Specialist Medical Review Council

Reasons for Decision

Section 196W
Veterans' Entitlements Act 1986

Re: Statement of Principles No. 67 of 2002
In Respect of Osteoporosis
Matter No. 2003/1
Requests for Review Declaration No. 11

SUMMATION

1. In relation to the Repatriation Medical Authority (the RMA) Statement of Principles No. 67 of 2002 in respect of osteoporosis and death from osteoporosis, made under subsection 196B (2) of the *Veterans' Entitlements Act 1986* (the VEA), the Specialist Medical Review Council (the Council) declares under subsection 196W (4) of the VEA, that it is of the view that there is sound medical-scientific evidence on which the RMA could have relied to amend Statement of Principles No. 67 of 2002.

2. The Council accordingly directs the RMA to amend Statement of Principles No. 67 of 2002 in accordance with the following directions;

    a) delete paragraph 5 (p) and replace it with :

        having an altered dietary pattern resulting in a decrease in average daily calcium intake to 400mg/day or less, for a period of 2 years before age 20 years, or for a period of 7 years after that age, or the equivalent combination thereof, before the clinical onset of osteoporosis; or

    b) delete paragraph 5 (zf) and replace it with:

        having an altered dietary pattern resulting in a decrease in average daily calcium intake to 400mg/day or less, for a period of 2 years before age

20 years, or for a period of 7 years after that age, or the equivalent combination thereof, before the clinical worsening of osteoporosis; or

c) amend the 'Other Definitions' in paragraph 8 by including:

"or the equivalent combination" in paragraphs 5 (p) and 5 (zf) means:

a calculation where one year of exposure before age 20 years is equivalent to 3.5 years of exposure after age 20.

d) delete paragraph 2 (b) (i) and replace it with:

bone mineral density is more than 2.5 standard deviations below the mean bone mineral density of young adult sex-matched controls.

THE SPECIALIST MEDICAL REVIEW COUNCIL

3. The Council is a body corporate established under section 196V of the VEA, and consists of such number of members as the Minister for Veterans' Affairs determines from time to time to be necessary for the proper exercise of the function of the Council as set out in the VEA. The Minister must appoint one of the Councillors to be the Convener.

4. When a review is undertaken of a Statement of Principles made by the RMA, the Council is constituted by 3 to 5 Councillors selected by the Convener. When appointing Councillors, the Minister is required to have regard to the branches of medical science expertise which would be necessary for deciding matters referred to the Council for review.

5. Dr Jonathan Phillips FRANZCP was the Convener of the Council for this review. He is the immediate past Chairperson of the Committee of Presidents of Medical Colleges and is currently Director Mental Health Services and Programs, Department of Human Services, South Australia. The other members of the Council were:

(i) Dr Charles Guest FAFPHM, Medical Director of the Health Protection Service of the ACT Department of Health and Community Care; and Visiting Fellow at the Australian National University, National Centre for Epidemiology and Population Health;

(ii) Professor John Eisman AO FRACP, who is currently Director of Bone and Mineral Research Program at the Garvan Institute of Medical Research, Professor of Medicine, University of NSW, Staff Endocrinologist at St Vincent's Hospital Sydney, and Editor in Chief of the *Journal of Bone and Mineral Research*; and

(iii) Professor Philip Sambrook FRACP, who is currently Florence & Cope Professor of Rheumatology at the Sydney University and Head of Department of Rheumatology at Royal North Shore Hospital. He is Medical Director of Osteoporosis Australia.

THE LEGISLATION

6. The legislative scheme for the making of Statements of Principles is set out in Parts XIA and XIB of the VEA.

7. The functions and powers of the Council must be seen in light of the function and purpose of Statements of Principles in the scheme of the VEA. The significance of Statements of Principles to claims under the VEA for pensions in relation to eligible service is apparent from sections 120A and 120B of the VEA. Section 120 is also of importance.

8. Fundamental to Statements of Principles is the concept of 'sound medical-scientific evidence', which has been defined in section 5AB (2) of the VEA. Information about a particular kind of injury, disease or death is taken to be sound medical-scientific evidence if:

(a) the information

(i) is consistent with material relating to medical science that has been published in a medical or scientific publication and has been, in the opinion of the Repatriation Medical Authority, subjected to a peer review process; or

(ii) in accordance with generally accepted medical practice, would serve as the basis for the diagnosis and management of a medical condition; and

(b) in the case of information about how that injury, disease or death may be caused meets the applicable criteria for assessing causation currently applied in the field of epidemiology[1].

9. The functions of the Council are set out in section 196W of the VEA. In this case, the Council was asked (under section 196Y of the VEA) by a person eligible to make a claim for a pension, to review the contents of Statement of Principles No. 67 of 2002 in respect of osteoporosis and death from

[1] This has been held to mean 'information which epidemiologists would consider appropriate to take into account' see *Repatriation Commission v Vietnam Veterans' Association of Australia NSW Branch Inc* (2000) 48 NSWLR 548 (the New South Wales Court of Appeal decision) per Spigelman CJ at paragraph 117.

osteoporosis, being a Statement of Principles determined by the RMA under section 196B (2)[2] of the VEA ('the reasonable hypothesis standard').

10. Specifically, the applicant contended that the dietary calcium factor (paragraph 5(p)) (in respect of which for all relevant purposes paragraph 5 (zf) is in the same terms) should not restrict to a maximum of four years the lapse of time between a calcium deficient diet on service and the clinical onset of osteoporosis.

11. In conducting its review, the Council must review all the information that was available to (before) the RMA at the time it determined, amended, or last amended the Statement of Principles and is constrained to conduct its review by reference to that information only.[3]

12. Under section 196W of the VEA, the Council can only reach the view that a Statement of Principles should be amended on the basis of sound medical-scientific evidence.

BACKGROUND

13. On 10 October 2002, the RMA under subsection 196B (2) of the VEA determined the Statement of Principles being instrument numbered 67 of 2002 in respect of osteoporosis.

14. On 14 October 2002 and 15 October 2002 respectively, in accordance with section 196D of the VEA and sections 46A and 48 of the *Acts Interpretation Act 1901* the Statement of Principles was tabled in the House of Representatives and in the Senate.

15. On 16 October 2002 the making of the instrument was notified in the Gazette (No. 41, p.2777).

16. An application dated 23 November 2002 for review of Statement of Principles number 67 of 2002 was received by the Council on 4 December 2002.

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[2] If the Authority is of the view that there is sound medical-scientific evidence that indicates that a particular kind of injury, disease or death can be related to:

(a) operational service rendered by veterans: or
(b) peacekeeping service rendered by members of Peacekeeping Forces; or
(c) hazardous service rendered by members of the Forces;

the Authority must determine a Statement of Principles in respect of that kind of injury, disease or death setting out:

(d) the factors that must as a minimum exist; and
(e) which of those factors must be related to service rendered by a person;

before it can be said that a reasonable hypothesis has been raised connecting an injury, disease or death of that kind with the circumstances of that service.

[3] *Vietnam Veterans' Association (NSW Branch) Inc v Specialist Medical Review Council and Anor* (full Federal Court decision) (2002) 72 ALD 378 at paragraph 35 per Branson J

Specifically the application was concerned with the decision of the RMA of 10 October 2002 to restrict to a maximum of four years the lapse of time between a calcium deficient diet on service and the clinical onset of osteoporosis.

17. Pursuant to section 196ZB of the VEA the Council published in the Gazette a notice of its intention to carry out a review of the information available to the RMA about osteoporosis, and inviting persons or organisations authorised so to do to make submissions to the Council (Gazette number 1 of 8 January 2003). The Council gazetted a series of subsequent notices as to the date by which written submissions must be received by the Council: Gazette Notice 14 of 9 April 2003; Gazette Notice 26 of 2 July 2003; and Gazette Notice 31 of 6 August 2003.

18. The Council held a meeting for the purposes of this review, and heard oral submissions complementing the written submissions on Wednesday 12 November 2003.

19. The applicant submitted a written submission and the applicant's representative made an oral submission complementing the applicant's written submission at the Council's meeting on 12 November 2003. The applicant was unable for personal reasons to be present at the hearing.

20. An expert in the field submitted two written submissions and made an oral submission complementing the first written submission at the Council's meeting on 12 November 2003.

21. The Repatriation Commission made two written submissions. Dr Jon Kelley, representing the Repatriation Commission, made an oral submission complementing the Commission's first written submission at the Council's meeting on 12 November 2003.

22. On 23 October 2003 the Council wrote to the applicant and the Repatriation Commission advising them of the Council's preliminary views of the scope of the review and pool of information. The applicant and the Repatriation Commission were invited to make written comments as to these preliminary views by close of business on 7 November 2003, or to make oral comments at the hearing on 12 November 2003.

23. The Council did not receive any written comments on its preliminary views on the scope of the review or on the pool of information by close of business on 7 November 2003. The Council did not receive any oral submissions concerning its preliminary views on the scope of the review and the pool of information at its hearing on 12 November 2003, save that the representative for the Repatriation Commission stated in his oral submission that he did not wish to make any submissions about any dietary matter other than early life calcium intake.

Pool of Information

24. The Council's preliminary view, as advised to the applicant and Repatriation Commission on 23 October 2003 (confirmed to the applicant's representative, the Repatriation Commission's representative and the expert in the field at the Council's hearing on 12 November 2003) was that the pool of information should include all the information that was available to the RMA when it determined, amended, or last amended the Statement of Principles.

Scope of Review

25. The Council's preliminary view, as advised to the applicant and Repatriation Commission on 23 October 2003 (and confirmed to the applicant's representative, the Repatriation Commission's representative and the expert in the field at the Council's hearing on 12 November 2003) was as follows:

> without limiting the scope of its review of the whole of the contents of the Statement of Principles, [the Council] presently proposes to have particular regard to whether there is sound medical-scientific evidence upon which the RMA could have relied to amend the Statement of Principles in any or all of the following ways:
>
> (i) the possible excision from the factors set out in paragraphs 5(p) and 5(zf) of the Statement of Principles of the latency period (the four years immediately prior to the clinical onset (or worsening) of osteoporosis);
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> (ii) whether the factors set out in paragraphs 5(p) and 5(zf) should:
>
> (a) stand alone; or
>
> (b) be in combination with factors in other subparagraphs of paragraph 5; or
>
> (c) contain any other aspects of diet (including any other dietary exposures and deficiencies in addition to or substitution for calcium); or
>
> (d) contain a 'stage of life' component of any exposure; and
>
> (iii) the possible excision from the Statement of Principles of the factors set out in paragraphs 5(p) and 5(zf).

Written submission Subsequent to Hearing

26. During the Council's deliberations, a further matter arose as to the definition of osteoporosis in paragraph 2(b)(i) of Statement of Principles No. 67 of 2002. The Council wrote to the applicant and the Repatriation Commission by letter dated 28 November 2003, advising of its preliminary view of the way in which the definition should be amended, and affording an opportunity to comment.

27. Also in its letter of 28 November 2003, the applicant and/or his representative and/or the expert in the field, and the Repatriation Commission were afforded an opportunity to make a written submission concerning:

    a) the Council's tentative alternative formulation of an altered diet factor (alternative altered diet factor), which Council presented at its hearing on 12 November 2003; and

    b) other particular questions raised by Councillors during the oral hearing on 12 November 2003.

28. A (depersonalised) copy of the Council's letter to the applicant dated 28 November 2003 is attached as Appendix A. A copy of the Council's letter to the Repatriation Commission dated 28 November 2003 is attached as Appendix B.

29. The Council received a written submission from the Repatriation Commission on its alternative altered diet factor, the associated matters outlined above and the definition of osteoporosis. The Council received a written submission from Professor Hooper on its alternative altered diet factor and the associated matters outlined above.

30. The written submissions it received are outlined with the other written submissions the Council received from Professor Michael Hooper (the expert in the field) and the Repatriation Commission. The Council's analysis of the medical science identified in those submissions is commented upon by the Council under the heading of 'The Council's Analysis of the Information Before the RMA'.

Applicant's Submission

31. The applicant contended that:

> there was expert opinion before the RMA that a calcium deficient diet on service 'would have contributed to a degree of skeletal impairment and increased risk of developing osteoporosis at a later date'. The dietary calcium factor (factor 5 (o)) (sic) should not, then, restrict the lapse of time to a maximum of four years.

32. The applicant's representative in her oral submission, complementing the applicant's written submission, urged the Council to look carefully at all the

material available to it, in order to see if there was a capacity to be 'a little more flexible about the age' by which the dietary calcium deficiency has to have occurred, or the age after which it has to have started'.

Expert's Submissions

33. The expert in the field made two written submissions (28 July 2003 and 12 February 2004), and an oral submission complementing the 28 July 2003 written submission, in favour of the applicant's contention.

34. Professor Hooper addressed the two central questions before the Council. The first was whether a low dietary calcium intake in early adult life could be a link or element in a reasonable hypothesis connecting osteoporosis to operational service. The second was whether the imposition of a latency period between exposure and the clinical onset of the disease was justified.

35. In Professor Hooper's view, there was no direct information referable to the first issue before the RMA. Rather, in his view, it was possible to extrapolate from the information available to (before) the RMA (see Appendix D for the articles upon which Professor Hooper relied).

36. Professor Hooper was of the view (based on his assessment of all the information before the RMA at the relevant times) that early calcium nutrition is important in determining peak adult bone mass (although he agreed that not all the information before the RMA was supportive of the association).

37. Further, Professor Hooper submitted that peak adult bone mass, and subsequent bone loss, are independent risk factors for osteoporosis, such that the amount of bone present at skeletal maturity is an important factor in determining adult susceptibility to osteoporosis and osteoporotic fragility fractures.

38. Professor Hooper considered it a reasonable hypothesis that dietary calcium deficiency in early years could contribute causally to osteoporosis in late adult life, with early calcium deficiency playing an important role in determining peak adult bone mass.

39. In Professor Hooper's view, there was no basis in the information before the RMA at the relevant times to justify the imposition of a latency period, ie a maximum period between the period of calcium deficiency and the clinical onset of osteoporosis.

40. Professor Hooper submitted that a person may unknowingly suffer from osteoporosis for many years, prior to sustaining an osteoporotic fracture, with the causal events having occurred many years prior to the fracture. In his submission, therefore, there were no reasonable grounds to impose a latency

period of any duration between the time of calcium deficiency and the time of clinical onset (or, by extrapolation, worsening) of osteoporosis.

41. Professor Hooper submitted in his 12 February 2004 written comments about the Council's alternative altered diet factor that an appropriate diet factor would be:

> …having an altered dietary pattern resulting in average daily calcium intake of 400mg/day, or less, (ie a diet that is deficient in dairy product or calcium fortified foods) for a period of 2 years before the achievement of peak bone mass, or for a period of 10 years after that age, before the clinical onset of osteoporosis…

42. Professor Hooper considered (based on his assessment of all the information before the RMA at the relevant times) that Ralston (1997) best summarised the evidence regarding peak bone mass. Ralston concludes that there was 'dispute about the age at which peak bone mass was attained' (page 480), and that 'more longitudinal studies are required to resolve this issue conclusively' (page 480).

43. In Professor Hooper's view there are no longitudinal studies in the information that was before the RMA at the relevant times that resolve the issue of the age at which peak bone mass is attained.

44. Notwithstanding the above, in Professor Hooper's view (written submission of 12 February 2004), it is reasonable to conclude:

(1) that the proposed cut-off of a dietary calcium intake of 400mg/day is appropriate. i.e. a diet with minimal dairy intake;

(2) that the duration of deficient dietary intake include service and post service periods;

(3) that removal of the latency period is appropriate;

(4) that the time of achievement of 90% of peak bone be considered to be 18-20 years of age;

(5) that further consolidation of peak bone mass occurs subsequently;

(6) that if an individual was genetically predisposed to a low peak bone mass that calcium deficiency in late adolescence and early adult life may reduce bone density sufficiently to result in clinical osteoporosis in later life with minimal trauma fractures and associated disability.

45. Professor Hooper based his conclusions on the information before the RMA at the relevant times, and in particular the studies by Parfitt (1983) and Heaney (1982).

46. Professor Hooper made no submission concerning the definition of osteoporosis in the Statement of Principles.

Repatriation Commission's submissions

47. The Repatriation Commission made two written submissions (June 2003 and December 2003), and an oral submission complementing its June 2003 written submission.

48. The Repatriation Commission noted that more than 60% of the published articles on calcium and osteoporosis were in the form of reviews, editorial or other opinion pieces, rather than original epidemiologic investigations. The Commission noted that the information comprised in excess of 20 reports on original investigations, dated mostly from 1996, but that these represented only a sample of the wider body of literature which could have been sourced by the RMA.

49. Notwithstanding its comments in paragraph 132 of its June 2003 written submissions (that the hypothesis that a low dietary intake of calcium at any stage of life will have an adverse impact on osteoporosis risk is left open by the evidence available to (before) the RMA), the Repatriation Commission in oral submissions indicated it had not reached any final conclusion.

50. Rather, the Repatriation Commission indicated it proposed to provide a balanced assessment of the evidence in the pool which it saw in favour and against a positive association between first, low dietary calcium intake and osteoporosis, and secondly, any relevant latency period. The articles upon which the Repatriation Commission relied (which were available to (before) the RMA) are listed in Appendix E.

51. On the positive side, the Commission noted that:

> evidence is available that a calcium replete diet helps optimise peak bone mass attainment and minimise bone loss with ageing. Conversely, a calcium deficient diet can be expected to result in lower peak bone mass and/or a greater rate of bone loss with ageing. Calcium intake has influence on bone mass throughout life (paragraph 112 of the Repatriation Commission's June 2003 written submission).
>
> The evidence indirectly supports a conclusion that a low calcium diet at any time in life would have a detrimental effect on bone mass that would persist throughout life and thus contribute to any later development of osteoporosis, even if that osteoporosis first manifested decades later (at paragraph 116).

52. The Repatriation Commission agreed with Professor Hooper that there was no rationale for a latency period of four years (or any other period) before the clinical onset (or, by extrapolation, worsening) of osteoporosis. However, the

Commission (in putting the negative case) posed the question of whether the altered dietary factor should be included in the Statement of Principles at all.

53. It submitted that none of the evidence available to (before) the RMA directly addressed the question of whether a limited period of low dietary calcium intake contributed to the development of osteoporosis many years later. In particular, it submitted that what evidence there was (of the evidence available to (before) the RMA) indicated that the effects of calcium intake on bone mass and osteoporosis varied with gender and age.

54. The Commission noted there was little if any evidence available to (before) the RMA concerning young adult men, and concluded that:

> relative to their elders, young men (20 to 30-year-olds) are accruing or maintaining bone mass rather than losing it, have lower dietary calcium requirements, and are better able to compensate for a low intake (paragraph 120).
>
> The long-term consequences of a limited period of dietary calcium deficiency are unknown and cannot be extrapolated from calcium supplement studies or the available observational studies in elderly subjects. The evidence on calcium supplementation is limited to two years of follow-up after cessation of supplements (paragraph 122).
>
> The notion that a low calcium intake for a period of time in early life will contribute to osteoporosis risk later in life makes intuitive sense; the difficulty is in finding evidence, available to the RMA, that actually points to that conclusion. To reach that conclusion requires an extrapolation of the evidence (paragraph 123).

55. In its further submission of December 2003, the Commission submitted that it favours retention of the existing osteoporosis definition. The Commission noted that bone mass falls gradually with age, and to remove from the definition any reference to bone mineral density in comparison to age-matched and sex-matched controls may make compensation available to a person simply on the basis of age.

56. In the Commission's view, the stipulation of a bone mineral density that is low in comparison with peers (1.0 standard deviation below the mean bone mineral density of age-matched and sex-matched controls, in addition to a bone mineral density that is more than 2.5 standard deviations below the mean bone mineral density of young adult sex-matched controls), provides scope for service to have made a contribution to the low bone mass, and is consistent with the aim in the VEA of providing compensation for war-caused or defence-caused disease.

REASONS FOR THE COUNCIL'S DECISION

The Council's Task

57. In conducting a review the SMRC follows a two-step process. It first identifies the pool of information, ie the sound medical-scientific evidence (as that term is defined in section 5AB(2) of the VEA (see paragraph 8 above)) which touches on (ie is relevant to) the issue of whether a particular kind of injury, disease or death can be related to operational service rendered by veterans. Having identified the pool of information, the second step is to determine whether there is sound medical-scientific evidence to indicate that the particular kind of injury, disease or death can be related to operational service[4].

58. The second step requires the Council to ascertain whether the sound medical-scientific evidence available to the RMA at the relevant times pointed to (as opposed to merely leaves open)[5] the relevant possibility (whether a calcium deficient diet (if found to exist in a particular case) could provide a link or element in a reasonable hypothesis connecting osteoporosis or death from osteoporosis to operational service [6] (the relevant association)). The Council had to find that the hypothesis contended for was reasonable, and not one which was 'obviously fanciful, impossible, incredible or not tenable or too remote or too tenuous'[7].

59. It was with this test firmly at the forefront of its collective mind that the Council considered the sound medical-scientific evidence in the pool of information and the submissions made by the applicant, the applicant's representative, the expert in the field and the Repatriation Commission referable to the contended factor.

60. The Council accepted that there was no direct evidence linking a calcium deficient diet to adult-onset of osteoporosis, and accepted further the submissions of both Professor Hooper and the Repatriation Commission that such an association required an extrapolation from the sound medical-scientific evidence in the pool of information. Nevertheless, the question for the Council was whether the sound medical-scientific evidence pointed to the relevant association. In forming that judgement, the Council was conscious that the reasonable hypothesis test is 'a test of possibility'[8] and 'an unusually light burden'[9].

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[4] see full Federal Court decision at paragraph 46 per Branson J.
[5] see full Federal Court decision at paragraph 49 per Branson J.
[6] See *Vietnam Veterans' Association of Australia (NSW Branch) Inc v Specialist Medical Review Council and Anor* (2002) 69 ALD 553 (Moore J decision) per Moore J at paragraph 29.
[7] See the full Federal Court decision in *Repatriation Commission v Bey* (1997) 79 FCR 364 which cited with approval these comments from Veterans' Review Board in *Stacey* (unreported 26 June 1985), all of which were in turn cited with approval in the Moore J decision at paragraph 33.
[8] see full Federal Court decision at paragraph 49 citing with approval Spigelman CJ in the New South Wales Court of Appeal decision at paragraph 111
[9] see full Federal Court decision at paragraph 55 per Branson J

61. The Council considered it was open to it to accept indirect evidence and extrapolate from the sound medical-scientific evidence in the pool of information[10]. Accordingly, in the Council's view, the information in the pool met the requirements of section 5AB of the VEA, as it was information which epidemiologists would consider appropriate to take into account.

Pool of Information

62. As mentioned above, the first step for the Council was to determine the pool of information, ie the pool of sound medical-scientific evidence. As set out in paragraph 24 above, the Council's preliminary view was that all the information available to (before) the RMA at the times it determined, amended or last amended the Statement of Principles, should be included in the pool of information.

63. The Council's final view of the pool of information for the review did not change, and hence the Council has taken into account in this review all the information that was available to (before) the RMA when it determined, amended, or last amended the Statement of Principles, as sent to the Council by the RMA in accordance with section 196K of the VEA (see Appendix C).

64. The Council noted the Repatriation Commission's criticisms of the information relied upon by the RMA when formulating Statement of Principles Number 67 of 2002. It also noted the Repatriation Commission's references to articles which were not available to (before) the RMA (see Appendix F). As mentioned above, the Council is unable to (and so did not) consider information which was not available to (before) the RMA at the relevant times.

Scope of Review

65. The Council decided to confine its attention to those matters identified in paragraph 25 above.

THE COUNCIL'S ANALYSIS OF THE INFORMATION BEFORE THE RMA

Should There Be An Altered Dietary Factor?

66. The second question for the Council to consider was whether the sound medical-scientific evidence in the pool of information pointed to a calcium deficient diet as a link or element in a reasonable hypothesis connecting osteoporosis to operational service.

[10] see Bradford Hill, A (1965) 'The Environment and Disease: Association or Causation?' *Proceedings of the Royal Society of Medicine* Section of Occupational Medicine, Meeting January 14 pages 295 to 300.

67. The Council considered that the studies dealing with calcium supplementation were relevant. This is so, notwithstanding that up to 80% of bone mass variance in young adults is accounted for by genetic factors[11], and that other environmental determinants such as sex hormones, exercise, body weight, smoking, and alcohol and sodium intake are relevant.

68. The Council's analysis of the sound medical-scientific evidence touching upon (ie relevant to) the potential association, and that which pointed to that association as a reasonable hypothesis, is discussed below[12]. The Council holistically took into account the sound medical-scientific evidence in the pool of information. As discussed in detail below, it was persuaded by that evidence. Particular studies are discussed in more detail below.

Sound Medical-scientific Evidence Which Points to the Relevant Association

69. Ferrari et al (1998) at page 207 found what was described as a 'remarkable increase' in bone mineral density gain in the appendicular skeleton in prepubertal girls receiving 850 mg/day of calcium supplement for one year, compared with those taking a placebo. They found that calcium supplements not only positively influenced bone mineral density gain, but also bone area and height, which:

> suggest [ed] that calcium was effective on the various constituents of bone mineral mass. Although it has not yet been proven that early dietary intervention, such as increasing calcium intake in childhood, will result in a determinant increase in peak bone mineral mass, our observation of increased bone dimensions, and persistent BMD differences between calcium and placebo-treated subjects one year after cessation of the trial suggests that a higher bone mineral mass achieved during childhood might be maintained later on (at page 207).

70. Nowson, CA et al (1997) reported the findings of their double-blind, 18 month study in which one twin in each pair was randomly assigned a 1000 mg/day calcium tablet, and the other a placebo tablet.

> When the effect of calcium supplementation on BMD [bone mineral density] was compared with placebo at approximately 6, 12 and 18 months, it was found that there was a 0.015 ± 0.007 g/cm ² greater increase in BMD (1.62 ± 0.84%) at the spine in those

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[11] See Ferrari, S et al (1998) – 'Stronger correlation coefficients among adult monozygotic twins as compared to dizygotic twins are indicative of a strong genetic influence on peak bone mineral mass, accounting for as much as 80% of lumbar spine and proximal femur bone mineral density' (at page 205).

[12] The sound medical-scientific evidence that touches on the potential association includes articles in favour of, against or ambivalent as to the relevant association.

> on calcium after 18 months. At the end of the first 6 months there was a significant within-pair difference of 1.53 ± 0.56% at the spine and 1.27 ± 0 .50% at the hip. However, there were no significant differences in the changes in BMD after the initial effect of the first 6 months. Therefore, we found an increase in BMD at the spine with calcium supplementation in females with a mean age of 14 years. The greatest effect was seen in the first 6 months; thereafter the difference was maintained, but there was no accelerated increase in BMD associated with calcium supplementation (at page 219).

71. The Council considered the study persuasive. As the authors noted, the use of twins ensured the subjects were well matched for skeletal maturity and pubertal status (page 223).

72. The Council also considered persuasive the paper by Matkovic, V (1996), who noted that those who have higher bone mass as young adults may be at a lower risk of developing osteoporosis later in life, such that starting bone mass seems to be the main predictor of subsequent bone mass measurements over time (page 556).

73. Matkovic in that paper discussed his earlier 1979 study of two communities with different dietary habits. He noted that both populations were losing bone with age at about the same rate, but those who started with more bone, ended up having higher bone mass and lower incidence of hip fractures. It was concluded that: 'other things being equal, a higher peak bone mass provided a larger reserve later in life'. Further, however:

> [t]he differences in bone mass and fracture rates were attributed primarily to calcium intake. The differences in bone mass between the communities were established at an early age (30 years), implying that if calcium intake is important, it may be during skeletal growth that it has its greatest impact. This was the first proposal of the hypothesis that increasing peak bone mass by calcium supplementation during skeletal formation may contribute to osteoporosis prevention …
>
> Overall, it is likely that variations in calcium nutrition early in life may account for as much as a 5 - 10% difference in peak adult bone mass. Such a difference, although small, probably contributes to more than 50% of the difference in the hip- fracture rate later in life (at page 557).

74. Matkovic notes his findings are consistent with the conclusions of studies by Hu et al (1993) and Sandler et al (1985).

75. The Council also had regard to the study by Nattiv, A (2000) in which it was concluded that:

> [o]ne of the most important preventive interventions contributing to optimal bone health in the (sic) children and young adults is adequate calcium nutrition. Bone mineral status of children ages 2 to 16 years old has been found to be positively associated with dietary

> calcium intake (Chan, 1991). Calcium supplementation was found to enhance the rate of increase of BMD [bone mineral density] in prepubertal white children in a 3-year double-blind, placebo-controlled trial (Johnston 1992). In another study, Lloyd and colleagues (1993) noted an increase in BMD of the lumbar spine and total body in adolescent Caucasian girls with calcium supplementation (at page 273).

76. The Council also had regard to (and considered important) the findings of the NIH Consensus Conference (2001):

> The bone mass attained early in life is perhaps the most important determinant of lifelong skeletal health… maximising bone mass early in life presents a critical opportunity to reduce the impact of bone loss related to aging (sic). Childhood is also a critical time for the development of lifestyle habits conducive to maintaining good bone health throughout life (at page 788).

77. The study by Burger et al (1998) was a longitudinal study which found that high dietary calcium intake was associated with a reduced rate of decline in bone mineral density. The Council considered these conclusions consistent with other sound medical-scientific evidence in the pool of information, notwithstanding the authors noted the possibility that unknown determinants of bone loss had confounded the associations observed (although adjustments had been made for potential confounders) (see at page 875).

78. Dawson-Hughes, B (1997) reported that supplementation with calcium and vitamin D had a significant positive effect over three years on bone mineral density measured at the femoral neck, spine, and total body (page 671). The effect in men was significant.

> In both men and women, calcium-vitamin D supplementation reduced total-body bone loss not only in the first year (an effect that could be ascribed to the closure of bone-remodelling space), but also in the second and third years, suggesting long-term effectiveness of supplementation in terms of the skeleton as a whole. The initial effects of supplementation at the hip and spine during year 1 were maintained but not increased during the ensuing two years of the study (pages 674/5).

79. The study by Huuskonen, J et al (2000) found that adjusted calcium intake predicted bone mineral density in every measurement site (page 706).

80. Metz, JA et al (1993) found that calcium intake was significantly ($p < 0.05$) and positively associated with mid and distal bone mineral content and bone density (at page 539).

81. The authors concluded that:

> [c]ross-sectional data for premenopausal women support the finding that calcium has a positive impact on bone mass. Other reports, however, have shown no benefit of dietary

> calcium on bone mass. Studies showing no effect of calcium may have had methodologic problems, either by lack of statistical power or imprecise measurement of dietary variables leading to misclassification. A recent metaanalysis of calcium intake and bone mass showed a consistent positive, albeit modest association between calcium intake and bone mass. Additional studies have shown that individuals with high calcium intakes have lower rates of hip fracture compared with those with lower intakes (at page 540).

82. Kanis et al (1999) found that:

> the consumption of cheese and milk was associated with a decrease in the risk of hip fracture [in men]. The effect was more marked for cheese than for milk. In the case of milk, the curve appeared J-shaped. At scores between 6 and 9 there was a protective effect but this was of marginal significance. At the highest score the relative risk was 0.94 (NS). The intake of hard and soft cheeses was associated with a significant decrease in risk. There was not, however, a clear dose-response and a threshold effect was evident in that additional protective effects were not observed when cheese intake was high (a score of more than 3 affecting 90% of controls). The questionnaire distinguished hard cheeses from soft cheeses such as fetta. Those taking any hard cheese (91% of controls) had a markedly decreased risk of hip fracture (RR = 0.58; 95% CI = 0.40 - 0.86;p < 0.01). There was, however, no clear dose-dependent effect and high cheese intakes were not associated with additional decrements in risk. The effect of intake of hard cheeses appeared to be greater in the recent past (RR = 0.71) and in young adulthood (RR = 0.7) than in childhood (RR = 0.91). So too was the effect of soft (low calcium) cheese consumption (RR = 0.53, 0.53 and 0.63 respectively) (see at pages 49 and 50).

83. The authors acknowledged that the role of calcium nutrition in hip fractures is controversial. Nevertheless, they stated that they had found a:

> significant effect of calcium intake in the form of cheese or milk, in that higher intakes were associated with a decreased risk of hip fracture. In the case of milk intake, the highest intakes were not associated with a protective effect, particularly milk taken in the recent past. This contrasts with the protective effect we showed for the highest category of cheese intake. A possible explanation is that there may have been selection in that the most vulnerable individuals may have previously died or survivors may have increased their habitual intake (at page 52).

84. Another study upon which the Council relied (for this consideration and for a number of elements in the characterisation of the altered dietary factor) was that of the Dubbo Osteoporosis Epidemiology Study. One of the strengths of this study was that the people of Dubbo, from whom the participants in the study were drawn are representative of the Australian population at large, being 98.6% Caucasian, and 1.4% Aboriginal. Given that the data were derived from an Australian study, the findings are directly relevant to the Australian veteran population.

85. Dubbo was selected for the study site because the age and sex distribution of the population closely resembles that of the Australian population generally. Further, the city is relatively isolated in terms of medical care, so that virtually complete ascertainment of all fractures occurring in the target population is possible (see for example, Nguyen et al (2001)).

86. Nguyen et al (2000) another paper written about the Dubbo study, noted the difficulties in finding a definite association between calcium intake and bone mass in people living in the community (as distinct from animal studies).

87. Similarly to Metz et al in paragraph 81 above**,** Nguyen et al ascribed the reasons for this to previous studies not necessarily taking into account confounding factors such as weight and age, and differences in population characteristics, genetic background, variations in the ranges of calcium intakes, and differences in bone mineral density measurement methods and sites being highly variable between studies. They noted the relatively small sample sizes of studies, without adequate power to define modest associations between dietary calcium intake and bone mineral density. Nevertheless, they noted the general consensus that dietary calcium moderately reduces the rates of cortical bone loss (at page 323).

88. In their 1996 paper, again based on the Dubbo study, Nguyen et al found that a higher dietary calcium intake was associated with higher bone mineral density at both the spine and hip. However, it did not extend to an apparent decrease in the risk of fracture[13] (page 261).

89. The study by Huopio, J et al (2000) found that dairy calcium intake was significantly lower in the fracture group than the non-fracture group (see at page 222). Nevertheless, it was concluded that a low calcium consumption was not found to be an independent risk factor for fracture once there had been adjustments for covariates. It was concluded that 'this supports the hypothesis that calcium protects from fracture and that the mechanism of protection is via inhibition of bone loss' (see at page 225).

90. As mentioned above, the information in the pool was not uniformly supportive of the relevant association between calcium intake and osteoporosis, as mediated by attainment and loss of bone mass. As mentioned above, this was agreed by Professor Hooper. The equivocal or negative sound medical-scientific evidence considered important by the Council is discussed below.

[13] The Statement of Principles contains a two-fold definition – that relating to a decrease in bone mineral density, and that relating to fracture.

Sound Medical-scientific Evidence Which Merely Leaves Open or Opposes the Relevant Association

91. Meyer et al (1997) stated that they did not find any clear association between calcium intake and hip fracture. However, they found that women with an estimated high intake of non-dairy animal proteins in combination with a low calcium intake did have an increased risk of fracture (RR = 1.96 (95% confidence interval 1.09 – 3.56)).

92. The Council noted that the authors considered this study had several limitations. Primarily, it was not known how well the nutritional data described the diet in the long-term, and portion size was ignored (see at page 120). The authors acknowledged the possibility that confounding variables (smoking and other lifestyle factors) were not fully taken into account (page 122). The authors' ultimate conclusion was that a negative calcium balance was a risk factor for hip fracture.

93. Cumming, RG et al (1997) concluded that: 'we were unable to find a substantial beneficial effect of dietary calcium on fracture risk' (at page 933).

94. However, the Council considered that Cumming's conclusions may have been influenced by his subject sample, and the fact that:

> compared with women having lower dietary calcium intakes those having higher intakes were more likely to have histories of osteoporosis and fractures, to have fallen in the past year, and to use estrogen replacement therapy' (at page 929).

95. Cummings' findings for milk drinking 'were essentially the same as for overall dietary calcium [ie] no association with any type of fracture except ankle fractures' (at page 930).

96. The Council noted the qualifications put on the results of the study by the authors themselves. As noted by the Council in paragraph 94 above, the most significant was the probability that people at high risk of fractures are more likely to start taking calcium supplements than people at lower risk, such that the subjects for this study were more likely to have a history of falls, fractures, or osteoporosis.

Findings on Whether There Should be an Altered Dietary Factor

97. The Council accepted the views of Professor Hooper and the 'positive case' put by the Repatriation Commission that the sound medical-scientific evidence supports the link between a calcium deficient diet and the failure to attain peak bone mass, and adult onset of osteoporosis.

98. Considering **all** the sound medical-scientific evidence which touched on the possibility of the relevant association, the Council was of the view that the sound medical-scientific evidence in the pool of information pointed to the relevant association between calcium intake and osteoporosis (given the relevant relationships between calcium and the attainment of peak bone mass, and evidence that a higher bone mass does protect against fracture risk). The Council considered the reasonable hypothesis test for this association had been satisfied.

99. Not only was the numerical weight of studies supportive of the relevant association, but the Council considered (in the exercise of its specialist expertise and judgement) that the studies in favour of the relevant association were more sound, less impacted upon by confounding factors, and more persuasive than those studies which were ambivalent or negative.

Latency – 4 Years Prior to the Clinical Onset (or worsening) of Osteoporosis

100. The Council could find no basis for the imposition of a latency period of four years prior to the clinical onset (or worsening) of osteoporosis. In fact, it could find no basis in the pool of information for a latency period of any duration.

101. The Council noted that its views in this respect were consistent with the submissions of both Professor Hooper and the Repatriation Commission.

102. Professor Hooper in his oral submission complementing his written submission of 28 July 2003, contended that osteoporosis is a condition that 'creeps up' over many years, with the causal event or events potentially occurring many decades before the incidence of a fracture (the usual catalyst for diagnosis). On this basis, there was in his submission no reasonable ground for imposing any latency period (whether of four years or any other duration) between the time of calcium deficiency and the clinical onset (or, by extrapolation, worsening) of osteoporosis.

103. The Repatriation Commission in its written submission, submitted that 'the rationale for [the 4 year] stipulation is not readily apparent from the submission prepared by the RMA secretariat medical officer for the RMA investigation into osteoporosis.' The Repatriation Commission submitted that it 'was difficult to find justification in the evidence for the position taken by the RMA', noting that it was also difficult to justify any alternate approach. In the Commission's oral submission complementing its written submission of June 2003, the Commission conceded that latency was hard to justify, and that it was hard to 'come up with anything that would justify what the RMA had done there'.

Findings on Latency

104. Given the Council's view that there was no sound medical-scientific evidence in the pool of information which justified a latency period of four years or any other duration, the Council's view was that the latency period of four years presently specified in the Statement of Principles should be deleted.

Dosage

105. The Council considered that the dosage presently specified in the Statement of Principles (<600 mg/day) was not an appropriate level having regard to the totality of the information which was available to (before) the RMA. Further, the Council considered that most of the adult population may well fall within that dosage. The Council noted that very few people in the ordinary adult population consume the recommended daily intake of calcium[14].

106. On the basis of the following studies touching on the issue of dosage, the Council's view was that a dosage of <400 mg/day was more appropriate. In practical terms that translated to a person consuming virtually no dairy products.

107. The Council noted that both Professor Hooper and the Repatriation Commission accepted that a dosage of <400 mg/day was a reasonable level. Particularly since it correlated, in practical terms, with a person consuming virtually no dairy products. Professor Hooper accepted that level 'scientifically' and considered it 'perfectly reasonable'. The Repatriation Commission considered it was 'a good level given the data and the Australian populations from Dubbo and Geelong', recognising that data as most applicable to the veteran population.

108. The study by Alekel, DL et al (1999) considered risk factors in Indian women, given that osteoporotic fractures occur in Indian men and women 10 - 20 years earlier than in their Caucasian counterparts.

109. The Council was conscious that there were many other contributors, and that the women also suffered from vitamin D deficiency. Nevertheless, the Council considered significant the finding that calcium intake from milk during the 20s

[14] The Consensus Conference records that the National Institute of Health (NIH) recommends calcium intakes of 800 mg/day for children aged 3 to 8 years; 1300 mg/day for children and adolescents aged 9 - 17 years, and 1000 - 1500 mg/day for older adults. It is estimated that only about 25% of boys and 10% of girls aged 9 - 17 meet these recommendations and only about 50% - 60% of the adult population meet the recommendation (at page 789).
Prestwood, KM et al (1998) consider that calcium intake is below 800 mg/day in 60% of adult men in the United States, and below 500 mg/ day in 25%. The authors state that about 900 mg/day is required to ensure calcium balance in 90% of male subjects (see at page 591).

was the second most important factor to femoral BMD, contributing almost 10% of the variance (see at pages 333 and 335).

110. It was noted that the calcium intake for Indian women was (only) 350 mg/day.

111. The article by Lau et al (2001) was a study considering a calcium intake of < 498 mg/day. At this dosage, those men and women whose dietary calcium intake was in the lowest three-quartiles (ie lower than 498 mg), had an increase in the relative risk of hip fracture ranging from 1.6 – 3 (at page 574).

112. Lau cites Holbrook et al (1988) as having found that women whose dietary calcium intake was below 440 mg/day had an RR of 2.5 for hip fracture (at page 579).

113. Meyer, HE et al (1997) reported the outcomes of their large Norwegian study. It was found that women with a calcium intake of < 435 mg/day had an increased risk of hip fracture compared to those with higher intakes. However, this was only if they also had a high non-dairy protein intake, which is likely to affect calcium losses.

114. In the Dubbo study (Nguyen et al 2001) the lowest dosage of calcium consumed by men was 436 mg/day. At that dosage men were twice as likely to be osteoporotic than those in the top tertile (> 710 mg/day). Higher dietary calcium intake was associated with higher BMD in both the spine and the hip, and dietary calcium intake was inversely related to age (for men but not women, see at page 594). Those with 300 mg/day had a significant increase, almost a doubling, of the risk of wrist and forearm fracture.

115. The authors noted that measurements of, among other things, dietary calcium intake at a single time point included measurement errors, and could have **under-estimated** the true association between this (and other) factors and fracture risk. The possibility for selection bias was also noted, in that the subjects who participated in the study were healthier than those who did not (at page 594).

116. Heaney, RP (1991) cites the largest body of evidence concerning calcium intake and age related bone loss as the study of Dawson-Hughes et al (1990) of women five years postmenopausal, which he considers the largest and best controlled study reported to that date. At a calcium intake of 400 mg/ day, unsupplemented women lost bone at a substantial rate, whereas supplemented women had little or no loss at any site (see at page 25S and Table 3). The loss was quite rapid.

Findings on Dosage

117. On the basis of the totality of the information in the pool, and particularly the sound medical-scientific evidence discussed above, the Council was of the view

(a view shared by Professor Hooper and the Repatriation Commission) that the sound medical-scientific evidence in the pool of information pointed to, as opposed to leaving open as a mere possibility, the appropriate dosage being an average daily calcium intake of 400 mg/day or less, rather than that of 600 mg/day or less as presently specified in the Statement of Principles.

Age at Which Exposure to a Calcium Deficient Diet Must Have Occurred

118. In the Council's view, the crucial time for exposure to a calcium deficient diet to occur is prior to the achievement of peak bone mass. There is academic debate as to the point at which peak bone mass is achieved, and there was considerable discussion at the hearing of oral submissions as to the time at which peak bone mass is attained. To some extent, it depends on the age at which each individual reaches puberty.

119. Professor Hooper, recognising that it was very difficult to pinpoint a precise age, contended there could be some argument that the early 20s should be specified, rather than 18 years (which was the Council's initial tentative view). Professor Hooper acknowledged the matter was the subject of debate, and that there was an inevitable element of arbitrariness whatever age was specified.

120. The Repatriation Commission submitted that the age by which 90% of peak bone mass is achieved is 20 years of age (paragraph 35 of its written submission of July 2003).

121. The sound medical-scientific evidence touching on this issue is discussed below.

122. Metz, JA et al (1993) goes so far as to say that:

> the precise timing of peak bone mass at specific skeletal sites is uncertain although reports have indicated that bone mass may peak any time during the second, third, or fourth decades, and the timing differs for compact and cancellous bone tissue. Bone mass of the lumbar vertebrae has been shown to peak as early as the second decade, however, Krolner and Nielsen reported that maximum lumbar mass was reached at age 34 y[ears]. Other studies have shown little effect of age beyond 20 y[ears] on midradial bone density in premenopausal women. These findings suggest that compact bone may also peak relatively early, ie , by the late second or early third decade of life.
>
> Ninety to 95% of bone mass is attained by the end of longitudinal growth (18 y[ears] of age) but an additional 5 - 10% of bone mass can be accrued after maximum height has been achieved. Although bone mass achieved by early adulthood primarily reflects bone mass achieved during growth, the additional gain in bone mass that may potentially occur is likely to be dependent on lifestyle factors practised during young adulthood (at page 537).

123. Matkovic (1996) goes further, and cites his 1995 study as supportive of the contention that by age 14 values for bone size, mass, and density of adolescent girls are similar to the corresponding values of their mothers, and thereafter, longitudinal bone growth diminishes while consolidation continues. He adds that by age 16 years, most epiphyses are closed (see at page 559).

124. Matkovic (1996), in that paper (reporting his finding in his 1994 study), having assessed bone mass and bone mineral density using dual x-ray absorptiometry and single photon absorptiometry at the spine, proximal femur, radius shaft, distal forearm and whole body, concluded that most of the bone mass at multiple skeletal locations is accumulated by late adolescence (at page 559). Bone mineral density of the proximal femur and vertebral body was shown to begin to decline immediately following peak bone mass formation at the age of approximately 18 years.

125. Nowson, CA et al (1997) concluded that peak bone mass is achieved at about 16 years in females, after which there is no appreciable increase (at page 219). The authors also noted that the achievement of peak bone density differs between boys and girls, with girls having a steep rise, particularly at the spine, at about age 12 years. The greatest increase in bone density in boys occurs later at about age 13 years, and the rate of increase is not as great as in girls (page 223).

126. The Council considered the information in the pool pointed to at least 90% of peak bone mass having been achieved by 18 to 20 years in males. It is potentially slightly earlier (16 - 18 years) in females, see Ferrari S et al (1998) who concluded that:

> [b]y the age of 16 to 18 years in females, and 18 to 20 years in males, bone mineral mass growth virtually ceases, but a marked scattering of BMD [bone mineral density] values for both genders is then apparent across the population (at page 206).

The variance was ascribed to genetic factors.

127. The NIH Consensus Conference (2001) concluded that:

> The bone mass attained early in life is perhaps the most important determinant of lifelong skeletal health (at page 788).

128. Prestwood, KM et al (August 1998) consider that in women, bone mass increases rapidly from the time of puberty until approximately the mid-20s and mid-30s, at which time peak bone mass is achieved (page 579).

129. Weighing the totality of sound medical-scientific evidence in the pool of information, and recognising that there may be variations on a case-by-case basis, the Council considered that the preponderance of relevant evidence

supported the attainment of at least 90% of peak bone mass, at the latest, for both males and females, by 18 to 20 years of age.

130. The Council noted the studies by Heaney (1982) at page 1086, Ralston (1997) at page 480 and Parfitt (1983) at page 1181 which raise the possibility of the consolidation of a remaining proportion (up to 10%) of peak bone mass achieved over an extended period up to 35 – 40 years of age. However, the Council considered this evidence was not strong, noting that at most a modest effect of low calcium intake could constitute a small effect on a small amount of additional bone consolidated.

Findings of the Age by which Exposure to a Calcium Deficient Diet Must Occur

131. The Council's initial view was that 18 years was that which was the most appropriate to specify as the age by which peak bone mass had been achieved, and so the age to include as the initial age by which the exposure to a calcium deficient diet must occur. However, taking into account Professor Hooper's and the Repatriation Commission's submissions (together with the totality of the sound medical-scientific evidence in the pool of information, particularly that discussed above), the Council's final decision was that the sound medical-scientific evidence pointed to the appropriate age by which the exposure to a calcium deficient diet must have occurred as 20 years.

132. The Council considered, on the basis of the sound medical-scientific evidence in the pool of information, and particularly that discussed above, that the sound medical-scientific evidence pointed to the attainment of at least 90% of peak bone mass by 20 years, with a subsequent period of consolidation.

Duration of Deficiency

133. Given its views on the age by which the initial 90% of peak bone mass is attained, and the longer period of consolidation, the Council considered that the altered dietary factor should specify a short duration of deficiency prior to the attainment of peak bone mass, and a longer period of deficiency thereafter.

134. The reason for a short period prior to the attainment of peak bone mass relies upon the sound medical-scientific evidence in the pool of information pointing to the maximisation of peak bone mass as a protection against osteoporosis. In the Council's view, the discussion in paragraphs 69 - 99 above pertains to this issue. The sound medical-scientific evidence analysed in those paragraphs, in the Council's view, points to, as opposed to merely leaves open, the conclusion that a calcium deficient diet prior to the attainment of peak bone mass has a long-lasting impact. This is so, although the Council notes that it is not known whether deficits in intake in one phase of growth can be repaired later, or how long the

opportunity for such repair may last (Matkovic (1996) at page 566 and Parfitt (1983) at page 1181).

135. The Council considered that the impact of a calcium deficient diet after the attainment of peak bone mass, was significantly less. Accordingly, a longer period of exposure was, in the Council's view appropriate. The Council considered that after the achievement of peak bone mass there was evidence of some responsiveness (albeit small) of the skeleton to calcium intake. The Council considered the period of exposure to a calcium deficient diet after the achievement of peak bone mass must therefore be considerably longer (than prior to the achievement of peak bone mass) to have a sustained and significant effect.

136. Professor Hooper, in his oral submission, complementing his written submission of 28 July 2003, considered it 'perfectly reasonable to have a shorter period [of exposure] before achieving peak bone mass and a longer period after achieving peak bone mass.' The Repatriation Commission similarly considered that 'differentiating prior to peak bone mass attainment … - and separating that out from subsequent [was] a good approach.'

137. The Council's initial view was that prior to the attainment of peak bone mass, the period of exposure should be 2 years, and thereafter, it should be 10 years. The Council considered that a shorter period than 2 years prior to the attainment of peak bone mass would not have a sustained effect, i.e., an effect that could not subsequently be reversed by a diet with an adequate calcium intake.

138. With respect to the period of exposure after the attainment of peak bone mass, the Council took into account the Repatriation Commission's comments that the proposed 10-year period was 'possibly a bit harsh', and closer to the (more stringent) 'on-balance standard of proof'. The Council's final decision was that the period of exposure after the attainment of peak bone mass should be set at 7 years.

139. The Repatriation Commission in its oral submissions identified one potential difficulty which the Council had been considering when formulating its tentative view as to the altered dietary factor (the Council having already formed the tentative view that a calcium deficient diet was a link or element in a reasonable hypothesis connecting osteoporosis to operational service). That issue was the difficulty of dealing with those veterans whose exposure to calcium deficiency spanned the specified ages for the attainment of peak bone mass, ie, those veterans who had a period (but not 2 years) of exposure prior to 20 years of age, and a period (not 7 years) subsequent to the attainment of peak bone mass at 20 years of age.

Findings on Duration of Deficiency

140. The Council's intention in formulating the different periods of exposure prior and subsequent to the attainment of peak bone mass was that such exposure should be cumulative, regardless of the age at which it commenced. Nevertheless, the altered factor needed to reflect the reduced significance of exposure after the attainment of peak bone mass (for the reasons discussed above).

141. The Council took into account the Repatriation Commission's suggestion for addressing this issue[15]. However, the Council ultimately determined that the preferable way of reflecting its intention was to specify that one year of exposure before age 20 is equivalent to 3.5 years of exposure after age 20.

Definition

142. The Statement of Principles contains a two-part definition of osteoporosis which relevantly provides as follows:

> Osteoporosis is considered to be present when:
>
> (i) bone mineral density is 2.5 standard deviations below the mean bone mineral density of young adult sex-matched controls, and bone mineral density is 1.0 standard deviation below the mean bone mineral density of age-matched and sex-matched controls; or
>
> (ii) there is radiological evidence of a fracture together with radiological evidence of reduced bone density in the region of the fracture prior to or at the time of the fracture.

143. The Council had no issue with the second component of the definition dealing with fracture. The discussion which follows concentrates upon the Council's consideration of the first component of the definition, that dealing with bone mineral density measurement.

144. The definition by reference to bone mineral density measurement, allowing diagnosis and treatment of osteoporosis before incident fracture, was made possible by the World Health Organisation (WHO) in 1994 (see Prestwood, KM et al (1998) at page 578).

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[15] The Repatriation Commission's suggestion was that the difficulty could perhaps be overcome by setting an age at which the exposure to the deficiency commences. For example, assuming the age was to be set at 20 years, the potential factor would have stated (adopting the Repatriation Commission's suggestion) that the exposure to the deficiency should commence at age 18 for a period of 2 years.

145. As mentioned above, in the course of its deliberations, the Council formed the preliminary view that the definition in paragraph 2 (b) (i) of the Statement of Principles concerning bone mineral density measurement was incorrect. In the Council's view, the correct definition (for this segment of the two-part definition, the other relating to fracture) should be internationally accepted, and so consistent with that used by the WHO and the National Institutes of Health (2001) (NIH).

146. The NIH Consensus Conference (2001) expressed this as 'bone density 2.5 standard deviations below the mean for young white adult women'. Nguyen et al (2000) at page 324 expressed it as '2.5 standard deviations below the young normal mean, taken as aged between 20 and 30 years old'.

147. The Council noted that the Repatriation Commission (see paragraphs 55 - 56 above) favoured retention of the existing osteoporosis definition. The Commission noted that bone mass falls gradually with age and to remove from the definition any reference to bone mineral density in comparison to age-matched and sex-matched controls may make compensation available to a person simply on the basis of age.

148. The Council understood the Repatriation Commission's concerns, and that the bone mineral density component of the definition may have been inserted into the Statement of Principles to adapt the WHO definition for compensation purposes because of the frequency of Osteoporosis in the elderly[16].

149. However, the Council considered that the reference in the bone mineral density component of the definition to '1.0 standard deviation below the mean bone mineral density of age-matched and sex-matched controls' was new, and not supported by sound medical-scientific evidence in the pool of information (or at all). It does not comprise any part of the WHO or NIH definitions.

150. The Council remained of the view that the bone mineral density component of the definition should accord with that which was internationally accepted, and supported by sound medical-scientific evidence. Accordingly, the Council decided that the bone mineral density component of the definition should be changed.

Findings on Definition

151. The Council concluded that the appropriate definition to include in the relevant limb of the definition section of the Statement of Principles is:

[16] RMA Medical Officer Supplementary Submission of 10/06/1997 to the RMA titled Osteoporosis, sub title Definition of osteoporosis pages 1-24 at page 2.

bone mineral density is more than 2.5 standard deviations below the mean bone mineral density of young adult sex-matched controls.

THE COUNCIL'S CONCLUSIONS

Final Characterisation of New Altered Dietary Factor

152. The Council, having considered all the sound medical-scientific evidence in the pool of information which touched on whether there should be an altered dietary factor and on the various elements of the altered dietary factor presently in Statement of Principles number 67 of 2002 (in paragraphs 5(p) and 5(zf)), decided that:

(i) there should be an altered dietary factor; and

(ii) the dietary factor as presently set out in the Statement of Principles should be removed in its present form (in paragraphs 5 (p) and 5 (zf)), and should be replaced with the following:

5(p) having an altered dietary pattern resulting in a decrease in average daily calcium intake to 400 mg/day or less, for a period of 2 years before age 20 years, or for a period of 7 years after that age, or the equivalent combination thereof, before the clinical onset of osteoporosis.

5(zf) having an altered dietary pattern resulting in a decrease in average daily calcium intake to 400 mg/day or less, for a period of 2 years before age 20 years, or for a period of 7 years after that age, or the equivalent combination thereof, before the clinical worsening of osteoporosis.

(iii) The following definition should be inserted:

'or the equivalent combination thereof' in paragraphs 5(p) and 5(zf) means:

a calculation where one year of exposure before age 20 years is equivalent to 3.5 years of exposure after age 20.

(iv) The definition in paragraph 2 (b) (i) should read:

bone mineral density is more than 2.5 standard deviations below the mean bone mineral density of young adult sex-matched controls.

DECISION

153. The Council made the directions in paragraph 2 above.

EVIDENCE BEFORE THE COUNCIL

Documents

154. The information considered by the Council (being the information that was available to (before) the RMA and sent to the Council by the RMA in accordance with section 196K of the VEA) was as is listed in Appendix C.

155. As mentioned above, the information upon which Professor Hooper and the Repatriation Commission relied (being information which was available to (before) the RMA and sent to the Council by the RMA in accordance with section 196K of the VEA was as is listed in Appendices D and E respectively.

156. The information to which the Repatriation Commission referred (being information which was not available to (not before) the RMA, and so was not considered by the Council in reaching its decision) is listed in Appendix F.

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Appendices

Appendix A	A depersonalised copy of the Council's letter to the applicant dated 28 November 2003.
Appendix B	A depersonalised copy of the Council's letter to the Repatriation Commission dated 28 November 2003.
Appendix C	All the information available to (before) the RMA.
Appendix D	The information upon which Professor Hooper relied, which was available to (before) the RMA.
Appendix E	Information upon which the Repatriation Commission, relied which was available to (before) the RMA.
Appendix F	Information to which the Repatriation Commission referred, which was not available to (not before) the RMA.

Appendix A

Friday, 28 November 2003

[name]
C/- Legal Aid Commission
Veterans' Advocacy Service
PO Box K847
HAYMARKET 1238

Dear [name]

1. I refer to the Council's review of Statement of Principles No. 67 of 2002, in respect to **osteoporosis,** requested by you.

2. Please find enclosed a copy of the transcript of the oral submissions (the transcript), complementing the written submissions, made at the Council's meeting of 12 November 2003 in Sydney.

Written Submission/s Subsequent to Hearing

3. At the hearing of oral submissions on 12 November 2003, Dr Phillips (as Convener of the Osteoporosis Review Council) indicated that the Council had formulated a tentative alternative altered diet factor (see the transcript at page 11). This tentative alternative formulation was written on the white board at the hearing. Quoted below is the formulation from the whiteboard:

> Having an altered dietary pattern resulting in a decrease in average daily calcium intake of 400mg/day, or less, for a period of 2 years before the age of 18 years, or for a period of 10 years after that age, before the clinical onset of osteoporosis.

4. Further, Dr Phillips stated (see transcript at page 11) that the Council had taken particular note of articles by Lau, Nguyen, Meyer and Heaney, and invited the presenters of oral submissions to make comments on the proposed alternative formulation should they wish to do so.

5. It was subsequently agreed by the Council that Professor Hooper and the Repatriation Commission would have the opportunity to consider again the information which was before the RMA (and so the Council), and to make a written submission (should they wish to do so) addressing the Council's tentative alternative formulation and other matters raised by Dr Guest and other Councillors.

6. If you or your representative (name), and/or Professor Michael Hooper do wish to make a written submission/s addressing the tentative alternative altered diet factor, and the other matters discussed below, please ensure any such submission is received at the address on page 1 by close of business on 2 January 2004.

7. Any such written submissions should be limited to:

   a) the Council's tentative alternative altered diet formulation as set out above;

   b) Professor Hooper's[17] appraisal of the best evidence in the information before the RMA (and so the Council) (as sent to you under cover of Council's letter of 11 April 2003) **in favour of or against the propositions**:

      (i) that calcium restriction in early adult life leads to clinically significant osteoporosis in later life (see the transcript at page 19 – Dr Guest to Professor Hooper);

      (ii) that peak bone mass is achieved at 18 years; and

         a. the level of deficiency before that time and duration of exposure (which the Council understands Professor Hooper agrees should be 400 mg per day, and should be a short time before the achievement of peak bone mass which he suggested ordinarily occurred between 18 - 20, two years being appropriate (see transcript pages 13, 15 and 17)); and

         b. the level of deficiency after that time and duration of exposure (which the Council again understands Professor Hooper agrees should be 400 mg per day and a longer period of time after the achievement of peak bone mass, 10 years being appropriate); and

         c. that a period of consolidation occurs after the achievement of peak bone mass (and if so, at what age does it begin and end).

Reply to Dr Kelley's Oral Submission

8. The Council notes that Professor Hooper was not present (due to having another commitment) during Dr Kelley's oral submission, complementing the Repatriation Commission's written submission (which commences at page 22 of the transcript).

[17] I have referred to Professor Hooper, as I anticipate he will be best placed to respond to these issues. Of course, that does not preclude any comment from you and/or your representative, [name], on these issues.

9. The Council notes particularly Dr Kelley's response to Dr Guest at page 24 of the transcript and following as to a nutritional deficiency during service potentially affecting a veteran's post-service diet such that the 10 year period (or whatever duration period is ultimately specified) may not necessarily need to be during service.

10. If Professor Hooper wishes to make any comments in reply to Dr Kelley's oral submissions, could he similarly address them in any written submission to be provided by close of business on 2 January 2004. (Council notes that [name] exercised a right of reply at the conclusion of Dr Kelley's submissions).

11. If any written comments are made with respect to the above matters, the Council requests that reference be made to the results of the studies and the facts, and not to the authors' opinions or interpretations of the data in the studies (see transcript at page 18 – per Councillor Dr Guest).

Proposed Change to the Definition of Osteoporosis

12. A separate matter arose during the Councillors' deliberations after the conclusion of the oral hearing. Again, in the event you, [name] or Professor Hooper wish to make any comments, please ensure they are incorporated in any written submission provided by close of business on 2 January 2004.

13. The Councillors are of the preliminary view that the definition of osteoporosis in the Statement of Principles concerning osteoporosis number 67 of 2002 is (partially) incorrect. They are of the present view that paragraph 2 (b) (i) of that definition should be amended (consistent with the definition adopted by the World Health Organisation and the National Institutes of Health) to read (only):

> bone mineral density is more than 2.5 standard deviations below the mean bone mineral density of young adult sex-matched controls

Limitations on Use of Transcript

14. The transcript has been prepared by Auscript Pty Ltd. The Council puts on record that understandably enough, given the technical nature of much of the material, there may be some (few) occasions when the transcription may not be an entirely accurate reflection of what was said or by whom.

15. Of course, the transcript is just that, a transcript of the oral submissions, complementing the written submissions, made at the Council's meeting on 12 November 2003 in Sydney. In no way should the transcript or any specific comment within it, be construed as representing a (final) decision by the Council.

Where to from Here

16. As foreshadowed at the hearing, the Council has also given the Repatriation Commission the opportunity to comment on these matters.

17. The Council will proceed to make a final decision on the basis of all the information before it (which it may take into account under the *Veterans' Entitlements Act 1986*) and any written submissions on the matters discussed above received at the address on page 1 as at close of business on 2 January 2004.

18. Once the Council's review regarding osteoporosis is complete, a copy of the Declaration is placed in the Commonwealth Notices Gazette and a number of copies of that Declaration and the Council's Reasons for Decision regarding osteoporosis will be posted to you. As stated at the hearing, the Council does not expect to gazette a decision for at least 3 months.

19. Thank you for your representative's and Professor Hooper's attendance at the hearing and their contribution to the review.

20. Please feel free to contact me on 03 9284 6784 in regard to this review.

Yours sincerely

B.John O'Connor Whyte
A/G REGISTRAR

Appendix B

Friday, 28 November 2003

[name]
President
Repatriation Commission
PO Box 21
WODEN ACT 2606

Dear [name],

1. I refer to the Council's review of Statement of Principles No. 67 of 2002, in respect to **osteoporosis,** requested by [a veteran].

2. Please find enclosed a copy of the transcript of the oral submissions (the transcript), complementing the written submissions, made at the Council's meeting of 12 November 2003 in Sydney.

Written Submission Subsequent to Hearing

3. At the hearing of oral submissions on 12 November 2003, Dr Phillips (as Convener of the Osteoporosis Review Council) indicated that the Council had formulated a tentative alternative altered diet factor (see the transcript at page 11). This tentative alternative formulation was written on the white board at the hearing. Quoted below is the formulation from the whiteboard:

> Having an altered dietary pattern resulting in a decrease in average daily calcium intake of 400mg/day, or less, for a period of 2 years before the age of 18 years, or for a period of 10 years after that age, before the clinical onset of osteoporosis.

4. Further, Dr Phillips stated (see transcript at page 11) that the Council had taken particular note of articles by Lau, Nguyen, Meyer and Heaney, and invited the presenters of oral submissions to make comments on the proposed alternative formulation should they wish to do so.

5. It was subsequently agreed by the Council that Professor Hooper would have the opportunity to consider again the information which was before the RMA (and so the Council), and to make a written submission (should he wish to do so) addressing the Council's tentative alternative formulation and other matters raised by Dr Guest and other Councillors. As a matter of procedural fairness, this opportunity was also afforded to the Repatriation Commission, notwithstanding Dr Kelley's comprehensive responses to the Council's questions.

6. If the Commission does wish to make a written submission addressing the tentative alternative altered diet factor, and the other matters discussed below, please ensure any such submission is received at the address on page 1 by close of business on 2 January 2004.

7. Any such written submission should be limited to:

   (a) the Council's tentative alternative altered diet formulation as set out above;

   (b) the Commission's appraisal of the best evidence in the information before the RMA (and so the Council) (as sent to it under cover of Council's letter of 11 April 2003) **in favour of or against the propositions**:

      (i) that calcium restriction in early adult life leads to clinically significant osteoporosis in later life (see the transcript at page 31 – Dr Guest to Dr Kelley);

      (ii) that peak bone mass is achieved at 18 years; and

         a. the level of deficiency before that time and duration of exposure (which the Council understands the Commission agrees should be 400 mg per day, and should be a short time before the achievement of peak bone mass which the Commission agreed ordinarily occurs between 18 - 20, two years being appropriate (see transcript at pages 24 and 33)); and

         b. the level of deficiency after that time and duration of exposure (which the Council again understands the Commission agrees should be 400 mg per day and a longer period of time after the achievement of peak bone mass, 10 years being in the Commission's view 'possibly a bit harsh' and more appropriate to the balance of probabilities standard of proof (see transcript at pages 34-5)); and

         c. that a period of consolidation occurs after the achievement of peak bone mass (and if so, at what age does it begin and end).

8. If any written comments are made with respect to the above matters, the Council requests that reference be made to the results of the studies and the facts, and not to the authors' opinions or interpretations of the data in the studies (see transcript at page 18 – per Councillor Dr Guest).

Proposed Change to the Definition of Osteoporosis

9. A separate matter arose during the Councillors' deliberations after the conclusion of the oral hearing. Again, in the event the Commission wishes to make any

comments, please ensure they are incorporated in any written submission provided by close of business on 2 January 2004.

10. The Councillors are of the preliminary view that the definition of osteoporosis in the Statement of Principles concerning osteoporosis number 67 of 2002 is (partially) incorrect. They are of the present view that paragraph 2 (b) (i) of that definition should be amended (consistent with the definition adopted by the World Health Organisation and the National Institutes of Health) to read (only):

> bone mineral density is more than 2.5 standard deviations below the mean bone mineral density of young adult sex-matched controls

11. The Council notes the Commission used this definition in its written submission at page 20 paragraph 127.

Limitations on Use of Transcript

12. The transcript has been prepared by Auscript Pty Ltd. The Council puts on record that understandably enough, given the technical nature of much of the material, there may be some (few) occasions when the transcription may not be an entirely accurate reflection of what was said or by whom.

13. Of course, the transcript is just that, a transcript of the oral submissions, complementing the written submissions, made at the Council's meeting on 12 November 2003 in Sydney. In no way should the transcript or any specific comment within it, be construed as representing a (final) decision by the Council.

Where to from Here

14. As foreshadowed at the hearing, the Council has also given [the applicant], his representative and/or Professor Hooper the opportunity to comment on these matters.

15. The Council will proceed to make a final decision on the basis of all the information before it (which it may take into account under the *Veterans' Entitlements Act 1986*) and any written submissions on the matters discussed above received at the address on page 1 as at close of business on 2 January 2004.

16. Once the Council's review regarding osteoporosis is complete, a copy of the Declaration is placed in the Commonwealth Notices Gazette and a copy of that Declaration and the Council's Reasons for Decision regarding osteoporosis will be posted to the Commission. As stated at the hearing, the Council does not expect to gazette a decision for at least 3 months.

17. Thank you for Dr Kelley's attendance at the hearing and his contribution to the review.

18. Please feel free to contact me on 03 9284 6784 in regard to this review.

Yours sincerely

B. John O'Connor Whyte
A/G REGISTRAR

Electronic Copies to:
[name] BH DC
[name] SH BDMS
[name] SMO BDMS DSU

Appendix C

SMRC Folder No	Title No.	Title
3	1	Medline Abstracts 1/95 – 9/95 Records 1-309
3	2	Medline Abstracts 1/95 – 9/95 Records 1-701
4	1	Gruber HE, Gutteridge DH and Baylink DJ. (1984) Osteoporosis associated with pregnancy and lactation: bone biopsy and skeletal features in three patients. *Metab Bone Dis & Rel Res*, Vol 5, pp 159-165.
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4	5	Goulding A. (1981) Fasting urinary sodium/creatinine in relation to calcium/creatinine and hydroxyproline/creatinine in a general population of women. *NZ Med J*, Vol 93, pp 294-297.
4	6	Gough AK, Lilley J, Eyre S, Holder RL and Emery P. (1994) Generalised bone loss in patients with early rheumatoid arthritis. *Lancet*, Vol 344(8914), pp 23-27.
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4	8	Gallagher JC, Kable WT and Goldgar D. (1991) Effect of progestin therapy on cortical and trabecular bone: comparison with estrogen. *The American Journal of Medicine*, Vol 90, February, pp 171-178.
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4	14	Drinkwater BL, Nilson K, Ott S, and Chesnut CH III. (1986) Bone mineral density after resumption of menses in amenorrheic athletes. *JAMA*, Vol 256(3), pp 380-382.
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4 and 12	17 and 56	Diamond T, Vine J, Smart R and Butler P. (1994) Thyrotoxic bone disease in women: a potentially reversible disorder. *Annals of Internal Medicine*, Vol 120(1), pp 8-11.
4	18	Dequeker J and Geusens P. (1990) Osteoporosis and arthritis. *Ann Rheum Diseases*, Vol 49, pp 276-280.
4	19	De Gennes C, Kuntz D and Vernejoul M. (1992) Bone Mastocytosis. A report of nine cases with a bone histomorphometric study. *Clinical Orthopaedics and Related Research*, No 279, June, pp 281-291.
4	20	Davies KM, Pearson PH, Huseman CA, Greger NG, Kimmel DK and Recker RR. (1990) Reduced bone mineral in patients with eating disorders. *Bone,* Vol 11, pp 143-147.

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Appendix D

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Appendix F

Title

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