Dissenting report in relation to MSAC assessment 1054.1: Hyperbaric oxygen therapy for the treatment of chronic non-diabetic wounds and non-neurological soft tissue radiation.

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Please accept the following concerning this matter. Unfortunately, in our capacity as the two hyperbaric oxygen therapy experts on this panel, we find ourselves unable to agree with the report as presented as a word document to us as a final draft on the 8th of September 2011. Below follows a summary of our objections and this document is intended to serve as a dissenting report to the findings of this 'Advisory Panel '.

We thank MSAC for the opportunity to present this report. We also acknowledge and appreciate the content of the amended 'Expert opinion' section of the draft report as an accurate representation of our submissions and discussions during the advisory panel meetings and teleconference. We maintain there are further significant areas where our expert opinion is not in agreement with material in the report. We suggest these remaining areas may have been amenable to resolution had a little more time been available to us for discussion and amendment to the report. This document is a summary of those areas.

General dissenting comments on the process

- We express our great concern regarding the process employed for this application. The process is designed for the assessment of new technologies and is demonstrably unsuited to the examination of existing, funded technologies. We have made this point on numerous occasions during the deliberations of the Advisory Panel and have not accepted at any point that the process employed was appropriate. Hyperbaric Oxygen Treatment (HBOT) is not a new technology, and the two conditions subject to this application have been fully funded by Medicare since the 1980's. The only appropriate methodology for examining the treatments that should receive public funding is to examine the evidence for <u>all</u> treatments proposed and to draw conclusions about the patients most appropriate for treatment with each of those modalities (if any). The narrow approach forced on this advisory panel is inadequate to the task and very likely to result in inappropriate funding decisions. It has been made abundantly clear to the advisory panel that we were 'stuck with' the current system and that we would simply have to accept it. We do not.

- The process has, in our opinion, failed the Australian people because the evidence base for treatments other than HBOT for soft tissue radiation injury and non-diabetic problem wounds is generally poor (as illustrated by the evidence presented by the applicants), while the evidence base for HBOT of the two conditions is at least as good or better than other available treatments. There is no avenue for acknowledging and dealing with this situation within the confines of the process used.

- We also object to the rushed nature of this final draft report. The final draft was presented to us with very limited time for comment, despite the addition of approximately 70 new pages of information and numerous changes since our final teleconference. Indeed, the minutes of that final teleconference did not arrive until the 30th September – more than two weeks after the final draft of the report and a full week after we were required to lodge our vote on whether or not we accepted the final draft. Furthermore, we did not have any expectation that this draft would be presented to us for 'signing off' rather than another round of discussions within the panel. We do not believe MSAC is best served by this precipitous requirement to agree or otherwise.

- Finally, we have been informed that the draft report has received the necessary votes for the panel to officially 'sign off' the document as it is currently written. We have not to this time received any information about the numbers in order to confirm that vote, nor have we been made aware of who may and may not have voting privileges on this advisory panel. As the two experts in hyperbaric medicine on this panel, we believe the voting procedures have been completed with undue haste.

Soft Tissue Radiation Injury

- We support the general assessment of the evidence and cost effectiveness analysis concerning HBOT for soft tissue radiation injury. There are however some inconsistencies in the language used to summarize the evidence for this condition compared with the text.

- We do not support the negative language used in the conclusions on page 27 and 118 of the report: *"The majority of comparative studies retrieved for this indication were of mediocre or poor methodological quality...."* We think it is important the conclusions accurately reflect the evidence

appraised in the full text of the document and submit that this conclusion should read "*The majority of comparative studies retrieved for this indication were of satisfactory to good methodological quality....* ". The report text seems to have been simply copied from the conclusions of the previous report without considering the new evidence. The new evidence includes three new Randomised Controlled Trials, one of which has full double blinding with sham placebo controls (highly unusual for the investigation of any therapy for soft tissue radiation injury). Our proposed conclusion is concordant with the text on page 119 of the report (Table 53), where the evidence base for soft tissue radiation injury is rated as good, and satisfactory to good for non-diabetic problem wounds.

Non-diabetic Problem Wounds

- We dissent from the way in which the report handles the non-diabetic problem wound data. There are important aspects of the ANZHMG wound study that have not been included despite being fully investigated and included in the applicant's submission.

- The conclusions and the executive summary should clearly document the reason behind the design and undertaking of the ANZHMG wound study. This study was undertaken as a *direct result* of the recommendations of MSAC 1054 in 2004. The 2004 report specifically called for this study to be undertaken and it is important that the current report should acknowledge this. This study provides specific evidence of the performance of HBOT in the Australian setting, and is therefore highly relevant to the application. The current report downplays this evidence, discarding it as "*low-level*", with no indication that this study was requested as a result of MSAC's own processes in 2004.

- Further, the report does not clearly state that the applicants advocate HBOT only for those wounds that are refractory to 'standard care'. The ANZHMG wound study enrolls patients only after three months of failed care. This is a minimum - in fact the median time to referral was 16 months in the early report and more than 19 months in the sixth year report. The advisory committee report should clearly acknowledge that HBOT is successful in approximately 80% of wounds that have been indolent and refractory to other therapies for long periods of time. The report and the economic modeling should both make it clear that HBOT is *not* advocated for the *initial treatment* of non-diabetic wounds. Because of the failure to acknowledge this reality, particularly in the economic analysis, there is an erroneous assumption that HBOT is *first line* and competes with standard care from the outset.

- Even with the flawed cost-minimization economic analysis provided for non-diabetic problem wounds, the additional cost of HBOT per patient is only $2151 AUD. Given the serious suffering and impairment of quality of life that results from chronic non-healing wounds, we assert that this is very effective use of health funds to achieve greater than 80% healing at 12 months.

- We further dissent with the presentation of the new evidence since the publication of MSAC 1054 in 2004. The 1054 report documented: "*in the absence of effective alternative therapies and in view of the progress of local data collections and an international trial, funding for HBOT should continue for existing MBS listed indications at eligible sites for a further three years.*" Since then, there has been very little new evidence generated in support of any treatment for indolent ulcers with the notable exception of HBOT. It is incongruous to acknowledge a significant local prospective analysis of the treatment of non-diabetic wounds that suggest an 80% success rate at one year, and yet to downgrade the support for the use of that treatment in the current 1054.1 report.

- We propose the addition of the important entry criteria for the ANZHMG wound study to pages 77 and 78 of the current report. Specifically, it should be clearly stated that these wounds must have been present for at least three months despite 'standard wound care' measures, and that radiation wounds were excluded. This study continues to collect data for the purposes of monitoring the use of HBOT in this area – and this should also be acknowledged in the document.

In this dissenting report, we have not provided a detailed critique of the specific areas of concern in the MSAC 1054.1 document, however can provide this if requested to do so.

Yours sincerely

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Associate Professor David Smart