Specialist Medical Review Council

Reasons for Decision

Section 196W
Veterans' Entitlements Act 1986

Re: Statements of Principles Nos. 245 of 1995 and 246 of 1995
Matter No. 95/2

DECISION

The Specialist Medical Review Council ('the Review Council') established pursuant to Part X1B of the *Veterans' Entitlements Act 1986* ('the Act'), having reviewed the contents of the Statements of Principles numbered 245 and 246 of the 1995 made under section 196B of the Act by the Repatriation Medical Authority ('RMA') established under Part X1A of the Act, on October 1996 declared

a) that it was of the view that the sound medical-scientific evidence available to the RMA at the time it made the Statement of Principles No 245 of 1995 was insufficient to justify the making of an amendment to that Statement of Principles;

b) that it was of the view that the sound medical-scientific evidence available to the RMA at the time it made the Statement of Principles No 246 of 1995 was insufficient to justify the making of an amendment to that Statement of Principles;

c) that it recommended that the RMA further investigate exposure to solvents as a possible factor for the purposes of subsections 196B(2) and 196B(3) of the Act, having regard to the reasons for decision of the Review Council in its review of the above Statements of Principles, the information that was available to the RMA when it made those Statements together with any further information which has since become available to the RMA and which may become available between the date of the Declaration and the completion by the RMA of its investigation.

FINDINGS ON MATERIAL QUESTIONS OF FACT

Events giving rise to the review

2. On 21 June 1995, the Repatriation Medical Authority, under subsections 196B(2) and (3) of the *Veterans' Entitlements Act 1986* (the Act), signed and therefore determined Statements of Principles, Instruments Nos. 245 and 246, respectively, of 1995. Those Statements of Principles each concerned motor neuron disease and death from motor neuron disease.

3. In accordance with section 196D of the Act and sections 46A and 48 of the *Acts Interpretation Act 1901*, on 26 June 1995 those Statements of Principles were tabled in both the House of Representatives and the Senate (House of Representatives 1995, *Debates*, vol. HR202, p.2326, Senate 1995, *Debates*, vol.S172, p.1788), and on 28 June ,1995 the making of those instruments was notified in the *Gazette* (No. GN 25, 28 June 1995, p.2376).

4. On 29 August 1995, a request (No. 95/2) was made under section 196Y of the Act by the Vietnam Veterans Association of Australia (NSW Branch) (VVAA (NSW)) for a review by the Review Council of the contents of instruments numbered 245 and 246 of 1995. The request was lodged with the Department of Veterans' Affairs.

5. On 31 August the Secretary of the Department of Veterans' Affairs advised the Specialist Medical Review Council and the Repatriation Medical Authority of the receipt of the application.

6. On 4 October 1995, in accordance with section 196ZB of the Act, the Review Council published a notice in the *Gazette* (No. GN 39, 4 October 1995, p.3754) stating that it intended to carry out a review of the information available to the Repatriation Medical Authority about motor neuron disease and death from motor neuron disease, and inviting persons or organisations authorised under subsection 196ZA(1) of the Act to make written submissions to the Review Council.

7. Subsection 196W(3) of the Act provides that the Review Council may carry out a review only if the period within which the Statement of Principles may be disallowed under section 48 of the *Acts Interpretation Act 1901* has ended and the Statement of Principles has not been disallowed. The disallowance period ended upon the expiration of 25 September 1995 this being the 15th sitting day after the tabling of those Statements of Principles in the House of Representatives and in the Senate. Neither of the Statements of Principles was disallowed.

The Review Council

8. The Specialist Medical Review Council is a body corporate established under section 196V of the Act 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 functions of the Review Council. The Minister must appoint one of the Councillors to be the Convener.

9. When a review is undertaken of a Statement of Principles made by the Repatriation Medical Authority, the Review Council is constituted by between three and five councillors selected by the Convener.

10. 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 Review Council for review.

11. Professor Cohen was the Convener of the Review Council for this review. He is a former Chairman of the Committee of Presidents of Medical Colleges, a past President of the Royal Australian College of Physicians as well as the Director of Post Graduate Medical Education at Sir Charles Gardiner Hospital. Professor Edward Byrne is Professor of Clinical Neurosciences in the University of Melbourne at St Vincent's Hospital and is an epidemiologist and medical scientist who has researched this disorder. Dr David Williams is a Staff Specialist Neurologist at the John Hunter Hospital in Newcastle. He was awarded a PhD from the University of Sydney on the topic of "Genetic factors in Motor Neuron Disease" and has undertaken original work concerning the genetics, molecular biology and epidemiology of motor neuron disease. He was a member of member of the Co-operative Research Group on Familial Amyotrophic Lateral Sclerosis and made a major clinical contribution to the identification of the Super-oxide Dismutase (SOD) enzyme mutation responsible for familial motor neuron disease.

The Legislation

12. The legislative scheme for the making and review of Statements of Principles is set out in Parts X1A and X1B of the Act.

13. Section 196B relevantly provides:-

> (1)……..
>
> (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.
>
> Note 1: For "sound medical-scientific evidence" see subsection 5AB (2).
> Note 2: For "peacekeeping service", "member of a Peacekeeping Force", "hazardous service" and "member of the Forces" see subsection 5Q (1A).
> Note 3: For "factor related to service" see subsection (14).
>
> (3) If the Authority is of the view that on the sound medical-scientific evidence available it is more probable than not that a particular kind of injury, disease or death can be related to:
> (a) eligible war service (other than operational service) rendered by veterans; or
> (b) defence service (other than 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:
> (c) the factors that must exist; and
> (d) which of those factors must be related to service rendered by a person;
> before it can be said that, on the balance of probabilities, an injury, disease or death of that kind is connected with the circumstances of that service.
>
> Note 1: For "sound medical-scientific evidence" see subsection 5AB (2).
> Note 2: For "defence service" and "hazardous service" see subsection 5Q (1A).
> Note 3: For "factor related to service" see subsection (14).

…

(14) A factor causing, or contributing to, an injury, disease or death is **related to service** rendered by a person if:

(a) it resulted from an occurrence that happened while the person was rendering that service; or

(b) it arose out of, or was attributable to, that service; or

(c) it resulted from an accident that occurred while the person was travelling, while rendering that service but otherwise than in the course of duty, on a journey:

(i) to a place for the purpose of performing duty; or

(ii) away from a place of duty upon having ceased to perform duty; or

(d) it was contributed to in a material degree by, or was aggravated by, that service; or

(e) in the case of a factor causing, or contributing to, an injury — it resulted from an accident that would not have occurred:

(i) but for the rendering of that service by the person; or

(ii) but for changes in the person's environment consequent upon his or her having rendered that service; or

(f) in the case of a factor causing, or contributing to, a disease — it would not have occurred:

(i) but for the rendering of that service by the person; or

(ii) but for changes in the person's environment consequent upon his or her having rendered that service; or

(g) in the case of a factor causing, or contributing to, the death of a person — it was due to an accident that would not have occurred, or to a disease that would not have been contracted:

(i) but for the rendering of that service by the person; or

(ii) but for changes in the person's environment consequent upon his or her having rendered that service.

14. The phrase "sound medical-scientific evidence", is defined in section 5AB of the Act as follows:-

5AB (1) ...

"sound medical-scientific evidence", in relation to a particular kind of injury, disease or death, has the meaning given by subsection (2).

(2) 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 kind of injury, disease or death may be caused — meets the applicable criteria for assessing causation currently applied in the field of epidemiology."

15. Section 196Y of Part X1B enables, inter alia, an organisation representing veterans to ask the Review Council to review the contents of a Statement of Principles.

16. Section 196W deals with the Review Council's functions and relevantly provides as follows:-

…

(2) If the Council is asked under section 196Y to review:

(a) the contents of a Statement of Principles in respect of a particular kind of injury, disease or death; or

(b) a decision of the Repatriation Medical Authority not to determine a Statement of Principles under subsection 196B(2), or a Statement of Principles under subsection 196B(3), in respect of a particular kind of injury, disease or death;
subject to subsection (3), the Council must, for that purpose, carry out a review of all the information that was available to the Authority when it:
(c) determined, amended, or last amended, the Statement of Principles; or
(d) decided, or last decided, not to determine a Statement of Principles;
in respect of that kind of injury, disease or death.

(3) If the Council has been asked to review the contents of a Statement of Principles, the Council may carry out a review under subsection (2) only if:
(a) the period within which the Statement of Principles may be disallowed under section 48 of the *Acts Interpretation Act 1901* has ended; and
(b) the Statement of Principles has not been disallowed.

(4) If after carrying out the review, the Council is of the view that there is sound medical-scientific evidence on which the Authority could have relied:
(a) to amend the Statement of Principles in force in respect of that kind of injury, disease or death; or
(b) to determine a Statement of Principles under subsection 196B (2), or a Statement of Principles under subsection 196B (3), in respect of that kind of injury, disease or death;
the Council must make a declaration in writing stating its views, setting out the evidence in support and:
(c) directing the Authority to amend the Statement of Principles, or determine a Statement of Principles (as the case may be), in accordance with the directions given by the Council; or
(d) remitting the matter for reconsideration in accordance with any directions or recommendations of the Council.

(5) If, after carrying out the review, the Council is of the view:
(a) that there is no sound medical-scientific evidence that justifies the making of a Statement of Principles, or an amendment of the Statement of Principles in force, in respect of that kind of injury, disease or death; or
(b) that the sound medical-scientific evidence available to the Authority is insufficient to justify the making of a Statement of Principles, or an amendment of the Statement of Principles, in respect of that kind of injury, disease or death;
the Council must make a declaration in writing to that effect giving the reasons for its decision. The Council may include in the declaration any recommendation that it considers fit to make about any future investigation that the Authority may carry out in respect of that kind of injury, disease or death.

17. 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 Act. The significance of Statements of Principles to claims under the Act for pensions in relation to eligible service is apparent from sections 120A and 120B which provide as follows:-

18. Section 120A provides:-

120A.(1) This section applies to any of the following claims made on or after 1 June 1994:
(a) a claim under Part II that relates to the operational service rendered by a veteran;
(b) a claim under Part IV that relates to:
(i) the peacekeeping service rendered by a member of a Peacekeeping Force; or
(ii) the hazardous service rendered by a member of the Forces.
Note 1: Subsections 120 (1), (2) and (3) are relevant to these claims.
Note 2: For “peacekeeping service”, “member of a Peacekeeping Force”, “hazardous service” and “member of the Forces” see subsection 5Q (1A).

(2) If the Repatriation Medical Authority has given notice under section 196G that it intends to carry out an investigation in respect of a particular kind of injury, disease or death, the Commission is not to determine a claim in respect of the incapacity of a person from an injury or disease of that kind, or in respect of a death of that kind, unless or until the Authority:

(a) has determined a Statement of Principles under subsection 196B (2) in respect of that kind of injury, disease or death; or

(b) has declared that it does not propose to make such a Statement of Principles.

(3) For the purposes of subsection 120 (3), a hypothesis connecting an injury suffered by a person, a disease contracted by a person or the death of a person with the circumstances of any particular service rendered by the person is reasonable only if there is in force:

(a) a Statement of Principles determined under subsection 196B (2) or (11); or

(b) a determination of the Commission under subsection 180A (2);

that upholds the hypothesis.

Note: See subsection (4) about the application of this subsection.

(4) Subsection (3) does not apply in relation to a claim in respect of the incapacity from injury or disease, or the death, of a person if the Authority has neither determined a Statement of Principles under subsection 196B(2), nor declared that it does not propose to make such a Statement of Principles, in respect of:

(a) the kind of injury suffered by the person; or

(b) the kind of disease contracted by the person; or

(c) the kind of death met by the person;

as the case may be.

19. Section 120B provides:-

120B.(1) This section applies to any of the following claims made on or after 1 June 1994:

(a) a claim under Part II that relates to the eligible war service (other than operational service) rendered by a veteran;

(b) a claim under Part IV that relates to the defence service (other than hazardous service) rendered by a member of the Forces.

Note 1: Subsection 120 (4) is relevant to these claims.

Note 2: For “hazardous service” and “member of the Forces” see subsection 5Q (1A).

(2) If the Repatriation Medical Authority has given notice under section 196G that it intends to carry out an investigation in respect of a particular kind of injury, disease or death, the Commission is not to determine a claim in respect of the incapacity of a person from an injury or disease of that kind, or in respect of a death of that kind, unless or until the Authority:

(a) has determined a Statement of Principles under subsection 196B (3) in respect of that kind of injury, disease or death; or

(b) has declared that it does not propose to make such a Statement of Principles.

(3) In applying subsection 120 (4) to determine a claim, the Commission is to be reasonably satisfied that an injury suffered by a person, a disease contracted by a person or the death of a person was war-caused or defence-caused only if:

(a) the material before the Commission raises a connection between the injury, disease or death of the person and some particular service rendered by the person; and

(b) there is in force:

(i) a Statement of Principles determined under subsection 196B (3) or (12); or

(ii) a determination of the Commission under subsection 180A (3);

that upholds the contention that the injury, disease or death of the person is, on the balance of probabilities, connected with that service.

(4) Subsection (3) does not apply in relation to a claim in respect of the incapacity from injury or disease, or the death, of a person if the Authority has neither determined a

Statement of Principles under subsection 196B(3), nor declared that it does not propose to make such a Statement of Principles, in respect of:

(a) the kind of injury suffered by the person; or
(b) the kind of disease contracted by the person; or
(c) the kind of death met by the person;

as the case may be.

20. Section 120 is also of significance and provides as follows:-

120.(1) Where a claim under Part II for a pension in respect of the incapacity from injury or disease of a veteran, or of the death of a veteran, relates to the operational service rendered by the veteran, the Commission shall determine that the injury was a war-caused injury, that the disease was a war-caused disease or that the death of the veteran was war-caused, as the case may be, unless it is satisfied, beyond reasonable doubt, that there is no sufficient ground for making that determination.

Note: This subsection is affected by section 120A.

(2) Where a claim under Part IV:

(a) in respect of the incapacity from injury or disease of a member of a Peacekeeping Force or of the death of such a member relates to the peacekeeping service rendered by the member; or
(b) in respect of the incapacity from injury or disease of a member of the Forces, or of the death of such a member, relates to the hazardous service rendered by the member;

the Commission shall determine that the injury was a defence-caused injury, that the disease was a defence-caused disease or that the death of the member was defence-caused, as the case may be, unless it is satisfied, beyond reasonable doubt, that there is no sufficient ground for making that determination.

Note 1: For "member of a Peacekeeping Force", "peacekeeping service", "member of the Forces" and "hazardous service" see subsection 5Q(1A).
Note 2: This subsection is affected by section 120A.

(3) In applying subsection (1) or (2) in respect of the incapacity of a person from injury or disease, or in respect of the death of a person, related to service rendered by the person, the Commission shall be satisfied, beyond reasonable doubt, that there is no sufficient ground for determining:

(a) that the injury was a war-caused injury or a defence-caused injury;
(b) that the disease was a war-caused disease or a defence-caused disease; or
(c) that the death was war-caused or defence-caused;

as the case may be, if the Commission, after consideration of the whole of the material before it, is of the opinion that the material before it does not raise a reasonable hypothesis connecting the injury, disease or death with the circumstances of the particular service rendered by the person.

Note: This subsection is affected by section 120A.

(4) Except in making a determination to which subsection (1) or (2) applies, the Commission shall, in making any determination or decision in respect of a matter arising under this Act or the regulations, including the assessment or re-assessment of the rate of a pension granted under Part II or Part IV, decide the matter to its reasonable satisfaction.

Note: This subsection is affected by section 120B.

21. Section 5U of the Act provides that a Note is taken to be part of the provision that it immediately follows.

The Statements of Principles

22. On the 21 June 1995 two Statements of Principles concerning motor neuron disease were made by the Repatriation Medical Authority. These are set out below:-

Instrument No 245 of 1995

Statement of Principles

concerning

MOTOR NEURON DISEASE

ICD CODE: 335.2

Veterans' Entitlements Act 1986 subsection 196B(2)

1. Being of the view that there is sound medical-scientific evidence that indicates that **motor neuron disease** and **death from motor neuron disease** can be related to operational service rendered by veterans, peacekeeping service rendered by members of Peacekeeping Forces and hazardous service rendered by members of the Forces, the Repatriation Medical Authority determines, under subsection 196B(2) of the *Veterans' Entitlements Act 1986* (the Act), that the factor that must as a minimum exist before it can be said that a reasonable hypothesis has been raised connecting **motor neuron disease** or **death from motor neuron disease** with the circumstances of that service, is:

   (a) inability to obtain appropriate clinical management for motor neuron disease.

2. Subject to clause 3 (below) the factor set out in paragraph **1(a)** must be related to any service rendered by a person.

3. The factor set out in paragraph **1(a)** applies only where:

   (a) the person's **motor neuron disease** was contracted before a period, or part of a period, of service to which the factor is related; and

   (b) the relationship suggested between the **motor neuron disease** and the particular service of a person is a relationship set out in paragraph 8(1)(e), 9(1)(e), 70(5)(d) or 70(5A)(d) of the Act.

4. For the purposes of this Statement of Principles:

   "ICD code" means a number assigned to a particular kind of injury or disease in the tenth edition of the *International Classification of Diseases* 9th Revision, effective date of 1 October 1993, copyrighted by the US Commission on Professional and Hospital Activities, and having the Library of Congress number 77-94472;

   "motor neuron disease" means a chronic and progressive degeneration of the anterior horn cells and the motor neurones of the cortex resulting in progressive muscular atrophy and bulbar palsy, attracting ICD code 335.2.

Dated this Twenty-first day of June 1995
The Common Seal of the)
Repatriation Medical Authority)
was affixed to this instrument)

Instrument No 246 of 1995

Statement of Principles

concerning

MOTOR NEURON DISEASE

ICD CODE: 335.2

Veterans' Entitlements Act 1986 subsection 196B(3)

1. Being of the view that on the sound medical-scientific evidence available to the Repatriation Medical Authority, it is more probable than not that **motor neuron disease** and **death from motor neuron disease** can be related to eligible war service (other than operational service) rendered by veterans and defence service (other than hazardous service) rendered by members of the Forces, the Repatriation Medical Authority determines, under subsection 196B(3) of the *Veterans' Entitlements Act 1986* (the Act), that the factor that must exist before it can be said that, on the balance of probabilities, **motor neuron disease** or **death from motor neuron disease** is connected with the circumstances of that service, is:

   (a) inability to obtain appropriate clinical management for motor neuron disease.

2. Subject to clause 3 (below) the factor set out in paragraph **1(a)** must be related to any service rendered by a person.

3. The factor set out in paragraph **1(a)** applies only where:

   (a) the person's **motor neuron disease** was contracted before a period, or part of a period, of service to which the factor is related; and

   (b) the relationship suggested between the **motor neuron disease** and the particular service of a person is a relationship set out in paragraph 8(1)(e), 9(1)(e) or 70(5)(d) of the Act.

4. For the purposes of this Statement of Principles:

   "ICD code" means a number assigned to a particular kind of injury or disease in the tenth edition of the *International Classification of Diseases* 9th Revision, effective date of 1 October 1993, copyrighted by the US Commission on Professional and Hospital Activities, and having the Library of Congress number 77-94472;

   "motor neuron disease" means a chronic and progressive degeneration of the anterior horn cells and the motor neurones of the cortex resulting in progressive muscular atrophy and bulbar palsy, attracting ICD code 335.2.

Dated this Twenty-first day of June 1995
The Common Seal of the)
Repatriation Medical Authority)
was affixed to this instrument)

Written and Oral Submissions

23. The *Gazette* notice published on 4 October 1995 (see paragraph 6 above) specified 3 November 1995 as the closing date for written submissions to be received by the Review Council. That date was later extended at the request of the parties seeking to make submissions. Written submissions were received from the Vietnam Veterans' Association of Australia (NSW Branch Inc) and the Repatriation Commission.

24. On 19 October 1995, the Repatriation Medical Authority provided to the Review Council, under section 196K of the Act, all the information that was available to it when it determined Statements of Principles Nos. 245 and 246 of 1995.

25. A copy of that material was then provided, by the Review Council, to each of the persons and organisations that had made written submissions to the Review Council. The Council then invited those persons and organisations to make supplementary submissions addressing the material that was available to the Repatriation Medical Authority.

26. In response to that invitation neither the VVAA (NSW Branch Inc) nor the Repatriation Commission made any amendment to its original written submission.

27. On 13 May 1996 the Review Council held a meeting in relation to this review for the purpose of hearing oral submissions. At that meeting, VVAA (NSW Branch Inc) was represented by Mr Arun Kendall and Dr Peter McCullagh and the Repatriation Commission was represented by Dr Keith Horsley.

Dr Keith Horsley

28. Dr Keith William Alexander Horsley appeared for the Repatriation Commission. In essence Dr Horsley stressed the unknown aetiology of Motor Neuron Disease. He drew heavily on the Bradford Hill criteria and then directed his discussion specifically to the two areas in which he indicated that possible causality might reside. These were exposure to solvents and the effect of trauma. Having drawn attention to the low increases in relative risk associated with solvents in various studies, he reiterated the view of the Commission, as presented to the Authority, that solvent exposure has been more consistently seen to be associated with an elevated risk than with no elevation.

29. Following on this elaboration Dr Horsley turned his attention to the matter of trauma, again within the intellectual structure of causality elaborated by Bradford Hill. In this matter Dr Horsley was concerned that a temporal association could easily be confounded by whether the disease preceded the trauma or vice versa.

Mr Arun Kendall

30. Mr Arun Kendall is a Senior Advocate of the Veterans' Advocacy Service of the Legal Aid Commission. The Council accepts that he is not legally qualified (section 196ZA refers) and spoke as an advocate for the Vietnam Veterans' Association of Australia (NSW Branch Inc).

31. He reiterated the need to look more widely than the Bradford Hill criteria. In support of this, he quoted extensively from the writings of Bradford Hill. In developing his theme Mr Kendall sought to stress that the legislation underlying the *Veterans' Entitlement Act 1986* is

beneficial. Mr Kendall submitted that the submissions made on behalf of the VVAA (NSW Branch Inc) were based on a premise that cause could be deduced from association and that even if they were wrong in this no great harm would have been done.

Dr Peter McCullagh

32. Dr Peter McCullagh also appeared on behalf of the Vietnam Veterans' Association of Australia (NSW Branch Inc). In his preamble Dr McCullagh sought assurance that material which should have been available to the Repatriation Medical Authority at the time of its decision would, if not so noted, be drawn to its attention. This assurance was given. Secondly - and repeatedly during his submission - Dr McCullagh introduced the case histories of individual veterans and gave anecdotal evidence of their illnesses and their fate.

33. However, the main burden of Dr McCullagh's presentation centred around the influence of solvents, particularly the complexity of their composition and the unpredictability of their eventual fate and transmutation when absorbed into the human body. He further elaborated on the susceptibility of certain individuals as contrasted with others and also the inability to inspect the factors operating which result in the affliction of one individual and the immunity of another.

34. The evidence of Dr McCullagh might be summarised under three major headings with regard to the effect of solvents on the possible development of Motor Neuron disease - selective toxicity; individual susceptibility and latency as each relates especially to war service.

35. Considerable discussion took place with Dr McCullagh and the Review Council around these points and, subsequently in the recalled presence of Dr Horsley.

36. At the conclusion of his presentation Dr McCullagh made it clear that he had not specifically addressed his submission or any comments to topic of trauma or other possible factors for motor neuron disease.

REASONS FOR DECISION

37. Statements of Principles provide, exclusively, the medical-scientific element within a suggested chain of causation in a claim for pension for an injury, disease or death. If the claimed injury, disease or death is of a kind that is the subject of a Statement of Principles, then, where subsection 120(3) applies, a hypothesis will be reasonable for the purposes of that subsection only if the Statement of Principles upholds that hypothesis.

38. Similarly, where subsection 120(4) applies instead, the Commission can be reasonably satisfied that the injury, disease or death was war-caused or defence-caused only if the Statement of Principles relating to that kind of injury, disease or death upholds the contention that the injury, disease or death is, on the balance of probabilities, connected with the person's service.

39. It is important to note that Statements of Principles made under subsection 196B(2) do not, of themselves, define a "reasonable hypothesis". A "reasonable hypothesis" can only ever arise in the context of a claim for pension and must relate to the connection between the particular circumstances of the particular person's service and his or her injury, disease or death.

40. Neither the Repatriation Medical Authority nor the Specialist Medical Review Council is concerned with the determination of the cause of injury, disease or death of a particular individual.

That evaluation must be made subsequently in assessing the relevance of a Statement of Principles to the case of a particular claimant.

41. However, one or more factors contained within a Statement of Principles must provide support for the medical-scientific link that forms part of a "reasonable hypothesis" when the Statement of Principles is relied upon to uphold a suggested chain of causation linking the particular circumstances of a veteran's service to his or her injury, disease or death. Therefore, the factors that are to be contained in a subsection 196B(2) Statement of Principles must be such that it can be said, in relation to every person for whom a factor is relevant and who has suffered or contracted, or who has died from, the relevant kind of injury or disease, that a "reasonable hypothesis" has been raised connecting that person's injury, disease or death with the circumstances of his or her service.

42. The inclusion of a particular factor in a Statement of Principles determined under subsection 196B(2) means that the Repatriation Medical Authority is satisfied that there is sound medical-scientific evidence that indicates that it can be said, in the case of every person to whom the Statement of Principles applies, that it would be a "reasonable hypothesis" that exposure of the person to that factor made a contribution to that person's injury, disease or death.

43. Similarly, for a Statement of Principles determined under subsection 196B(3), the inclusion of a particular factor in that Statement of Principles means that, on the sound medical-scientific evidence available, the Repatriation Medical Authority is satisfied that it can be said in the case of every person to whom that Statement of Principles applies, it is more likely than not that exposure of the person to that factor made a contribution to that person's injury, disease or death.

44. It was recognised that the Repatriation Medical Authority is required to consider the medical and scientific merit and relevance of any posited connection based on current epidemiological criteria. The Specialist Medical Review Council did not believe that this requires the slavish adoption of one set of criteria such as those enunciated by Sir Austin Bradford Hill although these are of considerable value in overviewing the topic. In this respect a factor of high relevance derived from an animal model might clinch the case for causality or, alternatively, might be of sufficient weight to exclude it. The Specialist Medical Review Council is required to evaluate the content of the Statements of Principles using all of the information on causality available to the Repatriation Medical Authority at the time that it made its decisions.

46. This Review Council believes that a review of any Statement of Principles must include a consideration of the whole of the Statement of Principles even though particular aspects of concern and the subjects of objection may only relate to parts of that whole. To do otherwise would be to disregard the effect of changing one factor without due regard to its influence on the total substance of the Statement of Principles as it was originally determined. This does not necessarily mean that each and every aspect of the Statement of Principles must be examined and potentially modified, only that the Review Council must clearly delineate and sequestrate any area of change, having regard to the impact on other aspects of the Statement of Principles.

47. The Review Council understood that the material available to the Repatriation Medical Authority was that conveyed to the Review Council for its consideration in the review. It was only on this basis that such a review could be concluded, for science is ever expanding in its questing and documentation. Allowance has been made in the legislation for new, cogent findings, which might alter outcomes, to be relayed to the Authority for its proper evaluation and response.

48. Having said this however, the Review Council was of the opinion that the material studied by the Authority in coming to its Statements of Principles was the most relevant and informative. None of the Review Council members was able to suggest important material extant at the time of the conclusion of the Statements of Principles which had not been included, nor did any of the witnesses advance evidence for such material which would have altered the outcome of our review. The Review Council found that the material that was available to the Repatriation Medical Authority covered the most commonly postulated causes of motor neuron disease and included all of the theoretical possibilities which have been advanced.

49. The Review Council could not support Mr Kendall in his observation that it would not be a mistake if one were to infer the causes of a condition simply from some identified associations. The Review Council, in performing its task of reviewing the Statements of Principles on motor neuron disease made by the Repatriation Medical Authority, was required to consider if there was sound medical-scientific evidence to amend the Statements of Principles i.e. that it met the applicable criteria for assessing causation currently applied in the filed of epidemiology.

50. With regard to information which was available to the Repatriation Medical Authority in the formulation of its conclusion, attention has been drawn already in the discussion above to the concerns raised by Dr McCullagh. The Review Council had no reason to doubt that the material that it received from the Authority was identical to that studied by the Authority. Individual cases and anecdotal evidence have a limited place in a review of this nature. Such Case Reports merely report on an observation and may simply be nothing more than co-incidence. Without relevant studies or other supporting epidemiological criteria such an association can rarely be seen as causal. Therefore the Review Council could attach little weight to the particular instances advanced by Dr McCullagh. The Review Council noted that these "cases" were not part of the material available to the Authority.

51. Although the Review Council did not bind itself strictly to the Bradford Hill criteria it believed them to be a sound starting point on which to base some of its final conclusions. Both Dr Horsley for the Repatriation Commission and Mr Kendall for the applicant had recourse to these well established guidelines.

52. The Bradford Hill criteria as understood and applied by the Review Council are as follows:

- strength of association
- dose response effect
- consistency of findings
- time relationship
- biological plausibility
- specificity of association and
- coherence of evidence

53. It was not disputed that some of these criteria are better than others in evaluating causality and that some indeed may be sufficiently strong as to wholeheartedly support or unreservedly nullify the argument. Dr Horsley drew attention to the lack of demonstration of a biological mechanism which might negate a true causal effect but averred that this was not always the case and put to the Review Council that in the particular matter of solvents and motor neuron disease he did not believe that the inability to show a definitive mechanism in the literature was inimical to the possible connection of solvent exposure to motor neuron disease.

Sound medical-scientific evidence

54. The Council could only make decisions on the basis of sound medical-scientific evidence as defined in section 5AB of the Act. Paragraph 5 AB(2) (b) refers to the applicable criteria for assessing causation currently used in the field of epidemiology. It is clearly the intention of Parliament that Councillors should apply their expertise in considering the matters before Council and that epidemiological considerations will figure strongly but not exclusively among them.

Applying scientific criteria

55. As the meeting of the Review Council evolved it was apparent that epidemiological considerations were paramount in the material available and in the submissions received.

56. When employing epidemiological criteria such as those of Bradford Hill it is essential that all other scientifically valid information should be included in the final assessment. It is contrary to the principles of epidemiology to consider one study in isolation without looking at all of the factors enumerated above. In this regard, it is relevant to note that subsection 196C(3) of the Act provides that, in forming any view during an investigation the Repatriation Medical Authority may rely only on sound medical evidence and "must consider and evaluate all evidence" made available to it. The Review Council was under a similar obligation when conducting this review: subsection 196W(2) provides that the Review Council "must carry out a review of all the information that was available to the Authority".

57. It is possible that the Review Council, being alternatively constituted, may approach the available material from a different direction yet, being bound by the test in the legislation of "sound medical-scientific evidence", the Review Council must be able to validate any variance it holds with the views of the Repatriation Medical Authority.

58. With these observations in mind the Review Council considered the various contentions contained in the Statements of Principles Nos 245 and 246 of 1995 and those addressed in the oral and written submissions.

The "trauma" theory

59. The suggestion that trauma to the bones, either by joint displacement or fracture, causes motor neuron disease has a particular problem of temporality. There was insufficient data to determine whether the association claimed in the studies presented to the Repatriation Medical Authority is one that reveals that motor neuron disease which has been present for decades is brought to light by trauma or whether those traumata themselves, by somehow affecting the body, cause the development of motor neuron disease. The problem was well covered in the Kurtzke study (Kurtzke JF and Beebe GW (1980)) "Epidemiology and Amyotrophic Lateral Sclerosis" Acta Neurol Scand. 1987; Vol 75: 145-150. In any event none of the submissions provided any strong argument on the material available to the Review Council. Dr McCullagh prepared no submission on this aspect, remarking only that in his opinion some biological plausibility attaches to the theory.

60. Dr Horsley who appeared to have been involved in preparing an original paper for the Authority agreed that the problem of temporality in the "trauma" theory was one that lacked

coherence in that the supposed cause appeared to be in decline while the supposed outcome, the disease itself, was on the increase.

61. For the Review Council the most important impediment to the inclusion of trauma was that the studies are usually retrospective and by recall. They are therefore open to serious bias in the results. There was also the paradox of cause and effect. It seems that it was not possible for Dr Horsley in his original submission to the Authority to convince them that the issue of temporal ambiguity had been adequately resolved nor was this Review Council persuaded.

62. The studies available relied on the gathering of histories of antecedent trauma which are not sufficiently sound scientifically. The problems of recall bias and matching of controls together with the weak association did not justify the Review Council displacing the findings of the Repatriation Medical Authority. The Review Council also found that there was little support from the perspective of "coherence". Some more definitive studies might emerge in the future but these would no doubt be considered by the Authority if brought to its attention. The Review Council found that there was no change that it would recommend to Statements of Principles Nos 245 and 246 of 1995.

The "solvent " theory

63. The material before the Authority was stronger in relation to solvents. Much of the literature referred to by Dr McCullagh was available to the Authority but his particular interpretation of the findings was not.

64. Dr McCullagh did not propose in his submission that the strength of association between organic solvents and motor neuron disease was particularly marked. He placed strong emphasis on the effect of methylphenyltetrahydropyridine (MPTP) and its relationship to the development of extrapyramidal disorders and forms of Parkinson's disease. There is no direct nexus between extrapyramidal disorders and motor neuron diseases and although Dr McCullagh drew heavily on an article by Seaton (Seaton, A (1992) "Organic Solvents and the nervous system: time for reappraisal?" *Quarterly Journal of Medicine*,, 84, 367) this article was not available either to the Authority or the Review Council. Although Dr McCullagh claimed that this article establishes aspects of consistency, temporality, exposure. biological plausibility, coherency and analogy supported by experimental data, the Review Council noted that it dealt not with the specifics of motor neuron disease but with neurological disease in general.

65. Dr Horsley provided a very useful summary of the postulated "causes" of motor neuron disease in his paper dated December 8 1995. It seemed that the Repatriation Commission, having originally argued a case for inclusion of solvents as a causal mechanism, had looked at further evidence and decided that it was:

> "still of the view that there is some evidence of a causal relationship, but would also note that the evidence is weak and accepts that the Authority may well have been correct in judging that the relationship was not truly causal."

66. Dr Horsley pointed out three biologically plausible mechanisms by which solvent exposure could result in motor neuron disease. The first of these was that organic solvents are known neurological toxins that destroy neurons leading to the clinical deficit postulated by Dr McCullagh in his written submission. The second was that organic solvents have been shown to induce inactive viruses and the third that they have been shown to have induced genetic damage (see

Hawkes CH, Cavanagh JB and Fox AJ (1989) Motorneurone Disease: a Disorder Secondary to Solvent Exposure, *Lancet,* January 14 pp73-75).

67. The Council looked for the article referred to in paragraph 66 within the materials available to it and discovered that only the first page was included. In the circumstances of this review the Review Council was of the view that the article would have been one that the Authority would have needed to consider so that reference to the whole of the article is within the meaning of "the evidence available". In this setting the suggestion of coherence suggested by Hawkes above and Gunnarsson et al. also added to the association between organic solvents and motor neuron disease (see Gunnarsson LG, Bodin L, Saderfelat B and Axelson AO (1992) A case-control study of motor neuron disease: its relations to heritability and occupational exposures, particularly solvents. *Brit J of Ind Med*, Vol 49, pp791-8).

68. The Gunnarsson study looked at the combined effect of a number of supposed factors including family history, male gender and occupational exposure. Thus the specificity of the association with solvents was not clear. Other obscure aspects related to the degree of exposure, the duration and actual substances which are collected under the term "organic solvents". Without such specifics there was great difficulty in determining whether an actual contention within a Statement of Principles could be reached.

69. Because of all of the above, this Council, was unable to say what such a contention, involving the level of exposure or the duration or the type of solvent, might be for the purposes of Instrument 245 or 246 of 1995. Without the particular evidence on the specific criteria of exposure to any solvent, a contention was not possible for either Statement of Principles.

Inability to obtain appropriate clinical management

70. The Repatriation Medical Authority included, as a factor that can contribute materially to the aggravation of motor neuron disease, the inability to obtain appropriate clinical management.

71. A Review Council, when considering the same aspect of prostate cancer, said, (SMRC Decision 95/1: "*Statements of Principles Nos 95 and 96 of 1995* (Malignant Neoplasm of the Prostate) 23 Jan 1996 p47, Commonwealth Gazette 31 January 1996;

> "As a matter of logic, if the Defence service authorities are under a duty to provide medical treatment for service personnel, and fail to do so, then if, as a result of that failure, the course of the disease progresses faster than it would have progressed had appropriate clinical management been provided, then, it must be said that the disease has been made worse by service, and the Commonwealth would be liable to pay pension."

72. It seemed to the Review Council that there was no dispute amongst those making submissions that this was an appropriate factor to be included "in accordance with generally accepted medical practice" and which "would serve as the basis for the diagnosis and management of a medical condition". The material quoted is contained within the legislation and to the review Council reflected a proper attempt to deal with the problem of diagnosis. In so doing it provides a prudent path for the consideration of what would have been "appropriate clinical management" and whether in fact a condition could have been diagnosed at the time and not simply argued for on the basis of hindsight and superior knowledge in the present day.

73. The Review Council considered that the current Statements reflect a determination that the Review Council would have made in respect of the "inability to obtain appropriate clinical

management". In reaching this view the Review Council assumed that both the Statements of Principles require that motor neuron disease must have been present during an eligible period of service, or prior to it, and that its presence should have, with normal medical prudence, been recognised and appropriate clinical management provided and that as a result of the failure to so provide, the condition was permanently worsened. This would be a rare occurrence indeed but if such circumstances existed they would certainly have contributed to the course of the disease and we would regard this as enough to be a relevant contention for both Instrument 245 and 246 of 1995.

Herbicides, insecticides, pesticides

74. Also contained within the material available to the Review Council were mentions of herbicides, insecticides and pesticides, either independently or in conjunction with each other or "solvents". Once again no submissions made to the Review Council for the purpose of this review advanced any further argument on the issue and that seemed a proper outcome. Any suggestion of a causal link was not supported by enough medical and scientific work to be sufficient to enable any reasonable person to accept the proposition. Such evidence as exists is weaker than that for solvents alone. Nor was there sufficient in the argument contained within the papers to establish that any combination of toxicides causes motor neuron disease.

75. Dr McCullagh in his written submission did not find much support for a connection to pesticides. In all he pointed to just three studies or reports and two of those involved simple Case Reports. Even the remaining article was more concerned with the solvents used in preparation of the particular insecticide that the insecticide itself.

76. The proposition was advanced in the material available to the Review Council from the RMA that paraquat ingestion causes motor neuron disease. The cases referred to all resulted in death very soon after the ingestion and the parallel with motor neuron disease has been made only because of some similar symptoms and post mortem findings. In the Review Council's view this was simply an association and not sufficient to indicate any causal link for either Instrument 245 or 246 of 1995.

Service in a particular area and slow viruses

77. A paper by Dr N. Bennett MBBS; FRACP; FRCP [Ed]; FRACMA, Specialist in Infectious diseases and dated 27/1/95 and which appeared at folio 2.7 was apparently submitted in support of a connection between service in New Guinea and motor neuron disease and possibly a slow virus infection as the agent of causation. With respect to the organisation submitting the material and to Dr Bennett it was not sufficient to argue from a previous position, in this case from Parkinson's Disease, that

> "the same evidence can be used to argue that another chronic neurological disorder, amyotrophic lateral sclerosis or motor neuron disease, can similarly, be caused by war service."

78. Dr McCullagh, in presenting material on the solvent issue, made reference to the documents available to the Authority and the Review Council in a 1994 report on a particular veteran's case. He sought to make a postulate, not on the scientific material available as to cause, but on the particular location and assumed consumption of dietary toxins from the cycad palm. Such references to individual cases did not assist the Review Council to make a judgement about

the scientific worth of the proposed cycad connection. Dr McCullagh did not make an oral submission on the matter of cycad palm as a cause for motor neuron disease.

79. Despite the fact that there was some limited information on these matters that would have been taken into account, there was no sound medical-scientific evidence, within the meaning of that term under the Act, to which the Repatriation Medical Authority or the Review Council could have responded to include any of these other proposed causes in either Statement of Principles.

Other factors

80. Contained within the material supplied to the Repatriation Medical Authority are some matters relating to other postulated causal factors. They appear to have been addressed in material supplied to the Authority by the Repatriation Commission. No discussion on the theories that **diet**, **electrical shock**, **heavy metals** such as lead and mercury, other **metals** such as aluminium and magnesium or **viral** infection occurred during these proceedings and the Review Council had no reason to view the evidence in a different manner to the Authority and therefore did not find any reason to include these as factors for either Statement of Principles.

Summary

81. After consideration of all the material the Review Council was of the view that apart from questions concerning exposure to solvents in the Statements of Principles No 245 and 246 of 1995, none of the submissions to the Review Council caused it to consider that further investigation was required in respect of any other possible or probable postulated "cause" of motor neuron disease.

EVIDENCE BEFORE THE REVIEW COUNCIL

82. The evidence that was considered by the Review Council consisted of all of the material which was available to the Repatriation Medical Authority and the written and oral submissions made to the Review Council. These materials are listed below.

83. Material supplied to the Repatriation Medical Authority as contained in the documentation includes a paper written by Dr Keith Horsley for the Repatriation Commission entitled "**Motor Neuron Disease**" and dated 13 April 1995 accompanied by the articles mentioned in the paper.

84. A submission from Mr Geoff Trevor Hunt of the Vietnam Veterans' Association of Australia (NSW Branch Inc) entitled "**Motor Neuron Disease**" and dated 25 April 1995 and a further letter that was undated but received by the RMA on 10 May 1995, containing additional material.

85. The Council also had written submissions from the Repatriation Commission dated 8 December 1995 entitled "**Motor Neurone Disease: Submission to the Specialist Medical Review Council**" and an oral presentation from Dr Keith Horsley for the Repatriation Commission.

86. The Vietnam Veterans' Association of Australia (NSW Branch Inc) provided an undated covering letter received by the Review Council on 7 December 1995 to a further submission entitled **"Submission to the Specialists Medical Review Council: Motor Neuron Disease and**

Exposure to Solvents and Insecticides". The accompanying submission is entitled "**A Hypothesis which provides the basis for an association between service with the Armed Forces and Motor Neuron Disease**" by Peter McCullagh MD, D. Phil., MRCP and dated 15 September 1995.

87. In addition to this material the RMA gathered the following articles for its own consideration:-

Gresham, Louise S, Molgaard, Craig A, Golbeck, Amanda L, Smith, Richard (1986) "Amyotrophic lateral sclerosis and heavy metal exposure: A case-control study" *Neuroepidemiology*. 1986; vol.5: pp.29-38.

Garruto, Ralph M, Yanagihara, Richard, Gajdusek, D Carleton (1988) "Models of environmentally induced neurological disease: epidemiology and etiology of amyotrophic lateral sclerosis and parkinsonism-dementia in the Western Pacific" *Environmental Chemistry and Health*. 1988; vol.12: pp.137-151.

Fonseca, R G, Resende, L A L, Silva, M D, Camargo, A (1993) "Chronic motor neuron disease possibly related to intoxication with organochlorine insecticides" *Acta Neurologica Scandinavia*. 1993; vol.88: pp.56-58.

Scottish Motor Neuron Disease research Group (1991) "The Scottish motor neuron disease register: a prospective study of adult onset motor neuron disease in Scotland. Methodology, demography and clinical features of incident cases in 1989" *Journal of Neurology, Neurosurgery, and Psychiatry*. 1992; vol.55: pp536-541.

Kurland, Leonard T, Radhakrishnan, Kurupath, Smith, Glenn E, Armon, Carmel, Nemetz, Peter N "Mechanical trauma as a risk factor in classic amyotrophic lateral sclerosis: lack of epidemiologic evidence" *Journal of the Neurological Sciences*. 1992; vol.113: pp133-143.

Garruto, Ralph M, Yase, Yoshiro (1986) "Neurodegenerative disorders of the western Pacific: the search for mechanisms of pathogenesis" *Trends in Neurosciences*. Aug, 1986: pp.368-374.

Kurland, Leonard T (1988) "Amyotrophic lateral sclerosis and Parkinson's disease complex on Guam linked to an environmental neurotoxin" *Trends in Neurosciences.* 1988; vol.11, no.2: pp.51-54.

Deapen, Dennis M, Henderson, Brian E (1986)"A case-control study of amyotrophic lateral sclerosis" *American Journal of Epidemiology*. 1986; vol.123, no.5: pp790-799.

Gresham, Louise S, Molgaard, Craig A, Golbeck, Amanda L, Smith, Richard (1987) "Amyotrophic lateral sclerosis and history of skeletal fracture: a case-control study" *Neurology*. Apr 1987; vol.37: pp.717-719.

Granieri, E, Carreras, M, Tola, R, Paolino, E, Tralli, G, Eleopra, R, Serra, G (1988) "Motor neuron disease in the province of Ferrara, Italy, in 1964-1982" *Neurology*. Oct. 1988; vol. 38: pp.1604-1607.

Armon, C, Daube, J R, O'Brien, P C, Kurland, L T, Mulder, D W (1991) "When is an apparent excess of neurologic cases epidemiologically significant?" *Neurology*. Nov.1991; vol.41: pp.1713-1718.