time as the evidence was poor"*

Professor Kearney wrote: *"I supported Dr King in presenting to MSAC a report that allowed MSAC to approve a positive recommendation on PET"*

So both Associate Professor King and Professor Kearney were party to the alterations and believed MSAC would have made a different recommendation if the true Supporting Committee report had been tabled.

Irrespective of the inference that their actions achieved a good outcome for the community through a "positive recommendation" despite what they regarded as only "poor" evidence for PET, it was not honest and ethical to let MSAC members think they were endorsing the true Supporting Committee report. This evidence also casts doubt upon the validity of the majority Standing Committee conclusion that:

> "there has been no evidence presented that Assoc. Prof. King (or anyone else) had any intention to mislead or to deceive MSAC or had any reason for doing anything inappropriate in the changes that were made to the Supporting Committee report by the Steering Committee."

The majority report also appears to accept that the Steering (Ministerial) Committee made the changes to the Supporting Committee report and that the action was justified as it was a "superior committee".

There are number of significant problems with the majority position.

1. If the Steering Committee had authorized the alterations, the document presented to MSAC ought to be found in the records of the Steering Committee. That document is not to be found.
2. If the Steering Committee was a "superior committee' and authorized to make changes to an MSAC Committee draft document, it would still have been improper and wrong to have that document passed off as document of the Supporting Committee. Yet, not only was the document presented to MSAC headed as if it were a genuine MSAC Supporting Committee document, the insertion of the "primary finding" was prefaced by the words *"The MSAC Supporting Committee concludes that"* . These actions clearly had a high risk of misleading MSAC
3. If the Steering Committee had authored the "primary finding" that MSAC unwittingly accepted as conclusion of its Supporting Committee, it would have been dishonest for the Steering Committee to report to the Minister that:

   Term of Reference 1
   To assess, in conjunction with MSAC and the profession, and with reference to available sources of evidence, the cost effectiveness, clinical effectiveness and safety of PET,
   especially in relation to other diagnostic modalities.

   General findings
   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 PET;

4. The Steering Committee was a unique event in the history of MSAC assessments, established at the request of the Minister because of the concerns over the potential expense of PET to the Commonwealth. If the Steering Committee had made the most important determination of the MSAC scientific report about the clinical value of PET without MSAC's knowledge, it is difficult to sustain the argument that there was no evidence of improper interference in MSAC's affairs. Yet the majority report concludes that;

   no evidence was provided to support the contention that there was inappropriate intervention by the Minister or Department officials into the MSAC assessment of PET.

   Until the circumstances in which the "primary finding" was inserted into the record of the 2000 PET review, it is impossible to reach a conclusion on the question of whether there was inappropriate Departmental or Government intervention into the MSAC assessment of PET.

Misleading or false evidence

With respect to the allegation of false evidence, I conclude that the Department's answers to Senator Harradine's question E03-045 were false and misleading, and that subsequent answers given the Standing Committee Hearing on the issue of honesty and accuracy of the answer to E03-045 are false and misleading.

Senator Harradine asked on notice;

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

The only honest and accurate answer to the question was "Yes". The Department submitted the contrary answer to the Parliament as follows;

"No. Supporting Committees of Medical Services Advisory Committees do not make findings. Neither do MSAC Supporting Committees make reports, that being the responsibility of MSAC."

The issue of the true findings of the Supporting Committee had been brought to the attention of the Department on multiple occasions since the MSAC report was published.

The Department was given the opportunity at public hearings in April 2006 and June 2007 to reconsider the honesty and accuracy of the information it provided to the Parliament. The Department's response on both occasions was effectively that it had provided the correct response to the different question of who is responsible for providing a report to the Minister.

Thursday, 14 June 2007 Senate CA 41

Mr Learmonth-…It appears to me that the answer is directed to the report proper which goes from MSAC to the minister—which, again, is the province of MSAC, not the supporting committee.

Thursday, 14 June 2007 Senate CA 41

Mr Learmonth—……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.

The Department's answer that Supporting Committee's of MSAC do not make findings or reports cannot be substantiated on the basis of the many MSAC documents presented in evidence to the Standing Committee, or the Department's evidence at the public hearings

Thursday, 14 June 2007 Senate CA 29

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.

This evidence establishes that MSAC requires Supporting Committees to make reports to the point of stipulating what those reports ought to contain.
It is therefore reasonable to assume MSAC regards these reports to be crucial to its decision making process, even though MSAC decides the content and makes the report to the Minister in its name.

Does it matter that misleading evidence was given or obfuscation occurred?

The Senate's Privilege Resolutions set out actions by witnesses which may have the tendency or effect of obstructing the Senate or its committees in conducting inquiries, and which may therefore be treated as contempt. These offences include giving false or misleading evidence.

The APS Code of Conduct requires that an employee must not provide false or misleading information in response to a request for information that is made for official purposes in connection with the employee's APS employment.

The APS Commissioner's Guide to Official Conduct for APS Employees and Agency Heads states:

> APS officers must be honest and professional.
>
> Answers to questions from Parliament or its Committees must always be accurate and inadvertent errors must be corrected quickly.

Therefore, the provision of false and misleading information in request to Question E03-045 and in response to the Committees attempts to clarify the matter must be regarded as a serious matter.

On the balance of probabilities I consider that the Department answers intended to mislead or obfuscate and can fairly be descried as an attempt to prevent the Committee from scrutinizing the Government's actions.

There are more recent examples where the Department has given false and misleading information to the Committee. The Department Secretary has acknowledged that she provided the committee with erroneous information 19 February 2008 in response to a request for information from the Standing Committee of October 2007. Given that the erroneous statement was the justification for the Department's claims that the changes to the Supporting Committee report would not have changed MSAC's conclusions about the clinical effectiveness of PET, I do not agree that the false information provided is of no consequence, either in the context of the Committee's responsibility to the public or the Committee's decision making process in relation to the PET matter.

It is for that reason that I recommend that the APS Commissioner be asked to investigate the matter of the Department's compliance with the Public Service Act with respect to the PET matter, and report to the Senate with respect to culpability and appropriate action.

Conclusion

The Committee has been provided with considerable evidence that the process followed in deciding the clinical value of PET during the 2000 PET review was not sound. The Senate has not been facilitated in its efforts to determine exactly what happened.

Obfuscation, errors and misleading evidence have certainly delayed recognition that 2000 PET review had serious problems, and has ultimately prevented this Senate Inquiry from determining the critical question of the authorship of the "primary finding" after more than 2 years of trying.

Although the Committee did not have the expertise to decide itself about the clinical value of PET, that aspect has eventually been agreed by MSAC. PET is now recognised for its effectiveness in preventing unnecessary treatments and investigations that increase the suffering of cancer patients for no patient benefit in a large number of cases.
It has been agreed by MSAC that PET is not just cost-effective, the technology probably decreases the cost of care in some common cancer indications.

The Committee is aware that cancer patients are particularly vulnerable to physical, emotional and economic trauma as they attempt to maximise the quality and duration of their lives. The Committee also understand that there is great need for reliable information so that patients and doctors can make the best treatment decisions.

It is of great concern that the external experts and stakeholders who contributed to the 2000 PET review tried very hard, yet failed to achieve recognition of their views that the evidence was more than sufficient to conclude that PET had real clinical value.

The long delay in getting the best information to vulnerable cancer patients is likely to have diminished their ability to help themselves and to have caused a great deal of needless suffering, irrespective of Medicare funding decision. That sad outcome appears to be the opposite of what was promised of MSAC.

Although the allegations that the Government has abused its power and the public's trust for no purpose other than to cover-up important health knowledge has not been proven, that conclusion cannot be ruled out. There was an agenda not to increase Commonwealth spending on PET and to "control" the expansion of the technology, and there was clear evidence of prejudice in relation to the quality of the scientific evidence even before any had been considered.

Senator Christine Milne
Australian Greens, Tasmania