Specialist Medical Review Council

Reasons for Decisions

Section 196W
Veterans' Entitlements Act 1986

Re: Statements of Principles Nos. 40 & 41 of 2004
In Respect of Malignant Neoplasm of the Small Intestine
Matter Nos. 2006/1 & 2
Requests for Review Declaration No. 12

SUMMATION

1. In relation to the Repatriation Medical Authority (the RMA) Statement of Principles No. 40 of 2004 in respect of malignant neoplasm of the small intestine and death from malignant neoplasm of the small intestine, made under subsection 196B(2) of the *Veterans' Entitlements Act 1986* (the VEA), the Specialist Medical Review Council (the Council) under subsection 196W(4) 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 to include the factors set out below;

   DIRECTS the RMA to amend Statement of Principles No. 40 of 2004 by including each of those factors; and

   FURTHER DIRECTS the RMA to determine and specify exposure criteria (including amount, frequency, and duration of a consumption habit) for each of those factors, having regard to the Council's comments in that regard as herein set out:

Factors to be included in Statement of Principles No. 40 of 2004

a) a dietary factor, namely exposure to fried, barbecued, salt cured or smoked foods, including ham, bacon, red meat and fish, consumed at least 3 times each week for at least 20 years;

b) a factor referable to exposure to more than 24 g of alcohol per day from beer or spirits;

c) a factor concerning obesity in men; and

d) so far as carcinoma in the first part (the bulb) of the duodenum only is concerned, Helicobacter pylori infection of long duration.

2. In relation to the RMA Statement of Principles No. 41 of 2004 in respect of malignant neoplasm of the small intestine and death from malignant neoplasm of the small intestine, made under subsection 196B(3) of the VEA the Council under subsection 196W(5) of the VEA:

DECLARES that it is of the view that the sound medical-scientific evidence available to the RMA is insufficient to justify any amendment of the Statement of Principles.

THE SPECIALIST MEDICAL REVIEW COUNCIL

3. The Council is a body corporate established under section 196V of the VEA, and consists of such number of members as the Minister for Veterans' Affairs determines from time to time to be necessary for the proper exercise of the function of the Council as set out in the VEA. The Minister must appoint one of the Councillors to be the Convener of the Council. It is sometimes appropriate for the Convener to appoint one of the Councillors selected for the purposes of the review as Presiding Councillor at all meetings of the Council for the purposes of that review.

4. 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 which would be necessary for deciding matters referred to the Council for review.

5. Dr Charles Guest FAFPHM was the Councillor appointed by the Convener as the Presiding Councillor for this review. Dr Guest is currently 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. The other members of the Council were:

(i) Dr Gregory Lockrey, a gastroenterologist who practices in a large University teaching hospital and in private practice. In addition he has had formal training in Epidemiology at Monash University; and

(ii) Professor James St John, a clinical gastroenterologist with a special interest in gastrointestinal tract cancer. Professor St John was Director of Gastroenterology at the Royal Melbourne Hospital from 1977 to 2001, and is currently an honorary Senior Associate with the Cancer Council Victoria; and

(iii) Associate Professor Michael Jefford, a medical oncologist working at the Peter MacCallum Cancer Centre in Melbourne, specialising in the treatment of gastrointestinal and urologic cancers.

THE LEGISLATION

6. 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].

7. 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 epidemiology. [2]

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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.

8. 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. 40 of 2004 in respect of malignant neoplasm of the small intestine and death from malignant neoplasm of the small intestine, being a Statement of Principles determined by the RMA under section 196B(2)[3] of the VEA ('the reasonable hypothesis test'); and
- Statement of Principles No. 41 of 2004 in respect of malignant neoplasm of the small intestine and death from malignant neoplasm of the small intestine, being a Statement of Principles determined by the RMA under section 196B(3)[4] of the VEA ('the balance of probabilities test').

9. The Applicant in her application contended that there was medical-scientific evidence upon which the RMA could have relied to include exposure to any or all of the following as a factor or factors in each of Statements of Principles Nos. 40 & 41 of 2004:

- potential carcinogens in the service diet;
- exposure to ionising radiation;
- long-term irritation of the gastrointestinal tract; and

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[3] (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] (3) If the Authority is of the view that on the sound medical-scientific evidence available it is more probable than not that a particular kind of injury, disease or death can be related to:
(a) eligible war service (other than operational service) rendered by veterans; or
(b) defence service (other than hazardous service) rendered by members of the Forces; or
(ba) peacetime service rendered by members;
the Authority must determine a Statement of Principles in respect of that kind of injury, disease or death setting out:
(c) the factors that must exist; and
(d) which of those factors must be related to service rendered by a person;
before it can be said that, on the balance of probabilities, an injury, disease or death of that kind is connected with the circumstances of that service.

– inappropriate clinical management. [5]

10. 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 Statements of Principles (the relevant times) and is constrained to conduct its review by reference to that information only. [6]

11. 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

12. On 10 November 2004, the RMA under subsections 196B(2) and (3) of the VEA, determined the Statements of Principles, being instruments respectively numbered 40 & 41 of 2004 in respect of malignant neoplasm of the small intestine.

13. On 17 November 2004 the making of the Statements of Principles was notified in the Gazette. [7]

14. An application dated 31 January 2005 for review of the Statements of Principles was received by the Council on 10 February 2005. The application summarised the decision of the RMA as:

> the refusal of the RMA to modify SOP malignant neoplasm of small intestine to allow for death from a terminal event relative to service related long-term GIT pathology disability. [8]

15. On 7 March 2005 in accordance with section 42 of the *Legislative Instruments Act 2003* the Statements of Principles were tabled in the House of Representatives and in the Senate.

16. 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 about malignant neoplasm of the small intestine available to the RMA at the relevant times, and

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5 A number of other matters were referred to by the Applicant in various documents and submissions to the RMA and the Council over time. These are discussed in the context of the scope of review in [37] and [46] below.

6 See *Vietnam Veterans' Association (NSW Branch) v Specialist Medical Review Council and Anor* (full Federal Court decision) [2002] 72 ALD 378, per Branson J at [35]: '*the SMRC in conducting its review is not only obliged to carry out a review of all of the information that was available to the RMA when it made the decision that gave rise to the request for a review (s196W(2)) but is constrained to conduct its review by reference to that information only.*'

7 Gazette Notice 46, 17 November 2004, p. 3716.

8 The grounds upon which the Applicant relied are set out in [9] above.

inviting persons or organisations eligible so to do to make submissions to the Council. [9] The Council gazetted two subsequent notices as to the dates by which written submissions must be received by the Council. [10]

The Information

17. 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.

18. By email dated 24 May 2005 the RMA sent to the Council an amended RMA Reference list. The RMA also provided copies of a further two articles, and advised that six articles, copies of which had been sent previously, had been sent in error.

19. 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 on 29 March 2005, taking into account the amendments to the information as notified by the RMA on 24 May 2005.

20. By letter dated 30 August 2006 the RMA under section 196K sent to the Council further information, which the RMA advised was available to (before) it at the relevant times. The RMA also requested that the Council retrieve other further information from the Council's archive. The Council had archived the information which had been sent to it by the RMA under 196K for the previously constituted Council's 1999 - 2003 review in respect of malignant neoplasm of the small intestine (see [32] ff below).

21. The Council held a meeting in Canberra to hear oral submissions complementing the written submissions on 8 September 2006. At the hearing of oral submissions the Council provided to both the Applicant and the Commission, access to all of the information (including further information), sent by the RMA under 196K to the Council, plus that information which the RMA had asked the Council to access from its archive.

22. The Applicant submitted several written submissions referable to the review, and at the Council's meeting on 8 September 2006 made an oral submission complementing her written submissions.

23. The Repatriation Commission made one written submission. A Medical Officer with the Department of Veterans' Affairs, representing the Repatriation Commission, made an oral submission complementing the Commission's written submission at the Council's meeting on 8 September 2006.

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9 Gazette Notice 15, 20 April 2005, p. 926.

10 Gazette Notice 25, 29 June 2005, p. 1447; and Gazette Notice 45, 16 November 2005, p. 2763.

24. By letters dated 30 November 2006 the Council provided to each of the Applicant and the Commission, copies of the further information to which access had been provided at the hearing of oral submissions.

25. By letter dated 28 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. However, there was a discrepancy concerning two pieces of information, which the RMA had previously advised (on 30 August 2006) had been available to (before) it at the relevant times.

26. By email dated 13 May 2008 the RMA clarified with the Council that the two articles referred to in [25] above had been inadvertently omitted from the list sent on 28 August 2007, and that they were information available to (before) the RMA at the relevant times.

27. On 13 May 2008 the RMA further confirmed the status of the information it had previously sent, and of that which was held in archives by the Council, as 'available' or 'new' information as respectively listed in Appendices B, D and F of these Reasons.

Notification of Scope of the Review and Pool of Information

28. By letters dated 9 March 2009 the Council advised the Applicant and the Commission of:

    a. the status of the information upon which the Council understood the Applicant (Appendices C and D) and Commission (Appendices E and F) relied, ie information which was available to the RMA at the relevant times, or new information; and

    b. the Council's proposed decision on the preliminary Pool of Information – Appendix A - and the information which the Council presently proposed not to include in the pool – Table 2.

29. In separate letters dated 9 March 2009 the Council wrote both to the Applicant and the Repatriation Commission advising of the Council's preliminary view on the scope of the review.

30. The Applicant and the Repatriation Commission were respectively invited to make any written comments on the Council's preliminary views of the scope of review and pool of information by close of business on 31 March 2009.

31. No written comments were received.

Previous Council's review of Statements of Principles in respect of malignant neoplasm of the small intestine

32. The Council has previously considered some of the contended factors under review, in a review it was asked by the Applicant to undertake of now revoked Statement of Principles No. 53 of 1996, as amended by Instrument No. 7 of 1998 in respect of malignant neoplasm of the small intestine. The Minister appointed, and the Convener selected, a completely freshly constituted Council to conduct this review, to ensure that there was no potential for an apprehension of bias or prejudgement.

33. On 28 February 2003 the (previously constituted) Council published its Reasons for Decision.

34. A copy of the (previously constituted) Council's Reasons for Decision [11] was included in the information which was forwarded to this Council by the RMA. However, the Council took the view that it should not rely on the (previously constituted) Council's Reasons, but that it should consider for itself all the information which was before the RMA when it determined, amended, or last amended the Statements of Principles now under review.

35. The Council was cognisant that not all the information before it had been before the (previously constituted) Council. Importantly, too, the (previously constituted) Council's review was conducted, and its Reasons for Decision were drafted, before the way in which the Council carries out its functions had been settled by the Courts. Thus, this Council and the previously constituted Council were operating within a different legal and administrative framework when undertaking their respective reviews.

36. Accordingly, the Council approached its task without any preconceptions, applying the two-stage process discussed below to the entirety of the information which was before the RMA at the relevant times.

SCOPE OF REVIEW

37. The Council's preliminary view, as advised to the Applicant and Repatriation Commission on 9 March 2009 was as follows:

> without limiting the scope of its review of the whole of the contents of the Statements of Principles, [the Council] presently proposes to have particular regard to whether there was sound medical-scientific evidence upon which the RMA could have relied to amend one or both of the Statements of Principles by including any or all of the following potential factors:

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[11] SMRC Folder 1/part 2, article 8. The previous Review Council's Declaration was published by Gazette Notice S 57 in February 2003.

- diet (which includes exposure to nitrosamines);
- ionising radiation;
- peptic ulcer; Helicobacter pylori infection; oesophageal reflux; and consequences of, and treatment with, cimetidine or other therapeutic agents as part of clinical management - all of which potential factors were identified by the Council as encompassed within the Applicant's term 'long-term irritation of the gastrointestinal tract', and addressing 'clinical management';
- obesity;
- alcohol; and
- tobacco smoking.

POOL OF INFORMATION

38. 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, ie when it determined, amended, or last amended the Statements of Principles. That comprises all the information that was available to the RMA when it determined the original Statements of Principles in 1995, and all the information subsequently available at all times when the Statements of Principles have been amended, or revoked and replaced, up to and including that information which was available in November 2004 when the RMA determined the Statements 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 malignant neoplasm of the small intestine which was in the possession of the RMA at the time it (the RMA) made the decision that triggered the Council's review.

39. The chronology of the RMA sending the information to the Council is detailed in [17] - [27] above.

40. In determining the proposed and then final decisions on the pool of information, the Council applied the methodology it had advised to each of the Applicant and Repatriation Commission on 9 March 2009, 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 at any time 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

(ii) in the Council's view 'touches on' (is relevant to) the potential factors within the scope of review [12] which have been evaluated by the Council according to epidemiological criteria, including the Bradford Hill criteria.[13]

41. For the purposes of making its 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 as detailed in [17] - [27] above; and
- which the RMA advised the Council was available to (before) it (the RMA) at the relevant times, which the Council accessed from its own archives, in accordance with the RMA's requests that it so do.

42. 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.

43. Information which the RMA advised was not available to (not before) the RMA at the relevant times was not taken into account by the Council for the purposes of the review, as it could only be considered as 'new information', see Appendices D and F.

44. A copy of the Council's preliminary decision on the proposed pool of information is attached at Appendix A.

APPLICANT'S SUBMISSIONS

45. The Applicant made a number of comprehensive written submissions, all of which were taken into account by the Council. These comprised: [14]

i. 18/03/2005;

ii. 18/08/2005;

iii. 12/01/2006; and

iv. 17/03/2008.

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12 See [37] above and [65] below.

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

14 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.

The Council generally and in these Reasons acknowledges 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.

46. The Applicant referred to a large number of matters of a disparate nature in her various submissions, which were not mentioned in her Application for Review as contended factors. The Council advised the Applicant in its letter to her of 9 March 2009 that its understanding was that she did not contend those matters should be included as factors in the Statements of Principles, nor that the various exposures she mentioned had any role to play in the development of malignant neoplasm of the small intestine. The Applicant, although given an opportunity to do so, made no comment in response to the Council's understanding of the factors for which she contended.

47. The Applicant in her submissions emphasised diet, submitting that '*long-term GIT pathology disability'* as the result of *'the dangers of nitrosamines in service rations … were the cause of her husband's illness and death.'*

48. The Applicant provided in her oral submissions complementing her written submissions:

    (i) a detailed history of her late husband's service and service-related health and illness, which included copies of hospital treatment records; and

    (ii) extensive materials that included papers on – diet, ionising radiation, Helicobactor pylori, bacteria & carcinogens, peptic ulcer, service diet, components of 'mustering' ie exposure to aviation fuels etc. This included information from a variety of sources.

49. In submitting that the decision of the RMA was *'fundamentally flawed,'* the Applicant requested that the Council consider that *'inappropriate treatment could indeed be applicable,'* her contention being that the treatment her husband had received over a fifty year period had masked the development of his tumour.

50. The Applicant set out in her written submissions, by way of paraphrasing or direct quotes, what she submitted were key passages from a number of medical-science articles, upon which she relied in support of the contended factors in her application for review. The Council has extracted from the Applicant's submissions references she made to the information, all of which was available to the RMA. The Council has included additional cited material to provide necessary context. [15]

[15] The Council notes that the Applicant did not provide the full citation, reference or page citation for any of the following extracts. Where possible, these have been sourced from the information by the Council.

— Chow, WH et al 1992, [16] RMA ID 7213 & 30739

> [...but weekly or more frequent consumption of red meat and monthly or more] frequent intake of salt-cured/smoked foods were associated with two to three fold increases in risk … (Abstract at p. 163); and
>
> It is also noteworthy that salt-cured/smoked foods have been related to stomach cancer [and red meat to colon cancer] (at p. 165); and
>
> International data has shown that small intestine cancer incidence-rates correlate significantly with rates for colon cancer, but not with stomach cancer (at p. 166 – 167).

— Sindelar, WF no date, [17] RMA ID 8619

> It is known that nitrosamines, which have been shown to be potent experimental GI carcinogens, are formed within the GI tract only in acid environments (at p. 617); and
>
> Neoplasms can arise from any of the tissues comprising the small intestine…(at p. 620); and
>
> Symptoms produced by proximal obstruction, including duodenum and proximal jejunum, are usually unrelenting nausea and vomiting with epigastric crampy pain (at p. 622);
>
> …body scans are not frequently helpful in the diagnosis of small intestinal neoplasms. The presence of fluid and gas in the small intestine can obscure mass effects in the bowel wall (at p. 624).

— Hecht, SS 1997, [18] RMA ID 14210

> Nitrosamines are a large group of potent carcinogens (Abstract at p. 181); and
>
> There is little doubt humans exposed to sufficient amounts of *N*-nitrosamines would be susceptible to their carcinogenic effects (Abstract at p. 181); and
>
> Human exposure to *N*-nitrosamines also occurs by nitrosation of amines in the body, via their acid or bacterial catalysed reaction with nitrate or by reaction products of nitric oxide generated during inflammation or infection (Abstract at p. 181); and

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16 Chow, W-H Linet, MS McLaughlin, JK Hsing, AW Co Chian, HT and Blot, WJ 1993, 'Risk factors for small intestine cancer', *Cancer Causes & Control*, vol. 4, pp. 163-169.

17 Sindelar, WF no date, 'Cancer of the Small Intestine', Chapter 20 of *unknown publication,* pp. 616-643.

18 Hecht, SS 1997, 'Approaches to cancer prevention based on an understanding of N-nitrosamine carcinogenesis' (44168), *Proceedings of the Society for Experimental Biology & Medicine*, vol. 216(2), pp. 181-91.

The use of nitrate as a preservative in cured or smoked meat or fish products raised concerns about nitrosamine formation, since the reaction of nitrate with amines occurs readily under a variety of conditions. Nitrate inhibits formation of a toxin by the anaerobic spore-forming bacteria *Clostridium botulinum* (at p. 182).

— Knekt, P et al 1999, [19] RMA ID 24646

Discusses the risk of gastro-intestinal cancers after exposure to nitrate, nitrite and N-nitroso compounds' (Abstract at p. 852). [20]

— Mettler, FA & Upton, AC 1995, [21] RMA ID 8995

The small intestine is [quite] sensitive to radiation [injury because of the rapidly proliferating cells] (at p. 246)…

[During the] chronic period, delayed effects are generally manifested as intermittent abdominal pain or obstruction (at p. 247).

— Griem, ML et al 1994, [22] RMA ID 4328

Patients with peptic ulcer are at increased risk of dying of cancer, related in part to [lifestyle factors and] treatment (Abstract at p. 842).

— Bismar, MM & Sinicrope, FA 2002, [23] RMA ID 31403

Radiation-induced injury to the gastrointestinal tract has been reported since the discovery of x-rays in 1898 (at p. 361); and

Diarrhoea can result from multiple causes listed here in the order of frequency, including bile salt malabsorption, bacterial overgrowth, severe fat malabsorption, and rapid intestinal transit time (at p. 362).

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19 Knekt, P et al 1999, 'Risk of colorectal and other gastro-intestinal cancers after exposure to nitrate, nitrite and N-nitroso compounds: a follow-up study', *Int J Cancer*, vol. 80(6), pp.852-856.

20 The Council notes that the Applicant did not provide any page reference for this citation, and the Council has not been able to source the extract in the form quoted.

21 Mettler, FA & Upton, AC. 1995, *Medical effects of ionizing radiation*, 2nd Edition, WB Saunders Company, Philadelphia, pp. 121-122.

22 Griem, ML et al 1994, 'Cancer Following Radiotherapy for Peptic Ulcer', *J Natl. Cancer Inst*, vol. 86, pp. 842-849.

23 Bismar MM & Sinicrope FA 2002, 'Radiation Enteritis', *Current Gastroenterology Reports*, vol. 4(5), pp. 361-365.

— Weiss, HA et al 1994, [24] RMA ID 7373

> It is established that ionizing radiation can induce cancer in many organs of the body (National Research Council 1990)…(at p. 327).

— Williamson, BJM et al 1983, [25] RMA ID 7237

> The concentration of small-bowel carcinomas in the duodenum and proximal jejunum suggests either a uniquely high concentration of carcinogen in these areas or local lack of resistance to neoplasia (at p. 176).

— Neugut, AI & Santos, J 1993 [26] RMA ID 12415

> Malignant tumours of the small bowel are rare…although adenocarcinomas share certain epidemiological features with colorectal cancer (Abstract at p. 551); and
>
> The epidemiology of adenocarcinomas of the small bowel is similar to that of…the large bowel, despite their widely differing incidence rates.

— La Vecchia, C & Tavani, A 2002, [27] RMA ID 24732

> [A relative risk (RR) of about 10 was observed in the first year after starting drug use, which declined toward unity thereafter. Thus] the excess risk of gastric cancer probably represented cases in which a neoplasm was mis-diagnosed as a gastric ulcer/dyspepsia (at p. 119). [28]

— Shindo, K et al 1996, [29] RMA ID 31847

> Gastric hypochlorhydria can induce bacterial over-growth in the jejunum (at p. 462).

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24 Weiss, H.A., Darby, S.C., & Doll, R 1994, 'Cancer mortality following x-ray treatment for ankylosing spondylitis', *International Journal of Cancer*, vol. 59, pp. 327-338.

25 Williamson, RC Welch, CE & Malt, RA 1983, 'Adenocarcinoma and lymphoma of the small intestine: distribution and etiologic associations', *Ann Surg*, vol. 197(2), pp. 172-178.

26 Neugut, AI & Santos, J 1993, 'The association between cancers of the small and large bowel' *Cancer Epidemiology, Biomarkers & Prevention*, vol. 2, pp. 551-553.

27 La Vecchia, C & Tavani, A 2002, 'A review of epidemiological studies on cancer in relation to the use of anti-ulcer drugs' *Eur J Cancer Prev*, vol. 11(2), pp. 117-123.

28 Moller, H et al 1989, Cancer occurrence in a cohort study of patients treated with cimetidine, *Gut,* vol. 30, pp. 1588-1562; in La Vecchia, C & Tavani, A 2002.

29 Shindo, K 1996, 'Alteration of bile acid metabolism by cimetidine in healthy humans', *Journal of Investigative Medicine,* vol. 44(8), pp. 462-469.

— Correa, P 2003, [30] RMA ID 30697

> Cancer research in the 20th Century thoroughly documented the role of major carcinogenic agents: ionizing radiation, chemical carcinogens, viruses and especially tobacco smoke…Chronic inflammation has long been suspected of playing a role in carcinogenesis, [but the mechanism by which inflammation causes cancer remains poorly understood] (at p. E3).

— Ross, RK et al 1990, [31] RMA ID 7230 & 30691

> …the mucosa of the small intestine under-goes rapid cell turnover [32] and most likely comes in contact with a large volume of potential carcinogens (at p.143); and
>
> [We were able to map 57% of all adenocarcinomas…to…7-centimeter length of the 2nd portion of the duodenum….the majority…in the 2nd portion were pinpointed to the periampullary region, where bile and pancreatic secretions enter the small intestine]. These observations suggest the strong possibility that these secretions, in rare instances, can serve as carcinogens to the small bowel mucosa. ..this finding is not a new one. Bile salts can be activated by anaerobic bacteria to substances chemically similar to established carcinogens [33] (at p. 144).

— Chen, CC et al 1993, [34] RMA ID 7212

> [Peptic ulcer disease is an]...hyperactivity syndrome, which would alter the alkaline environment of the small intestine (at p. 207); and
>
> The association of previous peptic ulcer disease with both malignancies [adenocarcinoma and carcinoid] is also a new finding (at p. 207).

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30 Correa, P 2003, 'Bacterial infections as a cause of cancer', *JNCI*, vol. 95(7), pp. E3.

31 Ross, RK et al 1991, 'Epidemiology of adenocarcinomas of the small intestine: is bile a small bowel carcinogen?', *Br J Cancer*, vol. 63, pp. 143-145.

32 Lightdale, CJ Koepsell, TD & Sherlock, P 1982, in Schottenfeld & Fraumeni, JF eds., Small Intestine, in *Cancer Epidemiology and Prevention,* WB Saunders Co, Philadelphia, pp. 692, in Ross, RK Hartnett, NM Bernstein, L & Henderson, BE 1991, 'Epidemiology of adenocarcinomas of the small intestine: is bile a small bowel carcinogen?' *Br. J. Cancer*, vol. 63, pp. 143-145.

33 Lowenfels, AB 1978, 'Does bile promote extra-colonic cancer?', *Lancet,* ii, p. 239; in Ross, RK et al 1990, 'Epidemiology of adenocarcinomas of the small intestine: is bile a small bowel carcinogen?' *Br J Cancer*, vol. 63, p.143.

34 Chen, CC Neugut, AL & Rotterdam, H 1994, 'Risk factors for adenocarcinomas and malignant carcinoids of the small intestine: preliminary findings', *Cancer epidemiology, biomarkers and prevention*, vol. 3, pp. 205-207.

— Kortbeek, J et al 1992, [35] RMA ID 7430

> Inflammatory bowel disease, like chronic inflammatory processes in other areas, is recognised to be associated with increased incidence of malignant change (at p. 122); and
>
> […a slowly growing intestinal carcinoid tumour could result, by unknown mechanisms, in] changes in adjacent mucosa…[which could be misinterpreted as inflammatory bowel disease] (at p. 124).

— Fawcett, AN 1996, [36] RMA ID 7936

> …duodenum ulcers and cancers tend to occur at different sites….majority of adenocarcinomas located in the duodenum or proximal jejunum ...[37]
>
> a man of 55 who had suffered dyspepsia for many years. Autopsy showed:…A simple ulcer had destroyed the whole of the mucosa and the sub-mucosa layers…(at p. 47).

— Hart, R & Levin, B 1992, [38] RMA ID 7474

> [Because the initial symptoms of] small bowel neoplasms are [vague], poorly defined, and often present for several months before a diagnosis is made, the clinician may consider [other more common diseases such as cholecystitis], peptic ulcer disease [or diverticulitis] (at p. 743).

— Neugut & Jacobsen 1993, [39] RMA ID 14103

> The risk factors for small bowel cancer include dietary factors similar to those implicated in large bowel cancer, cigarette smoking, alcohol intake, and other medical conditions, including Crohn's Disease, [familial adenomatous polyposis, cholecystectomy], peptic ulcer disease [and cystic fibrosis]. The protective factors may include rapid cell turnover, a general absence of bacteria, an alkaline environment, and low levels of activating enzymes of precarcinogens (Abstract at p. 243); and

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35 Kortbeek, J, Kelly, JK & Preshaw, RM 1992, 'Carcinoid tumours and inflammatory bowel disease', *J Surgical Oncology,* vol. 49, pp. 122-126.

36 Fawcett, AN 1966, 'Ulcer Cancer of the Duodenum', *British Journal of Surgery*, vol. 53(1), pp. 46-49.

37 Letulle, M 1897, [A case report], *Bull. Soc. Anat.* Paris, vol. 72, p. 721; in Fawcett, AN 1996, 'Ulcer cancer of the duodenum', *British J Surg,* vol. 53, no. 1, pp. 46 – 49.

38 Hart, R & Levin, B 1992, 'Neoplasms of the small bowel', in Calabresi, P & Schein, PS, *Medical Oncology,* 2nd Edition, McGraw Hill, New York, pp. 741-747.

39 Neugut, AI et al 1998, 'The epidemiology of cancer of the small bowel', *Cancer Epidemiology, Biomarkers & Prevention*, vol. 7, pp. 243-251.

…duodenal adenocarcinomas tend to cluster in the periampullary region. This clustering may implicate bile or its metabolites in the etiology of adenocarcinomas at this site (at p. 243).

— Swinson, CM et al 1983, [40] RMA ID 7232 & 3809

Current concepts of cancer view the development of malignancy as a multistage process initiated in most cases by environmental carcinogens (at p. 114).

— Keung, Y-K et al 2003, [41] RMA ID 30736

H. pylori has also been isolated in human stool specimens suggesting that a few *H. pylori* may be able to survive into the small and large intestines. [Therefore it is conceivable that these few *H. pylori* may be able to cause direct damage] to small intestinal mucosa [leading to hyperplasia of mucosa-associated lymphoid tissue (MALT) that eventually transforms into malignant lymphoma, similar to gastric MALT lymphoma] (at p. 1415).

— Varia, D et al 2003, [42] RMA ID 31358

Helicobacter pylori is a human pathogen that causes gastritis, peptic ulcer disease, and is well recognised as a class 1 gastric carcinogen (at p. 1543); and

…a large population study has recently demonstrated that *H pylori* infection was significantly associated with dyspepsia…Population based studies have also suggested that *H pylori* infection is a strong risk factor for ulcer disease (at p. 1546).

— Gasbarrini, G et al 1998, [43] RMA ID 30802

The policy of H. pylori eradication in patients with functional dyspepsia is still controversial…(Abstract at p. S244); and

Prescribing various combinations of drugs, with variable dosage and timings for patients, causes the emergence of resistant organisms, accounting for the vast majority of treatment failures (at p. S246).

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40 Swinson CM et al 1983, 'Coeliac Disease and Malignancy', *The Lancet*, January 15, pp. 111-115.

41 Keung, Y-K et al 2003, 'Mucosa-associated lymphoid tissue (MALT) lymphoma of the jejunum and Helicobacter pylori - chance association?' *Leukemia & Lymphoma*, vol. 44(8), pp. 1413-6.

42 Vaira, D et al 2003, 'Effect of Helicobacter pylori eradication on development of dyspeptic and reflux disease in healthy asymptomatic subjects', *Gut*, vol. 52, no. 11, p. 1543.

43 Gasbarrini, G et al 1998, 'New concepts concerning management of Helicobacter pylori infection: 2 years after the Maastricht Consensus Report', *Ital. J. Gastroenterol. Hepatol.*, vol. 30, suppl. 3, pp. S244-247.

— Woodward, TA & Levin, B 1995, [44] RMA ID 30761 & 7235

> *H. pylori* is considered the causative agent of chronic antral gastritis, an established precursor of the intestinal type of gastric carcinoma (at p. 14); and
>
> Pickled and smoked foods are replete with nitrosamines; current data implicate these agents as mediators of carcinogenesis, probably through their role as inducers of intestinal metaplasia (at p. 14); and
>
> *H. Pylori* is speculated to induce gastric carcinogenesis by several mechanisms: rapid cell turnover induced by infection, leading to higher risk for mutation; and mutation and malignant transformation induced by products of inflammation (e.g., superoxide and hydroxyl ions) (at p. 15).

— Mitchell, KJ et al 1995, [45] RMA ID 7227

> The diagnosis of a small bowel tumor should be considered in patients with vague chronic abdominal complaints (Abstract at p. 276)…

— Kummar, S et al 2002, [46] RMA ID 28236 & 30740

> The absence of effective screening methods [and the relative paucity of presenting symptoms] contribute to the higher percentage of advanced cases at the time of diagnosis…(at p. 3).

— Mayer, RJ 1994, [47] RMA ID 7225

> The most common primary cancers of the small bowel are adenocarcinomas, which account for about 50 percent of the malignant tumours. These neoplasms occur with the highest frequency in the distal duodenum and proximal jejunum, where they tend to ulcerate and cause haemorrhage or obstruction. Radiologically, they may be confused with chronic duodenal ulcer disease or with Crohn's disease if the patient has long standing regional enteritis (at p. 1429).

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44 Woodward, TA and Levin, B 1995, 'Cancers of the stomach and duodenum', *Gastroenterologist*, vol. 3, no. 1, pp. 14-19.

45 Mitchell, KJ Williams, ES & Leffall, LD 1995, 'Primary malignant small bowel tumors: an atypical abdominal emergency', *J Natl Med Assoc*. vol. 87, pp. 276-279.

46 Kummar, S, Ciesielski, TE & Fogarasi, MC 2002, 'Management of small bowel adenocarcinoma', *Oncology*, vol. 16(10), pp. 1364-1373.

47 Mayer, RJ 1994, 'Tumours of the Large and Small Intestine', in *Harrison's Principles of Internal Medicine,* 13th Edition, Isselbacher KJ, Braunwald E, Wilson JD, Martin JB, Fauci AS and Kasper DL (Eds) McGraw-Hill New York, Chapter 257, pp. 1429-1431.

— North, JH & Pack, MS 2000, [48] RMA ID 30686

> Several histologic types of cancer may arise in the small intestine (at p. 46); and
>
> Small intestine tumours are rare tumours….Diagnosis is often delayed because of the nonspecific nature of the symptoms…often in advanced stages before they are detected….the need for expeditious evaluation and treatment is obvious (at p. 49).

51. The Applicant identified in her submissions other medical-science, which was available to (before) the RMA, which she submitted supported her contentions. A list of the information upon which the Applicant relied which was available to (before) the RMA is at Appendix C. A list of material upon which the Applicant relied which was not available to (not before) the RMA is at Appendix D.

REPATRIATION COMMISSION'S SUBMISSIONS

52. The Repatriation Commission made a written submission in October 2005 [49] with the intention of addressing what it understood to be the potential factors contended by the Applicant.

53. A Medical Officer with the Department of Veterans' Affairs attended the hearing in September 2006 and made an oral submission in support of the Repatriation Commission's written submission of October 2005.

54. The Commission submitted that:

> For some of the factors discussed in this submission there is some evidence suggesting the possibility of a causal association. However…none of these factors warrants inclusion in either of the SOPs…; and
>
> There is no basis to include any general factor concerning long term gastrointestinal tract pathology. … [50]

55. A summary of the Commission's submissions is as follows:

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48 North, JH Pack, MS 2000, 'Malignant tumors of the small intestine: a review of 144 cases', *The American Surgeon,* vol. 66, no. 1, pp. 46-51.

49 This summary is taken from the Repatriation Commission's written submission and complementary oral submission.

The Council generally and in these Reasons acknowledges 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.

50 Repatriation Commission's written submission at page 16.

Peptic ulcer

a. The Commission submitted that the available information [51] raised the possibility that malignant neoplasm of the proximal duodenum only (not of the jejunum or ileum) may arise in a benign chronic duodenal ulcer, but that this did not indicate that a history of pre-existing duodenal ulcer led to a higher risk of developing duodenal adenocarcinoma.

b. In the Commission's view:

> the information available to the RMA leaves open the possibility that malignant neoplasm of the proximal duodenum may be associated with duodenal ulceration, but it is insufficient to indicate a causal association. [52]

Helicobacter pylori infection

c. The Commission submitted that the Wang et al. (2003)[53] study appeared to be the first to show an association between Helicobacter pylori infection and duodenal carcinoma, although the high proportion of duodenal carcinoma was not supported by other studies [54] in the information.

d. In the Commission's view:

> The Wang et al study could be seen as hypothesis generating….The lack of histological information…necessitates caution in interpreting the results. The available evidence is insufficient to indicate causation. [55]

Nitrosamines

e. The Commission submitted that it is difficult to assess exposure to nitrosamines, and to study nitrosamines and cancer risk, as there are 300 different nitrosamines, and the type of cancer that can arise is specific to the particular nitrosamine and to particular species of animal. Further, some

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51 Chow, WH et al 1993, 'Risk factors for small intestine cancer', *Cancer Causes & Control*, vol. 4, pp. 163-9;

Cortese, AF & Cornell, GN 1972, 'Carcinoma of the duodenum', *Cancer*, vol. 29, pp. 1010-1015; and

Fawcett, AN 1966, 'Ulcer Cancer of the Duodenum', *British Journal of Surgery*, vol. 53(1), pp. 46-49.

52 Repatriation Commission's written submission at page 7.

53 Wang, K-X Wang, J-L Cui, Y-B Li, C-P 2003, 'Detection of serum anti-Helicobacter pylori immunoglobulin G in patients with different digestive malignant tumors', *World J Gastroenterology*, vol. 9(11), pp. 2501-4.

54 Ibid Cortese, AF & Cornell, GN 1972; and

Ross, RK et al 1991, 'Epidemiology of adenocarcinomas of the small intestine: is bile a small bowel carcinogen?', *Br J Cancer*, vol. 63, pp. 143-145.

55 Repatriation Commission's written submission at page 9.

chemicals contained in foods can modify the metabolic activity of nitrosamines.

f. The Commission concluded from the information [56] that nitrosamines have been shown to be carcinogenic in animals, but that in humans:

> Diet appears to be a relevant risk factor for the disease, with limited, inconsistent but suggestive evidence for meat or fish that is preserved, or cooked in particular ways….The Commission's view is that the evidence, at present is insufficient to support any particular conclusions.[57]

Ionising radiation from barium meal x-rays

g. The Commission submitted that interpreting all the radiation studies in the information[58] was difficult as small intestine carcinomas, malignant carcinoid tumours and sarcomas were not differentiated.

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56 Wu, AH Yu, MC & Mack, TM 1997, 'Smoking, alcohol use, dietary factors and risk of small intestinal adenocarcinoma', *Int J Cancer*, vol. 70, pp. 512-7;

Ibid: Chow, JS et al. 1996;

Negri, E Bosetti, C La Vecchia, C Fioretti, F Conti, E & Franceschi, S 1999, 'Risk factors for adenocarcinoma of the small intestine', *Int J Cancer*, vol. 82, pp. 171-4;

Knekt, P et al 1999, 'Risk of colorectal and other gastro-intestinal cancers after exposure to nitrate, nitrite and N-nitroso compounds: a follow-up study', *Int J Cancer*, vol. 80(6), pp.852-856;

Weyer, PJ Cerhan, JR Kross, BC Hallberg, GR Kantamneni, J Breuer, G Jones, MP Zheng, W and Lynch, CF 2001, 'Municipal drinking water nitrate level and cancer risk in older women: the Iowa Women's Health Study', *Epidemiology*, vol. 12(3), pp. 327-338; and

Neugut, AI & Santos, J 1993, 'The association between cancers of the small and large bowel' *Cancer Epidemiology, Biomarkers & Prevention*, vol. 2, pp. 551-553.

57 Repatriation Commission's written submission at page 13.

58 Andersson, M & Storm, HH (1992). 'Cancer Incidence Among Danish Thorotrast-Exposed Patients', *Journal of the National Cancer Institute*, vol. 84 no. 17, pp. 1318-1325.

Nyberg, U Nilsson, B Travis, LB Holm, LE and Hall, P 2002, 'Cancer incidence among Swedish patients exposed to radioactive thorotrast: a forty-year follow-up survey', *Radiation Research*, vol. 157, pp. 419-425.

Boice, JD Jr, Day, NE Andersen, A et al., 1985, 'Second cancers following radiation treatment for cervical cancer. An international collaboration among cancer registries', *Journal of the National Cancer Institute*, vol. 74(5), pp. 955-975.

Boice, JD Jr Engholm, G Kleinerman, RA et al*.,* 1988, 'Radiation dose and second cancer risk in patients treated for cancer of the cervix', *Radiation Research*, vol. 116, pp. 3-55.

Kleinerman, RA Boice, JD Jr Storm, HH et al*.,* 1995, 'Second primary cancer after treatment for cervical cancer. An international cancer registries study' *Cancer*, vol. 76, pp. 442-52.

Fraser, P Carpenter, L Maconochie, N Higgins, C Booth, M and Beral, V 1993, 'Cancer mortality and morbidity in employees of the United Kingdom Atomic Energy Authority, 1946-86', *British Journal of Cancer*, vol. 67, pp. 615-624.

Cardis, E Gilbert, ES Carpenter, L et al*.,* 1995, 'Effects of low doses and low dose rates of external ionizing radiation: Cancer mortality among nuclear industry workers in three countries', *Radiation Research*, vol. 142, pp. 117-132.

h. The Commission noted that there was no evidence in the available information in respect of diagnostic x-ray procedures, but that there were ten studies in the information in respect of exposure to other (Thorotrast, therapeutically-irradiated and occupational exposure to atomic) radiation.

i. The Commission referred to one report and a book in the information, [59] and to a report which was 'new information,' [60] and submitted that they did not contain specific evidence on the risk of malignant neoplasm of the small intestine.

j. The Commission concluded:

> Overall the evidence on ionising radiation exposure leaves open the possibility that high dose exposure, particularly from therapeutic radiation to the region of the small bowel, could be associated with small bowel cancer. There is no evidence available that points to ionising radiation being associated with adenocarcinoma in particular. There is also no evidence that exposure to the much lower doses resulting from diagnostic radiation is associated with small bowel cancer. [61]

Omar, RZ Barber, JA and Smith, PG 1999, 'Cancer mortality and morbidity among plutonium workers at the Sellafield plant of British nuclear fuels', *British Journal of Cancer*, vol. 79(7/8), pp. 1288-1301.

Carpenter, LM Higgins, CD Douglas, AJ et al. 1998, 'Cancer mortality in relation to monitoring for radionuclide exposure in three UK nuclear industry workforces', *British Journal of Cancer*, vol. 78(9), pp. 1224-1232.

McGeoghegan, D and Binks, K 2000, 'The mortality and cancer morbidity experience of workers at the Springfields uranium production facility, 1946-95, *Journal of Radiological Protection*, vol. 20(2), pp. 111-137.

Howe, JR Karnell, LH Menck, HR Scott-Conner, C 1999, 'Adenocarcinoma of the small bowel. Review of the National Cancer Data Base, 1985-1995', *Cancer*, vol. 86, pp. 2693-2706.

Griem, ML Kleinerman, RA Boice, J D Stovall, M Sheffier, D and Lubin, J H 1994, 'Cancer Following Radiotherapy for Peptic Ulcer', *Journal of the National Cancer Institute*, vol. 86, pp. 842-849.

Weiss, HA Darby, SC and Doll, R 1994, 'Cancer mortality following x-ray treatment for ankylosing spondylitis', *International Journal of Cancer*, vol. 59, pp. 327-338.

59 UNSCEAR 2000, *Sources and effects of ionising radiation, volume II: Effects*, United Nations, New York, pp. 1-86; and

Mettler, FA and Upton, AC 1995, Medical effects of ionizing radiation (2nd Ed.), *WB Saunders Company*, Philadelphia, pp. 176-177, 200-201, 246-247, 402, and 405.

60 Ie, not available to (not before) the RMA.

Biological Effects of Ionizing Radiation Committee BEIR V 1990, 'Health effects of exposure to low levels of Ionizing Radiation,' *National Academy Press,* pages 1- 422.

61 Repatriation Commission's written submission at page 15.

Cimetidine

k. The Commission submitted that none of the reports [62] in the information on histamine-2 receptor antagonist use and the risk of gastrointestinal tract cancer provided any data on the risk of malignant neoplasm of the small intestine from cimetidine use.

THE COUNCIL'S TASK

The Information

56. 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.

57. 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 the Statements of Principles.

58. Further, the Council in taking account of the submissions made to it, ensured that it did so in the correct legal context. Information which could only be considered as new information, was not taken into account in making the review decision.

59. Any submissions, including the Applicant's and Repatriation Commission's respective submissions to the previously constituted Review Council, which concerned information which could only be considered by the Council as new information, were taken into account by the Council on that basis, ie, as new information.

The two-step process

60. In conducting a review the Council follows a two-step process. It first identifies the pool of information, ie by identifying from all the information that was

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62 Johnson, AG Jick, SS Perera, DR & Jick, H 1996, 'Histamine-2 receptor antagonists and gastric cancer', *Epidemiology*, vol. 7(4), pp. 434-6.

La Vecchia, C & Tavani, A 2002, 'A review of epidemiological studies on cancer in relation to the use of anti-ulcer drugs', *European Journal of Cancer Prevention*, Vol 11(2) pp 117-23.

Edwards, MddeB & Baltzan, M 1997, 'Confounding by indication, histamine-2 receptor antagonists, and gastric cancer', *Epidemiology*, vol 8(3), p. 335.

Colin-Jones, DG Langman, MJS Lawson, DH Logan, RFA Paterson, KR & Vessey, MP 1992, 'Postmarketing surveillance of the safety of cimetidine: 10 year mortality report', *Gut*, vol. 33, pp. 1280-1284.

available to the RMA at the relevant times the sound medical-scientific evidence (as that term is defined in section 5AB(2) of the VEA (see [38] - [41] above)) which 'touches on' (ie is relevant to) the scope of review.

61. The second step requires the Council to determine whether the sound medical-scientific evidence in the pool of information concerning the contended factors within the scope of review: [63]

    a. 'points to' (as opposed to merely leaves open)[64] the relevant possibility (ie whether a contended factor or factors (if found to exist in a particular case) could provide a link or element in a reasonable hypothesis connecting malignant neoplasm of the small intestine or death from malignant neoplasm of the small intestine to relevant[65] service[66]). The Council had to find that the hypothesis contended for was reasonable, and not one which was *'obviously fanciful, impossible, incredible or not tenable or too remote or too tenuous;'*[67] and if so,

    b. whether a contended factor or factors (if found to exist in a particular case) could provide a relevant connection between malignant neoplasm of the small intestine or death from malignant neoplasm of the small intestine and relevant[68] service according to a standard of satisfaction *'on the balance of probabilities'*, or as being *'more probable than not'*.

62. In these Reasons, where context permits, the association for both the reasonable hypothesis test (see [8] and footnote 3 above), and the balance of probabilities test (see [8] and footnote 4 above), are respectively referred to as the 'relevant association'.

63. It was with these tests 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 within the scope of review.

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63 See [37] above.

64 See full Federal Court decision at [49] per Branson J.

65 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.

66 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 [29].

67 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 [33].

68 Relevant service here refers to eligible war service (other than operational service), defence service (other than hazardous service), and peacetime service as those terms are defined in the VEA and the MRCA.

64. In forming its judgement of whether the sound medical-scientific evidence 'pointed to' the relevant association, the Council was conscious that the reasonable hypothesis test is *'a test of possibility'* [69] and *'an unusually light burden.'* [70] If the reasonable hypothesis test was found not to be satisfied, the balance of probabilities test necessarily could not be met.

Scope of Review

65. The Council decided to confine its attention to those matters identified by the Council in [37] above.

Pool of Information

66. The Council's final view on the pool of information was that it should comprise the sound medical-scientific evidence the Council had identified on a preliminary basis (Appendix A). In reaching this decision the Council took into account the written submissions and complementary oral submissions and considered whether any of the information to which it was referred should be in the pool.

67. The Council noted references to submissions which the Applicant and Repatriation Commission respectively had made to the previous Review Council.[71] The RMA advised the Council these were new information, ie they were not available to (not before) the RMA at the relevant times (see Appendices D and F). As mentioned above, the Council is unable to (and so did not) consider information and submissions which were not available to (not before) the RMA at the relevant times.

68. The Council considered all the evidence in the pool. However, given the large number of articles in the pool, the Council in these Reasons focused its discussion upon its analysis of those articles which it considered most pertinent to the issues before it.

69. Ultimately, matters of weight are questions for the Council in the exercise of its expertise and scientific judgement, noting that the Councillors are appointed to a particular review because of their specialist expertise in the particular condition (in this case malignant neoplasm of the small intestine).

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69 See full Federal Court decision at [49] citing with approval Spigelman CJ in the New South Wales Court of Appeal decision at [111].

70 See full Federal Court decision at [55] per Branson J.

71 The previous Council of 1999 - 2003 – See [32] ff above.

THE COUNCIL'S ANALYSIS OF THE INFORMATION IN THE POOL

PRELIMINARY COMMENTS

70. The Council noted that information concerning malignant neoplasm of the small intestine is limited. It is a rare cancer, which is somewhat surprising given that *'the small intestine accounts for over 90% of the mucosal surface of the whole gastrointestinal tract.'* [72]

71. The gastrointestinal tract is not a uniform organ. The small intestine comprises the duodenum, jejunum and ileum. It is not scientifically credible to extrapolate findings concerning, for example, cancer of the duodenum, to other parts of the small intestine. Different considerations apply to different components of the gastrointestinal tract, and different components of the small intestine may well have different susceptibilities to disease, including to malignant neoplasm.

72. The Council acknowledged and duly considered, too, that not only diseases, but their treatments, can conceivably contribute to malignant neoplasm of the small intestine. By way of example, just because cimetidine was previously administered as a recognised treatment for peptic ulcer, does not of itself preclude exposure to cimetidine from being a potential cause of disease.

73. Similarly, diseases themselves may conceivably cause or contribute to the development of another disease.

DOES THE SOUND MEDICAL-SCIENTIFIC EVIDENCE 'POINT TO' OR 'LEAVE OPEN' THE RELEVANT ASSOCIATION?

74. As mentioned above, 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' a potential factor (any or all of the potential factors in the scope of review, including those potential factors for which the Applicant contends) as a link or element in a reasonable hypothesis connecting malignant neoplasm of the small intestine or death from malignant neoplasm of the small intestine to relevant service (see [61] and the footnotes there cited), and if so, whether the relevant association exists on the balance of probabilities.

75. The only basis upon which the Council 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 either or both of the Statements of Principles.

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[72] Negri, E Bosetti, C La Vecchia, C Fioretti, F Conti, E and Franceschi, S 1999, 'Risk factors for adenocarcinoma of the small intestine', *Int J Cancer*, vol. 82, pp. 171-174.

Summary of findings

76. The review was very complex, because it considered multiple contended exposures, in circumstances where the information dealt with multiple diseases.

77. The Council analysed all the information in the pool with an open mind. It had regard to all of the factors for which the Applicant contended,[73] and those potential factors for which it identified from the information in the pool there was potentially some evidence in support. [74]

78. The Council considered that for exposure to:

- ionising radiation;
- the term used by the Applicant of 'long-term irritation of the gastrointestinal tract', which, as mentioned above, the Council considered comprised exposure to each of oesophageal reflux; peptic ulcer disease; treatment with cimetidine; and smoking; and
- cimetidine and other therapeutic agents [75]

there was:

- no information in the pool which 'touches on' (ie is relevant to);
- none of the information in the pool provided sufficient support for; or
- there was information in the pool which provided evidence against

an association between any of those exposures as a link or element in a reasonable hypothesis connecting malignant neoplasm of the small intestine with service. [76]

79. The Council was of the view that there is sound medical-scientific evidence on which the RMA could have relied to include factors on the reasonable hypothesis, but not balance of probabilities bases of the following:

- diet, which included exposure to nitrosamines;
- alcohol from beer and spirits, but not wine;
- obesity in men; and
- Helicobacter pylori infection of long duration, but only so far as carcinoma in the first part (the bulb) of the duodenum was concerned.

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73 See [9] above.

74 See the Council's scope of review as noted in [37] above.

75 See [72] above.

76 See [61] and footnote 66.

THE COUNCIL'S ANALYSIS OF THE INFORMATION IT CONSIDERED MOST IMPORTANT

Colin-Jones, DG et al 1992 (2)[77] - RMA ID 30694

80. This study was considered by the Council as relevant to the Applicant's term 'long-term irritation of the gastrointestinal tract'. The study considered the potential impacts on mortality of oesophageal reflux, peptic ulcer disease and cimetidine use.

81. It was a 10-year mortality report from the United Kingdom, the participants of which were identified from four prescription centres, followed over 10 years. A total of 9,928 cimetidine users were followed. Cimetidine was regularly prescribed as a treatment for dyspeptic symptoms. An early excess in mortality was ascribed to cimetidine being given during terminal illness, however, over the 10 year study, *'the 'all-cause mortality' ratio fell from 1.9 in year 1 to 1.0 in years 8 - 10.'* [78]

82. The study noted statistically significant increases in mortality ratios for a number of diseases, including of the stomach and duodenum, however none of the increases were attributable to cimetidine use. The authors concluded that there was a difference:

> between the overall statistical findings and the reality when the age of the patient, the presence of other pathology, use of alcohol and tobacco and patterns of cimetidine prescriptions [were] taken into account. The overall results of the study remain reassuring. [79]

Council's analysis

83. While the authors noted that prescription records are not always accurate, the Council considered that post-marketing surveillance is a powerful method for identifying potentially adverse outcomes of treatment, in circumstances where uncommon adverse effects may not be detected by randomised controlled trials.

84. The Council noted that malignant neoplasm of the small intestine was not a disease found to be a cause of death in this study. Of the diseases involving the stomach, duodenum, unspecified peptic ulcer and unspecified gastrointestinal bleeding (a total of 48 deaths in all) the authors concluded:

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77 The numbers in brackets after the authors and year of publication of articles cited by the Council refer to the articles listed at page 49 of these Reasons.

78 Colin-Jones, DG Langman, MJS Lawson, DH Logan, RFA Paterson, KR Vessey, MP 1992, 'Postmarketing surveillance of the safety of cimetidine: 10 year mortality report', *Gut*, vol. 33, pp. 1280-1284.

79 Ibid at page 1283.

> There was nothing remarkable about deaths in this group except perhaps for the longevity of the individuals concerned despite the many and varied diseases coexisting with their digestive problems. [80]

85. For those diseases that were considered in the study, the authors concluded that any excess of deaths was:

> attributable to the characteristics of the patients receiving cimetidine rather than to any adverse effect of the drug itself. [81]

86. Taking into account:

- the strength of the methodology of this study;
- that it did not identify malignant neoplasm of the small intestine as a cause of mortality for any of the patients in the study;
- that in respect of the diseases that were causative of mortality, death was attributable to characteristics of the patients rather than any adverse effect of cimetidine use; and
- the study's conclusion that it:

> provide[d] reassuring findings in a large cohort of cimetidine users after 10 years of follow-up [82]

the Council's view was that this report provided persuasive evidence against the relevant association. The Council considered that the study was evidence that exposure to cimetidine did not provide a link or element in a reasonable hypothesis connecting exposure to cimetidine to service.

87. Given the Council's finding that this study did not support the relevant association on the basis of a reasonable hypothesis, it necessarily could not do so on the balance of probabilities.

Griem ML et al 1994 (3) - RMA ID 4328

88. This study was considered by the Council to be relevant to peptic ulcer disease[83] and the contended factor of ionising radiation.

89. The purpose of this study was to: *'investigate the risk of death from cancer following radiotherapy for peptic ulcer'* after controlling for underlying disease or

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80 Ibid at page 1282.

81 Ibid at page 1284.

82 Ibid at page 1284.

83 Identified by the Council as encompassed within the Applicant's term 'long-term irritation of the gastrointestinal tract.'

lifestyle factors. [84] The methodology was: *'a mortality study … of 3609 patients with peptic ulcer; 1831 [of whom] were treated with radiation [85] and 1778 [of whom] were treated by other means.'* [86]

90. For those treated with radiotherapy, the radiation dose was centred on the stomach, however all of the stomach, pancreas and spleen, and portions of the left kidney, colon, liver, oesophagus, left lung and rib cage were in the direct field of radiation. The small intestine is an organ not in the direct line of radiotherapy treatment, however the authors noted that scatter radiation was received by the right kidney, gallbladder, small intestine and heart. [87] The authors noted that when part only of an organ was in the direct beam of the x-ray machine, the radiation dose was not equally distributed throughout the organ. They cited the colon as an example of partial exposure and uneven dose distribution.

91. The authors found a 32% excess mortality over that expected based on general population rates. There was similarly an excess mortality among the non-radiated patients. *'For both irradiated and non-exposed patients, significant excesses of death were seen for nonmalignant diseases of the digestive system, reflecting, in large part, complications associated with peptic ulcer.'* [88]

92. *'Among the irradiated patients, significant excesses were noted for cancers of the stomach, large intestine, pancreas, lung, breast and prostate. Among the nonexposed patients, only cancers of the lung and prostate were significantly increased…Contrasting irradiated patients with nonexposed patients, significant increases were noted for cancers of the stomach … pancreas … and leukaemia.'* [89]

93. The authors concluded that: *'patients with peptic ulcers are at an increased risk of dying of cancer, related in part to treatment, the underlying disease, and lifestyle factors such as cigarette smoking.'* [90] Radiotherapy, which the authors note is no longer used to treat peptic ulcer, was found to increase the risk of all cancers combined (as identified in the study) by approximately 50%.[91] *'Radiation risk increased with increasing dose and decreased with increasing age and*

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84 Griem, ML Kleinerman, RA Boice, J D Stovall, M Sheffier, D and Lubin, JH 1994, 'Cancer Following Radiotherapy for Peptic Ulcer', *J Natl. Cancer Inst*, vol. 86, pp. 842-849 at pages 842-3.

85 Between 1937 and 1965 (mean 1950), with average age at radiotherapy 49 years (ibid at page 843).

86 Ibid at page 842.

87 See ibid at page 843.

88 Ibid at page 843.

89 See ibid at page 844.

90 See ibid at page 845.

91 Ibid at page 847.

exposure.' [92] However, the authors found that radiotherapy did not increase the risk of colon cancer, which they ascribed to the non-uniform dosage of radiation to the large intestine.

Council's analysis

94. The Council agreed with the authors that: *'the exceptionally long follow-up for the expression of late effects, the accurate estimation of individual radiation dose, and the comparison group of patients with peptic ulcers who had not been treated with radiation to control for underlying risks and lifestyle factors'* [93] were strengths of the study. In particular, the Council considered the long period of observation [94] of the patients was particularly notable.

95. Radiotherapy is a subset of ionising radiation. While:

- irradiated patients had experienced some scatter radiation of more than 1 Gy of the small intestine; and
- there was an increased risk of cancer death generally

the authors did not report any instances of malignant neoplasm of the small intestine in either the irradiated or nonexposed study groups.

96. The Council also noted the findings in the report, consistent with *'several large-scale studies of peptic ulcer patients'* [95] that peptic ulcer can cause or contribute to the need for gastric surgery, and that gastric surgery has been linked with stomach cancer. Again, however, the authors noted no incidents of malignant neoplasm of the small intestine consequential upon gastric surgery as a treatment modality for peptic ulcer.

97. In the Council's view, this methodologically sound study provided no support for the relevant association, on either a reasonable hypothesis or balance of probabilities bases.

La Vecchia C, Tavani A, (4) 2002 - RMA ID 24732

98. The authors reviewed epidemiological studies on the use of H2-receptor antagonists, including cimetidine, and any identified increased gastric cancer

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92 Ibid at page 847.

93 Ibid at page 848.

94 Average 21.5 years.

95 Ibid at page 845.

risk. The studies reviewed included that by Colin-Jones et al discussed above,[96] and a study by the authors of this review. [97]

99. The findings of the study by Colin-Jones et al have been discussed above, i.e. that: *'an over 10-fold excess of gastric cancer was observed in the first year of the study in cimetidine users… this excess risk declined to about threefold in the second year and two fold in the third and fourth years… this declining trend suggested no causal relation between cimetidine and gastric cancer, but a substantial indication bias.*' [98]

100. A Danish cohort study [99] was reported as finding: *'a relative risk … of about 10 … in the first year after starting drug use, which declined toward unity thereafter. Thus, the excess risk of gastric cancer probably represented cases in which a neoplasm was misdiagnosed as a gastric ulcer/dyspepsia.'* [100]

101. The authors' 1989 study was reported as finding that:

> when the relation between gastric cancer risk and the use of H2-receptor antagonists was further examined in separate strata of sex, age, and other selected covariates (education, tobacco use, and alcohol and coffee consumption), no evidence of heterogeneity in the effect of H2-receptor antagonists emerged. Thus, there was no evidence of association between H2-receptor antagonist use and cancer risk for use started [greater than] 5 years before diagnosis … [101]

102. The author's overall conclusion was that:

> the findings of analytical epidemiological studies are consistent with the absence of a causal association between H2-receptor antagonist use and gastric cancer risk. [102]

Council's analysis

103. The Council was cautious in placing weight upon secondary reports of studies, in contrast to those studies in which it can fully assess for itself the data which underlies the authors' discussion and conclusions. In this case, however, some

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96 See [80] - [87] above.

97 La Vecchia et al 1992, 'Histamine-2 receptor antagonists and gastric cancer: update and note on latency and covariants' *Nutrition* 8: 177-81.

98 La Vecchia, C & Tavani, A 2002, 'A review of epidemiological studies on cancer in relation to the use of anti-ulcer drugs', *Eur J Cancer Prev*, vol. 11(2), pp. 117-123 at page 118.

99 Moller, H et al 1994, 'Cancer occurrence in a cohort of patients treated with cimetidine' *Gut* 30: 1558 - 62.

100 Op cit at page 119.

101 La Vecchia 1989, see La Vecchia 2002 at page 120.

102 La Vecchia 2002 at page 120.

of the primary studies were also in the information available to (before) the RMA, and so were the subject of review by the Council.

104. The studies reviewed by the authors reported no evidence supportive of the relevant association. Importantly too, none of the studies in this review reported any incidence of malignant neoplasm of the small intestine. Accordingly, the Council concluded that the report did not support the relevant association on either the reasonable hypothesis or balance of probabilities bases.

Wang K-X et al (5) 2003 - RMA ID 30614:

105. The stated purpose of the study was *'to investigate the seroprevalence of Helicobacter pylori infection in patients with different digestive malignant tumours'* by detecting *'the anti-Helicobacter pylori IgG antibody in 374 patients with different digestive malignant tumours and 310 healthy subjects (normal control group).*' [103]

106. The authors noted that clinical and epidemiological studies have demonstrated a close association between Helicobacter pylori and gastric cancer. [104] They sought to clarify any relationship with other digestive tumours.

107. The patient group included 101 patients with duodenal carcinomas of various types and in various sites. The authors noted that: *'at present, the definite aetiological factors of duodenal carcinoma are not clear'* [105] and that: *'ulcerous and genetic factors have been considered to be associated with duodenal carcinoma'.*[106]

108. The authors reported that:

> the results of our study showed that: 83.17% of the patients with duodenal carcinoma were infected by Helicobacter pylori, with the rate being 91.04% in ulcerous type and 94.20% in the bulb carcinoma. Therefore we conclude that Helicobacter pylori infection is associated with the development of duodenal carcinoma, especially with ulcerous type and in duodenal bulb.

Council's analysis

109. The Council acknowledged the authors' conclusion that Helicobactor pylori infection is associated with the development of carcinoma in the first part of the duodenum. The duodenum is the first part of the small intestine, and is itself

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[103] Wang, K-X Wang, J-L Cui, Y-B Li, C-P 2003, 'Detection of serum anti-Helicobacter pylori immunoglobulin G in patients with different digestive malignant tumors', *World J Gastroenterology*, vol. 9(11), pp. 2501-2504 at page 2501.

[104] See ibid at page 2501 and the studies there relied upon at footnotes 5 - 10.

[105] Ibid at page 2502.

[106] Ibid at page 2502.

divided into four parts - a first part (the bulb), a second part (the descending duodenum), and a third and a fourth part.

110. The study included 101 patients with duodenal carcinomas, of which 67 were of ulcerous type and 44 of proliferous type, with 65 located in the bulb and 42 in the descending part of the duodenum as manifested under gastroscopy. [107]

111. Helicobacter pylori is only found in the first part of the small intestine immediately after the stomach. The study did not consider patients with carcinoma of the jejunum or the ileum.

112. The Council concluded that the evidence 'pointed to' the relevant association so far as carcinoma in the first part (the bulb) of the duodenum only was concerned, on the reasonable hypothesis, but not on the balance of probabilities basis.[108] So far as the second part of the duodenum was concerned, there was no evidence of the relevant association, as the study disclosed no difference between those patients with cancer and the controls.

Chow W-H et al, (6) 1993 - RMA ID 7213

113. As consistently noted in the information in the pool, the authors' starting point was that malignant neoplasm of the small intestine is relatively rare, with its aetiology essentially unknown. They noted, however, that:

> clinical reports have suggested that certain nonmalignant intestinal disorders, including Crohn's disease, familial adenomatous polyposis and coeliac disease may predispose to increased occurrence. [109]

114. The authors undertook a case-control study, comparing questionnaire responses from next of kin of 430 persons who died from small intestinal cancer, compared to 921 controls who died from other causes. The focus of the questionnaires was demographic and lifestyle characteristics.[110]

115. The authors concluded that there were potential dietary risk factors for contracting small intestinal cancers. Most notable was the consumption of red meat at least once a week, which had an odds ratio exceeding 2, although increasing the exposure to a daily intake had no additional risk effect. [111]

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107 Ibid at page 2501.

108 The Council noted that the Repatriation Commission in its written submission at page 9 had described this study as *'hypothesis generating',* but had gone on to submit that the available evidence is *'insufficient to indicate causation'* [see [55d] above].

109 Chow, W-H Linet, MS McLaughlin, JK Hsing, AW Co Chian, HT and Blot, WJ 1993, 'Risk factors for small intestine cancer', *Cancer Causes & Control*, vol. 4, pp. 163-169 at page 163.

110 Ibid at page 163.

111 See ibid at page 164. See too Table 2 at page 166.

116. A mild increase in risk was also found for frequent consumption of salt cured/smoked foods, with an increased dose response for daily intake. The risk increased from 1.7 for an intake of salt cured/smoked foods 1 - 3 times per month, increasing to 2.1 for daily intake.

Council's analysis

117. This study dealt with all small bowel cancers combined, and did not differentiate by histology or site. However, the Council considered that it was a persuasive retrospective study, and one which was supportive of the relevant association between an intake of red meat, salt cured and smoked foods, and the onset of malignant neoplasm of the small intestine. It was a relatively large case-control study.

118. The study identified a 2 - 3 fold increase in risk with the consumption of red meat and salt cured/smoked foods. The odds ratio for red meat ranged from 2.4 (CI 1.1 - 5.3) - 3.1 (CI 1.4 - 6.7), depending on the frequency of consumption per week, and the odds ratio for salt-cured/smoked foods ranged from 1.3 (CI 0.8 - 2.0) - 2.1 (CI 1.2 - 3.8). These results are statistically significant.

119. The Council considered a potential weakness of the methodology was that information about lifetime dietary and lifestyle factors could not be validated, given that the information was obtained from first-degree relatives of the deceased. Secondly, the Council considered that the appropriateness of the control group was a potential weakness, noting however, that while controls were a little younger, cases and controls were well matched for gender, education, family income and occupation.

120. The Council gave very serious consideration to whether this information 'pointed to' the relevant association. The authors made a cautious interpretation, and the Council was conscious that there was no meaningful indication of the duration of exposure required for the relevant association, noting that the study had not found a dose response relationship. [112]

121. The Council recognised that the matter was not beyond doubt, and was a matter of professional judgement, however, it attached particular weight to the statistical power of this study (the large number of cases).

122. In addition, the Council was particularly cognisant of the direction from the full Federal Court that the reasonable hypothesis test is *'a test of possibility'* and *'an unusually light burden'.* [113]

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[112] The Council noted that the Repatriation Commission in its written submission at page 13 had described this study and other relevant studies as providing *'limited, inconsistent but suggestive evidence… [but] that the evidence at present is insufficient to support any particular conclusions.'* [see [55f] above].

[113] See [64] and footnotes 69 and 70 above.

123. Taking all relevant matters into account, the Council considered that this study 'pointed to' the relevant association as a reasonable hypothesis, so far as red meat and salt cured/smoked foods were concerned. The Council considered that to be the case, notwithstanding that the study did not clearly indicate the requisite dose-response relationship or duration of exposure. However, for this reason, the Council considered that the study did not support the relevant association on the balance of probabilities.

Chen CC et al, (7) 1994 – RMA ID 7212

124. This was a small case-control study from New York (only 19 cases and 52 controls). It used medical records for exposure assessment, and separated adenocarcinoma and malignant carcinoid tumours,[114] with 19 cases of the former and 17 of the latter. The authors found that when:

> analysing cigarette smoking and alcohol consumption as dichotomous exposures, we found both smoking and alcohol to be associated with adenocarcinoma of the small intestine. Adjusting each for the other did not affect these results significantly.[115]

125. The authors identified several limitations with their study, including small sample sizes (because of the rarity of these malignancies); that misclassification errors could thus have had a major impact on the observed associations; and concern as to the generalisability of their findings.[116]

Council's analysis

126. The Council considered that the evidence in this study supporting a posited link with alcohol and/or smoking was weak, given the small size of the study, and the very wide confidence intervals for the odds ratios. The Council noted that there was no differentiation between different types of alcohol, and that the confidence intervals included 1 when the risk for each of these potential factors (smoking and alcohol) was adjusted for the other. That is not statistically significant.

127. In the Council's opinion, this study 'left open' the relevant association on the reasonable hypothesis basis, and therefore necessarily did not satisfy the balance of probabilities test. The Council considered it was not able to attach much weight to the study at all, given the very small sample.

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114 The Council noted that 'carcinoid tumour' is excluded from the definition of malignant neoplasm of the small intestine in [2(b)] of the Statements of Principles.

115 Chen, CC Neugut, AL and Rotterdam, H 1994, 'Risk factors for adenocarcinomas and malignant carcinoids of the small intestine: preliminary findings', *Cancer Epidemiology, Biomarkers and Prevention*, vol 3, pp. 205-207 at page 206.

116 Ibid at page 206 - 7.

128. Given the methodological shortcomings with this study as identified by the authors and agreed by the Council, the Council did not find persuasive the findings suggesting an association between peptic ulcer and malignant neoplasm of the small intestine. The numbers in the study were so small (only two or three patients, and no controls), that the Council was not in a position to draw any conclusions.

Wu AH et al, (8) 1997 - RMA ID 30692

129. The purpose of this large, population-based, case-control study was to investigate the role of tobacco and alcohol use, and dietary factors in the aetiology of small intestinal adenocarcinoma. It was based on personal interviews with 36 diagnosed patient cases and 998 population controls.

130. The study found a non-significant increased risk of small intestinal adenocarcinoma for heavy cigarette smokers (defined as those individuals who had smoked at least 100 cigarettes during his/her entire life). [117]

131. So far as alcohol consumption was concerned, alcoholic intake was cumulated and expressed in grams of ethanol consumed per day. The findings were that the risk of small intestinal cancer tripled for those persons who drank at least 80g of ethanol per day, compared with non-drinkers and those drinking more moderately. The risk of small intestinal adenocarcinoma was not increased with moderate ethanol intake. [118]

132. The study found no statistically significant associations between the risk of small intestinal adenocarcinoma and intake of vegetarian meals, deep-fried foods, milk, eggs, fresh fruit and raw vegetables and bread. While the Council noted that the authors stated they had found no significant association with the risk of small intestinal adenocarcinoma arising from intake of beef, which seemingly would have been a finding inconsistent with Chow et al, it (the Council) could not evaluate that finding, as it was not accompanied by any data.

133. The authors did note an increased risk in males, in relation to frequent intake of fried bacon/ham, barbecued or smoked meats and smoked fish. The odds ratio for the intake of barbecued or smoked meat was statistically significant. For those men who ate the relevant foods at least 6 times a week, a 4.5 fold increased risk of intestinal adenocarcinoma was found (95% CI=1.5,13.2), compared with those men who ate the relevant foods less than twice a week. The increased risk was not observed in females.[119]

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117 Wu, AH Yu, MC and Mack, TM 1997, 'Smoking, alcohol use, dietary factors and risk of small intestinal adenocarcinoma', *Int J Cancer*, vol. 70, pp. 512-517 at page 513.

118 See ibid at page 513.

119 See ibid at page 513. See too Table II at page 514.

134. The study also found an association, in both men and women, between adding sugar (but not artificial sweeteners) to tea and coffee, and to those who drank non-diet carbonated soft drinks on a daily basis. [120] This finding was described by the authors as *'intriguing … [and] not previously reported, [and they could] not rule out that it [was] a chance finding because of the problem of multiple comparisons.'* [121]

135. The authors speculated that the significant increased risk for those men with frequent intake of fried bacon/ham, barbecued or smoked meat and smoked fish was due to those foods containing nitrosamines, *'many of which [according to the authors] are potent inducers of malignant tumours'.* [122]

Council's analysis

136. The Council considered that this was another persuasive paper, and noted that its findings were generally supportive of Chow et al. There was a large control group which was drawn from the general population, rather than comprising other hospital patients not suffering from small intestinal adenocarcinoma.

137. The identified 4.5 fold increase in risk in men with a high intake of fried, barbecued or smoked meat or fish is statistically significant. While the study involved a smaller number of cases than Chow (n = 36), the information here in most cases was obtained by direct interview rather than from next of kin questionnaires.

138. While the associations found were weaker in women, that in itself was consistent, in the Council's view, with the relevant association. Women were likely to be less exposed, and this itself could constitute a proxy dose response.

139. The Council considered that this study, which provided more evidence for a link with dietary factors in men - exposure to fried, barbecued or smoked ham, bacon, meat or fish - 'pointed to' the relevant association on the basis of a reasonable hypothesis, but not on the balance of probabilities.

140. The Council also considered that this study supported the relevant association with respect to heavy alcohol intake, although there was no dose response which would enable the Council to consider any potential association with lower levels of alcohol intake. Nevertheless, the Council considered that the study 'pointed to' the relevant association with heavy alcohol intake.

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120 See ibid at page 513 - 514.

121 See ibid at page 516.

122 See ibid at page 516.

Kaerlev, L et al 2000 (9) - RMA ID 31442

141. The objective of this multicentre case-control study with 95 cases and 3,335 controls, conducted from 1995 - 1997, was to ascertain whether tobacco smoking and the intake of different types of alcoholic drinks were associated with small bowel adenocarcinoma.[123] Population controls were used, with a control-case ratio higher than four. Next of kin responded where a case or control died before interview. [124]

142. Smoking history was expressed as pack years. Questions on alcohol consumption addressed average daily intake of specific alcoholic drinks - beer, wine, and spirits (an amalgamation of liqueur and aperitifs) - with total alcohol intake calculated from the average alcohol intake of each drink. [125] The data were collected for the period five years prior to interview.

143. The authors found that tobacco smoking was not associated with small bowel adenocarcinoma.

144. In contrast, a higher odds ratio was seen in heavy drinkers of both beer and spirits. Beer drinkers with an intake of 24 g or more of alcohol per day had an increased risk of small bowel adenocarcinoma. There was a similar association in heavy spirit drinkers. The authors recorded observing a significant dose response trend for both beer and spirits. [126]

145. Wine drinking and total alcohol intake were not associated with small bowel adenocarcinoma.

146. The authors concluded that there was a strong and consistent association between heavy intake of beer and spirits and small bowel adenocarcinoma, with no association with wine intake or tobacco smoking.[127] The authors suggested that exposure to alcohol per se is not associated with an increased risk, but that there are specific carcinogenic constituents in beer and spirits, or protective constituents in wine. However, the authors could not exclude the possibility that the findings may be due to uncontrolled confounding, for example by diet.

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123 Kaerlev, L Teglbjaerg, PS Sabroe, S Kolstad, HA & Ahrens, W et al. 2000, 'Is there an association between alcohol intake or smoking and small bowel adenocarcinoma? Results from a European multi-center case-control study', *Cancer Causes & Control*, vol. 11(9), pp. 791-797 at page 791.

124 Ibid at page 792.

125 Ibid at page 792 - 793.

126 See Table 3 at page 794.

127 Ibid at page 795.

Council's analysis

147. The Council considered this was a persuasive large study, with 70 cases of small bowel adenocarcinoma and 270 controls, controlled by age, sex and region.

148. The Council noted the authors' findings, which were that a high intake of more than 24 g of alcohol from beer or spirits per day was associated with small bowel adenocarcinoma, with OR 3.5 and 95% CI 1.5 - 8.0 for beer and OR 3.4 and 95% CI 1.3 - 9.2 for spirits. These findings were statistically significant. As mentioned above, no association was found with wine or total alcohol intake or tobacco.

149. The findings in this study generally supported the conclusion reached by Wu et al that there is an association between exposure to alcohol and small bowel adenocarcinoma. However, in the Council's view, the credibility of this study was enhanced because it differentiated between types of alcoholic drinks, and allocated an average alcohol content.

150. In the Council's view this study 'pointed to' the relevant association on the reasonable hypothesis, but not balance of probabilities bases, concerning an exposure to more than 24 g per day of alcohol from beer or spirits.

Negri E et al, (1) 1999 - RMA ID 30580

151. This was a case-control study, designed to investigate any relation between alcohol, tobacco and dietary habits and the risk of small intestinal adenocarcinoma. The study comprised 23 cases and 230 hospital controls, and the number of cases was admitted by the authors to be *'very limited, though comparable with the few other similar investigations.'* [128]

152. What the authors described as *'the most striking feature of [their] results, however, [was] the strong similarity between the dietary correlates of risk of adenocarcinoma of the small intestine and colon cancer.'* [129] As with colon cancer, the authors found that risk of small intestinal adenocarcinoma was directly related to the intake of bread, rice or pasta, sugar, and red meat, and inversely related to coffee, fish, vegetables and fruit.

Council's analysis

153. The Council considered that this study provided more supportive evidence of the relevant association on a reasonable hypothesis basis. The study found an increased risk with the intake of red meat, as well as with bread, pasta and rice.

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128 Negri, E Bosetti, C La Vecchia, C Fioretti, F Conti, E and Franceschi, S 1999, 'Risk factors for adenocarcinoma of the small intestine', *Int J Cancer*, vol. 82, pp. 171-174 at page 173.

129 Ibid at page 173.

154. The Council noted that it was a relatively small study, with only 23 cases and 230 hospital controls. The study was positive, given the high odds ratio (4.57) which supported the link between small intestinal adenocarcinoma and red meat intake, but with wide confidence intervals (1.01 - 20.81).

155. The Council was conscious that there were contradictions here with the findings of Wu et al concerning bread, rice or pasta, and noted that neither study provided any basis for explanation of that difference.

156. Notwithstanding it was conscious of the limitations of the study, taken in conjunction with other persuasive results, and always bearing in mind the very *'light burden'* of the reasonable hypothesis test, the Council considered that the study provided more evidence which 'pointed to' the relevant association on the reasonable hypothesis, but not balance of probabilities bases.

Wolk A et al, (10) 2001 - RMA ID 28810

157. The stated aim of this study was to assess the risk of total and site-specific incident cancers in relation to obesity. Cancer incidence in a large cohort of hospitalised patients in Sweden (some 28,129 patients) was compared with cancer incidence in the general Swedish population, with a follow-up of 29 years. [130]

158. Overall, the cancer incidence (all types of cancer) was found to be 33% higher in the obese; 25% among men and 37% among women.[131] Restricting the analysis to those patients with obesity as the only diagnosis reduced the overall excess cancer risk to 25%, while the exclusion of patients with alcohol-related diagnoses had little effect on overall cancer risk. [132]

159. Of particular relevance here, a previously unreported increased risk associated with obesity was found for cancer of the small intestine (standardised incidence ratio 2.8 (CI 1.6 - 4.5)). [133] However, only men were found to have a statistically significant increased risk of cancers of the small intestine (SIR 4.0; CI 2.2 - 9.3),[134] when data were stratified by sex.

160. The authors noted that the number of subjects was small for many of the cancer sites. Nevertheless, this was the first time an association had been documented between obesity and cancer of the small intestine. Given that the excess risk for

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130 Wolk, A Gridley, G Svensson, M Nyren, O McLaughlin, JK Fraumeni, JF Adam, HO 2001, 'A prospective study of obesity and cancer risk (Sweden)', *Cancer Causes & Control*, January, vol. 12(1), pp. 13-21 at page 13.

131 Ibid at page 16.

132 Ibid at page 18. See too Table 3 at page 16.

133 Ibid at page 18.

134 Ibid at page 16.

cancer of the small intestine had not previously been identified, the authors noted that further investigation was warranted. [135]

Council's analysis

161. The Council considered that this was a large and well constructed study. Separate analyses were done in those cases where obesity was the only discharge diagnosis; for patients with and without diagnoses of alcoholism; and for patients with and without diagnoses of diabetes.

162. The study found a clear, positive finding of an increased risk of malignant neoplasm of the small intestine in the obese male.

163. In the Council's view it 'pointed to' the relevant association on the reasonable hypothesis, but not balance of probabilities bases**.**

Samanic C et al, (11) 2004 - RMA ID 30506

164. This study assessed site-specific cancer risk in a large cohort (4,500,700) of male veterans (over 3,600,000 whites and over 830,000 blacks). The number of women and other non-white racial groups represented within Veterans' Affairs' hospitals in the United States was too small, and so they were excluded from the study, which was conducted from discharge records. The study had an average follow-up of 12 years per patient, up to 27 years. [136]

165. The study found an excess risk for cancer of the small intestine [137] (RR 1.58), and particularly of the duodenum, resulting from obesity. While for most cancer sites there was no significant differences in risk between whites and blacks, that was not the case with small intestinal cancer, with cancer risk at that site being elevated only for white veterans. [138]

Council's analysis

166. This study, as with the Wolk et al study, was large and well designed. The Council considered that the study provided further evidence that obesity is associated with a modest increase in risk for malignant neoplasm of the small intestine, particularly in white men.

167. In the Council's view the study 'pointed to' the relevant association for men on the reasonable hypothesis, but not balance of probabilities bases.

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135 Ibid at pages 18 - 19.

136 Samanic, C Gridley, G Chow, WH Lubin, J Hoover, RN Fraumeni, JF Jr 2004, 'Obesity & Cancer Risk Among White & Black United States Veterans', *Cancer Causes & Control*, vol. 15(1), pp. 35-43.

137 See Table 2 at page 38.

138 See ibid at pages 37 and 39.

THE COUNCIL'S CONCLUSIONS

168. The Council closely analysed all the information in the pool when considering all the contended factors within the scope of the review, however, it placed particular weight on the articles discussed in detail above.

169. The critical question for the Council was whether the sound medical-science *'points to, as opposed to merely leaves open, the possibility of the relevant association.'* [139] It is only if the Council answered that question in the affirmative, that it needed to consider whether the relevant association was established on the balance of probabilities.

170. The Council considered its task a very difficult question of judgement, and acknowledged that its various decisions on whether the reasonable hypothesis test had been met were necessarily a question of expert and professional judgement. It is a matter in respect of which reasonable minds may differ.

171. Always cognisant that the reasonable hypothesis standard is a '*test of possibility'* and *'an unusually light burden',* the Council considered that the combined effect of the studies by:

- Chow, Wu and Negri concerning a dietary factor;
- Wu and Kaerlev concerning an alcohol factor;
- Wolk and Samanic concerning an obesity factor; and
- Wang concerning an Helicobacter pylori factor for carcinoma of the first part (the bulb) of the duodenum only [140]

'pointed to' (as opposed to merely leaving open) the relevant association.

172. The Council's decision, therefore, was that there is sound medical-scientific evidence on which the RMA could have relied to include in Statement of Principles No. 40 of 2004 factors concerning an exposure to any of:

- alcohol in beer or spirits (but not wine);
- fried, barbecued, salt cured or smoked foods, including ham, bacon, red meat and fish;
- obesity in men; and
- so far as carcinoma of the first part (the bulb) of the duodenum only is concerned, Helicobacter pylori infection of long duration.

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139 See full Federal Court decision at [49] per Branson J and [61] above.

140 All these studies are analysed in detail above.

173. The Council considered that for exposure to:

- ionising radiation;
- the term used by the Applicant of 'long-term irritation of the gastrointestinal tract', which, as mentioned above, the Council considered comprised exposure to each of oesophageal reflux; peptic ulcer disease; treatment with cimetidine; and smoking; and
- cimetidine and other therapeutic agents;

there was:

- no information in the pool which 'touches on' (ie is relevant to);
- none of the information in the pool provided sufficient support for; or
- there was information in the pool which provided evidence against

an association between any of those exposures as a link or element in a reasonable hypothesis connecting malignant neoplasm of the small intestine with service. [141]

174. Noting the various limitations as detailed above, and in particular the inability to draw from the various studies a clear dose-response relationship, the Council concluded that the information in the pool was insufficient to justify the relevant association with any of the potential factors considered by the Council in this review [142] on the balance of probabilities.

Previous Review Council's decision

175. The Council was conscious that its decision differed from the conclusions reached by the previously constituted Council. While these are questions of judgement in respect of which reasonable minds may differ, the Council noted that there were also relevant objective reasons.

Did not deal with alcohol and obesity

176. The previous Review Council did not discuss or make any findings with respect to alcohol and obesity. Determining the scope of any particular review is a matter for the particular Review Council. The previous Review Council stated in its Reasons for Decision that its scope of review was limited to *'the factors contended for by the Applicant'* in that review.[143] In neither review did the Applicant contend that either exposure to alcohol or obesity should be factors in the applicable Statements of Principles.

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141 See [61] and footnote 66 above.

142 See [37] above.

143 See [60] of the previous Review Council's Reasons for Decision.

177. The present Council included these exposures within the scope of review because there were relevant data in the information available to (before) the RMA, which the Council considered was sound medical-scientific evidence, and which it had included in the pool of information. The Council noted that some of the sound medical-scientific evidence which it considered persuasive had not been available to the previous Review Council in its review. This included the study by Kaerlev concerning alcohol, which was only published in the academic literature in 2000.[144] Both studies concerning obesity which the Council considered persuasive had been published subsequent to the information available for the previous Review Council's review. Accordingly, the differently constituted Review Councils formed their respective views as to the inclusion, within the scope of review, of alcohol and obesity, on the basis of different information available to the RMA at the relevant times.

On Helicobactor pylori

178. The previously constituted Review Council did consider Helicobacter pylori as a potential factor, and concluded that the information available to it in its previous review did not 'point to' the relevant association.

179. The information which this Council considers 'points to' the relevant association here, between Helicobacter pylori and carcinoma of the first part (the bulb) of the duodenum only, was not available to the previous Review Council in its review. It was only published in the academic literature in 2003. Accordingly, the differently constituted Review Councils formed their respective views on the basis of different information available to the RMA at the relevant times.

On Diet

180. The Council noted that the previous Review Council had also considered that the Chow and Wu studies supported the relevant association.

181. However, while acknowledging that the matter was *'not entirely free from doubt,'* the previous Review Council had ultimately concluded *'that the 'case' for the possibility did not reach the requisite level of satisfaction, i.e. that of a reasonable hypothesis, [and] concluded that the articles did not point to, but merely left open the possibility of an association.'* [145]

182. The previous review Council had been, however, *'strongly of the view that the matter warrants investigation by the RMA, to find out if there [was] sound medical-scientific evidence indicating that exposure to nitrosamines is a link or element in a reasonable hypothesis connecting malignant neoplasm of the small*

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[144] The previous Review Council reviewed the information which was available to (before) the RMA in 1996, when Statement of Principles No. 53 of 1996 was determined, up to and including 1998, when that Statement of Principles was amended by Instrument No. 7 of 1998; see [32] above.

[145] The previous Review Council's Reasons for Decision of February 2003, at page 20.

intestine and death from malignant neoplasm of the small intestine with operational service', [146] and recommended that the RMA conduct an investigation.

183. The RMA conducted the investigation as recommended, but did not add a dietary factor to the Statements of Principles here under review.

184. This Council reached a different view, in the exercise of its expert judgement, from the previous Review Council and the RMA. Importantly, the Negri study was not in the information available to the previous Review Council, as it was only published in the academic literature in 1999. The Negri study was supportive of the positive findings in Chow, and in the Council's view, the sound medical-scientific evidence which touched on a potential dietary factor (Chow, Wu and Negri) 'pointed to' the relevant association.

185. The Council also considers that the difference in outcome with the previous Review Council is referable in part to the clarification of the Council's review task and methodology, as provided by the full Federal Court. The full Federal Court's decision was handed down on 20 December 2002, some two months prior to the publication of the previous Review Council's Reasons for Decision. Self-evidently, however, the full Federal Court's decision was not available to inform the previous review process, which had been ongoing since February 1999, with the previous Review Council's hearing of oral submissions complementing the written submissions taking place on 12 July 2002.

Formulation of factors to be included in Statement of Principles No. 40 of 2004

186. The Council was cognisant of the lack of any clear articulation in the studies of the requisite dose and duration of the exposures it concluded 'pointed to' the relevant association. That lack of specificity did not undermine the Council's confidence that the reasonable hypothesis test had been met. [147]

187. 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

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146 Ibid at pages 20 - 21.

147 It seemed to the Council that the Repatriation Commission's submission may have placed too much weight on these matters. In respect of a number of contended factors as discussed above, the Repatriation Commission submitted that there was information available to the RMA which was *'hypothesis generating*', '*suggestive'*, and *'suggesting the possibility of a causal association'* and yet the Repatriation Commission submitted that the information was insufficient to 'point to' the relevant association.

at step two. [148] The only analysis at the second step is to determine whether the information in the pool 'points to' or 'leaves open' the relevant association. The Council was firmly of the view, for the reasons detailed above, that the information in the pool did 'point to' the relevant association for the relevant exposures.

188. The Council acknowledged the expertise of the RMA in determining Statements of Principles, which set out the factors that must as a minimum exist. Accordingly, while the Council did its best to identify from the studies, data on dose and duration of the various exposures, the Council directed the RMA to formulate exposure criteria (including amount, frequency, and duration of a consumption habit), having regard to the Council's views as set out in these Reasons.

189. The Council directed the RMA to amend the reasonable hypothesis Statement of Principles (No. 40 of 2004) to include as separate factors exposure to:

- more than 24 g per day of alcohol from beer or spirits;
- fried, barbecued, salt cured or smoked foods, including ham, bacon, red meat and fish, consumed at least 3 times each week, for at least 20 years;
- obesity in men; and
- so far as carcinoma of the first part (the bulb) of the duodenum only is concerned, Helicobacter pylori infection of long duration.

190. The Council considered that the sound medical-scientific evidence available to the RMA is insufficient to justify any amendment to Statement of Principles No. 41 of 2004.

DECISION

191. The Council made the Declarations summarised in paragraphs 1 and 2 above.

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[148] *'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) full Federal Court decision, per Branson J at [47] -[49].

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.

EVIDENCE BEFORE THE COUNCIL

Documents

192. 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**.

193. As mentioned above, the information upon which the Applicant and the Repatriation Commission respectively 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.

194. 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**.

195. 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

of the Information before the RMA

1 Negri, E Bosetti, C La Vecchia, C Fioretti, F Conti, E and Franceschi, S 1999, 'Risk factors for adenocarcinoma of the small intestine', *Int J Cancer*, vol. 82, pp. 171-174.

2 Colin-Jones, DG Langman, MJS Lawson, DH Logan, RFA Paterson, KR Vessey, MP 1992, 'Postmarketing surveillance of the safety of cimetidine: 10 year mortality report', *Gut*, vol. 33, pp. 1280-1284.

3 Griem, ML Kleinerman, RA Boice, J D Stovall, M Sheffier, D and Lubin, JH 1994, 'Cancer Following Radiotherapy for Peptic Ulcer', *J Natl. Cancer Inst*, vol. 86, pp. 842-849.

4 La Vecchia, C & Tavani, A 2002, 'A review of epidemiological studies on cancer in relation to the use of anti-ulcer drugs', *Eur J Cancer Prev*, vol. 11(2), pp. 117-123.

5 Wang, K-X Wang, J-L Cui, Y-B Li, C-P 2003, 'Detection of serum anti-Helicobacter pylori immunoglobulin G in patients with different digestive malignant tumors', *World J Gastroenterology*, vol. 9(11), pp. 2501-2504.

6 Chow, W-H Linet, MS McLaughlin, JK Hsing, AW Co Chian, HT and Blot, WJ 1993, 'Risk factors for small intestine cancer', *Cancer Causes & Control*, vol. 4, pp. 163-169.

7 Chen, CC Neugut, AL and Rotterdam, H 1994, 'Risk factors for adenocarcinomas and malignant carcinoids of the small intestine: preliminary findings', *Cancer Epidemiology, Biomarkers and Prevention*, vol 3, pp. 205-207.

8 Wu, AH Yu, MC and Mack, TM 1997, 'Smoking, alcohol use, dietary factors and risk of small intestinal adenocarcinoma', *Int J Cancer*, vol. 70, pp. 512-517.

9 Kaerlev, L Teglbjaerg, PS Sabroe, S Kolstad, HA & Ahrens, W et al. 2000, 'Is there an association between alcohol intake or smoking and small bowel adenocarcinoma? Results from a European multi-center case-control study', *Cancer Causes & Control*, vol. 11(9), pp. 791-797.

10 Wolk, A Gridley, G Svensson, M Nyren, O McLaughlin, JK Fraumeni, JF Adam, HO 2001, 'A prospective study of obesity and cancer risk (Sweden)', *Cancer Causes & Control*, January, vol. 12(1), pp. 13-21.

11 Samanic, C Gridley, G Chow, WH Lubin, J Hoover, RN Fraumeni, JF Jr 2004, 'Obesity & Cancer Risk Among White & Black United States Veterans', *Cancer Causes & Control*, vol. 15(1), pp. 35-43.

Appendices

Appendix A	Preliminary list of the proposed pool of information, as advised to the Applicant and Repatriation Commission by letters dated 9 March 2009 (see [28] of the Reasons), and the final pool of information (see [66] 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 upon which the Applicant relied that the RMA advised was new information, that is information that was not available to (not before) 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	Material upon which the Repatriation Commission relied that the RMA advised was new information, that is information that was not available to (not before) the RMA.

APPENDIX A

SMRC Folder	SMRC Article Number	RMA ID or Reference	Title
2	64	7211	Adedeji, OA Trescoli-Serrano, C & Garcia-Zarco, M 1995, 'Primary duodenal carcinoma', Postgrad. Med. Journal, vol. 71, pp. 354-358.
2	67	4426	Andersson, M & Storm, HH 1992, 'Cancer Incidence Among Danish Thorotrast-Exposed Patients', Journal of the National Cancer Institute, vol. 84, No. 17, pp. 1318-1325.
2	21	7254	Arthaud, JB & Guinee, VF 1979, 'Jejunal and ileal adenocarcinoma: epidemiological considerations', Am. J. Gastroenterology, vol. 72(6), pp. 638-646.
3 5	7 31	30695 31784	Attanoos, R Billings, PJ Hughes, LE & Williams, GT 1995, 'Ileostomy polyps, adenomas, and adenocarcinomas', Gut, vol. 37, pp. 840-844.
5	28	31787	Beddetti, CD & DeRisio, VJ 1986, 'Primary adenocarcinoma arising at an ileostomy site. An unusual complication after colectomy for ulcerative colitis', Dis. Colon & Rectum, vol. 29, pp. 572-5.
2	70	507	Benson, GD Kowlessar, OD & Sleisenger, MH 1964, 'Adult celiac disease with emphasis upon response to the gluten-free diet', Medicine, vol. 43, pp. 1-40.
4	5	31403	Bismar, MM & Sinicrope, FA 2002, 'Radiation Enteritis', Current Gastroenterology Reports, vol. 4(5), pp. 361-5.
4	26	30952	Boice, JD Jr. et al. 1985, 'Second cancers following radiation treatment for cervical cancer. An international collaboration among cancer registries', JNCI, vol. 74(5), pp. 955-975.
4	31	30760	Boice, JD Jr. et al. 1988, 'Radiation dose and second cancer risk in patients treated for cancer of the cervix', Radiation Research, vol. 116, pp. 3-55.

5	21	31813	Boyle, JM Schreiber, H Rao, S & Berman, JH 1992, 'Carcinoma of the ampulla of vater after curative treatment for Hodgkin's disease', American J. Gastrenterology, March, vol. 87(3), pp. 372-4.
3	4	30713	Burke, CA Beck, GJ Church, JM & van Stolk, RU 1999, 'The natural history of untreated duodenal and ampullary adenomas in patients with familial adenomatous polyposis followed in an endoscopic surveillance program', Gastrointestinal Endoscopy, vol. 49(3, pt 1), pp. 358-364.
2	66	5770	Cardis, E Gilbert, ES Carpenter, L et al. 1995, 'Effects of low doses and low dose rates of external ionizing radiation: Cancer mortality among nuclear industry workers in three countries', Radiation Research, vol. 142, pp. 117-132.
2 5	24 33	7251 31782	Carey, PD Suvarna, SK Baloch, KG Guillou, PJ & Monson, JRT 1993, 'Primary adenocarcinoma in an ileostomy: a late complication of surgery for ulcerative colitis', Surgery, vol. 113(6), pp. 712-715.
3	44	16797	Carpenter, LM Higgins, CD Douglas, AJ Maconochie, NES Omar, RZ Fraser, P Beral, V & Smith, PG 1998, 'Cancer mortality in relation to monitoring for radionuclide exposure in three UK nuclear industry workforces', British Journal of Cancer, vol. 78(9), pp. 1224-1232.
2 5	33 26	7242 31789	Carter, D Choi, H Otterson, M & Telford, GL 1988, 'Primary adenocarcinoma of the ileostomy after colectomy for ulcerative colitis', Digestive Diseases & Sciences, vol. 33(4), pp. 509-12.
6	1	39966	Centre's of Disease Control 2004, A report of the Surgeon General's 'The Health Consequences of Smoking', Executive Summary, Centre's for Disease Control and Prevention, National Centre for Chronic Disease Prevention and Health Promotion, accessed via http://www.cdc.gov.Tobacco/sgr/sgr_2004/index.htm, pp. 1-21.
3 5	20 2	30633 32766	Charles, GA 1985 [LETTER] 'Do detergent residues damage the gut?' The Lancet, 19 January, vol. 1, No. 8421, p. 165.

5	3	32765	Chaturvedi, P Chamberlain, RS Chaturvedi, U Kuwajerwala, NK & Goswami, G 2004, 'Carcinoma of the ampulla of vater', http://www.emedicine.com/med/topic2676.htm, pp. 1-19.
2	63	7212	Chen, CC Neugut, AL & Rotterdam, H 1994, 'Risk factors for adenocarcinomas and malignant carcinoids of the small intestine: preliminary findings', Cancer Epidemiology, Biomarkers and Prevention, vol. 3, pp. 205-207.
3	48	14631	Chow, JS Chen, CC Ahsan, H & Neugut, A 1996, 'A population-based study of the incidence of malignant small bowel tumours: seer, 1973-1990', International Journal of Epidemiology, vol. 25(4), pp. 722-728.
2	62	7213	Chow, W-H Linet, MS McLaughlin, JK Hsing, AW, Co
4	35	30739	Chian, HT & Blot, WJ 1993, 'Risk factors for small intestine cancer', Cancer Causes & Control, vol. 4, pp. 163-9.
5	27	31788	Coen, LD Lambert, WG & Gray, PB 1988, 'Adenocarcinoma at the ileo-cutaneous junction following subtotal colectomy for ulcerative colitis', Acta Chir. Scand., vol. 154, pp. 685-6.
3	8	30694	Colin-Jones, DG Langman, MJS Lawson, DH Logan, RFA Paterson, KR & Vessey, MP 1992, 'Postmarketing surveillance of the safety of cimetidine: 10 year mortality report', Gut, vol. 33, pp. 1280-4.
3	5	30697	Correa, P 2003, 'Bacterial infections as a cause of cancer, JNCI, vol. 95(7), pp. E3.
2	4	8128	Cortese, AF & Cornell, GN 1972, 'Carcinoma of the duodenum'. Cancer, vol. 29, pp. 1010-1015.
2	19	7256	Dannenberg, A, Godwin, T Rayburn, J Goldin, H & Leonard, M 1989, 'Multifocal adenocarcinoma of the proximal small intestine in a patient with celiac sprue', J. Clin. Gastroenterology, vol. 11(1), pp. 73-76.
4	23	31266	Das, A Neugut, AI Cooper, GS & Chak, A 2004, 'Association of ampullary and colorectal malignancies', Cancer, vol. 100, pp. 524-30.

5	17	31817	deB Edwards, MD Baltzan, M 1997, 'Confounding by indication, histamine-2 receptor antagonists, and gastric cancer', Epidemiology, May, vol. 8(3), p. 335.
2	61	7214	Donohue, JH 1994, 'Malignant tumours of the small bowel', Surgical Oncology, vol 3, pp. 61-68.
3	6	30696	Ettorre, GM Pescatori, M Panis, Y Nemeth, J Crescenzi, A & Valleur, P 2000, 'Mucosal changes in ileal pouches after restorative proctocolectomy for ulcerative and Crohn's colitis', Dis. Colon & Rectum, vol. 43, pp. 1743-8.
5	9	32042	Evans, HS Moller, H Robinson, D Lewis, CM Bell, CMJ & Hodfson, SV 2002, 'The risk of subsequent primary cancers after colorectal cancer in southeast England', Gut, vol. 50, pp. 647-652.
2	30	7245	Falk, GL Young, CJ & Parer, J 1991, 'Adenocarcinoma arising in a duodenal duplication cyst: a case report'. Aust. NZ J. Surg., vol. 61, pp. 551-553.
2	5	7936	Fawcett, AN 1966, ' Ulcer Cancer of the Duodenum', British Journal of Surgery, vol. 53(1), pp. 46-49.
2	60	7215	Fielding, JR Prior, P & Waterhouse, JA 1972, 'Malignancy in Crohn's disease', Scand. J. Gastroenterology, vol. 7, pp. 3-7.
2	65	5214	Fraser, P Carpenter, L Maconochie, N Higgins, C Booth, M & Beral, V 1993, 'Cancer mortality and morbidity in employees of the United Kingdom Atomic Energy Authority, 1946-86', British J. Cancer, vol. 67, pp. 615-624.
2	59	7216	Fresko, D Lazarus, SS Dotan, J & Reingold, M 1982. 'Early presentation of carcinoma of the small bowel in Crohn's disease (Crohn's carcinoma): case reports and review of the literature', Gastroenterology, vol. 82, pp. 783-789.
5	37	31778	Fujimo, Y Ku, Y Suzuki, Y Ajiki, T Hasegawa, Y & Kuroda, Y 2001, 'Ampullary carcinoma developing after androgenic steroid therapy for aplastic anemia: report of a case', Surgery, vol. 129(4), pp. 501-3.

3	58	14145	Gasbarrini, G & Genta, RM 1997, 'Update on helicobacter pylori research. Malignancies', European Journal of Gastroenterology & Hepatology, vol. 9(6), pp. 621-3.
4	27	30802	Gasbarrini, G et al. 1998, 'New concepts concerning management of helicobacter pylori infection: 2 years after the Maastricht Consensus Report', Ital. J. Gastroenterol Hepatol, vol. 30(3), pp. S244-7.
5	11	31881	Gerritsen, RT Spoelstra, P & Breeuwsma, NG 1993, 'Carcinoma of the papilla of Vater in a brother and sister with familial adenomatous polyposis', Netherlands Journal of Medicine, August, vol. 43(1-2), pp. 22-5.
2 5	26 42	7249 31773	Gilson, TP & Sollenberger, LL 1992, 'Adenocarcinoma of an ileostomy in a patient with familial adenomatous polyposis: report of a case', Dis. Colon Rectum, vol. 35, pp. 261-265.
2	58	7217	Goedde, TA Rodriguez-Bigas, MA Herrera, L & Petrelli, NJ 1992, 'Gastroduodenal polyps in familial adenomatous polyposis', Surgical Oncology, vol. 1, pp. 357-361.
5	14	31827	Graham, S Blanchet, M & Rehrer, T 1977, 'Cancer in asbestos-mining and other areas of Quebec', JNCI, October, vol. 59(4), pp. 1139-1145.
2	57	7218	Gray, GM 1996, 'Diseases producing malabsorption and maldigestion', Scientific American Medicine, Dale, DC and Federman, DD (eds). Scientific American Inc., New York, Chapter 4, Section XI, p 7.
4	16	31273	Green, PHR & Jabri, B 2002, 'Celiac disease and other precursors to small-bowel malignancy', Gastroenterology Clinics of North America, vol. 31, pp. 625-39.
4	1	31495	Green, PHR Stavropoulos, SN Panagi, SG Goldstein, SL McMahon, DJ Aban, H et al. 2001, 'Characteristics of adult celiac disease in the USA: results of a national survey', Am. J. Gastroenterol, vol. 96, pp. 126-31.

2	56	7219	Greenstein, AJ Sachar, DB Smith, H Janowitz, HD & Aufses, AH 1981, 'A comparison of cancer risks in Crohn's disease and ulcerative colitis', Cancer, vol. 48, pp. 2742-2745.
2	68	4328	Griem, ML Kleinerman, RA Boice, J D Stovall, M Sheffier, D & Lubin, J H 1994, 'Cancer Following Radiotherapy for Peptic Ulcer', J. Natl. Cancer Inst., vol. 86, pp. 842-849.
2	55	7220	Gyde, SN Prior, P Macartney, JC Thompson, H Waterhouse, JA & Allan, RN 1980, 'Malignancy in Crohn's Disease', Gut, vol. 21, pp. 1024-1029.
5	22	31796	Hakansson, N Floderus, B Gustavsson, P Johansen, C & Olsen, JH 2002, 'Cancer incidence and magnetic field exposure in industries using resistance welding in Sweden', Occupational & Environmental Medicine, July, vol. 59(7), pp. 481-6.
2	73	504	Harris, OD Cooke, WT Thompson, H & Waterhouse, JAH 1967, 'Malignancy in adult coeliac disease and idiopathic steatorrhoea', American Journal of Medicine, vol. 42, pp. 899-912.
2	9	7474	Hart, R & Levin, B 1992, 'Neoplasms of the small bowel'. In P Calabresi & PS Schein, Medical Oncology (2nd ed.), McGraw Hill, New York, pp. 741-747.
5	1	32767	Hassan, C Zullo, A Speziale, G Stella, F Lorensetti, R Morini, S 2003, 'Adneocarcinoma of the ileoanal pouch anastomosis: an emerging complication?' Int. J. Colorectal Disease, vol. 18, pp. 276-8.
3	55	14210	Hecht, SS 1997, 'Approaches to cancer prevention based on an understanding of N-nitrosamine carcinogenesis' (44168). Proceedings of the Society for Experimental Biology & Medicine, vol. 216(2), pp. 181-91.
5	35	31780	Heppell, J De Zubiria, M Brais, M-F Durh, M-A Carioto, S Boivin, Y & Potvin, C 1990, 'An assessment of the risk of neoplasia in the long-term Ileal reservoirs using the DMH rodent method', Dis. Colon & Rectum, vol. 33(1), pp. 26-31.

5	12	31848	Herring, JA Hall, CC Johnson, JA Poole, GV Subramony, C Suvarna-Gurram, V & Hall, TJ 1996, 'K-ras mutation in a tubular adenoma originating at an ileostomy in a familial adenomatous polyposis patient', American J. Gastroenterology', March, vol. 91(3), pp. 587-91.
2	13	7378	Hizawa, K Iida, M Matsumato, T Kohrogi, N Kinoshita, H Yao, T & Fulishima, M 1993, 'Cancer in Peutz-Jeghers syndrome', Cancer, vol. 72, pp. 2777-2781.
2	72	505	Holmes, GKT Stokes, PL Sorahan, TM Prior, P Waterhouse, JAH & Cooke, WT 1976, 'Coeliac disease, gluten-free diet, and malignancy', Gut, vol. 17, pp. 612-619.
4	15	31309	Howdle, PD Jalal, PK Holmes, GK & Houlston, RS 2003, 'Primary small-bowel malignancy in the UK and its association with coeliac disease', QJ Med., vol. 96, pp. 345-353.
3	15	30687	Howe, JR Karnell, LH Menck, HR & Scott-Conner, C 1999, 'Adenocarcinoma of the small bowel. Review of the National Cancer Data Base', 1985-1995, Cancer, vol. 86, pp. 2693-706.
3 5	17 24	30685 31794	Hulten, L Willen, R Nilsson, O Safarani, N & Haboubi, N 2002, 'Mucosal assessment for dysplasia and cancer in the ileal pouch mucosa in patients operated on for ulcerative colitis - a 30-year follow-up study', Diseases of the Colon & Rectum, vol. 45, pp. 448-452.
5	5	32739	IARC 1989, 'International Agency for Research on Cancer Overall Evaluations of Carcinogenicity Risks to Humans: Occupational Exposures in Petroleum Refining; Crude Oil and Major Petroleum Fuels', vol 45, IARC, Lyon, France, pp. 1-322. NB: A copy of this publication is held in the RMA reference library - catalogue reference number "D21.2".
5	4	32743	IARC 1989, 'International Agency for Research on Cancer Overall Evaluations of Carcinogenicity Risks to Humans: The Rubber Industry; Summary of Data Reported and Evaluation,' vol 28 (Summary only), IARC, Lyon, France. [http://www-cie.iarc.fr/htdocs/monographs/vol28/rubber.html], pp.1-4.

3	25	30601	IARC 1990, 'International Agency for Research on Cancer Overall Evaluations of Carcinogenicity Risks to Humans: Chromium, Nickel and Welding,' vol 49, IARC, Lyon, France, pp. 1-677. NB: A copy of this publication is held in the RMA reference library - catalogue reference number "D21.5".
3	32	29793	IARC 1995, 'International Agency for Research on Cancer Overall Evaluations of Carcinogenicity Risks to Humans: dry cleaning, some chlorinated solvents and other industrial chemicals,' vol 63, IARC, Lyon, France, pp. 1-551. NB: A copy of this publication is held in the RMA reference library - catalogue reference number "D21.12".
5	32	31783	Iwama, T Kamikawa, J Higuchi, T Yagi, K Matsuzaki, T Kanno, J Maekawa, A 2000, 'Development of invasive adenocarcinoma in a long-standing diverted ileal J-pouch for ulcerative colitis'. Dis. Colon Rectum, vol. 43, pp. 101-4.
2	54	7221	Jagelman, DG DeCosse, JJ & Bussey, HJR 1988, 'Upper gastrointestinal cancer in familial adenomatous polyposis', The Lancet, vol. 1, pp. 1149-1150.
3	18	30684	Jess, T Winther, KV Munkholm, P Langholz, E & Binder, V 2004, 'Intestinal and extra-intestinal cancer in Crohn's disease: follow-up of a population-based cohort in Copenhagen County, Denmark', Aliment Pharmacol. Ther., vol. 19, pp. 287-293.
5	16	31818	Johnson, AG Jick, SS Perera, DR & Jick, H 1996, 'Histamine-2 receptor antagonists and gastric cancer', Epidemiology, July, vol. 7(4), pp. 434-6.
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APPENDIX B

SMRC Folder	SMRC Article Number	RMA ID or Reference	Title
1	1.1		Specialist Medical Review Council 2009, SMRC Information List MNSI II 2005 list updated, pp. 1-23.
1	1.2		Repatriation Medical Authority 2005, Registrar's 29 March covering letter to the information, p. 1.
1	1.2.1		Repatriation Medical Authority 2005, Reference list for investigation # 69-2', pp. 1-12.
1	1.3		Repatriation Medical Authority 2005, Registrars 18 April covering letter to the Information', p. 1.
1	1.4	3.1	Specialist Medical Review Council 2003, Declaration No.8 GN S57, 28 February, pp. 1-2. (also see SMRC Folder 1-part 2, Articles 7 and 8 below).
1	1.5		Repatriation Medical Authority 2003, Notice of investigation, GN 15 of 16 April, p. 1252.
1	1.6	2.11	Applicant 2003, Letter to the RMA dated 28 April and 8 Page submission attached, p. 1-9.
1	1.7	2.12	Name Provided (Not stated as per Privacy Act 1988) 2003, Request for an investigation/review by the RMA dated 2 June', pp. 1-4, with 4 article Abstracts attached. See 1.7.1 to 1.7.4.
1	1.7.1	28236 30740	Kummar, S et al. 2002, at SMRC Folders 3 & 4 article 36 & 34.
1	1.7.2	7230 30691	Ross, RK et al. 1991, at SMRC Folders 2 & 3, articles 45 & 11.
1	1.7.3	30759	Kaiser, A et al. 2002, at SMRC Folder 4, article 32.
1	1.7.4	30692 12376	Wu, AH et al. 1997, at SMRC Folder 3, articles 10 & 61.

1	1.8	2.14	Applicant 2004, Letter to RMA dated 9 February and 8 page Reasons for Rejection Review hearing 19/01/2004 attachment dated 16 February 2004, pp. 1-9.
1	1.9	2.15	Applicant 2004, Letter to RMA dated 30 August and 4 page Australian Appeals Tribunal attachment dated 6 August 2004, pp. 1-6.
1	2	2.13	Name Provided (not stated as per Privacy Act 1988) 2004, Request for an investigation/review by the RMA dated 13 February, pp. 1-2, with attachments at 2a & 2b.
1	2.1	2.13.1	Unknown author, n.d., 'DDT Lawsuit Overview - Find Trial Lawyers and Attorneys with Experience in DDT', p. 1.
1	2.2	2.13.2	Muir, P 2002, 'A history of pesticide use', web pages last updated October 2002, pp. 1-7. Patricia Muir, Oregon State University, Oregon, viewed n.d. (no date provided by the person making application to the RMA) http://oregonstate.edu/~muirp/pesthist.htm.
1	3		Repatriation Medical Authority 2004, Formal Investigation – RMA Medical Researcher Briefing Paper, RMA meeting September 2004, pp. 1-52.
1	4		Repatriation Medical Authority 2004, Summary Tables MN Small Intestines, pp. 1-22.
1 part 2	5		Repatriation Medical Authority 2007, Registrar's 28 August letter confirming afresh the information and further information, pp. 1-2 and Appendix A RMA Reference list for investigation #69-2 dated 16 October 2007, pp. 1-12.
1 part 2	6		Repatriation Medical Authority 2006, ‘Registrar's 30 August covering letter to further information’, pp. 1-2.
1 part 2	6.1	39966	Centre's of Disease Control 2004, ‘A report of the Surgeon General's ‘The Health Consequences of Smoking', Executive Summary’, Centre's for Disease Control and Prevention, National Centre for Chronic Disease Prevention and Health Promotion, accessed via http://www.cdc.gov.Tobacco/sgr/sgr_2004/index.htm, pp. 1-21.

1 part 2	6.2	39965	National Library of Medicine and NIH, Medlineplus Encyclopaedia, 'Medical Encyclopaedia: Meckel's diverticulum', accessed on 25 August 2006 by the RMA via http://www.nlm.nih.gov/medlineplus/ency/artilce/000234.htm, pp. 1-2.
1 part 2	7	3.1	Specialist Medical Review Council 2003, Declaration dated 27 February, Malignant Neoplasm of the Small Intestine, Matter No. 2002/2, pp. 1-2.
1 part 2	8	3.2	Specialist Medical Review Council 2003, Reasons for decision, Malignant Neoplasm of the Small Intestine, Matter No. 2002/2, pp. 1-40.
1 part 2	9	2.1	Applicant 1999, letter to the RMA dated 31 January re a long history of upper GIT pathology and on the Authority declaration of 14 January 1999 not to amend Statements of Principles Nos. 153 and 154 of 1996, as amended, pp. 1-2.
1 part 2	10	2.10.1	Repatriation Medical Authority 1998, 14 January (GN 27 January 1999) s196B(9) Declaration and Reasons not to amend Statements of Principles in force for MNSI, pp. 1-3.
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1 part 2	12		Repatriation Medical Authority, n.d., MNSI & Alcohol Use Brief, pp. 1-6.
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1 part 2	15	MNSI II 2.7; MNSI I F2, A16	Applicant 1998, 'Request for RMA review re chronic irritation encompassing H pylori dated 25 March with letter attached stating reasons', pp. 1-3.
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6	7	Medline Search of 42 citations and of 24 pages.
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6	9	Medline Search 1992 to November 1996 of 4 pages.

APPENDIX C

SMRC Folder	SMRC Article Number	RMA ID or Reference	Title
1	1.8	2.14	Applicant 2004, Letter to RMA dated 9 February and 8 page Reasons for Rejection Review hearing 19/01/2004 attachment dated 16 February 2004, pp. 1-9.
1	1.9	2.15	Applicant 2004, Letter to RMA dated 30 August and 4 page Australian Appeals Tribunal attachment dated 6 August 2004, pp. 1-6.
1	1.6	2.11	Applicant 2003, Letter to the RMA dated 28 April and 8 Page submission attached, p.1-9.
1-part 2	9	2.10	Applicant 1999, letter to the RMA dated 31 January re a long history of upper GIT pathology and on the Authority declaration of 14 January 1999 not to amend Statements of Principles Nos. 153 and 154 of 1996, as amended, pp. 1-2.
1-part 2	10	2.10.1	Repatriation Medical Authority 1999, 14 January (GN 27 January 1999) s196B (9) Declaration and Reasons not to amend Statements of Principles in force for MNSI, pp. 1-4.
1-part 2	13	MNSI II 2.9; MNSI I F1, A9	Applicant 1998, Letter to the RMA dated 01 September, p. 1; and submission including 1 page part letter from Professor John McCaffrey and Prince of Wales Hospital Randwick, NSW, page on H Pylori bacteria, pp. 1-3.
1-part 2	13.1	MNSI II 2.9.1; MNSI I F1, A9	McCaffrey, J (Professor) n.d., Medical opinion with 25 June 1998 submission notes to the RMA by Applicant, p. 1.
1-part 2	13.2	MNSI II 2.9.2; MNSI I F2, A9	Prince of Wales Hospital Randwick, NSW n.d., GUT Foundation page on H Pylori bacteria, p. 1.
1-part 2	14	MNSI II 2.8; MNSI I F1, A11	Applicant 1998, Letter to the RMA and submission dated 28 June proposing new factors, pp. 1-3.

1-part 2	15	MNSI II 2.7; MNSI I F2, A16	Applicant 1998, Request for RMA review re chronic irritation encompassing H pylori dated 25 March with letter attached stating reasons, pp. 1-3.
1-part 2	18	MNSI II 2.4; MNSI I F1, A16	Applicant 1997, Letter to the RMA dated 15 December and copy with RMA file note of 17/02/1998, pp. 1-2.
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APPENDIX D

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E	3		Georgeou, G 2003, cited by Unknown author 2003, 'What is coeliac disease?' *Women's Day*, p. 1.
E	4		Leigh, A n.d., 'A pain in the gut', *Health Wise*, unknown publisher, p. 41
E	5		Trace, J (Dr) 1993, Personal Heart Risk Screening for 'Name Provided' (removed by SMRC as per Privacy Act 1988), p. 1.
E	6		Unknown author n.d., 'Movements of the 14 Airfield Construction Squadron', p. 1.
E	7		Tracey, DJ 2000, [NOT SUBMITTED] 'Anatomica: the complete reference to the human body and how it works', accessed via goggle search by SMRC Secretariat 03/02/2009, p. 1.
D – 2	1		Repatriation Commission, n.d., Submission to the SMRC, pp. 1-9.
D - 2	2		Applicant 2002, letter of 26 June to the SMRC with attached summary of applicant's husbands' condition and treatment from 1943 Service to Death in 1995, p.1.
D - 2	3		Applicant 2002, Submission of 25 June to the SMRC re: 'Malignant Neoplasm of the Small Intestine', in addition to submission of 4th April 2002, pp.1-3.

D - 2	3.1	Goenka, MK et al. 1996 [ABSTRACT ONLY] 'Candida overgrowth after treatment of duodenal ulcer. A comparison of Cimetidine, Famotidine and Omeprazole', *Journal of Clinical Gastroenterology*, vol. 23, pp. 7-10.
D - 2	4	Harvey, WG 1951, Veteran medical notes dated 12/02/1951, 15/02/1951 and 16/02/1951, functional dyspepsia diagnosis, Greenslopes Military Hospital, with Applicant notes, n.d., p. 1.
D - 2	5	Applicant 2002, Note to the SMRC of 1 June with attachments, p. 1.
D – 2	5.3	Bansi, K (Dr) 1993, Medical Report of 1 June, "Small Bowel Series", p. 1.
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D – 2	5.6	Bansi, K (Dr) 1993, CT Scan-upper abdomen report of 3 June with Murphy AH (Dr) 1993, 4 June 'Chest Report', with applicant notes, n.d., p. 1.
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D - 2	12	Applicant 2002, 4 April 'Notes to the SMRC', pp. 1-2, and Applicant 1999, 9 September 'Check-list for AAT hearing, Submissions to the AAT' dated 1st November 1999, pp. 1-11.
D - 2	13	Collins, J n.d., [NEWSPAPER CLIPPING] 'Australia alone on vet cancer', *Sunday Mail,* Queensland Newspapers, with notes by Applicant, n.d., p. 1.
D - 2	14	Applicant 2001, 16 July 'Submission to the SMRC', pp. 1-5.
D – 2	15.1	Applicant 2001, 16 July 'Note to the SMRC', p. 1.
D – 2	15.2	Trace, J (Dr) 1997, letter of 29th June, Gilshenan and Luton, p.1.
D - 2	16	Applicant n.d., Transcribed Extract from the Anti-Cancer Society, and unknown Author 1993, retyped by applicant, 1 June, 'Small Bowel Series medical report', claimed to be by Dr Kewal Banst (Locum for Dr Johnston, ED and Dr Murphy, AH), [refer Folder D-2, Article 5.3] with by comments by the Applicant, n.d., p. 1.
D – 2	17	Ker, G n.d., Newspaper clipping 'Beef Kills Diggers Landmark ruling on cancer death', with comments typed by Applicant on the 1994 50yr reunion (14ACS Squadron) information on Service Diet, p. 1.

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D – 2	18	British Medical Association (BMA) n.d., 'Cancerphobia Carcinogens', *Family Health Encyclopaedia*, Dorling Kindersley Ltd, p. 229.
D – 2	19	Applicant n.d., Note on submissions previously submitted to the SMRC and copies of those documents, p. 1; Applicant 1998, 'Submission to the RMA' dated 28 June, pp. 1-2.
D – 2	20	Applicant 1999, letter to Registrar SMRC dated 26 February, p. 1, with 3 attachments.
D – 2	20.1	Applicant 1999, 'Reasons for Review of Statements of Principles SoP Code 152', RMA Decision of 14.01.99 dated 26 February, p. 1.
D – 2	20.2	Applicant 2001, Copy of 14 January 1999 'RMA decision not to amend SoPs in force' made at 3 November 1998 RMA meeting, with Applicant note dated 16 July, p. 1.
D – 2	20.3	Applicant 1999, 'Statement to SMRC seeking a Review of an RMA decision regarding a SOP Code 152 - Malignant Neoplasm of the Small Intestine', dated 26 February, p. 1.
D – 2	21	Applicant n.d., Two (2) notes and two (2) statements on irritants, pp. 1-3.
D – 2	22	Applicant 2001, Letter to SMRC confirming intention to proceed with a SMRC Review dated 20 March, p. 1.
D – 2	23	Applicant 2000, Letter dated 3 November to SMRC with correspondence Applicant sent to Minister, p. 1.
D – 2	23.1	Applicant 2000, Letter to the Minister for Veterans' Affairs (Mr Scott) 14 July, p. 1-4.
D – 2	23.2	Office of the Minister for Veterans' Affairs 2000, Reply by Adviser dated 6 September, pp.1-2.
D – 2	23.3	Applicant 2000, Letter to the Minister for Veterans' Affairs (Mr Scott) 26 September, pp. 1-3.

D – 2	23.4	Office of the Minister for Veterans' Affairs 2000, Reply by Adviser dated 12 October, p. 1.
D – 2	24	Applicant 1999, ‘Application for Review by SMRC’ dated 26 February, pp. 1-2.
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D – 2	25	Unknown Author 1998, [NEWSPAPER CLIPPING] Statements of principles explained at Repatriation Medical Authority workshop, *VetAffairs,* with Applicant notes, no date, p. 1.
D – 2	26	Applicant 1999, Letter to Registrar SMRC dated 26 February, p. 1.
D – 2	27	Towers, M 1995 [NEWSPAPER CLIPPING] 'Should we treat ulcer bug?' dated 7 May, *The Sunday Mail,* News Ltd Brisbane, p. 98.
D – 2	32	Holland, JF et al. eds., 1982, ‘Diagnostic Radiology of Cancer: Small Bowel’, *Cancer Medicine*, Lea & Febiger, Philadelphia, p. 452.
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APPENDIX E

SMRC Folder	SMRC Article Number	RMA ID or Reference	Title
2	67	4426	Andersson, M Storm, HH 1992, 'Cancer Incidence Among Danish Thorotrast-Exposed Patients', *Journal of the National Cancer Institute*, vol. 84, no. 17, pp. 1318-1325.
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3	48 3	14631	Chow, JS Chen, CC Ahsan, H Neugut, A 1996, 'A population-based study of the incidence of malignant small bowel tumours: seer, 1973-1990', *International Journal of Epidemiology*, vol 25, no. 4, pp. 722-728.
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	4	8128	Cortese, AF Cornell, GN 1972, 'Carcinoma of the duodenum', *Cancer,* vol. 29, no. 4, pp. 1010-1015.
5	17	31817	deB Edwards, MD Baltzan, M 1997, 'Confounding by indication, histamine-2 receptor antagonists, and gastric cancer', *Epidemiology*, May, vol. 8, no. 3, p 335.
2	30	7245	Falk, GL Young, CJ Parer, J 1991, 'Adenocarcinoma arising in a duodenal duplication cyst: a case report', *Aust NZ J Surg*, vol. 61, pp. 551-553.
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4	27	14145	Gasbarrini, G et al. 1998, 'New concepts concerning management of helicobacter pylori infection: 2 years after the Maastricht Consenses Report', *Italian journal of gastroenterology and hepatology. Supplement*, vol. 30 Suppl 3, pp. S244-7.
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APPENDIX F

SMRC Folder	SMRC Article Number	RMA ID or Reference	Title
E	8		National Research Council (U.S.), 1990, *Health Effects of Exposure to Low Levels of Ionizing Radiation: Beir V*, National Academy Press, pp. 1-422 print out of Executive Summary, pp. 1 & 1-9, accessed on 6 March 2009 by SMRC Secretariat via website of National Academies Press, Washington, U.S. [http://books.nap.edu/openbook.php?record_id=1224&page=1].
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