A MATTER RELATING TO THE POSITRON EMISSION TOMOGRAPHY (PET) REVIEW OF 2000

THE INQUIRY

1.1 In January 2006 the Senate Community Affairs Committee (the Committee) received correspondence from Dr Robert Ware raising a number of issues relating to the assessment of PET by the Medical Services Advisory Committee (MSAC) in 2000 and requesting an inquiry into 'the conduct of the Government's PET scanning policy since 1999'.[1] Issues associated with PET and the MSAC Review in 2000 had been the subject of questions by Senators during the Committee's estimates hearings over a period of time. In his correspondence, Dr Ware contended that the Department of Health and Ageing (the Department) had 'submitted, and then failed to retract, false information' in response to a question on notice during estimates proceedings.

1.2 The Committee agreed that, with an allegation of misleading evidence, it would hold a hearing to enable the issues in Dr Ware's correspondence to be raised and responded to by the Department. The Committee considered the matter at a public hearing in Canberra on 28 April 2006. This hearing generated a substantial volume of information and documents being provided to the Committee that required detailed assessment. The Committee considered that further hearings on this matter would be needed and these were held on 30 March 2007 and 14 June 2007. Members of the Committee also inspected the PET facilities at the Peter MacCallum Cancer Centre in East Melbourne on 22 August 2007.

1.3 The Committee's concern in this matter was whether false information had been given during the estimates proceedings and whether the processes used to make the decisions on the use and the funding of PET were appropriate, and reflected the contributions of people on the various expert committees. The Committee was not inquiring into the clinical value of PET or whether PET should have been viewed as clinically effective when it was first assessed by MSAC in 1999-2000.

1.4 A list of the documents authorised for publication by the Committee is at Appendix 1. A list of the witnesses who gave evidence at the hearings is available at Appendix 2. The Hansard transcript of evidence may be accessed through the Hansard website at http://www.aph.gov.au/hansard/.

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1 Correspondence from Dr Robert Ware, dated 26.1.06, p. 1.

BACKGROUND

Positron Emission Tomography (PET)

1.5 Positron Emission Tomography (PET) is a diagnostic imaging technology that uses short-lived radioisotopes to enable the non-invasive imaging of metabolic functions within the body. To conduct the scan a short-lived radioactive tracer isotope, which decays by emitting a positron and which has been chemically incorporated into a metabolically active molecule, is injected into a patient. The molecule most commonly used for this purpose is fluorodeoxyglucose (FDG). While computed tomography (CT) and magnetic resonance imaging (MRI) primarily provide information about anatomical structure, PET can image and quantify biochemical and/or physiological function. PET can be used as a means of diagnosis for a range of clinical conditions, including many cancers. The widespread use of PET is limited by the costs of cyclotrons required to produce the materials used for PET scanning as well as the need for trained staff and specialised equipment.

The Medical Services Advisory Committee (MSAC)

1.6 The Medical Services Advisory Committee (formerly the Medicare Services Advisory Committee), or MSAC is the main body responsible for assessing medical technology in Australia. Most MSAC members are appointed by the Minister, and are selected on the basis of their expertise and standing in medicine or health economics.

1.7 The then Minister for Health and Family Services[2], Dr Michael Wooldridge, established MSAC in April 1998, replacing the Australian Health Technology Advisory Committee (AHTAC). In launching MSAC, the Minister said the 'introduction of evidence based medicine and this committee means that the gap between research knowledge and clinical practice will narrow'. He noted that the 'MSAC committee is charged with overseeing a process where evidence and science are the only points of reference'.[3]

1.8 At the time PET was assessed, the MSAC terms of reference were to:

> 1. Advise the Minister for Health and Aged Care on the strength of evidence pertaining to new or emerging medical technologies and procedures in relation to their safety, clinical and cost effectiveness and under what circumstance public funding should be supported.
>
> 2. Advise the Minister on which new medical technologies and procedures should be funded on an interim basis to allow data to be assembled to determine their safety, effectiveness and cost effectiveness.

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2 Note: The Department of Health and Family Services was renamed as the Department of Health and Aged Care in 1998, and then as the Department of Health and Ageing in 2001.

3 Dr Michael Wooldridge, Minister for Health and Family Services, Launch of Medicare Services Advisory Committee, speech at Old Parliament House, 6.4.98, available from www.health.gov.au.

3. Advise the Minister on references related either to the new and/or existing medical technologies and procedures.

4. Undertake health technology assessment (HTA) work referred by the Australian Health Ministers' Advisory Council (AHMAC).[4]

1.9 The MSAC process for assessing medical technologies is in several stages. A description of the process from the first MSAC annual report during the time when PET was assessed provides a useful summary and is extracted below.

Stage 1 – Eligibility

The first stage of the MSAC assessment cycle involves consideration within the Department of Health and Aged Care of an application's eligibility for assessment by MSAC.

Stage 2 – Assessment

If an application is considered eligible for review it moves onto the second stage, assessment. MSAC utilises independent contractors to conduct the majority of the evidence based assessment. This involves the development of an evaluation protocol and assessing the available evidence on the safety, clinical effectiveness and cost effectiveness of the technology or procedure.

MSAC appoints a specialist Supporting Committee, chaired by a member of MSAC, to assist in the assessment of each application. This provides expert input into the assessment process as well as ensuring that the contractors' assessment is clinically relevant.

Stage 3 – Formulation of advice to the Minister

In formulating recommendations to the Minister, MSAC considers a range of information. This includes the assessment report and any feedback on the report received from the MSAC applicant or the Department.

MSAC recommendations generally fall into one of three categories:

- The evidence is strong and supports public funding;
- The evidence does not support public funding; or
- The evidence is inconclusive but suggests that the procedure could be safer, more effective, and more cost-effective than comparable procedures that attract public funding. In these circumstances, MSAC may recommend interim funding to enable data collection and further evaluation of the procedure.

Stage 4 – Decision

The Department makes a submission to the Minister for Health and Aged Care that combines MSAC's final assessment report and recommendations with policy advice from the Department. The Minister considers this information and makes a decision to endorse or reject the MSAC recommendations. To date the Minister has endorsed all MSAC recommendations.

4 MSAC, *Annual Report,* April 1998 – June 2000, p. 9.

Stage 5 – Implementation

If the Minister endorses a recommendation for Commonwealth funding of a new medical service, the appropriate consultative committee draws on MSAC's findings to determine funding levels. The appropriate committee is determined primarily by the nature of the service, however relevant committees include the Medicare Benefits Consultative Committee, the Consultative Committee on Diagnostic Imaging and the Pathology Services Table Committee.[5]

The review of PET

1.10 In 1999, MSAC received applications from Professor Ken Miles at Wesley Hospital and Dr John Morris at Peter MacCallum Cancer Centre seeking an extension of Medicare funding for the use of PET. The Chair of MSAC, Professor David Weedon, wrote to the then Minister for Health and Aged Care, Dr Michael Wooldridge, to advise him that MSAC had received an application to assess PET. Professor Weedon stated that MSAC agreed 'the role of PET in the Australian health system needs to be clarified, and appropriate funding models considered, so that the application can be assessed in the broader context' and sought advice on how the Minister wished to proceed.[6]

1.11 In response to this request for advice, the Minister instructed the Department of Health and Aged Care to set up a review of PET 'that would incorporate an assessment by MSAC, but also consider a broader range of issues including technical specifications, funding models, an appropriate distribution of services, and ongoing evaluation'.[7] The Diagnostic and Technology Branch of the Department conducted the review with the guidance of a Steering Committee comprising representatives of the medical profession, State and Territory governments and consumers. The Steering Committee was responsible for consideration of the broader policy issues associated with PET, and for the preparation of the review report and recommendations for presentation to the minister.[8]

1.12 Professor Weedon later explained the purpose of the Steering Committee:

> Because positron emission tomography (PET) has the potential to become a major expense for the Federal Government, MSAC recommended that the Minister establish a special committee (independent of the MSAC process, but with an MSAC member for coordination) to report on the need for this

5 MSAC, *Annual Report*, April 1998 – June 2000, pp. 14 - 15.

6 Correspondence between Professor David Weedon and Minister Michael Wooldridge, dated 9.6.99, p. 1 (supplementary documentation provided by Dr Robert Ware at 28.4.06 hearing).

7 Department of Health and Ageing, Additional information dated 29.5.06, p. 4.

8 *Report of the Review of Positron Emission Tomography*, August 2000, p. 1.

technology in Australia and its funding. The Minister has accepted this recommendation.[9]

1.13 The Department established an advisory committee (the Steering Committee) with the following 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.[10]

1.14 Following its process, MSAC convened a Supporting Committee to assess PET with the following members:

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.[11]

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9 David Weedon, 'Health technology assessment in Australia' (1999) 171 *Medical Journal of Australia*, p. 552.

10 *Report of Review of Positron Emission Tomography*, August 2000, p. 55.

11 *Report of Review of Positron Emission Tomography*, August 2000, p. 56.

1.15 The terms of reference for the review, as presented to the first meeting of the Steering Committee in October 1999 were:

> 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 comparable technologies such as magnetic resonance imaging.
> 2. To report on and assess, in conjunction with MSAC, the state of PET technology, recommending preferred technical specifications and approaches where appropriate.
> 3. To clarify the role of PET in Australian clinical practice, including:
>   - determining which indications/applications should be eligible for funding; and
>   - where funding is appropriate, determining suitable funding models.
> 4. To develop, in consultation with stakeholders including the profession and State and Territory governments, a national strategy aimed at ensuring appropriate distribution of and access to PET services.
> 5. To develop, in consultation with stakeholders including the profession and State and Territory governments, a data collection and analysis plan to enable the ongoing evaluation of PET.[12]

1.16 At its first meeting the Steering Committee considered the roles and responsibilities of the various bodies involved in the review:

> The MSAC Supporting Committee will oversight a technical evaluation of PET, including an assessment of clinical need, safety, effectiveness and cost effectiveness. The NHMRC [National Health and Medical Research Council] Clinical Trials Centre, under an existing contract with the Department, will conduct a systematic review of PET.
>
> The Steering Committee will focus on broad policy questions related to national health planning. The MSAC Supporting Committee's evaluation will inform the Steering Committee's consideration of and recommendation on safety standards, practice guidelines, accreditation and training, distribution of and access to PET services and ongoing evaluation.[13]

1.17 The MSAC Supporting Committee also discussed the terms of reference and the roles and responsibilities of the two committees. The minutes for 29 November 1999 noted:

> The committee agreed that in cooperation with the NHMRC CTC they were jointly responsible with the Steering Committee for ToR one, assessing the

12 Department of Health and Ageing, Additional information dated 29.5.06, p. 4; Minutes of Steering Committee meeting, 13 October 1999, p. 5.

13 Department of Health and Ageing, Additional information dated 29.5.06, pp. 4-5; Minutes of Steering Committee meeting, 13 October 1999, p. 2.

> clinical need, safety, clinical effectiveness and cost effectiveness of PET in relation to diagnostic modalities.
>
> …..
>
> It had been suggested that the Steering Committee would address ToR three, to clarify the role of PET in Australian clinical practice. However given time constraints and clinical experience, the committee members felt that the Supporting Committee was best placed to determine which indications/applications should be considered for funding (ToR 3, Part A).[14]

1.18 Dr Richard King, Chair of the Supporting Committee, took this proposal to a meeting with the MSAC Executive on 30 November 1999.

> There was in-principle endorsement of the proposed changes. However it was agreed that, rather than formally alter the terms of reference at this stage of the Review, the Chairs of the Steering and Supporting Committees should liaise closely to ensure that all terms of reference are addressed without duplication of effort between the two committees.[15]

1.19 The MSAC Supporting Committee reviewed the use of PET in the following indications:

- pre-operative staging of non-small cell lung cancer (NSCLC);
- potentially resectable melanoma;
- residual/ recurrent mass in patients treated for malignant glioma;
- suspected recurrence of colorectal cancer (CRC);
- medically refractory epilepsy; and
- assessment of myocardial viability in patients being considered for coronary revascularisation.

1.20 Between November 1999 and March 2000, the Supporting Committee met a number of times to scope the assessment and consider material prepared by the National Health and Medical Research Council Clinical Trials Centre. There was disagreement within the Supporting Committee regarding aspects of the contractor's assessment of PET. The minutes of meeting on 28 February 2000 note that the Chair advised members 'there was a place for members to put in a minority opinion'.[16] In response to Dr King's offer, Dr Hicks submitted a document headed, "Report of the MSAC Supporting Committee to the National PET Review". Dr Hick's document was edited by Dr King and Dr Kitchener, recommendations were added, and the new document was presented for discussion to the final Supporting Committee meeting, in addition to the draft report prepared by the contractors.

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14 Minutes of MSAC Supporting Committee meeting, 29 November 1999, p. 2.

15 Department of Health and Ageing, Additional information dated 29.5.06, p. 5

16 Minutes of MSAC Supporting Committee meeting, 28 February 2000, p. 8.

1.21 In a teleconference on 23 March 2000 the Supporting Committee agreed on the recommendations of a draft report.[17] No minority opinions were noted in the Supporting Committee draft report. During the teleconference, the Department 'clarified for members that the final evaluation report will be presented as MSAC's view not that of the Supporting Committee'.[18] The text of the recommendations from the MSAC Supporting Committee report is extracted below:

> **Recommendations**
>
> Based on the results of the NHMRC Clinical Trials Centre's evaluation and the clinical experience of Committee members, the MSAC Supporting Committee concludes that there is insufficient evidence of PET's clinical or cost effectiveness with respect to the six indications reviewed to warrant unrestricted MBS funding.
>
> While the Committee agree that unrestricted funding is unwarranted at this time, the evidence suggests that PET is safe, clinically effective and potentially cost effective in the indications reviewed. On this basis the MSAC Supporting Committee recommends that PET be funded for the following clinical scenarios.
>
> ….
>
> **Suggested Funding Mechanism**
>
> It is recommended that **interim** funding be made available for the above indications, subject to the **provision of data**.[19]

1.22 The Department has indicated that the 'path taken by material drafted by the contracted evaluators and considered by the supporting committee was first to the MSAC executive, then to the steering committee where it was modified and then to MSAC'.[20]

1.23 On 6 April 2000 the Steering Committee was advised that the MSAC executive had given its approval to consider the Supporting Committee's report. The minutes of that meeting note 'Dr King explained the findings and recommendations arising out of the MSAC Supporting Committee's technical evaluation'. The Steering Committee also referred to changes to the Supporting Committee report. The relevant parts of the minutes are extracted below.

> The [Steering] Committee agreed with the general conclusions and recommendations of the MSAC Supporting Committee. However, members suggested some minor changes to the wording of certain recommendations. These changes have been incorporated in the revised draft approved indications and revised draft Steering Committee finding and recommendations at Attachment A and B respectively.

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17 Minutes of MSAC Supporting Committee meeting, 23 March 2000, p. 3.

18 Minutes of MSAC Supporting Committee meeting, 23 March 2000, p. 4.

19 Minutes of MSAC Supporting Committee, 23 March 2000. [bold in original]

20 Department of Health and Ageing, Additional information dated 29.5.06, p. 5.

Action(s) arising:

The Department will amend the wording of some of the Supporting Committee's recommendations for inclusion in the MSAC Supporting Committee and the Ministerial report.[21]

1.24 The recommendations contained in the draft Supporting Committee report after amendment by the Steering Committee (and as presented to MSAC) are extracted below:

General Findings

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;
- in most indications PET is used in addition to other diagnostic modalities. This was the case in the diagnostic algorithm used for the current assessment;
- in terms of adverse patient reaction to administration of FDG, FDG PET is safe; and
- further evaluation of the technology is necessary.

Approved Recommendations

The PET Review 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.

While the Committee agree that unrestricted funding is unwarranted at this time, the evidence suggests that PET is safe, potentially clinically effective and potentially cost effective in the indications reviewed. On this basis the MSAC Supporting Committee recommends that PET be funded for the following clinical scenarios.

….

Funding Recommendation

It is recommended that **interim** funding be made available for the above indications, subject to the **provision of data.**

1.25 MSAC considered the assessment of PET on 24 May 2000 and Dr King spoke to the altered Supporting Committee draft report. In the minutes of the meeting there was no indication that MSAC members were aware that the Supporting Committee draft report had been altered without the consent of the Supporting committee members. Dr King confirmed in evidence that the MSAC members were not informed that the findings and recommendations in the documents they were considering had not been authorised by the Supporting committee members. This is because Dr King did not consider that the changes were material, advising:

21 Minutes of Steering Committee, 6 April 2000, p. 2. [bold in original]

> I did not think it was a substantive change and I think it made it a more logical continuation of the first recommendation by the subcommittee, which was that there was insufficient evidence on PET's clinical effectiveness. If there was insufficient evidence of PET's clinical effectiveness, how can it be said in the next sentence that it was clinically effective?[22]

1.26 The minutes of the MSAC meeting also indicated that:

> Dr Jackson has been asked to critique the draft report, and will also speak to it.
>
> In October 1999, the Minister for Health and Aged Care directed the Department to conduct a review of PET from a national perspective. Professor Kearney chairs the steering committee which is undertaking the review. MSAC was asked to contribute to the review's findings by undertaking an assessment of the technology under its criteria of safety, effectiveness and cost-effectiveness.
>
> Consideration of the two applications for PET funding has been deferred pending the completion of the Commonwealth PET review. While the applicants have not, therefore, been asked for comments on the report, both were represented on the supporting committee.[23]

1.27 Dr Terri Jackson's commentary tabled at the MSAC meeting on 24 May 2000 discussed the roles and responsibilities of the various bodies involved in the PET review. Her commentary also discusses the need for a 'seamless' MSAC report to address the 'practical problem' which could result from differing findings and recommendations in the multiple reports.

> MSAC's role in endorsing this Report is different from our standard role in recommending services for CMBS [Commonwealth Medicare Benefits Schedule] listing. Here we have been asked by the Minister to provide scientific advice to a Ministerial Review Committee chaired by Dr Brendon Kearney.
>
> …
>
> It may be that the Minister intended the Supporting Committee to report directly to the Commonwealth review, in which case MSAC has no formal role other than lending administrative support and we are not obliged to consider it further.
>
> However, previous MSAC reports have been *MSAC documents* (with due acknowledgement of the work of the supporting committee and the agency preparing background information). To achieve this in future,
>
> **I would suggest that we adopt as policy the preparation of 'seamless' drafts from Supporting Committees (in the 'voice' of MSAC) for MSAC endorsement.**

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22 *Committee Hansard* 30.3.07, p.33 (Dr King).

23 Minutes MSAC meeting, 24 May 2000, p. 2.

> **Where the Supporting Committee is unable to reach consensus, alternative text be provided expressing the alternatives supported by Committee members for MSAC final determination.**
>
> **Whatever our decision about the substance of the PET Report, I suggest that it be edited into a 'seamless' format for endorsement by the MSAC Executive prior to public release or publication.**[24]

1.28 The draft report notes that in general discussion during the MSAC meeting:

> Dr King noted that funding issues are the prerogative of the Commonwealth Review Steering Committee but that the objective was to retain funding at the current level. He also advised that a key objective of the three-year data collection would be to obtain data on PET's impact on clinical management.[25]

1.29 The draft report of the MSAC meeting also notes that:

> On the strength of the evidence, members endorsed the thrust of the draft recommendations – that interim public funding for PET should be supported under the conditions outlined by Dr King … It was determined that the exact wording of the recommendations will be determined within the next fortnight, then sent to all members for comment and endorsement, and finalised by the Executive and Dr King.[26]

1.30 During a teleconference on 9 June 2000, MSAC noted 'that a majority of MSAC members – 9 members out of 14, with Dr Kitchener abstaining – endorsed the recommendations of the MSAC supporting committee for PET'.

> It was agreed that the MSAC report on the clinical applications of PET should feed into the Commonwealth Review Steering Committee report, ie, there should not be two separate reports going forward to the Minister. MSAC might attract criticism if it were deemed to have gone beyond its ambit. Hence, MSAC's recommendations to the Review will end with the discussion of 'approved indications', and not extend to the discussion from 'Suggested funding mechanisms' onwards.[27]

1.31 The Department noted that the published MSAC assessment report 'was a consolidation of supporting committee report, contractor's report and the finding and recommendations of steering committee'.[28]

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24 Dr Terri Jackson, Commentary on MSAC Supporting Committee Report for the Review of Positron Emission Tomography (PET) Services, tabled at MSAC meeting 24 May 2000 provided in Department of Health and Ageing, Additional information, dated 29.5.06 (Attachment 8) [bold and italics in original].

25 MSAC, Draft report of meeting, 24 May 2000, p. 3.

26 MSAC, Draft report of meeting, 24 May 2000, p. 4.

27 MSAC, Minutes of meeting, 9 June 2000, p. 1.

28 Department of Health and Ageing, Additional information dated 29.5.06, p. 6.

1.32 The final recommendations of the published *MSAC assessment report* are extracted below.

> **Recommendations**
>
> MSAC concludes that:
>
> • there is insufficient evidence at this time from which to draw definitive conclusions about the clinical effectiveness and cost-effectiveness of FDG PET;
>
> • in most indications, FDG PET is used in addition to other diagnostic modalities (and this was the case in the diagnostic algorithm used for the current assessment);
>
> • in terms of adverse patient reaction to administration of FDG, FDG PET is safe; and
>
> • further evaluation of the technology is necessary.
>
> **Approved indications**
>
> MSAC concludes that, with respect to the indications reviewed, there is insufficient evidence on FDG PET's clinical or cost-effectiveness to warrant unrestricted Medicare Benefits Schedule (MBS) funding.
>
> While unrestricted funding is not warranted at this time, the evidence suggests that FDG PET is safe, potentially clinically effective and potentially cost-effective in the indications reviewed. On this basis MSAC recommends that FDG PET be funded on an interim basis for the following clinical scenarios.
>
> ….
>
> **Suggested funding mechanism**
>
> MSAC recommends that interim funding be made available for the above indications, subject to the provision of data.
>
> MSAC recommends that individual FDG PET facilities' access to interim funding be dependent on those facilities' collection of data relating to FDG PET's clinical and/or cost-effectiveness and the provision of that data to a central coordinating body. Data collection should occur within MSAC-approved prospectively designed studies that are capable of providing evidence to enable more long-term decisions to be made regarding the role of FDG PET in Australian clinical practice.[29]

1.33 The *MSAC Assessment Report* on PET was attached to the *Report of the Review of Positron Emission Tomography* produced by the Steering Committee. The Steering Committee noted in the Report that an 'integral part of the review was a

29 *Positron emission tomography MSAC assessment report*, March 2000, pp. 87 – 88 [bold in original].

technical and scientific evaluation of PET, conducted by a supporting committee of the Medicare Services Advisory Committee (MSAC)'.[30]

1.34 The *Report of the Review of Positron Emission Tomography* also notes that:

> MSAC concluded that there is insufficient evidence on PET's clinical or cost-effectiveness with respect to the six indications reviewed to warrant unrestricted MBS funding. However, the evidence suggests that PET is safe, clinically effective and potentially cost-effective in the indications reviewed.
>
> Many potential questions concerning the use of PET have not been addressed in the current assessment report. It should not be assumed that there is no role for PET in the areas not addressed.[31]

1.35 However in its own findings and recommendations the Steering Committee found:

> 5. The review steering committee accepts MSAC's conclusion that there is insufficient evidence on FDG PET's clinical or cost-effectiveness with respect to the indications reviewed to warrant unrestricted funding through the Medicare Benefits Scheme (MBS).
>
> 6. While the steering committee agrees that unrestricted funding is unwarranted at this time, the evidence suggests that FDG PET is safe, potentially clinically effective and potentially cost-effective in the indications reviewed. On this basis the steering committee recommends that FDG PET be funded on an interim basis for the following clinical conditions…[32]

1.36 Notably, the word 'potentially' does not precede 'clinically effective' in the first description of the *MSAC Assessment Report* on PET. The recommendations of the *Report of the Review of Positron Emission Tomography* were endorsed by the Minister for Health and Aged Care in August 2000.

1.37 MSAC has produced a number of further assessment reports regarding the use of PET. Following an assessment of PET for non-small-cell lung cancer and solitary pulmonary nodules, MSAC recommended that public funding should be supported. Similarly MSAC recommended public funding should be supported for the use of PET prior to surgery in patients with refractory epilepsy. These recommendations were accepted by the Minister for Health and Ageing on 2 March 2005.[33]

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30 *Report of Review of Positron Emission Tomography*, August 2000, p. xi.

31 *Report of Review of Positron Emission Tomography*, August 2000, p. xiii.

32 *Report of Review of Positron Emission Tomography*, August 2000, p. xviii.

33 Department of Health and Ageing, Additional information dated 19.02.08, p. 4.

ISSUES

1.38 Dr Ware, in his initial correspondence to the Committee, called for an inquiry into the Commonwealth's policy on PET and raised a number of concerns regarding the review and treatment of PET by MSAC. These included that, at the outset, the Review of PET had the objective of retaining funding for PET at the current level and that the Commonwealth had, over a period of years, promoted unsound healthcare information regarding the clinical value of PET.[34] Dr Ware's main contention was that the Commonwealth had compromised the independence of the MSAC by: preventing the processing of properly submitted applications; direct ministerial intervention in the process; and not following standard operating procedures for the MSAC.[35] In particular he argued that the Supporting Committee's report had been altered without the agreement of its members.[36]

1.39 The Committee also received evidence from Professor Rodney Hicks, who was a member of the MSAC Supporting Committee which assessed PET. Professor Hicks considered the changes made by the Steering Committee to the Supporting Committee's report changed the substance of the recommendations and did not reflect the evidence. In particular he noted the Supporting Committee had not been offered the opportunity to dissent or present a minority opinion regarding the changed Supporting Committee report presented to MSAC. He also raised his concerns that inaccurate information as to the clinical value of PET had been published under the names of the experts on the Supporting Committee.

1.40 Professor Hicks stated:

> The primary finding that there was 'insufficient evidence at the time to make definitive conclusions about the clinical or cost effectiveness of PET', made in response to the first term of reference of the PET Review, cast unequivocal and pejorative doubt on whether this technology 'works'... This finding was never presented to us and is fundamentally in conflict with both our actual recommendation and the body of the report… By inserting this primary recommendation at the very start of the report, readers are left with the impression that the experts involved in performing a review of the scientific evidence, including experts like myself had found the evidence fundamentally wanting. This had the effect of influencing local and international health-policy makers, the medical profession and patients seeking 'the best possible evidence' regarding this technology.[37]

34 Correspondence, Dr Robert Ware, dated 26.1.06, pp. 2 & 7.

35 Correspondence, Dr Robert Ware, dated 26.1.06, pp. 5 & 6.

36 Correspondence, Dr Robert Ware, dated 26.1.06, p. 6.

37 Correspondence, Professor Rodney Hicks, dated 6.6.07, p. 1.

Changes to Supporting Committee document

1.41 A large number of amendments were made between the versions of the report. There appear to be two main disputed differences between the recommendations of the Supporting Committee draft report attached to the minutes of the meeting of 23 March 2000 and the Supporting Committee report considered by MSAC on 24 June 2000. The first is the inclusion of the 'General finding' that 'there is insufficient evidence at this time from which to draw definitive conclusions about the clinical effectiveness and cost-effectiveness of PET' (separate from the results of the six specific indications reviewed). The second is the addition of the word 'potentially' before 'clinically effective' in the recommendations. See comparison in Table 1.

Table 1 – Comparison of original Supporting Committee report recommendations and altered recommendations

Recommendations of draft report approved by the Supporting Committee	*Recommendations of altered Supporting Committee report as considered by MSAC*
Recommendations Based on the results of the NHMRC Clinical Trials Centre's evaluation and the clinical experience of Committee members, the MSAC Supporting Committee concludes that there is insufficient evidence of PET's clinical or cost effectiveness with respect to the six indications reviewed to warrant unrestricted MBS funding. While the Committee agree that unrestricted funding is unwarranted at this time, the evidence suggests that PET is safe, clinically effective and potentially cost effective in the indications reviewed. On this basis the MSAC Supporting Committee recommends that PET be funded for the following clinical scenarios. …. **Suggested Funding Mechanism** It is recommended that **interim** funding be made available for the above indications, **subject to the provision** of data	**General Findings** 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; • in most indications PET is used in additional to other diagnostic modalities. This was the case in the diagnostic algorithm used for the current assessment; • in terms of adverse patient reaction to administration of FDG, FDG PET is safe; and • further evaluation of the technology is necessary. **Approved Recommendations** The PET Review 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. While the Committee agree that unrestricted funding is unwarranted at this time, the evidence suggests that PET is safe, potentially clinically effective and potentially cost effective in the indications reviewed. On this basis the MSAC Supporting Committee recommends that PET be funded for the following clinical scenarios. …. **Funding Recommendation** It is recommended that **interim** funding be made available for the above indications, **subject to the provision** of data.

1.42 The Committee heard evidence from Associate Professor Richard King who acknowledged that, as Chair of the Supporting Committee, he took responsibility for the changes made by the Steering Committee to the Supporting Committee's report. He argued that amendments were made to parts of the recommendations which did not read together logically.

1.43 Associate Professor King stated:

> 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.[38]
>
> …
>
> 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. If you can point out to me how they have changed the meaning, I would be more than happy to accept that we have made a mistake. But 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—which were all the indications reviewed—to warrant unrestricted MBS funding.[39]
>
> …
>
> If there had been a change of intent, I would not have supported it, but I cannot honestly see how inserting the word 'potentially' into the second recommendation does not act in synchrony with the first recommendation, which is that there is insufficient evidence on PET's clinical effectiveness. That certainly makes it potentially clinically effective, but you cannot then turn around in the next paragraph and say it is clinically effective if the evidence says that there is not clinical effectiveness. If you were to read the report and we had left in that it was clinically effective in the second line, people from all around the country and internationally would say: 'But you haven't proved your point. You've said in the first line that there is insufficient evidence and in the second one, you've said it's clinically effective. How can that be? [40]

1.44 Associate Professor King also stated:

> The concern seems to be the editorialising and the probity of editorialising one senior committee over a junior committee, which happens in my experience quite frequently… I cannot see in anything that has been said by

38 *Committee Hansard*, 30.3.07, p. 33. (Assoc. Prof. Richard King).

39 *Committee Hansard*, 30.3.07, p. 34. (Assoc. Prof. Richard King).

40 *Committee Hansard*, 30.3.07, p. 35. (Assoc. Prof. Richard King).

> Dr Ware that MSAC is in any way at fault in this regard. If you are finding fault—and I do not believe that there is fault—then the fault is that of the ministerial review committee wanting to have wording that it could live with and my fault in not warning the members of the subcommittee.[41]

1.45 The Department indicated that changes were made to the Supporting Committee's report by the Steering Committee, but the details of what was actually agreed cannot be verified on the basis of the documentary evidence available. The Department considered that the substance of the report (that there was insufficient clinical evidence on which to make definitive recommendations) remained consistent.[42]

Views of other MSAC Supporting Committee members

1.46 Following Professor Hick's evidence in relation to the lack of options for the Supporting Committee to dissent to the final report, the Committee agreed to write to other members of the MSAC Supporting Committee to give them the opportunity to comment on the matters raised. Several of the MSAC Supporting Committee members indicated that they did not feel that the findings and positions of the Supporting Committee on PET were accurately reflected in the final MSAC report. Professor Michael Millward commented:

> The recommendations in the document presented to MSAC diverges from this [the MSAC Supporting Committee report], in particular the insertion of the word 'potentially' in front of 'clinically effective' in the final paragraph. I do not believe this can be considered an 'editorial' change.[43]

Professor Kenneth Miles stated:

> ….the Supporting Committee's view was that there was sufficient evidence for clinical effectiveness, but insufficient evidence of cost-effectiveness in the Australian healthcare system.[44]

Professor Andrew Scott commented:

> The report that was finally submitted to MSAC (as stated in Appendix A) does not completely reflect the position of Supporting Committee. In particular, the use of 'potential clinical effectiveness' is not consistent with the views of the Supporting Committee.[45]

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41 *Committee Hansard*, 30.3.07, p. 46 (Assoc. Prof. Richard King).

42 Department of Health and Ageing, answer to question on notice 2, 14.6.07 hearing (dated 3.9.07).

43 Correspondence, Prof. Michael Millward, dated 8.8.07, p. 1.

44 Correspondence, Prof. Kenneth Miles, dated 7.8.07, p. 1.

45 Correspondence, Prof. Andrew Scott, dated 12.8.07, p. 1.

1.47 However Professor Brendon Kearney[46] and Dr John Primrose considered the final MSAC report did reflect the Supporting Committee's report. Dr Primrose commented:

> I can see no difference in meaning between the two versions of the 'Recommendations' contained in Appendix A of Senator Humphries letter. The second is merely an expanded and clearer version of the first.[47]

1.48 An alternative explanation was offered by Professor Robert Thomas, who indicated that:

> My memory was that the committee could not find hard evidence that PET improved outcomes in cancer but clinical effectiveness was agreed because of better cancer diagnosis and staging. The original report rather confusingly states this varied outcome in the first two paragraphs. I have agreed that there is a subtle change in the final wording which does not make the clinical effectiveness element as clear as in the supporting committee report. The significance of this change is in the eye of the beholder.[48]

1.49 Professor Michael Fulham disputed the Supporting Committee recommendations even before they were altered by the Steering Committee. He argued the benchmarks used in the assessment for PET were inappropriate.

> …I was convinced of the clinical effectiveness of PET as it related to the 6 indications that were discussed. The benchmark, however, that was set for the evidence to support the clinical effectiveness of PET, i.e. randomised controlled trials (RCTs), by the NH&MRC representative on the MSAC Supporting Committee was, in my opinion, inappropriate for an imaging technology. Despite arguments to the contrary during the meetings that were held, this was the standard that was promoted and upheld by the Chairman of the Committee. It was also emphasised by the clinicians that this standard had not been set for MR imaging where unrestricted Medicare funding had been recently granted and it seemed inconsistent and unreasonable to apply this standard to PET. It is true that in 1999/2000 there was a paucity of RCT data on the effectiveness of PET (but also for all other imaging modalities) and as such it was the opinion of the NH&MRC representatives and the Chairman that clinical effectiveness was not proven – so in this circumstance the first part of the "Recommendations" in Appendix A is correct "Based on the results of the NHMRC….evaluation" but the second phrase "and the clinical experience of the committee members", as it related to me and my experience, however is incorrect.[49]

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46 Correspondence, Prof. Brendon Kearney, dated 15.8.07, p. 1.

47 Correspondence, Dr John Primrose, dated 15.8.07, p. 1 (Department of Health and Ageing).

48 Correspondence, Prof. Robert Thomas, dated 7.8.07, p. 1.

49 Correspondence, Prof. Michael Fulham, dated 19.8.07, p. 2.

The independence of MSAC

1.50 A key concern raised by Dr Ware was that the independence of MSAC's assessment of PET had been compromised by the ministerial review and Steering Committee. This concern regarding 'political interference' was shared by Professor Hicks who believed 'there was an agenda to restrict the availability of PET and not to have an increase in PET funding'.[50] Professor Hicks stated:

> I have no evidence to support this, but my suggestion to the committee is that there was a political objective in the PET review…
>
> At the first meeting [of MSAC], 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…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 none at all. 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.[51]

1.51 Dr Ware commented:

> It is always difficult to know why people do things if you are not there at the time; and this is clearly speculation on my part. I believe that what happened was that the government, and the minister particularly, were under enormous pressure over the MRI scan scam. That was well known; it was on The 7.30 Report. That was an administrative debacle…Everyone there knew that the issue of conflict confidentiality was paramount and that the minister was absolutely ropeable about what happened with MRI.
>
> I believe that the minister had made a decision that he did not want to fund any more PET scanners… I believe that there was a deliberate effort to massage the scientific data, or the data that the public were going to use in their own health care, to fit a political objective. I cannot prove that.[52]

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50 *Committee Hansard*, 14.6.07, pp. 16 & 19 (Prof. Rodney Hicks).

51 *Committee Hansard*, 14.6.07, p.14 (Prof. Rodney Hicks).

52 *Committee Hansard*, 30.3.07, p. 21 (Dr Robert Ware).

1.52 However Associate Professor King stated:

> We did not have communication from the minister at all in relation to this… nobody was going to the minister, the reason no-one was going to talk to the minister at that stage about anything to do with diagnostic imaging was that the MRI scandal was still happily going in the background. However, at no time did we, at any committee I was on, receive any advice from the minister or the department as to what our outcomes should be.[53]

1.53 The Department argued that MSAC was entitled to make its own assessment of the evidence in the Supporting Committee report and that the 'final recommendation about the safety, effectiveness and cost-effectiveness of the technology or procedure is vested with MSAC'.[54] It noted that MSAC had before it a variety of information including the Supporting Committee's report, the contractor's report and the draft Steering committee's finding and recommendations. It also noted that 'MSAC member Dr Terri Jackson, a health economist with the Monash University Health Economics Unit, provided the critique of the evidence before MSAC'.[55] The Department stated:

> MSAC is not a cipher. Consistent with its usual way of operating, and with the support of Dr Jackson's written and verbal critique, MSAC analysed not just the conclusions of the documents before it, but the substance of the analysis in the evidence.[56]

1.54 The Department highlighted that the 'Minister responded to the MSAC chair's request for direction on how to approach an assessment of PET by establishing the PET Review, which was to incorporate an MSAC assessment'.[57] It also noted that the conclusion that 'funding should be provided on an interim basis, and for a defined set of indications, were reached on a number of occasions and by each of the bodies involved in the PET review'.[58] The Department went on to state:

> The process of conveying advice to MSAC, based on evidence compiled by the evaluators, and the considered opinions of members of the supporting committee, had no effect on MSAC's advice to the government. For example, it has been asserted that the insertion of the word 'potentially' in conclusions of the supporting committee might somehow have had a determinative effect on MSAC's view. This is not so either in this specific instance or generally.[59]

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53 *Committee Hansard*, 30.3.07, p. 46 (Assoc. Prof. Richard King).

54 Department of Health and Ageing, Additional information dated 3.9.07, p. 2.

55 Department of Health and Ageing, Additional information dated 29.5.06, p. 6.

56 Department of Health and Ageing, Additional information dated 29.5.06, p. 9.

57 Department of Health and Ageing, Additional information dated 29.5.06, p. 10.

58 Department of Health and Ageing, Additional information dated 29.5.06, p. 9.

59 Department of Health and Ageing, Additional information dated 29.5.06, p. 9.

1.55 The Department indicated it has undertaken 'thorough and extensive investigations of the processes and procedural activities which occurred during the Commonwealth review and the MSAC assessment of PET in 2000'. On the basis of this review the Department had found 'no evidence of fraud committed in relation to the review, by any officer in the Department or by any member of the MSAC Committees involved in the PET evaluation'.[60]

Dissenting views in Supporting Committee

1.56 The Committee was concerned that the members of the Supporting Committee were not given the opportunity to express dissenting opinions in relation to their report after it had been altered by the Steering Committee. The Department highlighted that the 'minutes of the third supporting committee meeting of 28 February 2000 note that the chair of the committee advised members there was a place for members to put in a minority opinion'.[61] However this occurred before the report was altered by the Steering Committee on 6 April 2000, and it appears that the Supporting Committee members were given no opportunity to express dissent to those changes.

1.57 In addition, the guidelines given to the Supporting Committee at the time that PET was assessed did not address the situation where members wished to place dissenting views on the record. The Department has acknowledged there was a flaw with the process of seeking final approval of the Supporting Committee's recommendations.[62] The Department noted it was not until August 2000 that guidelines for members of MSAC Supporting Committees were changed to include the following:

> 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 these views are held, should be stated.[63]

1.58 Professor Hicks asserted that he had provided a 'document in response to the Chair's offer' which was sent to the Department secretariat prior to the final meeting of the Supporting Committee on 23 March 2000.[64] While the Department confirmed that

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60 Department of Health and Ageing, Additional information dated 3.9.07, p. 4.

61 Department of Health and Ageing, Additional information dated 29.5.06, p. 10.

62 Department of Health and Ageing, answer to question on notice 4, 14.6.07 hearing (dated 3.9.07).

63 Department of Health and Ageing, answer to question on notice 3, 14.6.07 hearing (dated 3.9.07); MSAC, *Guidelines for members of MSAC supporting committees*, August 2000, p. 3.

64 Correspondence, Prof. Rodney Hicks, dated 5.10.07, p. 2.

the document was received, it argued that it formed part of the Supporting Committee's deliberations and should not be viewed as a minority report as it was discussed and incorporated into the Supporting Committee's draft report at the March meeting.[65]

1.59 The Department acknowledged that there was a flaw with the process of seeking final approval of the Supporting Committee's recommendations.

> It does not appear that the Supporting Committee was given the opportunity to formally sign off on its advice to the MSAC before it was considered by the MSAC Executive, the Steering Committee and subsequently the full MSAC. [66]

It also noted that MSAC processes have subsequently been amended to ensure clarity and consistency of procedure.[67]

1.60 Some of the other members of the Supporting Committee indicated that they may have, or would have, made dissenting views if they had been offered the opportunity. Professor Scott commented he had been 'provided with operating guidelines for the Supporting Committee, which do not contain information on recording of dissenting views'. He stated:

> If I had been aware of the alterations to the report, I would most likely have requested that the Recommendations be changed back to that which was agreed by the Supporting Committee. I am unsure of what the process for that would have been. A dissenting view as a final recourse would have been a possibility.[68]

1.61 Professor Millward noted 'the changes were made after the MSAC supporting committee had seen what it thought was the final report. Therefore there was no opportunity to comment on what was presented to MSAC… I expect I would have expressed a dissenting view...'.[69]

1.62 Professor Miles commented:

> I was not given an adequate opportunity to comment or disagree with the Supporting Committee's report because the report was amended beyond mere editorial changes after the final meeting of the Committee without being referred back to the Committee for approval of these changes or

65 Department of Health and Ageing, Additional information dated 19.2.08, p. 3.

66 Department of Health and Ageing, answer to question on notice 2, 14.6.07 hearing (dated 3.9.07).

67 Department of Health and Ageing, answer to question on notice 2, 14.6.07 hearing (dated 3.9.07).

68 Correspondence, Professor Andrew Scott, dated 12.8.07, p. 1.

69 Correspondence, Professor Michael Millward, dated 8.8.07, p. 1.

> opportunity to dissent. If I had been made aware of these changes, I would have requested my dissenting views be recorded.[70]

Withdrawal of the report / publishing of an errata note

1.63 In their evidence to the Committee, Dr Ware and Professor Hicks argued for the withdrawal of the MSAC assessment report. One of Dr Ware's desired outcomes was 'to have the deceptive and dangerous recommendations of the 2000 PET review withdrawn from the public domain'.[71] Professor Hicks also stated that the 'change in the findings… and the impact that that has had on patients, have damaged my international reputation'.[72]

1.64 Professor Hicks had previously contacted the Department of Health and Ageing to request his name be removed from the MSAC assessment report. The Secretary of the Department, Ms Jane Halton replied:

> You request in your letter that your name be removed from the MSAC PET report, in the absence of amendments reflecting your criticisms. Given the report has been in general circulation for over three years, and no reprints are anticipated, it would be impracticable to effect your request at this time.[73]

1.65 In his evidence to the Committee, Professor Hicks stated:

> I would like to have my name removed as one of the people who have endorsed this report, as I have requested repeatedly of Jane Halton in the department. I ask senators to request that my name be acknowledged as a dissenting view on this report… I would like the opportunity to have the recommendation that our committee of experts actually put to Professor King—that was heavily edited by him before the formulation of that draft report that you saw—included as an appendix to this document, as a PDF on the MSAC website.[74]

1.66 Professor Fulham considered '…there would be little tangible benefit from having the report withdrawn'. He continued:

> As to an errata note being issued I am ambivalent and I am not sure that it will achieve much; at RPA we will perform over 5,000 patient PET studies this year and our clinical program is second to none in providing a high quality clinical service to patients and referring Drs and each day we show

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70 Correspondence, Professor Kenneth Miles, dated 7.8.07, p. 2.

71 *Committee Hansard*, 30.3.07, p. 7 (Dr Robert Ware).

72 *Committee Hansard*, 30.3.07, p. 65 (Prof. Rodney Hicks).

73 Correspondence Secretary, Department of Health and Ageing to Professor Rodney Hicks, 10 February 2004, provided in Department of Health and Ageing, Additional information dated 25.5.06 (Attachment 10.2).

74 *Committee Hansard*, 30.3.07, p. 65 (Prof. Rodney Hicks).

> the clinical value of PET in patient management. An errata note will have no effect on this.[75]

1.67 However other members of the Supporting Committee supported an errata note being issued. For example Professor Scott stated:

> I believe that as a member of a Supporting Committee it is appropriate that the report to MSAC accurately reflect the views of the Committee. It would therefore be appropriate to consider allowing an errata to state that members of the MSAC Supporting Committee did not agree with all (or part) of the report sent to MSAC.[76]

1.68 Professor Miles submitted that:

> I would support an errata note being issued provided that the note indicated the manner in which the members of the MSAC Supporting Committee did not agree with the findings of the final MSAC report regarding PET, i.e. that the Supporting Committee found that PET was clinically effective for the 6 clinical indications reviewed, but that there was insufficient evidence of cost-effectiveness in the Australian healthcare system. If such a specific errata is not possible, then I would support withdrawal of the report.[77]

1.69 The Department indicated it had sought legal advice and consulted with the National Archives of Australia regarding Professor Hicks' request to have his name removed from both reports. The advice the Department received was that as Professor Hicks is on the public record as having been a participant in the Supporting Committee for the Review the removal of Professor Hicks' name would change the historical record, contrary to s. 24 of the *Archives Act 1983*.

1.70 The Department proposed to upload a disclaimer specific to the *MSAC Reference 2 Positron Emission Tomography* website noting Professor Hicks' earlier request that *'The primary conclusion in the reports arising out of the Medical Services Advisory Committee (MSAC) 2000 review of Positron Emission Tomography (PET) undertaken by MSAC does not reflect the opinion of Professor Rodney Hicks'*. The Department indicated it would be writing to Professor Hicks to seek his confirmation that 'these proposed arrangements address the substance of his concerns'.[78]

1.71 The Department noted that standard MSAC practice was now for final reports and decisions to be made available on the MSAC website. The site includes a 'pop-up' disclaimer for each review stating that *'MSAC recommendations do not necessarily reflect the views of all individuals who participated in the MSAC evaluation*'. In addition MSAC is currently reviewing how an individual's dissenting views might be

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75 Correspondence, Professor Michael Fulham, dated 19.8.07, p. 2.

76 Correspondence, Professor Andrew Scott, dated 12.8.07, p. 2.

77 Correspondence, Professor Ken Miles, dated 7.8.07, p. 2.

78 Department of Health and Ageing, Additional information dated 3.9.07, p. 3.

made known in its publicly available information.[79] The Department reported that the MSAC Executive had agreed that should this situation arise again a disclaimer specific to the report will be uploaded onto the MSAC website noting that:

> The primary conclusion in the XXX report arising out of the review of XXX undertaken by the Medical Services Advisory Committee (MSAC) does not reflect the opinion of XXX (insert name).[80]

Department of Health and Ageing

1.72 In his initial correspondence with the Committee, Dr Ware stated that the Department 'submitted, and then failed to retract, false information in response to a question on notice' put during Community Affairs Senate Legislation Committee proceedings.[81] Additionally Dr Ware stated that Department officers had engaged in dishonesty in response to questions about the formulation and conduct of the Commonwealth's policy towards PET.[82]

1.73 During his evidence Dr Ware alleged:

> I believe these documents will also provide you with irrefutable evidence that the Department of Health and Ageing has breached the Australian Public Service Code of Conduct[83] by providing false and misleading information to this committee on multiple occasions. Even though senior department officers were made aware of these material errors of fact, no action has been taken to correct the public record…[84]

1.74 Dr Ware highlighted the answers the Department had provided to a Question on Notice from Senator Harradine on 5 November 2003.

> (a) Did the Scientific Supporting Committee in its report find that PET scanning was clinically effective and possibly cost effective?
>
> (b) Why were the expert opinions ignored in the final decision?
>
> (c) Is it correct that a specialist from the Peter MacCallum Clinic wrote to the Chair of Scientific Supporting Committee and the chair of the Medical Services Advisory Committee (MSAC) requesting that his name be removed from any connection with MSAC's downgrading of the Scientific Supporting Committee's report?

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79 Department of Health and Ageing, Additional information dated 3.9.07, p. 3.

80 Department of Health and Ageing, answer to question on notice 10, 14.6.07 hearing (dated 3.9.07).

81 Correspondence, Dr Robert Ware, dated 26.1.06, p. 1.

82 Correspondence, Dr Robert Ware, dated 26.1.06, p. 10.

83 The *Public Service Act* 1999 s. 13 outlines the APS Code of Conduct. The Code provides that an 'APS 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'.

84 *Committee Hansard*, 30.3.07, p. 3 (Dr Robert Ware).

The Department responded:

> (a) No. Supporting Committees of the Medical Services Advisory Committee (MSAC) do not make findings. Neither do Supporting Committees make reports, this being the responsibility of MSAC. Some members of the Supporting Committee did provide separate written advice to MSAC and this advice made stronger claims about the effectiveness and cost-effectiveness of PET than those of MSAC's findings.
>
> (b) Expert opinions were not ignored in the final decision. However, MSAC's recommendations in relation to PET were primarily based on analysis of the evidence from the international scientific literature, not individual clinical opinion.
>
> (c) A specialist from Peter MacCallum Cancer Institute (also a member of MSAC PET Supporting Committee) wrote to the Secretary for the Department of Health and Ageing on 5 December 2003, referring to his letter dated 2 April 2003, which he noted had not been sent at that time due to an administrative error within his office. In the April letter, he requested that, in the absence of specific changes to the 2000 report of the Review of positron emission tomography, and the associated MSAC report, his name be removed from those documents.
>
> This specialist was one of seven clinicians on the PET supporting committee, which also included representatives of MSAC and the Department. As is typical of an MSAC review process, the supporting committee's members expressed a range of views in the course of the committee's deliberations. However, no committee member other than the specialist in question made a formal statement of dissent in relation to the PET review's findings.[85]

1.75 The Department rejected Dr Ware's allegations concerning the conduct of Departmental officers during this matter stating that 'all Departmental officers have acted with integrity and professionalism in dealing with this controversial and difficult issue'.[86] The Department stated it had 'made every effort to ensure that the secretariat support provided to MSAC is professional and that record keeping for the MSAC Committee is accurate'. However the Department also noted that:

> In responding to the queries of Dr Ware, Professor Hicks and members of this Committee, it has become apparent that the quality of minute taking at the time was not what it should have been. Further, over the years there have been instances where the Department has supplied incorrect documents in response to these queries, in large part due to the confusion in nomenclature of the various parts of the process for that 1999 assessment.[87]

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85 Senate Community Affairs Committee, Additional information received, Volume 6, Index and Answers to Estimates Questions on Notice, Health and Ageing Portfolio, Supplementary Budget Estimates 2003-2004, 5 November 2003, pp. 168-7 (E03-045).

86 Department of Health and Ageing, Additional information dated 19.2.08, p. 4.

87 Department of Health and Ageing, Additional information dated 3.9.07, pp. 3-4.

The role of MSAC

1.76 During the hearing on 30 March 2007 there was discussion regarding possible reform of MSAC. In May 2004, MSAC undertook a review of its procedures and methods in order to identify opportunities to improve approaches to, and management of, the assessment of health technologies. In November 2004, MSAC agreed to implement a number of actions which were developed using ideas contained in many of the submissions, and which fitted within its terms of reference. The review was completed in May 2005.[88]

1.77 However Dr Ware argued for further reforms to MSAC which he stated 'needs to be under legislative control'. He quoted from the Australian Medical Association submission to the MSAC review to highlight his concerns:

> Until MSAC is established on a similar footing to PBAC [Pharmaceutical Benefits Advisory Committee], it will not enjoy the confidence of the medical profession. The establishment of MSAC was an attempt to establish a more independent body at arm's-length from the government. MSAC is not established independently of the department or the government. Its agenda in relation to existing MBS items is almost exclusively determined by the department and its secretariat. It is made up of departmental officers with line responsibility to senior departmental officers. The relationships between the department and the MSAC secretariat and MSAC itself are unclear.[89]

1.78 In the review report MSAC agreed to a number of reforms to improve the transparency of MSAC assessment processes. These included developing 'a presentation and associated material that will provide clear, consistent direction to Advisory Panels [Supporting Committees] about the roles and responsibilities of panel members, as well as the contracted evaluators and the department'.[90] However the report does not appear to address the relationship between MSAC and the Department and the issue of the independence of evidence-based advice.

CONCLUSION

1.79 As previously stated the Committee's interest in this matter related to whether the practices and procedures used in assessing PET were appropriate and whether false information had been provided during estimates proceedings of the Committee.

1.80 In the opinion of the Committee, 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. The Committee is also satisfied that there has been no evidence presented that would indicate that the MSAC decision regarding

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88 MSAC, *Report of a Review of the Medical Services Advisory Committee*, May 2005.

89 *Committee Hansard*, 30.03.07, p. 16 (Dr Robert Ware).

90 MSAC, *Report of a Review of the Medical Services Advisory Committee*, May 2005, p. 32.

PET turned on any amendments made to the Supporting Committee's report. Despite the inclusion of the 'General findings' and other changes to the report, the interim funding recommendations of the Supporting Committee were adopted by MSAC and the Minister. While changes were made to the report by the Steering Committee, the Committee does not consider they were material enough to mislead the medical professionals on MSAC as to the clinical value of PET given the other research, analysis and data available to them.

1.81 However the issues raised by Dr Ware and Professor Hicks highlight the importance of ensuring the independence of scientific and technical evidence based assessments of new medical technologies. Allowing the Supporting Committee's report to be viewed and altered by the Steering Committee, and by officers from the Department, invited questions of impropriety into an assessment process which was held up as being based wholly on scientific and technical evidence. This situation was compounded by the fact that members of the Supporting Committee had no notification that changes were being made or the opportunity to have their dissent to the changes recorded.

1.82 The Committee also notes that in the previously outlined stages of the assessment process, MSAC, in formulating recommendations to the Minister, considers 'a range of information' including 'the assessment report and any feedback on the report received from the MSAC applicant…'.[91] In the MSAC assessment of PET this did not occur, as parties involved with the applications (Professor Hicks and Professor Miles) were part of the Supporting Committee. The Committee understands that conflicts of interest regarding developing medical technologies are common and, in many instances, unavoidable given the relatively small pool of clinical expertise in Australia. In future, it would be preferable if applicants to MSAC in relation to a new medical technology were not invited to participate as part of the Supporting Committee assessing the technology.

1.83 The Committee has noted the review of MSAC assessment processes and the reforms to improve the transparency of MSAC decisions. This review does not appear to have considered the specific issue of the independence of MSAC advice from the Minister or the Department. Arguments were put to the Committee that MSAC should, like the Pharmaceutical Benefits Advisory Committee (PBAC), be constituted as a statutory body, at arm's length from the Government.

1.84 During the hearing on 30 March 2007 a number of allegations were made regarding Associate Professor King in his role as Chair of the Supporting Committee. In essence, these suggest that Associate Professor King was responsible for altering the recommendations of the Supporting Committee regarding PET and/or fraudulently misrepresenting to MSAC that the report was the unaltered recommendations of the Supporting Committee (after it had been altered by the Steering Committee).

91 MSAC, *Annual Report,* April 1998 – June 2000, pp. 14 - 15.

1.85 As the Chair of the Supporting Committee, Associate Professor King has taken responsibility for the changes that were made by the Steering Committee to the Supporting Committee report recommendations. However there has been no evidence presented that Associate Professor 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. In the opinion of the Committee these allegations are without foundation.

1.86 The MSAC assessment of PET highlights the dangers of ambiguities arising in the roles and responsibilities of the bodies involved in the review of new medical technologies. The Committee considers that the roles and responsibilities of the Supporting and Steering Committees in the review of PET were not clear. For example the Supporting Committee minutes indicate it agreed 'it was jointly responsible with the Steering Committee for ToR [term of reference] one, assessing the clinical need, safety, clinical effectiveness and cost effectiveness of PET in relation to diagnostic modalities'. The Department has also noted this was a relatively new process with unique circumstances:

> ….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.[92]

1.87 The majority of the Committee consider that it was perhaps a mistake for Associate Professor King to agree to the changes to the wording of the recommendations without informing and obtaining the written consent of the rest of the Supporting Committee. It was perhaps also a poor procedural decision not to ensure that the changes made were clearly recorded as the Steering Committee's when the draft Supporting Committee report was given to MSAC for its consideration. However these deficiencies in the assessment process could also reflect the quality of the secretariat support by the Department to both the Steering Committee and the MSAC Supporting Committee.

1.88 The Committee has considered the matters raised by Dr Ware in relation to the evidence provided by officers of the Department of Health and Ageing. The Committee is concerned about the quality of the responses from the Department to questions on notice during earlier estimates hearings. While literally correct the answer provided by the Department to Senator Harradine's question on notice (E03-045) appears disingenuous and unhelpful, at best, when considered next to the wording of the report of the MSAC Supporting Committee on 23 March 2000.

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92 *Committee Hansard*, 14.6.07, p.22 (Mr David Learmonth, Department of Health and Ageing).

1.89 The Committee notes that the Government Guidelines for Official Witnesses before Parliamentary Committees and Related Material state that it is the duty of the public servants 'to assist ministers to fulfil their accountability obligations by providing full and accurate information to the Parliament about the factual and technical background to policies and their administration'. These guidelines are aimed at encouraging the freest possible flow of such information between the public service, the Parliament and the public.[93] The Committee is concerned that the Department has not maintained this standard.

1.90 In addition, the Committee wishes to record its disappointment with the conduct of officers of the Department of Health and Ageing when appearing to answer questions on this matter. At the hearing on 14 June 2007, Department officers had not adequately prepared to answer relevant questions from Senators and frequently had to take questions on notice. Delayed responses to the questions taken on notice have made it difficult for the Committee to finalise its deliberations in this matter.

1.91 The Committee was particularly distressed at the extensive delay by the Secretary of the Department, Ms Jane Halton, in correcting the record in correspondence dated 16 June 2008 that related to comments in earlier correspondence dated 19 February 2008 that incorrectly attributed certain views to Professors Weedon and King in correspondence with Professor Hicks in early 2001. Ms Halton conceded that 'the error was not detected, despite the letter [dated 19 February 2008] being subjected to a number of checks, including by external lawyers'.[94]

1.92 The Committee considers that it is likely this matter would have been dealt with considerably earlier if the Department of Health and Ageing had been more effective in communicating information, either in response to Senators' questions, in response to freedom of information requests or otherwise.

1.93 The Committee notes the Department now intends to offer Professor Hicks an erratum to appear on the MSAC website. However, given the range of views expressed by the other members of the Supporting Committee, the Committee considers that they should also be offered the opportunity to have their dissent acknowledged.

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93 *Government Guidelines for Official Witnesses before Parliamentary Committees and related material*, November 1989, p. 3. Available from www.pmc.gov.au.

94 Department of Health and Ageing, Additional information dated 16 June 2008, p.1.

Recommendation

1.94 That the Department of Health and Ageing and the Medical Services Advisory Committee coordinate to issue a disclaimer or erratum to institutions likely to hold physical or electronic copies of the *MSAC Assessment Report: Positron Emission Tomography* or the *Report of the Review of Positron Emission Tomography* to indicate which members of the Supporting Committee did not agree that the final report reflected their views.

Senator Claire Moore
Chair

June 2008