



Specialist Medical Review Council

Reasons for Decisions

*Section 196W
Veterans' Entitlements Act 1986*

**Re: Statement of Principles No. 42 of 2004
In Respect of Neoplasm of the Pituitary Gland**
Matter Nos. 2007/1
Requests for Review Declaration No. 13

SUMMATION

1. In relation to the Repatriation Medical Authority (the RMA) Statement of Principles No. 42 of 2004 in respect of neoplasm of the pituitary gland and death from neoplasm of the pituitary gland, made under subsection 196B(2) of the *Veterans' Entitlements Act 1986* (the VEA), the Specialist Medical Review Council (the Council) under section 196W of the VEA:

DECLARES that it is of the view that there is sound medical-scientific evidence on which the RMA could have relied to amend the Statement of Principles:

DIRECTS the RMA to amend Statement of Principles No. 42 of 2004 by excising the factor (at 5. (a)):

'for ACTH secreting pituitary adenomas only, undergoing Bilateral Adrenalectomy within the ten years before the clinical onset of neoplasm of the pituitary gland; or'

FURTHER DIRECTS the RMA to amend Statement of Principles No. 42 of 2004 by excising the factor (at 5. (b)):

'for ACTH secreting pituitary adenomas only, undergoing Bilateral Adrenalectomy within the ten years before the clinical worsening of neoplasm of the pituitary gland; or'

and replace it by inserting:

'for ACTH secreting pituitary adenomas only, undergoing Bilateral Adrenalectomy before the clinical worsening of neoplasm of the pituitary gland; or'

FURTHER DIRECTS the RMA to amend Statement of Principles No. 42 of 2004 by making any consequential amendments to paragraphs 6 to identify the 'Factors that apply only to material contribution or aggravation'.

AND DECLARES that it is of the view that the sound medical-scientific evidence is insufficient to justify any amendment of the Statement of Principles to include as a factor exposure to:

'Biological and Chemical Warfare' and 'Nerve Agents'

or any other factor.

THE SPECIALIST MEDICAL REVIEW COUNCIL

2. 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. When a review is undertaken 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 that would be necessary for deciding matters referred to the Council for review.
3. Clinical Associate Professor Jonathan Phillips FRANZCP was the Convener of the Council for this review. He is a consultant in private practice, and a past Chairperson of the Committee of Presidents of Medical Colleges. The other members of the Council were:
 - (i) Dr Charles Guest FAFPHM, Chief Health Officer in the Australian Capital Territory, Executive Director of the Population Health and Research Division at ACT Health and Adjunct Professor at the Australian National University Medical School; and
 - (ii) Professor Albert Frauman FRACP, FACP (USA), FCP (USA), FRSM (UK), Director of the Drug Evaluation Unit, University of Melbourne and Director of Clinical Pharmacology and Therapeutics at the University of Melbourne and at the Austin Hospital; and

- (iii) Professor Ken Ho FRACP, Director of the Pituitary Research Unit at the Garvan Institute of Medical Research and Chairman of the Department of Endocrinology at St Vincent's Hospital in Sydney.

THE LEGISLATION

- 4. The legislative scheme for the making of Statements of Principles is set out in Parts XIA and XIB of the VEA. Statements of Principles operate as templates, which are ultimately applied by decision-makers in determining individual claims for benefits under the VEA and the *Military Rehabilitation and Compensation Act 2004* (the MRCA)¹.
- 5. Fundamental to Statements of Principles is the concept of 'sound medical-scientific evidence', which is 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 epidemiology².
- 6. 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. 42 of 2004, in respect of neoplasm of the pituitary gland and death from neoplasm of the pituitary gland, being a Statement of Principles

¹ See sections 120, 120A and 120B of the VEA and sections 335, 338 and 339 of the MRCA.

² 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.

determined by the RMA under section 196B(2)³ of the VEA ('the reasonable hypothesis test').

7. Specifically, the Applicant contended that there was medical-scientific evidence upon which the RMA could have relied to include 'chemical and biological warfare' and 'nerve agents' as a factor in Statement of Principles No. 42 of 2004.
8. 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 (the relevant times) and is constrained to conduct its review by reference to that information only⁴.
9. 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

Application for review by the Council

10. On 10 November 2004, the RMA under subsection 196B(2) of the VEA determined the Statement of Principles being the instrument numbered 42 of 2004 in respect of neoplasm of the pituitary gland.
11. On 16 November 2004 in accordance with section 42 of the *Legislative Instruments Act 2003* the Statement of Principles was tabled in the House of Representatives and in the Senate.
12. On 17 November 2004 the making of the Statement of Principles was notified in the Gazette (No. 46, p. 3716).

³ 196 B provides;
(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; or
(ca)warlike or non-warlike service rendered by members;
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.

⁴ *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.

13. An application dated 27 January 2005 for review of Statement of Principles number 42 of 2004 was received by the Council on 9 February 2005. Specifically the application was concerned with the decision of the RMA of 10 November 2004 not to include 'chemical and biological warfare' and 'nerve agents' as factors in that Statement of Principles.
14. Pursuant to section 196ZB of the VEA the Council published in the Gazette a notice of its intention to carry out a review of all the information available to the RMA about neoplasm of the pituitary gland, and inviting persons or organisations authorised so to do to make submissions to the Council (Gazette number 15 of 20 April 2005, p. 925). The Council gazetted two subsequent notices as to the dates by which written submissions must be received by the Council⁵.

The information sent by the RMA to the Council

15. By letter dated 29 March 2005 the RMA, under section 196K of the VEA, sent to the Council the information the RMA advised was available to (before) it at the relevant times.
16. By letters dated 8 July 2005 the Council sent to each of the Applicant and the Repatriation Commission a copy of the information sent by the RMA to the Council.
17. By letters dated 2 and 29 August 2006 the RMA under section 196K sent to the Council further information which the RMA then advised was available to (before) it at the relevant times. The RMA also advised the Council that it had not considered and or obtained some information cited or referred to in submissions made to it (the cited information). As the Council was not initially advised by the RMA whether the cited information was available to it, the Council itself tried to source the cited information, in some instances without success.
18. By letter dated 24 April 2007 the Council sent to the applicant a copy of the further information sent by the RMA to the Council.
19. By letter dated 17 August 2007 the RMA 'confirmed afresh' to the Council all the information which the RMA said was available to (before) it at the relevant times, and sent to the Council a copy of a submission made to the RMA, which it had not previously provided to the Council.
20. By letter dated 23 August 2007 the Council wrote to the Applicant:
 - advising that the Council had received from the RMA further information;

⁵ Gazette Notice 25 of 29 June 2005, p. 1446 and Gazette Notice 45 of 16 November 2005, p. 2762.

- providing a copy of that information;
 - requesting confirmation from the Applicant of the information upon which he relied;
 - inviting the Applicant to provide copies of the cited information upon which he relied which neither the RMA and/or the Council had been able to source; and
 - advising of the Council's preliminary views on the scope of the review and the pool of information.
21. The Applicant was invited to make:
- any written comments as to the Council's preliminary views by close of business on 31 August 2007; and
 - any complementary oral comments at the hearing of oral submissions, including any submissions referable to the cited information which neither the RMA nor the Council had been able to source.
22. By letter dated 30 August 2007 the Council wrote to the Repatriation Commission in the same terms as in the letter to the Applicant of 23 August 2007, but enclosing copies of all further information. The Repatriation Commission was invited to make any written comments as to the Council's preliminary views by close of business on 7 September 2007, and to make any complementary oral comments at the hearing of oral submissions.
23. Neither the Applicant nor the Repatriation Commission provided the Council with copies of any of the cited information.
24. The Council held a meeting to hear oral submissions complementing the written submissions on Tuesday 11 September 2007. At the hearing the Council provided access to all of the information.
25. The Applicant submitted two written submissions referable to the review (but not addressing the Council's proposed scope of review and pool of information decisions), and at the Council's meeting on 11 September 2007 made an oral submission complementing his written submissions.
26. The Repatriation Commission made two written submissions. In respect of the Council's preliminary views on the scope of the review the Repatriation Commission stated that it did not wish to make any comment or written submission regarding the possible excision or amendment of the existing SoPs factor concerning bilateral adrenalectomy. The Repatriation Commission stated it did not wish to propose any alteration to the Council's preliminary views on the pool of information. A Medical Officer with the Department of Veterans' Affairs, representing the Repatriation Commission, made an oral submission

complementing the Commission's written submissions at the Council's meeting on 11 September 2007.

27. As mentioned above the RMA incrementally sent to the Council the information under cover of letters dated 29 March 2005, 2 August 2006, 29 August 2006. By letter of 17 August 2007:
 - it 'confirmed afresh' the information;
 - advised that the cited information was not available to the RMA; and
 - advised that the NAS IOM 1994⁶ publication which the RMA had previously advised the Council in 2005 and 2006 was available to it, was not available to it at the relevant times.
28. Given the amount of information received, and the need for the Council to advise the Applicant and Repatriation Commission of its proposed decisions on the Pool of information and the Scope of the Review, as soon as possible in advance of the hearing of oral submissions set down for 11 September 2007, the Council did not at the time appreciate that it proposed in its preliminary Pool of Information decision to include cited information that the RMA had advised was not available to it.
29. On 9 May 2008 the Council realised its error and sought clarification from the RMA on the precise legal status of the cited information. By email dated 12 May 2008 the RMA wrote to the Council and confirmed:
 - that the cited information was not available to it;
 - that the NAS IOM 1994, publication was available to it (contrary to the RMA advice of 17 August 2007); and
 - the information that was available to (before) the RMA at the relevant times.
30. By letters dated 18 December 2008 the Council wrote to the Applicant and the Repatriation Commission advising:
 - of the Council's error regarding the cited information;
 - of the RMA's advice confirming the legal status of the cited information, ie that it was not available to (not before) it;
 - of the RMA's advice of 9 May 2008 that the NAS IOM 1994 was available;
 - that the Council had necessarily revised its preliminary decision on the proposed pool of information⁷; and

⁶ National Academy of Sciences (NAS), Institute of Medicine (IOM) 1994, *Veterans and Agent Orange: Health Effects of Herbicides used in Vietnam*, The National Academies Press, Washington D.C., pp. 1-812.

- detailing the Applicant's and Repatriation Commission's opportunity to comment.
31. The confirmation by the RMA that the cited information was not available to (not before) it, meant that the legal status of the cited information was different from the (erroneous) basis upon which the Council had been proceeding. The RMA's advice of the change of status of the NAS IOM 1994 publication also impacted on the proposed pool of information.
32. The Council's preliminary decision as to the proposed pool of information had included some cited information that the Council was satisfied:
- was sound medical-scientific evidence;
 - 'touched on' (was relevant to) the review; and
 - was considered appropriate to take into account by epidemiologists.
33. As a matter of law, the Council can only take into account for the purposes of its review, information which was available to (before) the RMA. The cited information which the Council had previously proposed to include in the pool of information, therefore, could no longer be taken into account for the purposes of the review, and necessarily had to be removed from the proposed pool of information. The cited information could only be taken into account by the Council as 'new information'. After receipt of the RMA email of 12 May 2008 the Council was satisfied that the NAS IOM 1994 publication met the criteria set about immediately above (paragraph [32]) and proposed to include that publication in the Pool of Information.
34. Both the Applicant and the Repatriation Commission were advised that they had no right to comment on the Council's decision to exclude the cited information from the proposed pool of information for the following reasons:

⁷ The Council advised of the proposed inclusion in the Pool of Information of:
 NAS IOM 1994, *ibid* at footnote 7; and
 The Council advised of the excision from the Pool of Information of:
 House, WB Goodson, LH Gadberry, HM Dockter, KW 1967, *Assessment of Ecological Effects of Extensive or Repeated use of Herbicides*, Midwest Research Institute, Kansas City, pp 1-369; reproduced by National Technical Information US Dept of Commerce, Springfield.
 Sinclair, IM 1982, Report on the use of herbicides, insecticides and other chemicals by the Australian Forces in South Vietnam – Summary of files not found in South Vietnam based Army Headquarters and Units, Book 1, pp 1-A-1 to 1-E-15; Report and Ministerial Statement, pp. 3278-3286; Report – Royal Australian Air Force, pp. 1-5; Report Australian Army, Book 1, pp. 1-1 to 1-G-1; Book 2, pp. 2-1 to 2-8; and Book 3, pp. 3-1 to 3-3-A-1.
 Young, AL Calcagni, JA Thalken, CE Tremblay, JW 1978, *The Toxicology, Environmental fate and Human risk of herbicide Orange and its Associated Dioxin*, Prepared for The Surgeon General United States Air Force, Washington, D.C. by USAF Occupational and Environmental health Laboratory, Aerospace Medical Division (AFSC), Brooks Air Force Base, Texas. pp 1-400.

- the Council is legally constrained only to review that information which the RMA advises was available to (before) the RMA at the relevant times;
- the Council's revised decision was accordingly legally mandated and no exercise of judgement or discretion was involved; and further
- the VEA prohibits those making submissions to the Council from making submissions on a legal matter.

SCOPE OF REVIEW

35. The Council's preliminary view, as advised to the Applicant and Repatriation Commission on 23 and 30 August 2007 respectively 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:

- (a) The possible inclusion of a factor or factors in the Statement of Principles for which the Applicant contends under the rubric 'chemical and biological warfare' and 'nerve agents' as listed at Table 3, a copy of which is attached;

- (b) the possible:

- (i) excision, or
- (ii) amendment

of a factor or factors, referred to at paragraph 5(a) of the Statement of Principles: 'for ACTH secreting pituitary adenomas only, undergoing bilateral adrenalectomy within the ten years before the clinical onset of neoplasm of the pituitary gland' as listed at Table 3; and

- (c) the possible:

- (i) excision, or
- (ii) amendment

of a factor or factors, referred to at paragraph 5(b) of the Statement of Principles: 'for ACTH secreting pituitary adenomas only, undergoing bilateral adrenalectomy within the ten years before the clinical worsening of neoplasm of the pituitary gland' as listed at Table 3.

POOL OF INFORMATION

36. As mentioned above, the RMA is obliged under section 196K of the VEA to send to the Council all the information that was available to it (the RMA) at the relevant times, i.e. when it determined, amended, or last amended the Statement of Principles. That comprises all the information that was available to the RMA when it determined the original Statement of Principles in 1997, and all the information subsequently available at all times when the Statement of Principles has been amended, or revoked and replaced, up to and including that information which was available in November 2004 when the RMA determined the Statement of Principles under review. In other words, within 28 days after being notified that the Council has been asked to conduct a review, the RMA must send to the Council all the information in respect of neoplasm of the pituitary gland which was in the possession of the RMA at the time it (the RMA) made the decision that triggered the Council's review.
37. The chronology of the RMA sending the information to the Council; the initial uncertainty as to the legal status of the cited information; the Council's misunderstanding of the legal status of the cited information after the RMA had advised the Council that the cited information was not available to (not before) the RMA at the relevant times; the Council's identification of its error, and the RMA's confirmation of the legal status of the cited information; and the advice that the NAS IOM 1994 publication was available; and the consequence for the Council's preliminary decision on the proposed pool of information; and the Council's advice to the Applicant and Repatriation Commission of the consequential change are all detailed in paragraphs [15 to 34] above.
38. In determining the pool of information the Council applied the methodology it had advised the Applicant and Repatriation Commission on 18 December 2008 (revised from that advised on 23 and 30 August 2007 respectively) ie that the pool of information should comprise the information:
- that was available to (before) the RMA at the relevant times;
 - which was sent by the RMA to the Council under section 196K of the VEA; and
 - which was considered by the Council to be sound medical-scientific evidence as defined in section 5AB(2) of the VEA being information which:
 - i) epidemiologists would consider appropriate to take into account; and
 - in the Council's view, 'touches on' (is relevant to) 'chemical and biological warfare' and 'nerve agents' and has been evaluated by the

Council according to epidemiological criteria, including the Bradford Hill criteria.⁸; or

- in the Council's view, 'touches on' (is relevant to) 'undergoing bilateral adrenalectomy' and has been evaluated by the Council according to epidemiological criteria, including the Bradford Hill criteria.
39. For the purposes of making its revised preliminary and then final decisions on the proposed pool of information, the Council took into account all the information sent to it by the RMA on 29 March 2005, 2 August 2006, 29 August 2006, 17 August 2007 and 12 May 2008, save and except the cited information. The Council then applied the two-stage process discussed below to the information within the pool, all of which was available to (before) the RMA at the relevant times.
40. Information which the RMA advised was not available to (not before) the RMA at the relevant times, including the cited information, was not taken into account by the Council for the purposes of the review, but was considered as 'new information'.
41. A copy of the Council's preliminary decision on the proposed pool of information (which erroneously included cited information) is attached at **Appendix A (i)**. A copy of the Council's revised proposed pool of information is attached at **Appendix A (ii)**. The Council confirmed its revised proposed decision on the pool of information as its final decision.

APPLICANT'S SUBMISSIONS

42. The Applicant made a number of comprehensive written submissions to the RMA and to the Council, all of which were taken into account by the Council.
43. In his application to the Council of January 2005, the Applicant stated that his grounds for review were as follows:

The RMA ignored the sound medical scientific evidence I supplied in my detailed submission.

One has to take into consideration that this issue has already been debated in the Federal Court 1992, *Repatriation Commission v Schar* ALR 1992. Whereupon Schar was successful.

At least at *Repatriation Commission v Schar* we discussed/debated the issue of chemical and biological warfare in South Vietnam during the war years. The

⁸ 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.

references used/referred in instru[ment] 42 of 2004 did not contain any references to CBW [chemical and biological warfare] in South Vietnam during the War Years.

44. Further written submissions were prepared by the Applicant on or about October 2005 and May 2007, and received by the Council on or about 19 October 2005 and 25 May 2007 respectively.
45. These submissions were in addition to the Applicant's submissions to the RMA dated March 2003 and 1 May 2003 (Amended Submission to the RMA), which were included in the information sent by the RMA to the SMRC under section 196K of the VEA.
46. As mentioned above, the Applicant also made a comprehensive oral submission complementing his written submissions⁹.
47. In summary, the Applicant's primary submission was that he had provided sound medical-scientific evidence upon which the RMA could have relied to have included a 'chemical and biological warfare' and 'nerve agents' factor(s) in the Statement of Principles under review.
48. In support of this submission, the Applicant relied upon his own case heard before the Administrative Appeals Tribunal (the AAT) on 23 December 1991¹⁰.
49. The RMA confirmed in its letter of 12 May 2008 that the decision of the AAT (as represented by Deputy President BH Burns) was not available to (not before) it. This meant the Council could not take it into account for the purposes of the review. The Council was of the view that the AAT decision did not meet the criteria for sound medical-scientific evidence (see paragraph [5], above). The Council also notes that the AAT decision was made and handed down before the Statement of Principles regime was introduced into the VEA in 1994. It necessarily applied a different statutory test. However the Council considered the applicant's submissions referable to the AAT decision, as new information.
50. Essentially the Applicant contended that the 14 step reasonable hypothesis put forward at the AAT by Dr Peter McCullagh¹¹ addressing exposure to the herbicides "Diquat" and "Paraquat"¹² in the development of prolactinomas of the

⁹ The discussion of the Applicant's submissions set out in these Reasons is derived from the written submissions and the complementary oral submission here identified.

¹⁰ The AAT decision transcript is new information, that is it is information which the RMA advised was information which was not available (not before) the RMA. *Re Repatriation Commission and Schar* (1991) 25 ALD 503, pp. 1-13.

¹¹ Dr McCullagh is reported in the 1991 AAT Decision as being an experimental pathologist and a Senior Research Fellow at the John Curtin School of Medical Research at the Australian National University, Canberra.

¹² The 1991 AAT Decision states "Diquat" and "Paraquat" are the active constituents of Reglone and Gramoxone respectively, which are herbicides and were used for perimeter clearance around Nui Dat.

pituitary should be accepted as sufficient evidence to amend the relevant Statement of Principles to include a 'chemical and biological warfare' and or 'nerve agents' factor(s).

51. In explaining his hypothesis to the AAT Dr McCullagh had relied upon articles by:

- Snyder, SH and D'Amato, RJ 1985¹³, in respect of evidence of environmental causes for the depletion of dopamine producing cells in the brain; and
- Grcevic, N et al 1977¹⁴, in respect of paraquat poisoning involvement with the death of dopamine producing cells.

52. The Applicant contended in submissions made to the Council (as he had in earlier submissions to the RMA) that these two articles were sound medical-scientific evidence. The Council's findings referable to the submission on these articles can be found under the heading of New Information at paragraph [155 to 193].

53. The Applicant particularly relied upon the AAT decision, and Deputy President Burns' comments that:

We were most impressed by Dr McCullagh and his evidence. It is a strong hypothesis, not fanciful or unreasonable, it is pointed to by the facts and relates closely to the particular circumstances of this case (at paragraph 42).

On the whole of the material before the Tribunal, we find we cannot be satisfied beyond reasonable doubt that the respondent's pituitary adenoma was not war-caused, there being a reasonable hypothesis connecting the pituitary adenoma to the respondent's war-service (at paragraph 43).

54. In the Applicant's submission, the information which the RMA took into account in its investigation did not contain important studies of the specific chemical and biological warfare used in South Vietnam, which he contended may be held by the Department of Defence, and submitted further that the RMA's response to his submissions:

does not state any qualitative analysis process...goes immediately into quantitative analysis of civilian environments, totally ignoring any military, warlike, battlefield conditions...

¹³ This is new information, that is it is information which the RMA advised was information which was not available (not before) the RMA. Snyder, SH & D'Amato, RJ 1985, 'Predicting Parkinson's Disease', *Nature*, vol. 317, 19 September, pp. 198-199. Also see paragraphs [185 to 189] of these Reasons.

¹⁴ This is new information, that is it is information which the RMA advised was information which was not available (not before) the RMA. Grcevic N, Jadro-Santel D, Jukie S 1977, 'Cerebral changes in Paraquat poisoning'; in Roizin L, Shiraki H, Grcevic N (eds) 1977, *Neurotoxicology*, Raven Press, New York, vol. 1, pp. 469-484. Also see paragraph [176 to 184] of these Reasons.

55. The Applicant highlighted circumstances and conditions he and other soldiers faced in South Vietnam which he contended were different to that of the civilian environment:

There were no labels on drums to provide soldiers information on the safe use of the product,

There were no safety briefings discussing safety, health and welfare,

There was no protection of the drinking water for soldiers and Vietnamese civilians, (Hearing transcript at p. 9)

The relevant Department of Defence failed in their duty of care to provide labels on drums in accordance with legislation, safety briefings with the material data reports in relation to safety, health and welfare, and to protect the water sources that the soldiers and civilians were drinking, showering, washing of teeth, washing ones hair and clothes. (Hearing transcript at p. 12)

56. The Applicant provided comprehensive descriptions of what he submitted were the:

hazards and risks of the chemical and biological warfare program including the nerve gas program and use of other chemicals while he was posted at Nui Dat, including the prophylaxis regime soldiers received and data on the amount of various insecticides and other chemicals used over a 12 month period at Nui Dat.

57. The Applicant emphasised that the contention for exposure to 'chemical and biological warfare' and 'nerve agents' was to a 'cocktail' of these agents, and not an exposure to individual 'chemical and biological warfare' and 'nerve agents' in isolation from each other. The Applicant contended that the RMA had not taken the cocktail of exposures into account:

The RMA appears only to have evaluated the principal ingredient.

58. The Applicant was critical in his submissions of the material¹⁵ outlined below and made the following comments¹⁶ in his complementary oral submission at the Council's meeting on 11 September 2007.

- House, WB Goodson, LH Gadberry, HM Dockter, KW 1967, Assessment of Ecological Effects of Extensive or Repeated use of Herbicides, Midwest Research Institute, Kansas City, reproduced by

¹⁵ Some of this material is new information, that is it is information which the RMA advised was information which was not available (not before) the RMA. That is, House, WB et al 1967 and Young, AL et al 1978 and Sinclair, IM 1982 and Pollak, JK nd, in Steele et al eds, 1989. The Council's analysis and finding referable to new information can be found under the heading of New Information at paragraph [155 to 193].

¹⁶ The Council has presented the references to these passages as set out in the written submissions to it. However, the Council acknowledges its sources in accordance with the 'Author-date' system described in the Commonwealth of Australia 2002, *Style manual*, 6th edn, John Wiley & Sons Australia Ltd, pp. 187-232. The Council notes that the Applicant did not provide the page citation for any of the following extracts. Where possible, these have been sourced by the Council.

National Technical Information US Dept of Commerce, Springfield. pp 1-369. DVA Library at 615.95.

- Young, AL Calcagni, JA Thalken, CE Tremblay, JW 1978, The Toxicology, Environmental fate and Human risk of herbicide Orange and its Associated Dioxin, Prepared for The Surgeon General United States Air Force, Washington, D.C. by USAF Occupational and Environmental health Laboratory, Aerospace Medical Division (AFSC), Brooks Air Force Base, Texas. pp 1-400.

There is no reference for a request to the United States Army South Vietnam General's plans, reports, chemical and biological warfare risk assessments, United States Chemical Corp South Vietnam chemical and biological warfare risk assessments, any amendments, notes or signed off by the United States President, as well as peer review studies from the United States Department of Defence repository.

The above report[s] is referring to the agricultural use of herbicides in accordance with the 1947 Federal Insecticide, Fungicide and Rodenticide Act. This requires all pesticides be registered by the United States Agricultural Department.

The above report therefore fails for the test of authority and process in relation to battlefield injuries, diseases and death for South Vietnam. (Hearing transcript at p. 10)

- National Academy of Sciences (NAS) publications 1994, 1996, 1998, 2000, 2002 Veterans and Agent Orange: Health Effects of Herbicides used in Vietnam. The National Academies Press Washington D.C.

Same [refers to the comments on House et al., 1967 and on Young et al., 1978] goes for the Veterans' and Agent Orange report. (Hearing transcript at p. 10)

- Sinclair, IM 1982. Report on the use of herbicides, insecticides and other chemicals by the Australian Forces in South Vietnam – Summary of files not found in South Vietnam based Army Headquarters and Units; Report and Ministerial Statement, Report – Royal Australian Air Force; Report Australian Army.

the paper there was altered – clearly demonstrate the agricultural use of chemicals when it should have been what was happening in Vietnam.

A report of the spraying of herbicides of Australian – First Australian Task Force, Nui Dat, Vietnam, by Major ES Holt, May 1968¹⁷...The supply of the chemicals proved difficult, as the quantity needed was in one case greater than the annual requirement for Australia, Nui Dat was approximately a 100 acre military camp. It was found that the original spraying team from

¹⁷ Holt, February 1968 Australian Army Operational Research Group, (AAORG) 2/68, 'A report of the spraying of herbicides at 1st Australian Task Force Viet Nam', cited by the Applicant in his September 2002 Submission to the RMA, p. 4; his March 2003 submission to the RMA, pp. 6, 20 & 21; his 1 May 2003 Amended Submission to the RMA, pp. 6, 20, 21 & 25; and in his October 2005 submission to the SMRC, p. 16.

the ...(indistinct)...squad had been medically affected by the chemicals.
(Hearing transcript at p. 11)

- Pollak, JK n.d. Were the methods used by the Evatt Royal Commission¹⁸ – to evaluate toxic effects on reproduction and development – valid? pp. 45-54. In Steele, EJ Bellett, AJD McCullagh, PJ and Selnger, B eds. 1989, *Evatt revisited*¹⁹:

...a report dated November 1995 by the VVA into the Evatt Royal Commission, Associate Professor John Pollak had this to say, as follows
“This report has a number of serious errors of fact, misinformation and quotation taken out of context. Some they use selectively or added data or ignored, and lacks appreciation of the fundamental biological, biochemical and pharmacological principles.” (Hearing transcript at p. 12-13)

59. The Applicant contended that documents and research specific to ‘chemical and biological warfare’ in South Vietnam were not obtained by the RMA and in some instances may not have been released into the public arena by the US (United States of America) or Australian Department of Defence repositories. The Council has not attempted to provide a comprehensive list of the material or sources of information referred to by the Applicant, but notes that he specifically referred to examples such as research by HM Pollak into the mixture of chemicals, research by Mr Lugg²⁰, Australian Army plans, reports, chemical and biological warfare risk assessments, Army scientific advisors’ office documents and the New Zealand Parliamentary Inquiry New Zealand Health Committee report, all of which he referred to or cited in his submissions to the Council (and earlier to the RMA) and all of which he contended should have been reviewed by the RMA and sent to the Council for it to take into account in its review.
60. While the Council noted the Applicant's submission about materials (listed in Appendix D) that were not available to (not before) the RMA²¹ the Council was not able to take them into account for the purposes of the review and for that reason, the Council took them into account as new information. The Council’s findings referable to new information can be found under the heading of New Information at paragraph [155 to 193].

¹⁸ Evatt, P 1985, *Royal Commission on the use and effects of chemical agents, on Australian Personnel in Vietnam*, Final Report July 1985, vols. 1-9, Australian Government Publishing Service, Canberra.

¹⁹ Steele, EJ Bellett, AJD McCullagh, PJ and Selnger, B eds. 1989, *Evatt revisited: interpretation of scientific evidence – Proceedings of a conference which re-examined the findings of the Royal Commission on the use and effects of chemical agents on Australian Personnel in Vietnam*, Centre for Human Aspects of Science and Technology, Special Publication October 1989, University of Sydney, pp. 1-105.

²⁰ The Applicant claims Mr Lugg was employed from 1945 to 1975 at Defence Standards Laboratories, Australia’s Chemical and Biological Warfare Department (at 2005 written submission, p. 12). Australian Government Senate Question on Notice 4568 confirms Mr Lugg’s employment and includes a list of published and unpublished articles/papers written by Mr Lugg (at SMRC Folder E, article 10).

²¹ Including the referred to or cited information at paragraph 63.

REPATRIATION COMMISSION'S SUBMISSIONS

61. The Repatriation Commission made two written submissions (October 2005 and September 2007), and an oral submission complementing its written submission²².
62. A Medical Officer with the Department of Veterans' Affairs represented the Repatriation Commission at the Council's meeting on 11 September 2007, and was the principal author of the Repatriation Commission's written submission to the Council.
63. The Commission submitted that within the information available to the RMA there was:

no human epidemiological studies available that provide any specific information on the risk of pituitary neoplasm from exposure to pesticides or to any of the other chemicals referred to by the applicant. (2007, September Submission, at p. 4)
64. The Commission in its submission identified what it submitted were relevant animal data.²³ The Repatriation Commission submitted that the following were relevant:
 - a study²⁴ which was a long term bioassay concerning 2,3,7,8-tetrachlorodibenzo-para-dioxin in rats found that the 'findings included a significantly reduced' incident of tumours of the pituitary gland;

²² The discussion of the Repatriation Commission's submissions set out in these Reasons is derived from the written submissions and complementary oral submission here identified. The Council has presented references as set out in the written submissions to it. However, the Council acknowledges its sources in accordance with the 'Author-date' system described in the Commonwealth *Style manual* (as per footnote 16).

²³ Kociba, RJ et al 1978, 'Results of a two year chronic toxicity and oncogenicity study of 2,3,7, 8-tetrachlorodibenzo-p-dioxin in rats', *Toxicology and Applied Pharmacology* vol. 46, pp. 279-303. In National Academy of Sciences, Institute of Medicine 1994, 'Veterans and Agent Orange: Health Effects of Herbicides used in Vietnam', *The National Academies*, Press Washington D.C., pp. 1-812.

Evatt, P 1985, *Royal Commission on the use and effects of chemical agents, on Australian Personnel in Vietnam*, Final Report July 1985, vol. 4: Cancer, Australian Government Publishing Service, Canberra, pp. 1-440.

Gold, EB 1981, 'Epidemiology of pituitary adenomas', *Epidemiologic Reviews*, vol. 3, pp. 163-183.

²⁴ The RMA in its 12 May 2008 letter to the Council confirming its advice on the information which was available to (before) the RMA at the relevant times, stated that the NAS IOM 1994 publication was information which was available to (before) the RMA. The RMA did not source or include the Kociba, RJ et al 1978 paper (which was cited in the NAS 1994 publication at pp. 138-139) , and advised that that paper was not information which was available to (before) it. Thus, the Kociba, RJ et al 1978 paper was taken into account by the Council as 'new information'. The Council's findings about this article can be found under the heading of New Information at paragraph [159 to 166].

- the Evatt Royal Commission was unable to identify any information specific to pituitary neoplasms; and
- a 1981 review of the epidemiology of pituitary adenomas found that the evidence was ‘generally unresponsive of a role for known chemical carcinogens in causing pituitary neoplasms.’

65. The Commission suggested there was what it described as ‘good evidence’ about the levels of exposure to the various contended individual chemical, biological, and nerve agents, and the levels in Vietnam for Australian service personnel who served in Vietnam relative to other exposures in other settings like industry and agriculture and from industrial accidents. The Commission stated that this information was contained in the Agent Orange²⁵ reports and the Evatt Royal Commission²⁶.

66. Further, in the Commission's view even if the above animal evidence was positive, the only outcome to be derived from that would be in respect of establishing biological plausibility, ‘the animal evidence obviously can’t address other epidemiological criteria’.

67. The Commission conceded that:

It’s not that the Commission’s view is that these agents [chemical, biological and nerve agents] do not cause or cannot cause neoplasm of the pituitary, it’s just that the scientific literature is silent on the subject. (2007, 11 September Oral Submission, at p. 20)

The Commission submitted in conclusion that in the absence of supportive human epidemiology there was no basis to include in the Statement of Principles any factor for herbicides and other chemicals as contended by the Applicant.

68. The Commission²⁷ questioned the comprehensiveness of the information sent to the Council by the RMA under section 196K of the VEA. It claimed:

that the health consequences of exposure to herbicides (and their contaminants) used during the Vietnam war have been widely studied in Vietnam veterans and a range of other exposed persons. (at p. 5)

Further, the Commission was of the view that the ‘RMA... has available a good deal of information on this subject’, and that the ‘RMA has made extensive use of such material in relation to SOPs for other diseases.’

69. The Commission referred to examples of such information²⁸ including the series of studies on the morbidity and mortality of Australian veterans of the Vietnam War. However the Commission observed that:

²⁵ NAS IOM 1994, 1996, 1998, 2000, 2002 Veterans and Agent Orange: Health Effects of Herbicides used in Vietnam. The National Academies Press Washington D.C.

²⁶ Evatt, P 1985, *ibid* – also see footnote 18 and 23.

²⁷ Repatriation Commission 2005, October Submission to the Council, pp. 1-6.

pituitary neoplasms do not appear to have been an outcome of interest to investigators and an incidental finding of an association does not appear to have emerged in any of the general morbidity and mortality studies.

70. The Commission submitted that it could not identify data specific to pituitary neoplasms in any of the information it commented upon and/ or referred to (above).

Repatriation Commission's comments on the Scope of Review and Pool of Information

71. The Commission stated that it would focus its submission on 'chemical and biological warfare' and 'nerve agents' and that it did not propose to make any comment or written submission regarding the existing factor concerning 'bilateral adrenalectomy'.
72. The Commission concurred with the Council's preliminary decision on the proposed pool of information.
73. The materials referred to by the Commission that were not available to (not before) the RMA (which the Commission contended were in existence at the relevant times and/or were in the possession of the RMA, and so could have been accessed by the RMA) are listed in Appendix F. The Council noted the Commission's submissions about the new information, but was unable to take them into account for the purposes of the review because they were not available to (not before) the RMA at the relevant times. The Council's findings referable to new information can be found under the heading of New Information at paragraph [155 to 193].
74. The Council also noted that the DVA had made a submission to the RMA in 1997 and submitted a list of abstracts, with a Medline search report. The Council included these abstracts in a list of the information that appeared to be 'relied upon' by the Repatriation Commission, and asked the Repatriation

²⁸ NAS IOM 1994, Veterans and Agent Orange: Health Effects of Herbicides used in Vietnam. The National Academies Press Washington D.C., pp. 1-812. (At the time the submission on this information was made to the SMRC the RMA had advised the status of the NAS IOM 1994 publication was that it was available and it was not until a latter date that the status changed and was then clarified by the RMA as available information on 12 May 2008.)

NAS IOM 1996, 1998, 2000, 2002 Updates, Veterans and Agent Orange: Health Effects of Herbicides used in Vietnam, National Academies Press Washington D.C.

Wolfe, WH Michalek, JE Miner, JC Rahe, A Silva, J Thomas, WF Grubbs, WD Lustik, MB Karrison, TG Roegner, RH et al 1990, 'Health status of Air Force veterans occupationally exposed to herbicides in Vietnam. I. Physical health', JAMA, Oct 10, vol. 264, no.14, pp. 1824-31.

Commonwealth Department of Veterans' Affairs 1998, Morbidity of Vietnam Veterans: A study of the health of Australia's Vietnam veteran community. Volume 1 Male Vietnam veterans survey and community comparison outcomes, pp. 1-111. Available online at: www.aihw.gov.au/veteran/previous_studies/index.cfm

Commission to confirm if this was the case. The Repatriation Commission advised the Council that it did not rely upon this information and further the RMA advised the Council that some of the abstracts were new information. That is, they are information which was not available to (not before) the RMA. The Council's findings referable to new information can be found under the heading of New Information at paragraph [155 to 193].

REASONS FOR THE COUNCIL'S DECISION

The Council's Task

75. The fundamental and primary importance of 'the information' sent by the RMA under section 196K of the VEA to the Council cannot be overstated. The integrity of the information is absolutely critical to the Council's review role and functions.
76. The Council was very mindful of meeting its obligations under the VEA to review all and only the information that was available to (before) the RMA at the relevant times, in order to determine whether there was sufficient sound medical-scientific evidence upon which the RMA could have relied to amend (or make) the Statement of Principles.
77. Further, the Council in taking account of the submissions made to it, ensured that it did so in the correct legal context. The Council identified its error concerning the cited information and clarified its legal status with the RMA. Information which could only be considered as new information was not taken into account in making the review decision.
78. The Council was also cognisant of its natural justice obligations to those persons and organisations making submissions to it. It was to ensure complete transparency, fairness, and discharge of its natural justice obligations that the Council provided each of the Applicant and Repatriation Commission with an opportunity to make a supplementary written submission after the Council had identified its error concerning the legal status of the cited information and had received the RMA's confirmation by letter dated 12 May 2008 that:
 - the cited information was not available to (not before) the RMA; and
 - the NAS IOM 1994 publication was available to (before) the RMA at the relevant times.
79. In conducting a review the Council follows a two-step process. It first identifies the pool of information, ie it identifies from all the information that was available to (before) the RMA at the relevant times what the Council considers to be sound medical-scientific evidence (as that term is defined in section 5AB(2) of

the VEA (see paragraph [5] above)) which 'touches on' (ie is relevant to) whether a particular kind of injury, disease or death can be related to service.

80. The second step requires the Council to determine whether the sound medical-scientific evidence in the pool of information points to (as opposed to merely leaves open)²⁹ the relevant possibility (whether 'chemical and biological warfare' and 'nerve agents' (if found to exist in a particular case) could provide a link or element in a reasonable hypothesis connecting neoplasm of the pituitary gland or death from neoplasm of the pituitary gland to relevant³⁰ service³¹). The Council has to find that the hypothesis contended for is reasonable, and not one which is 'obviously fanciful, impossible, incredible or not tenable or too remote or too tenuous'³².
81. In these Reasons the association for the reasonable hypothesis test (at paragraph [6 and 80]) is referred to as the 'relevant association'.
82. 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 and the Repatriation Commission referable to the contended factors.
83. In forming its judgement of whether the sound medical-scientific evidence pointed to (as opposed to merely leaving open) the relevant association, the Council was conscious that the reasonable hypothesis test is 'a test of possibility'³³ and 'an unusually light burden'³⁴.

Scope of Review

84. The Council decided to confine its attention to those matters identified in paragraph [35] above.

Pool of Information

85. The chronology of the Council's preliminary proposed decision on the pool of information, and its revised proposed decision on the pool of information are detailed in paragraphs [15 to 34] above.

²⁹ See full Federal Court decision at paragraph 49 per Branson J.

³⁰ Relevant service here refers to operational, peacekeeping and hazardous service, and warlike and non-warlike service as those terms are defined in the VEA and the MRCA.

³¹ 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.

³² 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.

³³ 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.

³⁴ See full Federal Court decision at paragraph 55 per Branson J.

86. The Council's final view on the pool of information was that it should comprise the sound medical-scientific evidence the Council had identified in its revised preliminary decision on the pool of information, made following the RMA's letter to the Council dated 12 May 2008, and as advised to the Applicant and Repatriation Commission in letters and the attached table (Appendix A (ii)) each dated 18 December 2008.
87. The Council noted the Applicant's and the Commission's respective references to materials which were (new information) not available to (not before) the RMA at the relevant times (see Appendices D and F). As mentioned above, the Council is unable in undertaking the review to consider (and so did not) information which was not available to (not before) the RMA at the relevant times.

THE COUNCIL'S ANALYSIS OF THE INFORMATION BEFORE THE RMA

88. Having settled the pool of information, the second question for the Council to consider was whether the sound medical-scientific evidence in the pool of information points to any or all of the contended factors being a link or element in a reasonable hypothesis connecting neoplasm of the pituitary gland to relevant service (see paragraphs [6 and 80], and footnotes 3 and 29).
89. Notwithstanding the issues raised by the Applicant which deal with matters other than the information (see paragraphs [47 to 56 and 58 and 59]), the Council reiterates that the only basis upon which it can review the contents of a Statement of Principles is by reviewing all the information that was available to (before) the RMA at the relevant times, in order to ascertain whether there was sound medical-scientific evidence upon which the RMA could have relied to amend the Statement of Principles.
90. The Council considered all the evidence in the pool. However, given the large number of articles in the pool, the Council in these Reasons focuses upon its analysis of those articles which it considered most pertinent to the issues before it.
91. Ultimately, matters of weight are questions for the Council in the exercise of its expertise and scientific judgement, noting, as did the Applicant, that the Councillors are appointed to a particular review because of their specialist expertise in the particular condition (in this case neoplasm of the pituitary gland).

Preliminary Comment on the Pituitary Gland

92. An important consideration in the Council's analysis of the information, was that the pituitary gland is not a homogeneous gland but is composed of distinct cell types that are controlled by factors / stimuli that are cell type specific. Therefore

an understanding of the pituitary gland was necessary to appreciate the evidence and therefore similarly these reasons in respect of any causal factors associated with pituitary tumours³⁵. The Council notes that the Pituitary Gland³⁶

...is located at the base of the brain, attached to by a stalk to the hypothalamus;
and

...is the most complex endocrine gland, having several functions including control of several other glands.

93. The Pituitary gland has two major components³⁷:

...the anterior lobe or adenohypophysis and the posterior lobe or neurohypophysis;

The anterior lobe which itself is regulated by the hypothalamus secretes a number of important hormones. These include the following seven:

Growth hormone (somatotropin or GH), which is essential for normal growth...;

Prolactin (lactogenic hormone) which regulates the secretion of milk;

Adrenocorticotrophic hormone (ACTH), which controls the secretion of hormones from the adrenal cortex; two gonadotrophic hormones,

one of which (follicle-stimulating hormone (or FSH) controls the formation of ova by the ovary in the female and sperms by the testis in the male,

and the other (Luteinizing hormone or LH) the secretion of sex hormones by the gonads;

Melanocyte-stimulating hormone (MSH), which controls the pigment-producing cells of the skin; and

Thyrotrophic hormone (TSH), which stimulates thyroid gland activity.

The posterior lobe stores and releases two hormones:

³⁵ Gold, EB 1981, 'Epidemiology of pituitary adenomas', *Epidemiologic Reviews*, vol. 3, pp. 163-183; at p. 163. Also see paragraph [100 to 105] of these Reasons.

³⁶ At page 768; Walton, J Barondess, JA and Lock, S (eds.) 1994, *The Oxford Medical Companion*, Oxford University Press, New York, pp. 1-1038. Similar information can be sourced from other well respected medical dictionaries available in Public Libraries.

³⁷ Ibid at p. 768 and 769.

Oxytocin, which initiates labour...stimulates uterine contraction, and also plays a part in lactation; and

Antidiuretic hormone (ADH), which stimulates renal retention of water and has a blood-raising effect.

94. Further, the Council considered histological and functional pituitary tumour classifications³⁸ useful in understanding cell and stimuli specificity:

Histological – the type of cell they originate from:

The anterior lobe;

Chromophobe cells...Chromophobe adenomas... produce symptoms by compressing the normal portions of the pituitary gland, optic chiasm, hypothalamus and adjacent brain...;

Eosinophil cells...Eosinophilic adenomas give rise to hyperpituitarism, acromegaly in adults and gigantism in children...; and

Basophil cells...Basophilic adenomas are generally small and are associated with Cushing's disease.

Functional - whether or not a tumour was hormone secreting:

Producing an excess of:

Growth hormone, resulting in gigantism or acromegaly;

Prolactin, resulting in amenorrhea with or without galactorrhea in women and decreased libido, gynecomastia, galactorrhea, impotence and infertility in men;

Adrenocorticotrophin hormone (ACTH), resulting in Cushing's disease³⁹; and rarely

Thyrotropin, resulting in thyrotoxicosis.

In some cases there may be a combination of these hypersecretory states.

³⁸ Ibid. Gold at p. 164; The format for the quotes has been varied from that of the text for emphasis only.

³⁹ Op. cit., Walton, J Barondess, JA and Lock, S (eds.) 1994, CUSHING'S SYNDROME is the complex of symptoms and signs which results from the effects of excessive corticosteroid activity on the tissues, whether these result from primary overactivity of the adrenal cortex itself, from over-stimulation by excessive corticotrophin secretion by the anterior pituitary gland, or from exogenous administration of corticosteroids, at p. 270.

95. Another important matter was that the information submitted by the RMA to the Council did not contain any original research studies which 'touched on' (ie was relevant to) whether 'chemical and biological warfare' and 'nerve agents' could provide a link or element in a reasonable hypothesis connecting neoplasm of the pituitary gland to service. The Council also had in mind the submission by the Applicant that the information "...*did not contain any references to CBW [chemical and biological warfare]...*"⁴⁰ and the submission by the Repatriation Commission that there "...*was no human epidemiological studies...on the risk from exposure to pesticides or to any of the other chemicals...*"⁴¹ in the information.
96. However, the Council also noted and duly considered that there was data⁴² from secondary references and reports relevant to whether chemicals may be linked to pituitary tumours in animals. The submission by the Repatriation Commission also commented upon "relevant animal data"⁴³ and the Commission's view⁴⁴ having considered the animal data was "*that there are no human epidemiological studies available that provide any specific information on the risk of pituitary neoplasm from exposure to pesticides or to any other chemicals...*" and the Commission concluded "*that in the absence of supportive human epidemiology there was no basis to include any factor for chemicals... as contended by the Applicant.*"
97. However, the Council was cognisant that the Full Federal Court expressly stated that epidemiological tools were to be utilised at step one of the process (determining the pool of information) and not at step two⁴⁵. The only analysis at

⁴⁰ see paragraph [13 and 43] of these Reasons concerning the Applicants request for a review by the SMRC dated January 2005.

⁴¹ See paragraph [63 and 64] of these Reasons and footnote 23 and 24.

⁴² Gold, EB 1981, 'Epidemiology of pituitary adenomas', *Epidemiologic Reviews*, vol. 3, pp. 163-183;

Also see Kociba, RJ et al. 1978 and 1979; Grcevic, N et al. no date; and Synder, SH & D'Amato, RJ 1998, which are considered under New Information at paragraphs [162 to 189].

⁴³ See paragraph [64] of these Reasons.

⁴⁴ Repatriation Commission submission at paragraph [66 and 67] of these Reasons.

⁴⁵ Full Federal Court decision, per Branson J at [47] -[49];

'The terms of s 5AB (2)...make it clear that it is at the stage of step one, not step two, that information is evaluated in the light of material published in learned journals, accepted medical practice and, if relevant, applicable epidemiological criteria for assessing causation. Information which satisfies the criteria set out in s 5AB(2) is 'sound medical-scientific evidence' within the meaning of the Act.

*The second step...is to...determine whether there is 'sound medical-scientific evidence' that **indicates** that the particular kind of injury, disease or death **can be** related to operational service rendered by veterans...That is...the RMA [and on review, the Council] must evaluate and characterise the relevant 'sound medical-scientific evidence' and form a view as to whether it points to, as opposed to merely leaves open, the possibility of the particular injury, disease or death being related to operational service rendered by veterans'* (emphasis in the original); and

See too per Branson J at [51], in which her Honour stated that the Council in conducting its review must necessarily take the same steps as the RMA is required to take.

the second step is to determine whether the information in the pool 'points to' or 'leaves open' the relevant association.

98. In these circumstances the Council wanted to acknowledge all the information available to (before) the RMA and the information and data it was directed to or that was relied upon by the Applicant and Commission in the correct legal context. The Council had to review all and only the information that was available to (before) the RMA at the relevant times to decide if there was sound medical-scientific evidence including that of animal studies that could provide a link or element in a reasonable hypothesis, a hypothesis that was not '*obviously fanciful, impossible, incredible or not tenable or too remote or too tenuous*'⁴⁶. The Council noted the submissions about new information and data, but was not able to take them into account for the purposes of the review, because they were not available to (not before) the RMA at the relevant times.

Literature Reviews & Textbook

Gold, EB 1981 (1), Levy, A and Lightman, S 2003 (2), Melmed, S 2003 (3), Asa, SL and Ezzat, S 1998 & 2002 (5&6) and Melmed, S and Jameson, JL 2002 (7)

99. The authors of these 5 literature reviews and 1 text book review some 500 original medical science articles, the then current medical science data concerning pituitary adenomas in papers published in the period 1981-2003. Collectively the authors reviewed the epidemiological, molecular, genetic and cellular characteristics of pituitary tumour development and normal and abnormal pituitary functioning.

Gold, EB 1981 (1)

100. The Author of this literature review noted that only limited data was available regarding risk and causal factors in human populations, with much of the relevant data on the development of these adenomas from animal studies, which may or may not have direct applicability to the development of these adenomas in humans.
101. Possible exogenous risk factors for pituitary adenomas derived from experiments in animals were identified by the author as including radiation, chemical carcinogens, oestrogens and oral contraceptives (OC's). The author noted methodological shortcomings of such studies such as 'lack of control of numbers of animals studied' and the uncertainty as to whether findings in animal studies are directly applicable to humans. However the author acknowledged such studies:

⁴⁶ See paragraph [79 and 80] and footnotes 29 to 32.

...make important contributions regarding likely modes of pathogenesis of pituitary adenomas...and important clues for future epidemiologic investigations in humans. (at p. 175)

102. Gold reported that the possibility of a relationship between chemical carcinogens and pituitary adenomas was derived mostly from experiments in mice and rats. However, in three studies⁴⁷, rats which were not experimentally treated with any chemicals were found to have a relatively high occurrence of spontaneous pituitary adenomas. In addition the findings included some variation in occurrence of pituitary tumours by strain of rat and sex.
103. The author also reviewed four animal (rats and mice) studies⁴⁸ which reported on pituitary adenomas followed intracranial injection or implantation of various chemicals. The findings in these studies were of an apparent lack of a marked increased frequency, or only a slight increase, of pituitary adenomas following exposure to carcinogenic chemicals.
104. The author concluded that animal study findings are noteworthy in that studies in humans of other tumour sites or of malignant tumours for the most part were conducted in occupational groups with known exposures to specific chemicals and were largely mortality studies, so that pituitary adenomas would not likely appear as an outcome of such exposure.
105. The author further concluded:

Although clinically symptomatic pituitary adenomas are characterized by relatively low incidence rates, asymptomatic pituitary adenomas may be a relatively frequent development during the ageing process, as shown in animal and autopsy studies, the latter indicating that approximately 25 per cent of

⁴⁷ At p. 174 – Note: these secondary sources are not in the information sent by the RMA to the SMRC for this review:

Wolfe, JM Bryan, WR and Wright, AW, 1938, 'Histologic observations on the anterior pituitaries of old rats with particular reference to the spontaneous appearance of pituitary adenomata', *Am J Cancer*, vol. 38, pp. 352-372;

Ito, A et al. 1972, 'Incidence and character of the spontaneous pituitary tumours in strain CR and W/Fu male rats', *JNCI*, vol. 49, pp. 701-711; and

Burek, JD & Hollander, CF 1977, 'Incident patterns of spontaneous tumours in BN/Bi rats', *JNCI*, vol. 58, pp. 99-105.

⁴⁸ At p. 174-175 – Note: these secondary sources are not in the information sent by the RMA to the SMRC for this review:

Weil, A & Hetherington, AW 1942, 'Experimental tumours of the hypophysis of the white rat', *Journal of Mt Sinai Hospital*, vol. 9, pp. 842-849;

Perese, DM & Moore, GE 1960, 'Methods of induction and histogenesis of experimental brain tumors', *J Neurosurg*, vol. 17, pp. 677-699;

Oberling, C et al. 1936, 'la production experimentale de tumours hypophysaires chez le rat', *CR Seanc Soc Biol.*, vil 123, pp. 1152-1154;

Perry, IH & Lockhead, MS 1939, 'The experimental production of adenoma of the pituitary', *Am J Cancer*, vol. 35, pp. 422-423.

individuals dying of causes unrelated to and without symptoms of pituitary disease have pituitary adenomas. (at p. 179)

In animals causal factors for pituitary adenomas have been found to include hypothyroidism, radiation exposure, susceptibility of certain strains of animals – possibly suggesting genetic differences – gonadectomy, estrogens, chemical carcinogens such as methylcholanthrene and dibenzanthracene, and OCs [oral contraceptives]. (at p. 179)

However, the role(s) of these agents in the aetiology of pituitary adenomas in humans has only begun to be investigated. In particular, epidemiologic studies of young women concerning use of OCs have been undertaken. The findings of these studies thus far have not shown any consistent relationship between use of OCs and development of pituitary adenomas, although the numbers of cases in the studies reported to date have been small. Thus the role(s) of OCs and other chemicals and exogenous agents remains uncertain but these risk factors offer provocative areas for future epidemiologic examination. (at p. 179)

Levy, A and Lightman, S 2003 (2)

106. The authors of this literature review summarise current thinking on the precise origin and development of pituitary tumours, noting that despite the prevalence of these tumours, the precise molecular origin and development of the majority of them remains unclear.

107. The authors report;

Pituitary adenomas are known to be remarkably common. Their presentation through space occupation, hormone secretion or pituitary failure is relatively infrequent. (at p. 94)

When they do become overt their clinical behaviour in most cases is remarkably benign...(at p. 94)

Pituitary adenomas occasionally appear to stop growing altogether...(at p. 94)

Long term follow up of hyperprolactinaemic patients indicates that pituitary adenomas may in some cases also resolve of their own accord. (at p. 94)

Truly malignant, metastatic behaviour...typical of other common malignancies such as those of the lung, colon, or breast, is extremely rare. (at p. 95)

Pituitary adenomas frequently retain their ability to synthesize and secrete hormone and occasionally acquire new function...(at p. 95)

When hormone secretion is present, it frequently remains regulated and responsive to normal trophic influences, retaining some of the qualitative if not quantitative characteristics of normal pituitary responses. (at p. 95)

In a review of 57 patients with Cushing's syndrome and 8 with Nelson's syndrome⁴⁹, removal of tissue that was histologically indistinguishable from normal pituitary gland in 17 patients nevertheless resulted in a cure in 14. (at p. 95)

108. The authors present their consideration of the findings of studies on the proliferation of cells in the pituitary gland in response to transient but often repeated stimuli, the clonal architecture of the normal pituitary and clonality of pituitary tumours and a detailed consideration of the chromosomes and proteins which may be associated, responsible or present at the time of tumour development.

109. The authors summarise their main findings of:

...activating GNSI mutations are the only known unequivocal association of sporadic pituitary adenomas and menin and germ line PRKAR1A mutations the only associations with familial predisposition to pituitary adenomas (at p. 111); and

Otherwise, it remains uncertain whether the molecular defects that have been found within the pituitary are acquired and pathogenic, or whether in part, they are amplifications of variations within structurally normal pituitary tissue. (at p. 111)

110. The authors conclude that there has been an acceleration in the rate at which molecular defects have been associated with the origin and development of defined pituitary adenomas over recent years and clear evidence that classical mechanisms of tumour formation are associated with few of these tumours.

111. The authors further conclude that quantitative molecular defects capable of inducing persistently abnormal growth in model systems and human tissues have now been identified in the majority of human pituitary adenomas. The definition of certain molecular defects responsible for familial pituitary adenoma formation may allow future determination of other common specific mechanisms of some pituitary tumour formation. Mutations in key molecules that control secretion and growth have been identified but causes of these mutations are unknown.

112. The authors final conclusions are:

⁴⁹ Oxford Concise Medical Dictionary 6th Edn 2002: "Nelson's Syndrome" "negative feedback loops". Nelson's Syndrome is a condition in which an ACTH-producing pituitary tumour develops after loss of negative feedback following bilateral adrenalectomy for Cushing's syndrome. Negative feedback loops are physiological loops for the control of hormone production by various glands. High levels of a circulating hormone act to reduce production of the releasing factors triggering its own production, i.e., they have a negative feedback on these trigger factors. As circulating levels of the hormone fall, the negative feedback is reduced and the releasing factor starts to be produced again allowing the hormone level to rise again, Oxford University Press, p. 460. Also see footnote 39 at paragraph [94] – Cushing's Disease.

...that an accumulation of genetic defects results in a single cell misinterpreting or ignoring essentially normal extracellular signals and dividing sequentially to produce a discrete monoclonal expansion, the propagation of which may be facilitated by permissive exogenic [environmental] factors, but the overall extent of which is unlikely to depend on these factors. (at p. 112)

In light of published data, however, it is worth considering the possibility that in some cases pituitary adenomas are not tumours in the normally accepted sense, but the result of an exuberant but essentially normal trophic response that fails to return to normal after a transient growth stimulus has passed. (at p. 112)

Melmed, S 2003 (3)

113. The author of this literature review discusses the mechanisms underlying hereditary based deficient or excessive functioning of the pituitary gland (hereditary pituitary hypoplasia, reversible pituitary hyperplasia, excess hormone production), and tumour initiation and promotion associated with normal and abnormal pituitary differentiation in health and disease.
114. The authors note five highly differentiated cell types in the pituitary and that tumours may arise from any of these cells, resulting in hormone secretion depending on the cell of origin. Excess pituitary hormone secretion is usually associated with invariably benign monoclonal adenomas arising from a specific cell type and pituitary chromosome instability is an early hallmark of pituitary adenoma development and growth. The authors explain the factors regulating pituitary growth, from hypoplasia through hyperplastic, and adenoma development at the cellular and genetic level.

Wass, JAH and Besser, M 1995 (4)

115. In this text the aetiology of anterior pituitary tumours is described by the authors as:

largely unknown and it is probable that there are various causes for their development (Molitch 1987)⁵⁰. All cell types in the pituitary can become neoplastic.
116. The authors go on to describe elevated hormonal factors and possible genetic factors in the development of pituitary tumours and concludes that the existing weighted evidence that exists suggests that for the majority of pituitary tumours there is a primary pituitary abnormality. The authors postulate that in the future other types of pituitary tumour will be found to have oncogenic mutations that allow cells to bypass their normal requirements for trophic hormone stimulation.

⁵⁰ Molitch 1987, is cited in Wass, JAH and Besser, M 1995, which was available to the RMA. However Molitch 1987 was not information available to (before) the RMA and the full citation is not in the pages of the Wass and Besser 1995 information sent by the RMA to the SMRC.

117. Bilateral adrenalectomy⁵¹ is also described:

Cushing's disease may be associated with normal or elevated adrenocorticotrophic hormone levels, but in Nelson's syndrome (post-bilateral adrenalectomy enlargement of the pituitary and pigmentation) the level of adrenocorticotrophic hormone is invariably very elevated. Corticotroph adenomas tend to be small and are frequently microadenomas. Only rarely are they large and they may be highly invasive.

Asa, SL and Ezzat, S 1998 & 2002 (5&6)

118. In the 1998 literature review the authors postulate that the majority of pituitary tumours develop from transformed cells that are dependent on hormonal and/or growth factor stimulation for tumour progression. After describing the tumours, their epidemiology and classification, the authors review the studies indicating roles for hormonal stimulation in the development of pituitary tumours and the data concerning the molecular events underlying cell transformation to show that two theories of the cause of pituitary tumours, hormonal stimulation and intrinsic pituitary defect, have merit and that the cause of pituitary tumours is likely a model of the multistep process of carcinogenesis in which molecular genetic alterations provide the initiating event that transforms cells, while hormones and/or growth factors play a role in promoting cell proliferation.
119. In the later 2002 review authors review mouse models to validate the roles of hormones and growth factors implicated in pituitary development, noting there are many differences in disease pathogenesis between mice and humans.

Melmed, S and Jameson, JL 2002 (7)

120. In this text the authors describe disorders of the anterior pituitary and hypothalamus including the anatomy and development of the pituitary gland, classification of pituitary tumours and genetic syndromes associated with them, their diagnosis, evaluation and treatment.
121. The authors describe several causal genetic events implicated in the development of pituitary tumours and note that compelling evidence favours hormonal contribution to growth and behaviour of pituitary tumours.
122. The authors explain that the pituitary gland responds dynamically to complex signals that can induce reversible involution or growth of cells from hypothalamic and peripheral hormonal signals. Among factors causing hyperplasia are activating mutations of receptor and signal transducing molecules, loss of function mutations of tumour suppressor genes excessive production of trophic hormones including hypothalamic hormones and oestrogens.

⁵¹ Relevant to the Council's reasons at paragraph [194 to 219].

Council's analysis of Gold, EB. 1981 (1), Levy, A and Lightman, S 2003 (2), Melmed, S 2003 (3), Asa, SL and Ezzat, S 1998 & 2002 (5&6) and Melmed, S and Jameson, JL 2002 (7)

123. In the Council's view these are comprehensive and in depth reviews and textbooks which have remained informative.
124. The Council's preliminary comments [paragraphs 92 to 98 above] are essential to an understanding of these publications. In particular, that the pituitary gland is not a homogeneous gland; it is composed of distinct cell types. Factors or stimuli that impact on each cell type are cell specific. Further, that the cause of a particular cell-type tumour cannot be extrapolated from animal studies and epidemiologic observations. Put simply a stimulus that causes growth of one cell type may not have an effect on another cell type and the effect in an animal and human cell also differ.
125. Gold considered possible environmental risk factors for pituitary adenomas, including chemical carcinogens, but identified that there was no medical-scientific evidence of these exposures having a causal contribution to the development of these tumours in humans. The Council considered that the findings of Gold's 1981 review of the medical science literature did not point to the relevant association, but left open the possibility of the relevant association.
126. The Council noted that none of the other publications above make mention of any environmental agent as a causative factor in the development of pituitary tumours and therefore considered that the findings of the other authors of the other literature review and textbooks did not point to the relevant association.

Council's comment–Studies⁵² in respect of Oestrogen

127. The Council noted the inclusion in the information of evidence relevant to oestrogen as a possible cause of prolactinomas, one type of pituitary gland tumour. The Council considers the findings of these studies relevant only in that they provide an example of findings and discussion about a specific pathway for the development of a specific pituitary tumour, that of a prolactinoma.
128. Accordingly, while the Council considered these two studies describe a possible causal mechanism, explaining how oestrogen may cause particular types of pituitary tumours, the Council considered these mechanisms to be specific to oestrogen induced tumours. In the Council's view (for the reasons described at paragraph [124]) the same mechanisms do not provide a possible pathway or support the possibility of a relevant association with 'chemical and biological warfare' and 'nerve agents' and the formation of (other types of) pituitary tumour.

⁵² Heaney, AP et al 2002 (8); and Scheithauer, BW et al 1989 (9). Also see 'Articles cited...' list at the end of these Reasons.

129. While the Council considered this information in making its preliminary scope of review decision, it did not included 'oestrogen' in its preliminary or final decisions on the scope of the review as the studies are not relevant to 'chemical and biological warfare' and 'nerve agents' and thus the Council has only commented as above.

SHOULD THERE BE A 'CHEMICAL AND BIOLOGICAL WARFARE' AND 'NERVE AGENTS' FACTOR(S) ?

Council's analysis – 'Chemical and Biological Warfare and Nerve Agents'

NAS IOM 1994 and 1996, 1998, 2000 and 2002 updates (10)

130. The reports⁵³ of findings⁵⁴ of the National Academy of Sciences (NAS) Institute of Medicine (IOM) are summarised on the basis of an association (if any) between specific health problems and exposure to herbicides:

...sufficient evidence of an association, limited/suggestive evidence, inadequate /insufficient evidence to determine whether an association exists and limited/suggestive evidence of NO association.

Methodologically the findings were determined on whether a statistical association exists, the increased risk of each disease for those exposed during Vietnam service (United States of America forces) and whether a plausible biologic mechanism or other evidence of a causal relationship exists⁵⁵.

131. The committee's findings were that:

Although there have been numerous health studies of Vietnam veterans, most have been hampered by relatively poor measures of exposure to herbicides or TCCD, in addition to other methodological problems. (at page 14)

⁵³ On 6 February 1991 the Congress of the United States of America directed the Secretary of Veterans Affairs to request the National Academy of Sciences (NAS) to conduct a comprehensive review and evaluation of the available scientific and medical information regarding the health effects of exposure to Agent Orange and other herbicides used during the Vietnam conflict.

The NAS is a nongovernmental organisation dedicated to the furtherance of science and technology and to their use for the promotion of general public welfare. The 16 members of the the NAS Institute of Medicine (IOM) Committee which undertook the review and evaluation (as with all IOM committees), voluntarily serve without compensation and are drawn from Universities and the private sector, and are elected by their peers on the basis of exemplary professional achievement. This Committee's expertise included experts from occupational and environmental medicine, toxicology, epidemiology, pathology, clinical oncology, psychology, neurology and biostatistics. As with all reports from the IOM, the committee's work was reviewed by an independent panel of distinguished experts.

⁵⁴ NAS IOM 1994, id; Executive Summary Table 1-1 at p. 6.

⁵⁵ NAS IOM 1994,id., at p. 221.

...the inadequate control for important confounders, and the uncertainty about the nature and magnitude of exposure... it is not possible for the committee to quantify the degree of risk likely to be experienced by veterans because of their exposure to herbicides in Vietnam. (at page 15)

The available quantitative and qualitative evidence...suggests that Vietnam veterans as a group had lower exposure...than the subjects in many occupational and environmental studies. (at page 15)

...those with documented high exposures, such as participants in Operational Ranch Hand...could have risks approaching those in the occupational and environmental studies. (at page 15)

132. The Committee made six major research recommendations to resolve areas of continuing scientific uncertainty concerning the health effects of the use of herbicides in Vietnam. These included epidemiologic studies of Vietnam veterans.

Council's analysis

133. The Council notes that the Commission referred it to a citation in this report, at pp.138-139, in respect of the 1978 study by Kociba et al⁵⁶ on the authors findings concerning carcinogenicity of 2,3,7,8-tetrachlorodibenzo-*para*-dioxin (TCDD) in animals.
134. Importantly the Council notes that the Council is restricted to the information sent to it by the RMA, the information which was available to the RMA when it made the Statements of Principles subject to review. The information available to the NAS committee was far more extensive including that of original medical science research data. Thus, the Council and the NAS committee were operating within a different legal and administrative framework when undertaking their respective functions.
135. The Council did not identify in the findings of this committee any sound medical-scientific evidence in respect to the human endocrine system generally or specifically in respect to the human pituitary gland or pituitary gland tumour. The updates (1996-2002) to the 1994 report provided no new data or findings in respect to the pituitary gland.
136. The Council considered that the findings from this report and its subsequent updates (1996-2002) did not point to the relevant association.

⁵⁶ Kociba, RJ et al 1978 is new information. That is, it is information which was not available to (not before) the RMA. As such the SMRC has commented upon this information at paragraph [159-166] of the these Reasons.

Evatt, P 1985 (11)

137. The Royal Commission reviewed human and animal data⁵⁷ from all around the world.
138. The report was prepared with senior consultant medical scientific expertise lead by Prof JD Mathews FRACP and Reproductive, Neurotoxicology, Carcinogenesis, and Genetic Toxicology experts, with 50 other medical consultants.
139. The Royal Commission based its conclusions about herbicides, pesticides, drugs and solvents in relation to cancer on the evidence of Dr Bernard Stewart BSc, MSc, PhD (then Principal Research Fellow in the Childrens' Leukaemia and Research unit, Prince of Wales Hospital, NSW and IARC WHO committee member), Dr Ian Munroe BSc, MSc, PhD Genetic Toxicologist and Dr Philippe Shubik BM, BCh, PhD, DM Carcinogenesisist, all expert consultants to the Commission). In particular Dr Stewart's evidence was that:

TCDD and DDT are the chemicals whose activity as carcinogens is best established in experimental animals. (at p. VIII-396)

In respect of DDT, the available epidemiology do not establish carcinogenicity in humans...TCCD cannot be regarded as having been established as carcinogenic in humans. (at p. VIII-396)

Certain...remaining chemicals are capable of producing benign tumours in mice...may be suggestive of human hazard...the activity of these chemicals seems to infer that they might be active as promoting agents rather than exhibiting complete carcinogenic activity in humans. (at p. VIII-396)

140. Dr Stewart concluded:

If speculation upon the worst possible ...what I believe to be credible scenario...it would be predicted that some increase in environmentally determined promotional influences might be experienced by the exposed population...To be biologically effective, exposure to promoters normally involves a long period, that is a significant proportion of either the animals or humans' lifetime...we have not got that in the the present human situation. (at p. VIII-397)

141. Dr Ian Munroe's oral evidence was:

⁵⁷ including that of Australian Veterans Health Studies (AVHS) Mortality Report 1984 (Dr MJ Fett as Principal Investigator); Ranch Hand 1 of 1983 and 2 of 1984 (Colonel Lathrop as Principal Investigator); Veterans Affairs USA human data; Greenwald et al (undated); Kogan et al 1985; and Occupational and Industrial studies data, from the Table of Contents, vol. 4, chapter VIII, p. v-viii.

...based at least upon my knowledge of the animal toxicity studies....I would not expect long term effects....in animal studies it is fairly clear now that long term high dose exposure, certainly to near toxic doses of dioxin is required over a very long period of time, essentially lifetime in order to produce toxic effects like cancer...(at p. VIII-398)

142. The Royal Commission having regard to this evidence concluded:

...that no long term effect in cancer induction has been caused to Australian personnel...by chemical exposure in Vietnam whether to any particular chemical or...combination of chemicals. (at p. VIII-398)

143. The evidence before the Royal Commission on dapsone⁵⁸ included submissions by Dr Phillips Shubik in which he stated:

...I would select dapsone as the most likely compound to pose a potential carcinogenic hazard. This compound is an aromatic amine which has been found to give rise to mesenchymal tumours of the spleen and thyroid tumours in rats. (at p. VIII-381)

144. The Royal Commission having regard to the evidence on dapsone before it was of the view:

...that cancer induction by reasons of dapsone ingestion in Vietnam is unlikely but is not fanciful and a claim based on such allegation should be treated on the basis that a reasonable hypothesis exists connecting the cancer with service in Vietnam. (at p. VIII-398)

Council's analysis

145. The Council notes that the report:

"...[on] reaching a decision as to whether a particular issue has been proved to the reasonable satisfaction of the Commission, it may be that such a decision might reflect relevant epidemiological findings in accordance with the epidemiological principles referred to [in the report]."

146. The approach taken on the Royal Commission is different from that which the Specialist Medical Review Council must follow as set out by the Full Federal Court⁵⁹ case, in which the court confirmed epidemiological principles are taken into account in deciding the Pool of Information, but not in deciding whether or not the Reasonable Hypothesis (RH) or Balance of Probabilities (BoP) tests are satisfied.

⁵⁸ Dapsone was used in a anti-malarial prophylactic campaign for Australian soldiers in Vietnam.

⁵⁹ *Vietnam Veterans' Association (NSW Branch) Inc v Specialist Medical Review Council and Anor* (full Federal Court decision) (2002) 72 ALD 378.

147. The Council notes the Commission referred the Council to volume 4 on Health Effects - Cancer of the Royal Commission's Final report, which includes extensive material on the carcinogenicity of various chemicals, including most of the pesticides referred to by the applicant. However, neither the Commission in its submission to the Council nor the Council itself identified evidence in relation to the pituitary gland or to pituitary gland tumours in vol. 4 or in the Commission's Final Report as a whole.
148. The Council considered that the findings of the Evatt Commission did not point to and left open the possibility of the relevant association between the contended factor(s) and neoplasms of the pituitary gland.

THE COUNCIL'S CONCLUSIONS ON WHETHER THERE SHOULD BE A 'CHEMICAL AND BIOLOGICAL WARFARE' 'NERVE AGENTS' FACTOR(S)

149. The Council, having closely analysed all the information in the pool, placed particular weight on the articles discussed in detail above. The critical question for the Council was whether the sound medical-scientific evidence 'points to, as opposed to merely leaves open, the possibility of the⁶⁰ relevant association.
150. In the absence of original research studies in the information sent by the RMA to the Council on the subject, 'chemical and biological warfare' and 'nerve agents' the Council placed great weight on the literature reviews and articles published in highly credible journals by eminent authors. The findings of these major reviews do not mention exposure to 'chemical and biological warfare' and 'nerve agents' in the origin and development of human pituitary tumours.
151. While the Council notes there was some sound medical-scientific evidence⁶¹ in the information that chemicals may be linked to pituitary tumours, as mentioned above (see paragraph [125]) the relevance of any chemical to the cause of a particular tumour cell-type cannot be extrapolated from these animal and epidemiological observations. A stimulus that causes growth of one cell type may not have an effect on another cell type and the effect in an animal and human cell may also differ. Hence the Council's view above that the findings from animal studies have limited direct application for the development of human pituitary gland tumours. In the Council's view this evidence did not point to, but left open the possibility of the relevant association.
152. The Council notes that oestrogen is one stimulus that causes growth and tumour development of lactotrophs, cells that produce the hormone prolactin⁶². Oestrogens do not stimulate the growth of any other pituitary cell type.

⁶⁰ see full Federal Court decision at paragraph 49 per Branson J, and paragraph 84 of these Reasons.

⁶¹ Particularly see Gold, EB 1981, id; at paragraphs [100 to 105].

⁶² Heaney, AP et al 2002, id.(7).

Epidemiological evidence linking the use of oral contraceptives to pituitary tumours concern prolactin secreting tumours only⁶³. That is, in the Council's view this evidence does not point to any possible link between chemical and biological warfare and nerve agents and pituitary tumours.

153. While always cognisant that the reasonable hypothesis standard is a low threshold and an unusually light burden, the Council's conclusion was that the sound medical-scientific evidence was insufficient to point to chemical and biological warfare and nerve agents as a potential link or element in a reasonable hypothesis connecting neoplasm of the pituitary gland with relevant service (see paragraphs [6 and 80] and footnotes 3 & 29).
154. Accordingly, the Council concluded that the sound medical-scientific evidence was insufficient to justify amending the reasonable hypothesis Statement of Principles (number 42 of 2004) to include a 'chemical and biological warfare' and 'nerve agents' factor(s).

COUNCIL'S ANALYSIS OF THE NEW INFORMATION – 'CHEMICAL AND BIOLOGICAL WARFARE AND NERVE AGENTS'

155. The status of the information discussed below is 'new information', that is, it is information that was not available to (not before) the RMA. Accordingly, it has not been taken into account for the purposes of the review.
156. Rather, the Council has considered the new information to determine whether, in the Council's view, it warrants the Council making any directions or recommendations to the RMA.
157. In the Council's view any such direction or recommendation should only be made by the Council if it formed the view that the new information:
 - a. comprised sound medical-scientific evidence as defined in section 5AB(2) of the VEA being information which:
 - i) epidemiologists would consider appropriate to take into account; and
 - b. in the Council's view, 'touches on' (is relevant to) 'chemical and biological warfare' and 'nerve agents' and has been evaluated by the Council according to epidemiological criteria, including the Bradford Hill criteria; and

⁶³ Gold, EB 1981, *ibid.* (8).

- c. could potentially satisfy the reasonable hypothesis and/or balance of probabilities tests (as appropriate; see paragraph [6 and 80] above for the relevant considerations for the reasonable hypothesis test).

158. Applying the above criteria to the new information referred to the Council by the Applicant and by the Commission, the Council in these Reasons focussed its analysis on the following articles.

Kociba, RJ et al 1978⁶⁴ (14)

159. This early article reports an increased incidence of certain carcinomas, but reduced incidence of tumours of the pituitary and certain other organs in rats maintained for 2 years on diets supplying 2,3,7, 8-tetrachlorodibenzo-p-dioxin (TCDD). The authors reported the data to indicate that continuous doses of TCDD sufficient to induce severe toxicity increased the incidence of some types of tumours, while reducing other types, including pituitary tumours.

Exposure to 2,3,7,8-Tetrachlorodibenzo-p-Dioxin

160. The authors' reported in respect of "squamous cell carcinoma in female rats or maybe keratinizing squamous cell carcinoma" "...significantly reduced incidences in tumours of the pituitary, uterus, pancreas, mammary glands, pancreas, and adrenal gland..."

Council's analysis

161. The Council notes the authors' primary finding of significant liver damage in this 2 year study of rats fed a range of doses of TCCD.

162. The Council considers interesting the authors finding that "female rates given 0.1 ug/kg/day had a significant decrease in the incidence of pituitary changes, including hemangiectasis and adenoma formation" but male rats did not⁶⁵.

163. The Council concludes that while there was no reported difference in tumours for male rats, this study indicates it is possible that dioxin acts to protect from pituitary adenomas.

164. The Council notes that the reduced incidence of pituitary tumours reported by Kociba et al in rats treated for two years on TCCD (dioxin) is contrary to the findings of Gold, EB where the findings, again in rats, were in respect of induced methylcholanthrene and dibenzanthracene.

⁶⁴ Kociba, RJ et al 1978, id., at footnote 24.

⁶⁵ Kociba, RJ et al 1978, at p. 300. The Council also notes that the use of significant by the authors is in respect of statistical significance.

165. The Council considers that the Kociba et al findings are important as they directly relate to the contended factor of chemical and biological warfare, but nevertheless in the Council's view findings in animal studies are limited as discussed previously in these reasons.
166. The Council considered that the findings from this study could not potentially point to the relevant association.

Kociba, RJ et al 1979⁶⁶ (15)

167. This subsequent article by the same authors reported that even the highest dose levels of 2,4,5-T did not adversely affect tumour incidence in rats.

Exposure to 2,4,5-Trichlorophenoxyacetic Acid

168. The authors report that this study revealed no oncogenic response in rats, even when the duration of 2,4,5-T administration extended over most of the lifespan at a range of doses including at a dose high enough to induce toxicity.
169. The authors report that the incidence over the whole study (2 years) of pituitary adenoma formation(s) was 22 of 86 male rats for dose 0mg/kg/day and 10 of 50 male rats for dose 30mg/kg/day and similarly 42 of 86 female rats for dose 0mg/kg/day and 19 of 50 female rats for dose 30mg/kg/day.⁶⁷

Council's analysis

170. As above the Council considered that the Kociba et al findings are important as they directly relate to the contended factor of chemical and biological warfare, but nevertheless in the Council's view findings in animal studies are limited as discussed previously in these reasons.
171. The Council notes the authors provided no explanation for the paradoxical finding (1978 and 1979) of the incidence of pituitary tumours.
172. The Council considers that the findings from this study could not potentially point to the relevant association.

⁶⁶ Kociba, RJ et al 1979, 'Results of a two year chronic toxicity and oncogenic study of rats ingesting diets containing 2,4,5-trichlorophenoxyacetic acid (2,4,5-T)', *Food and Cosmetics Toxicology*, vol. 17, pp. 205-221. In National Academy of Sciences 1994, *Veterans and Agent Orange: Health Effects of Herbicides used in Vietnam*. The National Academies Press Washington D.C., pp. 1-812.

⁶⁷ Kociba, RJ et al 1979, id., at p. 216-217, Table 3 and p. 218-219, Table 4.

Grcevic, N et al⁶⁸ date unknown (16)

173. This is a report of a post mortem study of the brains of two patients who died following ingestion of paraquat⁶⁹. The patients had survived the acute intoxication for 9 and 11 days respectively, suffering initial vomiting, nausea, abdominal pains, dizziness and general malaise followed by jaundice and renal failure, coma and death.
174. The authors report adverse changes in the brains, which could have been attributable to paraquat ingestion. No mention is made of the pituitary gland of either patient.

Council's analysis

175. The Council notes that this study was referred to the Council by the Applicant who cited it as exhibit 31 in *Re Repatriation Commission and Schar*.
176. The Council considers that the Grcevic, N et al findings are potentially important as they directly relate to the contended factor of chemical and biological warfare, but the authors do not mention any impact on human pituitary tumours.
177. Further, the Council notes the findings relate to two case studies, which limits the applicability of the findings to any conclusions for the wider population, even if the findings were supportive of the relevant association, which they are not.
178. The Council notes the proposed link between this study and the relevant association relates to the potential injury caused by paraquat to dopamine neurones and the contention that the loss of dopamine neurones may cause a type of tumour.
179. The Council could find in this study no data on the development of a ACTH secreting tumour and further no data of a biochemical link with pituitary gland tumours.
180. The Council considers that the findings from this study could not potentially point to the relevant association.

⁶⁸ Grcevic N, Jadro-Santel D, Jukie S 1977, 'Cerebral changes in Paraquat poisoning'; in Roizin L, Shiraki H, Grcevic N (eds) 1977, *Neurotoxicology*, Raven Press, New York, vol. 1, pp. 469-484.

⁶⁹ 1,1'-dimethyl 4,4'-bipyridylum dichloride, Gramoxan®, Weedol®.

Synder, SH & D'Amato, RJ 1985⁷⁰ (17)

181. This article discusses the possibility that exposure to specific environmental toxins may predispose people to develop Parkinson's disease later in life.
182. This is a review of literature. The authors consider then recent literature of the specific environmental toxin cyperquat, which the authors say has a similar structure to the herbicide paraquat and some studies speculated may underline most cases of Parkinson disease.

Council's analysis

183. The Council notes this review was cited in *Re Repatriation Commission and Schar* (AAT case) and considers this review is similar to the Grcevic, N et al study in that it proposes a theoretical link between injury by exposure to toxins (dioxins) to dopamine neurones causing a tumour.
184. However, the Council concluded that the review provides no information additional to that of the Grcevic, N et al study which would support this theoretical link or the relevant association.
185. The Council considered that the findings from this study could not potentially point to, the relevant association.

Other new information referred to the Council

186. The Council applied the above criteria (see paragraph [157]) to other new information (the other new information) referred to the Council by the Applicant⁷¹ and by the Commission⁷², as it was of the view that this information did touch on

⁷⁰ Synder, SH & D'Amato, RJ 1985, 'Predicting Parkinson's Disease', *Nature*, vol. 317, 19 September, pp. 198-199.

⁷¹ Applicant referred to 'other new information'. Also see paragraph [58]:
House, WB Goodson, LH Gadberry, HM Dockter, KW 1967, Assessment of Ecological Effects of Extensive or Repeated use of Herbicides, Midwest Research Institute, Kansas City, reproduced by National Technical Information US Dept of Commerce, Springfield. pp 1-369.
Young, AL Calcagni, JA Thalken, CE Tremblay, JW 1978, The Toxicology, Environmental fate and Human risk of herbicide Orange and its Associated Dioxin, Prepared for The Surgeon General United States Air Force, Washington, D.C. by USAF Occupational and Environmental health Laboratory, Aerospace Medical Division (AFSC), Brooks Air Force Base, Texas. pp 1-400.
Sinclair, IM 1982, Report on the use of herbicides, insecticides and other chemicals by the Australian Forces in South Vietnam – Summary of files not found in South Vietnam based Army Headquarters and Units, Book 1, pp 1-A-1 to 1-E-15; Report and Ministerial Statement, pp. 3278-3286; Report – Royal Australian Air Force, pp. 1-5; Report Australian Army, Book 1, pp. 1-1 to 1-G-1; Book 2, pp. 2-1 to 2-8; and Book 3, pp. 3-1 to 3-3-A-1.
Pollak, JK n.d., Were the methods used by the Evatt Royal Commission – to evaluate toxic effects on reproduction and development – valid? pp. 45-54. In Steele, EJ Bellett, AJD McCullagh, PJ and Selinger, B eds. 1989, Evatt revisited, pp. 1-105.

⁷² Commission referred to 'other new information'. Also see paragraph [73]:

(was relevant to) the relevant association. That is, the Council considered the other new information was 'sound medical-scientific evidence' and was information 'relevant to' 'Chemical and Biological warfare & Nerve Agents' (ie was within the scope of the review). However, in the Council's view this information was not 'potentially able to satisfy the reasonable hypothesis test'. While the 'other new information' (listed at footnotes 71 and 72 below) provides an analysis of the effect of Chemical and Biological Warfare & Nerve Agents on humans (and a range of other analyses), on the basis of a consideration of a large body of medical science, it provides no further data specific to neoplasms of the pituitary gland than the information analysed by the Council above.

187. Having considered the 'other new information' and in forming the view that it could not potentially meet the reasonable hypothesis test, the Council limited its written analysis of new information to that which the Applicant relied upon in support of his contentions and to that which the Commission identified as information which was 'relevant animal data'.

Re Repatriation Commission and Schar (1991) 25 ALD 503 (18)

188. The Council noted the importance the Applicant placed on the medical science as presented in the decision of his AAT case. The Applicant referred to his case in the written grounds of his application and his submission about this information is summarised at paragraph [48 to 53].
189. The Council's analysis of the medical science relied upon by the Applicant in his AAT case and written submissions to the Council and the Council's conclusions are at paragraphs [173 to 185].
190. The Council noted that the RMA advised that the transcript of the decision of the AAT was new information as it was information that was not available to (not before) the RMA. The Council considered it information which was not sound medical-scientific evidence.

The Council's conclusions on the analysis of the new information on 'chemical and biological warfare' 'nerve agents' factor(s)

191. The Council noted the Commission's submission on new information that there is 'no data specific to pituitary neoplasm' and that 'neoplasm of the pituitary do

Wolfe, WH Michalek, JE Miner, JC Rahe, A Silva, J Thomas, WF Grubbs, WD Lustik, MB Karrison, TG Roegner, RH et al 1990, 'Health status of Air Force veterans occupationally exposed to herbicides in Vietnam. I. Physical health', *JAMA*, Oct 10, vol. 264, no.14, pp. 1824-31.

Commonwealth Department of Veterans' Affairs 1998, Morbidity of Vietnam Veterans: A study of the health of Australia's Vietnam veteran community. Volume 1 Male Vietnam veterans survey and community comparison outcomes, pp. 1-111. Available online at: www.aihw.gov.au/veteran/previous_studies/index.cfm.

not appear to have been an outcome of interest...and an incidental finding does not appear to have emerged...' (see paragraph [69]).

192. The Council's view on all of the new information is that it could not potentially point to the association between the contended factor and neoplasms of the pituitary gland.
193. Accordingly, the Council concluded that the new information did not warrant the Council making any directions or recommendations to the RMA.

SHOULD THERE BE AN 'UNDERGOING BILATERAL ADRENALECTOMY' FACTOR ?

Council's analysis – 'Undergoing Bilateral Adrenalectomy'

194. The Council considered the following articles (already considered above in respect of the Chemical and Biological warfare and nerve agent factor) relevant to consideration of the existing factors in the Statement of Principles in respect of undergoing Bilateral Adrenalectomy.

***Wass, JAH and Besser, M (1995) (4)*⁷³**

195. The authors describe bilateral adrenalectomy, a treatment for Cushing's Disease⁷⁴ and the development (origin/occurrence) of Nelson's syndrome⁷⁵:

Cushing's disease may be associated with normal or elevated adrenocorticotrophic hormone levels, but in Nelson's syndrome (post-bilateral adrenalectomy enlargement of the pituitary and pigmentation) the level of adrenocorticotrophic hormone is invariably very elevated. Corticotroph adenomas tend to be small and are frequently microadenomas. Only rarely are they large and they may be highly invasive.

Council's analysis

196. The authors' finding of elevated levels of adrenocorticotrophic hormone after bilateral adrenalectomy points to the relevant association between undergoing bilateral adrenalectomy and worsening of neoplasm of the pituitary gland at any time after the surgery.

⁷³ The numbers in brackets after the authors of cited articles refer to the list of Cited articles at the end of these Reasons.

⁷⁴ See footnote 39, at paragraph [94] above.

⁷⁵ See footnote 49, at paragraph [107] above.

Asa, SL and Ezzat, S 1998 and 2002 (1&2)

197. In the 1998 paper, the authors postulate that the majority of pituitary tumours develop from transformed cells that are dependent on hormonal and/or growth factor stimulation for tumour progression.
198. The Authors reviewed medical science literature in respect of Bilateral Adrenalectomy:

Lack of suppressibility of corticotroph adenomas by glucocorticoids was suggested by one study (232) as a mechanism involved in the pathological ACTH secretion in Cushing's disease and Nelson's syndrome. This report has not been confirmed by other investigators (233) Similarly, rare reports of somatic mutations in the GCR with diminished glucocorticoid inhibition were noted in Nelson's syndrome (237) and ectopic Cushing's syndrome (238). (at p. 809)⁷⁶

Council's analysis

199. The Council agreed with the authors that the removal of the inhibiting effect of the feedback loop from the adrenal glands on the growth of pituitary tumours, a consequence of bilateral adrenalectomy surgery, is a mechanism involved in freeing the tumour to grow.
200. The Council considered the findings of the authors in respect of undergoing bilateral adrenalectomy, as a treatment for Cushing's Disease, were strong sound medical-scientific evidence of a causal relationship of worsening of pituitary tumour at any time after the surgery.
201. The Council considered that the findings from this study point to (as opposed to merely leaving open) the relevant association between undergoing bilateral adrenalectomy and worsening of neoplasm of the pituitary gland at any time after the surgery.

⁷⁶ Medical science literature referred to by Asa & Ezzat 1998 by way of a citation (via the number in brackets) provided in the text by the Authors. While Asa & Ezzat was available information, these articles are not information, which was available to (before) the RMA.

223 – Trouillas, J et al 1988, 'The TSH secretion in the human pituitary adenomas' *Pathol Res Pract*, vol. 183, pp. 596-600.

233 – Horvath, SE et al 1990, 'Human pituitary corticotroph adenomas in vitro: morphologic and functional responses to corticotrophin-releasing hormone and cortisol', *Neuroendocrinology*, vol. 51, pp. 241-248.

237 – Karl, M et al 1996, 'Nelson's syndrome associated with a somatic frame shift mutation in the glucocorticoid receptor gene', *J Clin Endocrinol Metab*, vol. 81, pp. 124-129.

238 – Ray, DW et al 1994, 'Human small cell lung cancer cell lines expressing the proopiomelanocortin gene have aberrant glucocorticoid receptor function', *J Clin Invest*, vol. 93, pp. 1625-1630.

Imai, T Funahashi, H Tanaka, Y et al. 1996 (12)

202. This publication reports a review of 122 patients with Cushing syndrome who underwent adrenalectomy from 1957 to 1993.
203. The authors described Cushing syndrome as the clinical manifestation of chronic glucocorticoid excess or hypercortisolism occurring spontaneously from five endogenous causes: four relating to the adrenal glands and the fifth secondary to excess secretion of adrenocorticotropin (ACTH) by a pituitary tumour.
204. The authors reported, amongst other things, the development of Nelson's syndrome in four of 16 patients followed up who underwent adrenalectomy for treatment of Cushing syndrome, and subsequent pituitary operation; Nelson's syndrome being one of two major disadvantages of total adrenalectomy for Cushing's disease. They noted Nelson's syndrome as a complication of total adrenalectomy for Cushing's disease and that patients who undergo pituitary operation primarily or undergo pituitary irradiation are less likely to develop Nelson's syndrome after total adrenalectomy.
205. The authors concluded that adrenalectomy continues to play an important role in the treatment of Cushing syndrome and in selected cases bilateral total adrenalectomy continues to be an alternative treatment for either Cushing's disease or ectopic ACTH syndrome.

Council's analysis

206. The Council considered this study demonstrates that the clinical worsening of an ACTH secreting pituitary tumour following bilateral adrenalectomy is a well-recognised condition known as Nelson's Syndrome and is less likely to occur when treatment for the pituitary tumour, before adrenalectomy, includes tumour surgery or irradiation.
207. The Council considered the findings of the authors in respect of surgery and irradiation prior to undergoing bilateral adrenalectomy were strong sound medical-scientific evidence of a causal relationship between undergoing bilateral adrenalectomy and the worsening of the pre-existing pituitary tumour.
208. The Council considered that the findings from this study point to (as opposed to merely leaving open) and support the relevant association between undergoing bilateral adrenalectomy and worsening of neoplasm of the pituitary gland at any time after the surgery.

Sonino, N Zielezny, M Fava, GA Fallo, F & Boxcaro, M 1996 (13)

209. A review of long-term treatment outcomes of a large cohort of patients with Cushing's Disease (n = 162) followed for 7 years identified age, disease severity (urinary cortisol and ACTH concentrations) and depression as risk factors for recurrence of tumours. The report notes (consistently with then available literature) about a quarter of the patients who underwent bilateral adrenalectomy developed Nelson's syndrome during follow-up.

Council's analysis

210. The Council considered it relevant that this article notes, consistently with then available literature, about a quarter of the patients who underwent bilateral adrenalectomy developed Nelson's syndrome during follow-up.
211. The Council considered the findings of the authors, were strong sound scientific-medical evidence of a causal relationship between worsening of a pre-existing neoplasm of the pituitary gland and bilateral adrenalectomy at any time after the surgery.
212. The Council considers that the findings from this study point to (as opposed to merely leaving open) the relevant association.

THE COUNCIL'S CONCLUSIONS ON WHETHER THERE SHOULD BE A 'UNDERGOING BILATERAL ADRENALECTOMY' FACTOR(S)

213. The Council, having closely analysed all the information in the pool, placed particular weight on the articles discussed in detail above. The critical question for the Council was whether the sound medical-scientific evidence 'points to, as opposed to merely leaves open, the possibility of the⁷⁷ relevant association.
214. The sound medical-scientific evidence supports that in the normal body, ACTH stimulate the production from the adrenal glands of cortisol; cortisol in turn feeds back on the pituitary gland to inhibit ACTH secretion, providing a brake on the system. In the Council's view in patients with ACTH producing tumours (called Cushing's Disease), it is well established that removal of the adrenal glands can cause at any time the growth of a pre-existing tumour due to loss of negative feedback.
215. The clinical worsening of an ACTH secreting pituitary adenoma at any time following bilateral adrenalectomy is a well-recognised condition known as Nelson's syndrome. There was no data or findings pointing to a limit in time of 10 years or any other time after bilateral Adrenalectomy for the worsening of

⁷⁷ see full Federal Court decision at paragraph 49 per Branson J, and paragraph [80] of these Reasons

pituitary tumour. The sound medical–scientific evidence does not support the initiation or creation of pituitary tumour *de novo*; rather it relates to an exacerbation of a pre-existing pituitary tumour.

216. Neither the Applicant nor the Commission made any submission on factors 5(a) and (b) of the Statement of Principles concerning the development of pituitary tumours following bilateral adrenalectomy.
217. While always cognisant that the reasonable hypothesis standard is a low threshold and an unusually light burden, the Council’s conclusion was that the sound medical-scientific evidence and particularly those articles closely analysed above, strongly points to (as opposed to merely leaving open) undergoing bilateral adrenalectomy as a potential link or element in a reasonable hypothesis connecting worsening of neoplasm of the pituitary gland with relevant service (see paragraphs [6 and 80] and footnotes 3 and 29).
218. Accordingly, the Council concluded that in the information (which the Council considered sound medical-scientific evidence) the evidence was sufficient to justify the making of the reasonable hypothesis Statement of Principles No. 42 of 2004 to include a factor in respect of ACTH secreting pituitary adenomas, of the undergoing bilateral adrenalectomy before the worsening of neoplasm of the pituitary gland’ factor.
219. However, the Council concluded that in the information (which the Council considered sound medical-scientific evidence) the evidence was insufficient to justify the making of the reasonable hypothesis Statement of Principles No. 42 of 2004 to include criteria in the factors, in respect of ACTH secreting pituitary adenomas;
 - in respect of the clinical onset of the neoplasm of the pituitary gland or
 - in respect of any latency period.

DECISION

220. The Council made the declarations summarised in **paragraph 1** above.

COUNCIL COMMENT ON STATEMENT OF PRINCIPLES No. 43 of 2004

221. The Council was asked under section 196Y of the VEA to review the contents of Statements of Principles 42 of 2004 dated 10 November 2004 (the reasonable hypothesis Statement of Principles). The Council was not asked and accordingly had no jurisdiction to review some or all of the contents of Statement of Principles 43 of 2004, also dated 10 November 2004, in respect of neoplasm of the pituitary gland (the balance of probabilities Statement of Principles).

222. The Council notes that on 13 November 2002 the RMA notified in the Gazette an investigation of both the Statements of Principles (Nos. 37 and 38 of 1997) in force at that time concerning neoplasm of the pituitary gland, and that the RMA revoked and replaced those Statements of Principles with Nos. 42 and 43 of 2004 which it determined on the same date, and which are in identical terms in respect of the factors identified. Therefore, the Council considered it likely that when the RMA made the balance of probabilities Statement of Principles, it had available to it the same information as the Council has considered in this review. If that is true, then the logical consequence of the Council's findings in respect of the reasonable hypothesis Statement of Principles (the reasonable hypothesis being a lower standard than the balance of probabilities) is that the balance of probabilities Statement of Principles should be amended in the same fashion as the Council has directed the reasonable hypothesis Statement of Principles be amended.
223. However, as the Council's jurisdiction does not extend to Statement of Principles 43 of 2004, the Council notes the issue in these reasons and suggests the RMA gives consideration to amending Statement of Principles No 43 of 2004 in the same way as Council's directions to it to amend Statement of Principles 42 of 2004.

EVIDENCE BEFORE THE COUNCIL

Documents

224. The information considered by the Council (being the information that the RMA advised was available to (before) the RMA at the relevant times and which the RMA sent to the Council in accordance with section 196K of the VEA) is listed in **Appendix B**.
225. As mentioned above, the information upon which the Applicant and the Repatriation Commission relied (being information which the RMA advised was available to (before) the RMA at the relevant times and which the RMA sent to the Council in accordance with section 196K of the VEA) is listed in **Appendices C and E** respectively.
226. The information to which the Applicant referred (being information which the RMA advised was new information, that is, information which was not available to (not before) the RMA at the relevant times, and so was not considered by the Council in reaching its review decision) is listed in **Appendix D**.
227. The information to which the Repatriation Commission referred (being information which the RMA advised was new information, that is, information which was not available to (not before) the RMA at the relevant times, and so was not considered by the Council in reaching its review decision) is listed in **Appendix F**.

Articles cited in the Council's analysis

Information before the RMA:

- 1 Gold, EB. 1981, 'Epidemiology of pituitary adenomas', *Epidemiologic Reviews*, vol. 3, pp. 163-183.
- 2 Levy, A Lightman, S 2003, 'Molecular defects in the pathogenesis of pituitary tumours', *Frontiers in Neuroendocrinology*, vol 24(2), pp. 94-127.
- 3 Melmed, S 2003, 'Mechanisms for pituitary tumorigenesis: the plastic pituitary', *Journal of Clinical Investigation*, vol. 112(11), pp. 1603-1618.
- 4 Wass JAH and Besser M (1995), *Pituitary Tumours*, Oxford Textbook of Oncology, Peckham M, Pinedo H and Veronesi U [eds], Oxford University Press, vol 2, chapter 16.3, pp. 2122-2136.
- 5 Asa, SL & Ezzat, S 1998, 'The cytogenesis and pathogenesis of pituitary adenomas', *Endocrine Reviews*, vol. 19(6), pp. 798-827.
- 6 Asa, SL & Ezzat, S 2002, 'The pathogenesis of pituitary tumours', *Nat Rev Cancer*, vol. 2(11), pp. 836-49.
- 7 Melmed, S & Jameson, JL 2002, Disorders of the anterior pituitary and hypothalamus, Harrison's Online, McGraw Hill, Chapter 318, accessed 18 June 2004 at http://harisons.accessmedicine.com.server-java/Arkoid/amed/harisons/co_chapters/ch328/ch328_p01.html
- 8 Heaney, AP Fernando, M & Melmed, S 2002, 'Functional role of estrogen in pituitary tumor pathogenesis', *J Clin Invest*, vol. 109, pp. 277-283.
- 9 Scheithauer, BW Kovacs, KT Randall, RV & Ryan, N 1989, 'Effects of estrogen on the human pituitary: a clinicopathologic study', *Mayo Clin. Proc*, vol. 64, pp. 1077-1084.
- 10 National Academy of Sciences, Institute of Medicine 1994, 'Veterans and Agent Orange: Health Effects of Herbicides used in Vietnam', *The National Academies Press*, Washington D.C., pp. 1-812. (Held in the RMA Library at H 19.1, also held in the DVA Library at 615.951). Also the 1996, 1998 (pre-publication copy), 2000 and 2002 updates (referenced in full in Appendix B).

- 11 Evatt, P 1985, *Royal Commission on the use and effects of chemical agents, on Australian Personnel in Vietnam, Final Report July 1985, vol. 4: Cancer*, Australian Government Publishing Service, Canberra, pp. 1-440. (held in the RMA Library at H 1, also held in the DVA Library at 615.951).
- 12 Imai, T Funahashi, H Tanaka, Y et al. 1996, 'Adrenalectomy for treatment of Cushing Syndrome: Results in 122 patients and long-term follow-up studies', *World Journal of Surgery*, vol. 20, pp. 781-787.
- 13 Sonino, N Zielesny, M Fava, GA Fallo, F & Boxcaro, M 1996, 'Risk factors and long-term outcome in pituitary-dependent Cushing's disease', *Journal of Clinical Endocrinology and Metabolism*, vol. 81(7), pp. 2647-2652.

New Information; information which was not available to (not before) the RMA at the relevant times:

- 14 Kociba, RJ et al. 1978, 'Results of a two year chronic toxicity and oncogenicity study of 2,3,7, 8-tetrachlorodibenzo-p-dioxin in rats', *Toxicology and Applied Pharmacology*, vol. 46, pp. 279-303.
- 15 Kociba, RJ et al 1979, 'Results of a two year chronic toxicity and oncogenic study of rats ingesting diets containing 2,4,5-trichlorophenoxyacetic acid (2,4,5-T)', *Food and Cosmetics Toxicology*, vol. 17, pp. 205-221.
- 16 Grcevic, N et al. undated, 'Cerebral changes in Paraquat poisoning', cited in Roizin et al., eds. 1977, *Neurotoxicology*, Raven Press, New York, vol 1; cited as exhibit 31 in *Repatriation Commission v Schar* ARL 1992.
- 17 Synder, SH & D'Amato, RJ 1985, 'Predicting Parkinson's disease', *Nature*, vol 317, 19 September, pp. 198-199; cited as exhibit R21 in *Repatriation Commission v Schar* ARL 1992.
- 18 Administrative Appeals Tribunal *Re Repatriation Commission and Michael Schar* (1991) 25 ALD 503, pp. 1-13.

Appendices

Appendix A (i)	Preliminary list of the proposed pool of information, as advised to the Applicant and Repatriation Commission by letters dated 23 August 2007 and 30 August 2007 respectively (see paragraphs [20 and 22] of the Reasons).
Appendix A (ii)	Preliminary list of the REVISED proposed pool of information, as advised to the Applicant and Repatriation Commission by letters dated 18 December 2008 (see paragraphs [30 and 38 to 41] of the Reasons), and the final pool of information (see paragraph [86] of the Reasons).
Appendix B	Information that the RMA advised was available to (before) the RMA at the relevant times and which the RMA sent to the Council in accordance with section 196K of the VEA.
Appendix C	Information upon which the Applicant relied (being information which the RMA advised was available to (before) the RMA at the relevant times and which the RMA sent to the Council in accordance with section 196K of the VEA).
Appendix D	Material that the RMA advised was not available to (not before) the RMA (which the Applicant contended was in existence at the relevant times, and so could have been accessed by the RMA).
Appendix E	Information upon which the Repatriation Commission relied (being information which the RMA advised was available to (before) the RMA at the relevant times and which the RMA sent to the Council in accordance with section 196K of the VEA).
Appendix F	Information upon which the Repatriation Commission relied being information which the RMA advised was not available to (not before) the RMA at the relevant times.

APPENDIX A (i)

SRMC Folder	SMRC Article Numbers	RMA ID or Reference	Title
2	15	31327	Asa, SL & Ezzat, S 1998, 'The cytogenesis and pathogenesis of pituitary adenomas', <i>Endocrine Reviews</i> , vol. 19(6), pp. 798-827.
2	14	31336	Asa, SL & Ezzat, S 2002, 'The pathogenesis of pituitary tumours', <i>Nat Rev Cancer</i> , vol. 2(11,) pp. 836-849.
2	19	31296	Cannavo, S Venturino, M Curto, L De Menis, E D'Arrigo, C Tita, P Billeci, D Trimarchi, F 2003, 'Clinical presentation and outcome of pituitary adenomas in teenagers', <i>Clin Endocrinol (Oxf)</i> , Apr, vol. 58(4), pp 519-527.
2	29	9573	Chapuis, Y Pitre, J Conti, F Abboud, B Pras-Jude, N and Luton, J-P 1996, 'Role and operative risk of bilateral adrenalectomy in hypercortisolism', <i>World J. Surg</i> , vol. 20, pp. 775-780.
2	56	9436	Cookson, KM 1994, 'The parenteral toxicity of Cyclofem', <i>Contraception</i> , vol. 49(4), pp. 335-345.
2	46	9454	Esiri, MM 1992, <i>The Pituitary Gland</i> , Oxford Textbook of Pathology, McGee Jo, Isaacson PG and Wright NA eds., Oxford University Press, vol. 2b, chapter 26, pp. 1931-1940.
4	4	15729 45041	Evatt, P 1985, <i>Royal Commission on the use and effects of chemical agents, on Australian Personnel in Vietnam, Final Report July 1985, vol. 2: Toxicology and General Health</i> , Australian Government Publishing Service, Canberra, pp. 1-39 and 1-182.
4	5	15730 45042	Evatt, P 1985, <i>Royal Commission on the use and effects of chemical agents, on Australian Personnel in Vietnam, Final Report July 1985, vol. 3: birth Anomalies</i> , Australian Government Publishing Service, Canberra, pp. 1-196.
4	6	15731 45043	Evatt, P 1985, <i>Royal Commission on the use and effects of chemical agents, on Australian Personnel in Vietnam, Final Report July 1985, vol. 4: Cancer</i> , Australian Government

- Publishing Service, Canberra, pp. 1-440.
- 4 7 15732 Evatt, P 1985, *Royal Commission on the use and effects of*
45044 *chemical agents, on Australian Personnel in Vietnam, Final*
Report July 1985, vol. 5: Mental Well-being, Australian
Government Publishing Service, Canberra, pp. 1-261.
- 4 8 15733 Evatt, P 1985, *Royal Commission on the use and effects of*
45045 *chemical agents, on Australian Personnel in Vietnam, Final*
Report July 1985, vol. 6: Mortality, Class Action VVAA and
Section 47, Australian Government Publishing Service,
Canberra, pp. 1-128, 1-61 and 1-19.
- 4 9 17105 Evatt, P 1985, *Royal Commission on the use and effects of*
45046 *chemical agents, on Australian Personnel in Vietnam, Final*
Report July 1985, vol. 7: Benefits and Treatment,
Australian Government Publishing Service, Canberra, pp.
1-456.
- 4 10 45047 Evatt, P 1985, *Royal Commission on the use and effects of*
chemical agents, on Australian Personnel in Vietnam, Final
Report July 1985, vol. 8: Conclusions, Recommendations
and Epilogue, Australian Government Publishing Service,
Canberra, pp. 1-57 and 1-52.
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2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) on
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no.1, pp. 127-135.
- 2 13 31364 Hamid, T & Kakar, SS 2003, 'PTTG and cancer', *Histol*

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- 2 5 31586 Heaney, AP Fernando, M & Melmed, S. 2002, 'Functional role of estrogen in pituitary tumor pathogenesis', *J Clin Invest*, vol. 109, pp. 277-283.
- 2 23 25494 Hengstler, JG Van der Burg, B Steinberg, P Oesch, F 1999, 'Interspecies differences in cancer susceptibility and toxicity', *Drug Metabolism Reviews*, vol. 31, no. 4, pp. 917-70.
- 4 12 House, WB Goodson, LH Gadberry, HM Dockter, KW 1967, *Assessment of Ecological Effects of Extensive or Repeated use of Herbicides*, Midwest Research Institute, Kansas City, reproduced by National Technical Information US Dept of Commerce, Springfield, pp. 1-369.
- 2 27 9673 Imai, T Funahashi, H Tanaka, Y et al. 1996, 'Adrenalectomy for treatment of Cushing Syndrome: Results in 122 patients and long-term follow-up studies', *World Journal of Surgery*, vol. 20, pp. 781-787.
- 2 28 9574 Imai, T Funahashi, H Tanaka, Y et al. 1996, 'Adrenalectomy for treatment of Cushing Syndrome: Results in 122 patients and long-term follow-up studies', *World Journal of Surgery*, vol. 20, pp. 781-787.
- 2 43 9457 Kaiser, FE Orth, DN Mukai, K and Oppenheimer, JH 1983, 'A pituitary parasellar tumor with extracranial metastases and high partially suppressible levels of adrenocorticotropin and related peptides', *J Clin Endocrinol Metab*, vol 57, pp. 649-653.
- 2 9 31409 Kemink, SAG Wesseling, P Pieters, GFFM Verhofstad, AAJ Hermus, ARMM Smals, AGH 1999, *Erratum. Journal of Endocrinological Investigation*, vol 22, pp. 582.
- 2 10 31408 Kemink, SAG Wesseling, P Pieters, GFFM Verhofstad, AAJ Hermus, ARMM Smals, AGH 1999, 'Progression of a Nelson's adenoma to pituitary carcinoma; a case report and review of the literature', *Journal of Endocrinological Investigation*, vol. 22, pp. 70-75.
- 2 26 25466 Kurokawa, Y & Inoue, T 1998, [Abstract & reference list only in English - balance of article in Japanese] 'Risk assessment of dioxins and the effect as the endocrine disrupters', Kokuritsu Iyakuhin Shokuhin Eisei Kenkyujo

- hokoku, *Bulletin of National Institute of Health Sciences*, vol. 116, pp. 1-12.
- 2 6 31444 Levy, A & Lightman, S 2003, 'Molecular defects in the pathogenesis of pituitary tumours', *Frontiers in Neuroendocrinology*, vol. 24, no. 2, pp. 94-127.
- 2 52 9440 Liebelt, AG 1994, *Tumours of the pituitary gland*, IARC Scientific Publications, Lyon, France, No.111, pp. 527-47.
- 2 24 25492 Lindstrom, G Hooper, K Petreas, M Stephens, R Gilman, A 1995, 'Workshop on perinatal exposure to dioxin-like compounds, 1 Summary', *Environmental Health Perspectives*, vol. 103, suppl. 2, pp. 135-142.
- 4 33 3236 MacLennan, R & Smith, P 1994, Veterans and agent orange: Health effects of herbicides used in Vietnam'. Report prepared for Department of Veteran Affairs commenting on the NAS report, Canberra, pp. 1-19.
- 2 7 31430 Melmed, S 2003, Mechanisms for pituitary tumorigenesis: the plastic pituitary', *Journal of Clinical Investigation*, vol. 112, no. 11, pp. 1603-1618.
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- 4 15 39750 Melmed, S & Jameson, JL 2002, Disorders of the anterior pituitary and hypothalamus, Harrison's Online, McGraw Hill, Chapter 328, accessed 18 June 2004 at http://harisons.accessmedicine.com.server-java/Arkoid/amed/harisons/co_chapters/ch328/ch328_p01.html.
- 2 42 9458 Milne, R & Vessey, M 1991, 'The association of oral contraception with kidney cancer, colon cancer, gallbladder cancer (including extrahepatic bile duct cancer) and pituitary tumours', *Contraception*, vol 43, no. 6, pp. 667-691.
- 2 34 9513 Mirabelli, D Ciccarelli, E and Merletti, F 1987, 'Pituitary adenomas in a cosmetics factory', *British Journal of Industrial Medicine*, vol. 44, p. 845.
- 4 17 18294 National Academy of Sciences Institute of Medicine 1994, *Veterans and Agent Orange: Health Effects of Herbicides used in Vietnam*, The National Academies Press, Washington D.C., pp. 1-812.
- 4 18 1926 National Academy of Sciences Institute of Medicine 1996,

- Veterans and Agent Orange: Health Effects of Herbicides used in Vietnam, Update 1996*, The National Academies Press, Washington D.C., pp. 1-365.
- 4 19 14862 National Academy of Sciences Institute of Medicine 1998, *Veterans and Agent Orange: Health Effects of Herbicides used in Vietnam, Prepublication Copy of Update 1998*, The National Academies Press, Washington D.C., pp. 1-482.
- 4 20 29491 National Academy of Sciences Institute of Medicine 2001, *Veterans and Agent Orange: Health Effects of Herbicides used in Vietnam, Update 2000*, The National Academies Press, Washington D.C., pp.1-664.
- 4 21 29493 National Academy of Sciences Institute of Medicine 2003, *Veterans and Agent Orange: Health Effects of Herbicides used in Vietnam, Update 2002*, The National Academies Press, Washington D.C., pp. 1-619.
- 2 32 9515 Pituitary Adenoma Study Group 1983, 'Pituitary adenomas and oral contraceptives: a multicenter case-control study', *Fertility & Sterility*, vol. 39, no. 6, pp. 753-760.
- 2 12 31375 Sanno, N Teramoto, A Osamura, RY Horvath, E Kovacs, K Lloyd, RV Scheithauer, BW 2003, 'Pathology of pituitary tumors', *Neurosurg Clin N Am*, Jan 14, no. 1, pp. 25-39.
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- 2 51 9441 Schmidt, RE & Hubbard, GB 1996, *Tumours of the endocrine glands*, IARC Scientific Publications, Lyon, France, no. 126, pp. 307-13.
- 4 27 Sinclair, IM 1982, *Report on the use of herbicides, insecticides and other chemicals by the Australian Forces in South Vietnam – Summary of files not found in South Vietnam based Army Headquarters and Units; Report and Ministerial Statement, Report – Royal Australian Air Force; Report Australian Army*, Department of Defence, Canberra.
- 2 30 9554 Sonino, N Zielesny, M Fava, GA Fallo, F and Boxcaro, M 1996, 'Risk factors and long-term outcome in pituitary-dependent Cushing's disease', *Journal of Clinical*

Endocrinology and Metabolism, vol. 81, no. 7, pp. 2647-2652.

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|---|---------|----------------|--|
| 2 | 37 | 9463 | Wass, JAH & Besser, M 1995, <i>Pituitary Tumours</i> , in Oxford Textbook of Oncology Peckham M, Pinedo H and Veronesi U eds., Oxford University Press, vol 2, chapter 16.3, pp. 2122-2136. |
| 4 | 30 | | Young, AL Calcagni, JA Thalken, CE Tremblay, JW 1978, <i>The Toxicology, Environmental fate and Human risk of herbicide Orange and its Associated Dioxin</i> , Prepared for The Surgeon General United States Air Force, Washington, D.C. by USAF Occupational and Environmental Health Laboratory, Aerospace Medical Division (AFSC), Brooks Air Force Base, Texas. pp 1-400. |
| 2 | 8
16 | 31423
31312 | Zhang, X Li, Q Hu, P Cheng, H Huang, G 2002, 'Two case reports of pituitary adenoma associated with <i>Toxoplasma Gondii</i> infection', <i>Journal of Clinical Pathology</i> , vol. 55, no. 12, pp. 965-966. |

APPENDIX A (ii)

SRMC Folder	SMRC Article Numbers	RMA ID or Reference	Title
2	15	31327	Asa, SL & Ezzat, S 1998, 'The cytogenesis and pathogenesis of pituitary adenomas', <i>Endocrine Reviews</i> , vol. 19(6), pp. 798-827.
2	14	31336	Asa, SL & Ezzat, S 2002, 'The pathogenesis of pituitary tumours', <i>Nat Rev Cancer</i> , vol. 2(11,) pp. 836-849.
2	19	31296	Cannavo, S Venturino, M Curto, L De Menis, E D'Arrigo, C Tita, P Billeci, D Trimarchi, F 2003, 'Clinical presentation and outcome of pituitary adenomas in teenagers', <i>Clin Endocrinol (Oxf)</i> , Apr, vol. 58(4), pp 519-527.
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APPENDIX B

SRMC Folder	SMRC Article Numbers	RMA ID or Reference	Title
1 3	1		Specialist Medical Review Council 2008, SMRC Information List NPG I: updated 2005 list, pp. 1-7.
1	2		Repatriation Medical Authority 2005, Registrar's 29 March 2005 Cover letter to Information: Statement of Principles No. 42 of 2004, p. 1, with enclosure of Repatriation Medical Authority 2004, 22 November Reference List for investigation #277-1, pp. 1-4.
3	2		Repatriation Medical Authority 2006, Chairperson of the RMA 2 August 2006 Letter on Further Information and New Information, pp. 1-4.
3	3		Repatriation Medical Authority 2006, Registrar's 29 August Letter on Further and New Information: Statement of Principles No. 42 of 2004, pp. 1-2.
3	4		Repatriation Medical Authority 2007, Registrar's 17 August 2007 Cover letter confirming the Information: Statement of Principles No. 42 of 2004, p., 2, with attached 17 Aug 2007 Reference List for investigation # 277-1, pp. 1-5.
3	22		Repatriation Medical Authority 2008, Deputy Registrar's 12 May email finalising the reconciliation of the Information and New Information, p. 1.
3	21	1.1	Department of Veterans Affairs 1997, 'Original departmental submission - 1997 NPG', pp. 1-6 with References, pp. 1-2 and Medline searches: <1992 to January 1997> and <1992 to December 1996>, pp. 1-23.
1	3	1.2 1.3	Applicant 2002, 16 October Request for an investigation/review, pp. 1-2 and attached submission of 19 September 2002, pp. 1-8, with 5 article Abstracts RMA ID numbers 25492, 25466, 25494, 25481, 25562, pp. 1-5.
1	4	1.4	Name provided (not stated as per the <i>Privacy Act, 1988</i>) 2004, 13 February Request for an investigation/review, pp.

1-2, with Attachment A; DDT Lawsuit Overview, p. 1, and a Patricia Muir maintained Web page 2002, A History of Pesticide Use, last updated October 18, pp. 1-7, as Attachment B.

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| 1 | 5 | 1.5 | Applicant 2003, 7 March Covering letter, p. 1 and March 2003, Submission to the RMA on 'Chemical and biological warfare weapons in South Vietnam (1962-1973)', pp. 1-28, with 13 attachments. |
| 1 | 6 | 1.5.1 | Applicant no date, Photos, pp. 1-2. Cited and submitted in March 2003, Submission to the RMA as Attachment 1. |
| 1 | 7 | 1.5.2 | Unknown Author no date, 'Pesticide labels and safe use of pesticides', pp. 44-62. Cited and submitted in March 2003, Submission to the RMA as Attachment 2. |
| 1 | 8 | 1.5.3 | Vincent, D 1967, [LETTER] 30 September Use of herbicides in 1 ATF Area, <i>Australian Military Forces</i> , pp. 1-3, with Annexures A to E, pp. 1-5. Cited and submitted In March 2003, Submission to the RMA as Attachment 3. |
| 1 | 9 | 1.5.4
1.6.5 | Bennett, PH 1982, [LETTER] April 'Report on progress to date on the Report of Australian Army involvement in the use of herbicides / defoliant in South Vietnam', pp. 1-3. Cited and submitted in Applicant's March 2003, Submission to the RMA as Attachment 4 and in 1 May 2003, Amended Submission 2 as Annex 5; with Schuck, 1987 (below), and Edwards, AR 1971 [LETTER] (below) and Wills, HA 1970 [LETTER] (below). |
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1.6.6 | Wells, AD for Graham, SC 30 Jan 1967, 'Herbicides for defoliation.' pp. 1-2. Cited and submitted in Applicant's March 2003, Submission to the RMA as Attachment 5 and in 1 May 2003, Amended Submission 2 as Annex 6. |
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1.6.9 | Hay, RA 1969, [LETTER] 'Lessons learned accidental herbicide damage', MACV publications, 13 Sept, p. 1, with attached Unknown author and no date, Accidental Herbicide Damage Vietnam Lessons learned No. 74, pp. 1-10. Cited and submitted in Applicant's March 2003, Submission to the RMA as Attachment 10 and in 1 May 2003, Amended Submission 2 as Annex 9. |
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1.6.3 | Tange, AH 20/07/1971, Declassified Secret Advice on South Vietnam - Use of herbicides, pp. 1-2. Cited and submitted in Applicant's March 2003, Submission to the RMA as Attachment 11 and in 1 May 2003, Amended Submission 2 as Annex 3. |
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APPENDIX C

SRMC Folder	SMRC Article Numbers	RMA ID or Reference	Title
1	3	1.2 1.3	Applicant 2002, 16 October Request for an investigation/review, pp. 1-2 and attached submission of 19 September 2002, pp. 1-8, with 5 article Abstracts RMA ID numbers 25492, 25466, 25494, 25481, 25562, pp. 1-5.
1	4	1.4	Name provided (not stated as per the <i>Privacy Act, 1988</i>) 2004, 13 February Request for an investigation/review, pp. 1-2, with Attachment A; DDT Lawsuit Overview, p. 1, and a Patricia Muir maintained Web page 2002, A History of Pesticide Use, last updated October 18, pp. 1-7, as Attachment B.
1	5	1.5	Applicant 2003, 7 March Covering letter, p. 1 and March 2003, Submission to the RMA on 'Chemical and biological warfare weapons in South Vietnam (1962-1973)', pp. 1-28, with 13 attachments.
1	6	1.5.1	Applicant no date, Photos, pp. 1-2. Cited and submitted in March 2003, Submission to the RMA as Attachment 1.
1	7	1.5.2	Unknown Author no date, 'Pesticide labels and safe use of pesticides', pp. 44-62. Cited and submitted in Applicant's March 2003, Submission to the RMA as Attachment 2.
1	8	1.5.3	Vincent, D 1967, [LETTER] 30 September 'Use of herbicides in 1 ATF Area', <i>Australian Military Forces</i> , pp. 1-3, with Annexures A to E, pp. 1-5. Cited and submitted In March 2003, Submission to the RMA as Attachment 3.
1	9	1.5.4 1.6.5	Bennett, PH 1982, [LETTER] April 'Report on progress to date on the Report of Australian Army involvement in the use of herbicides / defoliant in South Vietnam', pp. 1-3. Cited and submitted in Applicant's March 2003, Submission to the RMA as Attachment 4 and in 1 May 2003, Amended Submission 2 as Annex 5.
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APPENDIX D

SRMC Folder	SMRC Article	RMA ID or Reference	Title
	Numbers		
D	2	not submitted to SMRC or RMA	Abbott, T no date, cited (quote) in Applicants October 2005 submission to the SMRC, p. 19.
D	2	not submitted to SMRC or RMA	Attorney General of the United States no date, citing 'United Nations 1969 Resolution 2603-A', cited (paraphrased comments by applicant) in Applicants October 2005 submission to the SMRC, p. 5.
D	2	not submitted to SMRC or RMA	Buckingham, WA no date, <i>Operation Ranchhand</i> , unknown publisher, cited (extracts only) in Applicants October 2005 submission to the SMRC, p. 10.
D	2	not submitted to SMRC or RMA	Cramer, CM Major General 1945, Opinion as to the legality under international law of certain crop-destroying chemicals which can be sprayed by airplane against enemy cultivations, cited in United States Court of Appeal 30 September 2005 05-1953-CV, cited (quote) in Applicants October 2005 submission to the SMRC, p. 5.
D	2	not submitted to SMRC or RMA	Denning, 1948, 'Armstrong and Larkin v Minister of Pensions (1948)' 3 WPAR 1465 at page 1468, cited in Applicants October 2005 submission to the SMRC, p. 20.
D	2	not submitted to SMRC or RMA	<i>Re Repatriation Commission v O'Brien</i> 1985 155 CLR 422 at pages 428-429. Cited (quote) in Applicants October 2005 submission to the SMRC, p. 20.
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and cited (quote) in Applicants March 2003 submission to
the RMA, p. 10 and cited (quote) in Applicants May 2003
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APPENDIX E

SRMC Folder	SMRC Article Numbers	RMA ID or Reference	Title
3	7	15731 45043	Evatt, P 1985, <i>Royal Commission on the use and effects of chemical agents, on Australian Personnel in Vietnam, Final Report July 1985, vol. 4: Cancer</i> , Australian Government Publishing Service, Canberra, pp. 1-440.
2	36	9511	Gold, EB 1981, 'Epidemiology of pituitary adenomas', <i>Epidemiologic Reviews</i> , vol. 3, pp. 163-183.
3 4	15 17	18294	National Academy of Sciences Institute of Medicine 1994, <i>Veterans and Agent Orange: Health Effects of Herbicides used in Vietnam</i> , The National Academies Press, Washington D.C., pp. 1-812.
3 4	16 18	1926	National Academy of Sciences Institute of Medicine 1996, <i>Veterans and Agent Orange: Health Effects of Herbicides used in Vietnam, Update 1996</i> , The National Academies Press, Washington D.C., pp. 1-365.

APPENDIX F

SRMC Folder	SMRC Article	RMA ID or Reference	Title
	Numbers		
3 4	1 31		Commonwealth Department of Veterans' Affairs 1998, Morbidity of Vietnam Veterans: A study of the health of Australia's Vietnam veteran community. Volume 1 Male Vietnam veterans survey and community comparison outcomes, pp. 1-111. Available online at: www.aihw.gov.au/veteran/previous_studies/index.cfm . Cited by Repatriation Commission 2005, Written submission to the SMRC, p. 5.
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