



Specialist Medical Review Council

Declaration and Reasons for Decisions

Section 196W
Veterans' Entitlements Act 1986

Re: Statements of Principles Nos. 89 & 90 of 2011 (Diabetes Mellitus)

Request for Review Declaration No. 24

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APPENDIX A – THE CONSTITUTED COUNCIL AND LEGISLATIVE FRAMEWORK OF THE REVIEW

The Specialist Medical Review Council

1. As mentioned in paragraph [2] of the Declaration and Reasons document, the Council is a body corporate established under section 196V of the VEA. It consists of members as determined by the Minister for Veterans' Affairs from time to time to be necessary for the proper exercise of the function of the Council as set out in the VEA.
2. The composition of each Review Council changes from review to review depending on the issues relevant to the particular Statement/s of Principles under review. When a review is undertaken, three to five Councillors selected by the Convener, constitute the Council.¹ When appointing Councillors the Minister is required to have regard to the branches of medical-science that would be necessary for deciding matters referred to the Council for review
3. The Minister must appoint one of the Councillors to be the Convener. If the Council does not include the Convener, the Convener must appoint one of the Councillors selected for the review, to preside at all meetings as Presiding Councillor.
4. **Professor Charles Guest**, the Convener of the SMRC presided for this review. Professor Guest is a public health physician with ACT Health and the Australian National University. He is President of the Australasian Faculty of Public Health Medicine.
5. The other members of the Council were:
 - (i) **Professor Don Chisholm AO**, who is a leader in the fields of diabetes research, patient care and medical education. He established the Diabetes Centre at St Vincent's Hospital, Sydney and is a past President of the Australian Diabetes Society. He is Honorary Endocrinologist, St. Vincent's Hospital, Professor, University of NSW (conjoint appointment), Senior Principal Research Fellow, Diabetes & Metabolism Program, Garvan Institute of Medical Research and Member, Advisory Council St Vincent's and Mater Health. Professor Chisholm is a Fellow of the Royal Australasian College of Physicians and member of the Endocrine Society of Australia (ESA).
 - (ii) **Professor John Funder AO**, who is a Senior Fellow at Prince Henry's Institute of Medical Research at Monash Medical Centre, and holds honorary appointments at Monash, Melbourne University, and the University of Queensland. He has been President of the Australian Society for Medical Research (1979) and the Endocrine Society of Australia (1984), and Chairman of the International Society for Endocrinology (1996-2000).
 - (iii) **Adjunct Professor Ian Gardner**, who is a medical specialist with more than thirty years global experience in Occupational, Environmental and Public

¹ Two of the Councillors for this review, Professors Guest and Chisholm, served on a previous SMRC review of Diabetes mellitus statements of principles, gazetted in 1996. That review concerned smoking and did not touch on the current contention.

Health Medicine. He holds an academic appointment as Adjunct Professor in Occupational and Environmental Medicine at the University of Queensland Centre for Military and Veterans' Health. He has been a visiting professor and external examiner in Occupational Medicine at the National University of Singapore and the Chinese University of Hong Kong in Shatin. He is Senior Physician in Occupational and Environmental Medicine, Defence Centre for Occupational Health and Safety, Canberra, having worked with Defence since 2001. Adjunct Professor Gardner has twice been elected as President of the Australasian Faculty of Occupational and Environmental Medicine of the Royal Australasian College of Physicians. He is a joint editor of the textbook, "International Occupational & Environmental Medicine".

- (iv) **Associate Professor Jenny Gunton**, who is the Faculty and Group Leader, Diabetes and Transcription Factors Lab, Garvan Institute. She is Staff Specialist, Diabetes and Endocrinology, Westmead Hospital, Associate Professor (conjoint), Faculty of Medicine, University of Sydney and Associate Professor (conjoint), St Vincent's Clinical School, University of New South Wales. Associate Professor Gunton is President of the Australian Diabetes Society and a Fellow of the Royal Australasian College of Physicians.

The Legislation

6. The legislative scheme for the making of Statements of Principles is set out in Parts XIA and XIB of the VEA. They are determined by the RMA, and set out those criteria (conditions or exposures), known as factors, that must as a minimum exist before it can be said that an injury, disease or death can be connected with service, on either or both of the two statutory tests, the reasonable hypothesis test² and the balance of probabilities test. 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)³.
7. Fundamental to Statements of Principles is the concept of 'sound medical-scientific evidence' (as noted in [9]) , which is defined in section 5AB(2) of the VEA.

² The reasonable hypothesis test is set out in section 196B(2) of the VEA which provides;
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
- (caa) British nuclear test defence 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.

³ See sections 120, 120A and 120B of the VEA and sections 335, 338 and 339 of the MRCA.

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.⁴
8. The functions of the Council are set out in section 196W of the VEA. In this review, 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:
- (a) Statements of Principles No. **89 of 2011** concerning diabetes mellitus and death from diabetes mellitus, being a Statement of Principles determined by the RMA under section 196B(2)⁵ of the VEA ('the **reasonable hypothesis test**'); and
 - (b) Statements of Principles No. **90 of 2011** concerning diabetes mellitus and death from diabetes mellitus being a Statement of Principles determined by the RMA under section 196B(3)⁶ of the VEA ('the **balance of probabilities test**').

⁴ 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.

⁵ 196B(2) provides;

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
- (caa) British nuclear test defence 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.

⁶ 196B(3) provides;

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 and British nuclear test defence 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:

9. 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 (at the relevant times) and is constrained to conduct its review by reference to that information only.⁷ The RMA is obliged under section 196K of the VEA to send the information to the Council 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 diabetes mellitus that was in the possession of the RMA at the time it (the RMA) made the decision that triggered the Council's review. The chronology of the RMA sending this information is outlined in **Appendix B**
10. Under section 196W of the VEA, the Council can only reach the view that a Statement of Principles should be amended based on sound medical-scientific evidence (as defined above in paragraph [7]).

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- (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.

⁷ *Vietnam Veterans' Association (NSW Branch) Inc v Specialist Medical Review Council and Anor* (full Federal Court decision) (2002) 72 ALD 378 at paragraph 35 per Branson J.

APPENDIX B – APPLICATION TO THE COUNCIL FOR THIS REVIEW

11. On **1 July 2011**, the RMA under subsections 196B(2) and (3) of the VEA determined Statements of Principles Nos. **89 & 90 of 2011** in respect of diabetes mellitus. On **8 July 2011** the Statements of Principles were registered on the Federal Register of Legislative Instruments. The Statements of Principles took effect from **13 July 2011**.
12. On 18 August 2011, 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.
13. An Application for Review of Statements of Principles Nos. **89 & 90 of 2011** in respect of diabetes mellitus, was received by the Council on 9 September 2011. The Applicant contended that the Statements of Principles should include a factor or factors concerning **exposure to dioxin through consumption of water (on ships) contaminated by '2,4,5-T (Agent Orange)'**.
14. Pursuant to section 196ZB of the VEA the Council published in the Gazette a Notice of its Intention to Carry Out a Review of all the information available to the RMA about diabetes mellitus and invited eligible persons or organisations so authorised to make submissions to the Council.⁸ The Council gazetted a subsequent notice as to the dates by which written submissions must be received by the Council.⁹

⁸ Gazette Notice No. GN 41, 19 October 2011

⁹ Gazette Notices No. GN 46, 23 November 2011

APPENDIX C – THE SCOPE OF THE REVIEW AND THE POOL OF INFORMATION

The information sent by the RMA to the Council

15. As mentioned in [9] of the declaration and reasons document, the RMA is obliged under section 196K of the VEA to send to the Council within 28 days after being notified that the Council has been asked to conduct a review.
16. By email dated **2 November 2011**, 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, as listed in **Appendix E, Table 2**.
17. By agreement between the RMA and the Council, information the RMA advised was available to (before) it at the relevant times is posted on a secure website (referred to as FILEForce). It is made accessible by the Council to the Repatriation Commission and the Military Rehabilitation and Compensation Commission (the Commissions), the Applicant, and other participants in the review via confidential password. The information that was available to (before) the RMA at the relevant times was posted on FILEForce on **4 November 2011**.

The Council's preliminary and final view on the scope of the review.

Proposed Scope of Review

18. The Council's preliminary decision on the scope of the review, as advised to the Applicant and Commissions on **4 October 2013** was as follows:

Without limiting the scope of the Council's review of (some or the whole of) the contents of the Statements of Principles, the Council proposed to have particular regard to whether there was sound medical-scientific evidence upon which the RMA could have relied to amend either or both of the Statements of Principles in any or all of the following ways:

- (i) the possible inclusion of a factor or factors in Statement of Principles No 89 of 2011 for which the Council understands the Applicant contends, for

having been on board a vessel and having been exposed to dioxin diluted in water supplied on that vessel, including but not limited to consuming potable water, when the supply had been produced by evaporative distillation of estuarine Vietnamese waters.

and, only if a reasonable hypothesis is supported:

- (ii) the possible inclusion of a factor or factors (as set out above) in Statement of Principles No. 90 of 2011

Proposed Pool of Information

19. In determining its preliminary view on the proposed pool of information the Council applied the methodology (as advised to the Applicant and Commissions) that the pool of information should comprise the information that:
 - was available to (before) the RMA at the relevant times
 - was sent to the Council by the RMA under section 196K of the *Veterans' Entitlements Act 1986* (the VEA);

from which it selected the information that (again on a preliminary basis) it considered:

- to be sound medical-scientific evidence as defined in s.5AB(2) of the VEA¹⁰,
- 'touches on' (is relevant to) the proposed scope of review as set out above; and
- epidemiologists would consider appropriate take into account.¹¹

Notification of Preliminary Decisions on Proposed Scope of Review and Proposed Pool of Information

20. In separate letters, dated **4 October 2013**, to the Applicant and the Commissions, the Council in summary:
- advised of the Council's preliminary decisions on the scope of the review [see paragraph 14] and the studies on which the review would be based (the pool of information [see 56]
 - invited the Applicant and Commissions to make any written comments as to the Council's preliminary decisions by close of business on 18 October 2013; and
 - advised that if any written comments were made, any complementary oral comments could be made at a hearing of oral submissions complementing the written submissions.
21. Neither the Applicant nor the Commissions sought any alteration to the Council's proposed scope of review or to the pool of information.
22. The Council held a meeting on **22 November 2013** to consider all the written submissions and the complementary oral submission.

Final scope and pool of information.

23. The Council's final decision after taking into account all written and oral submissions, was that the scope of the review and the pool of information for this review would remain the same as the proposed scope and pool sent to the Applicant and Commission on a preliminary basis.

¹⁰ s.5AB(2) of the VEA provides that: Information about a particular kind of injury, disease or death is taken to be *sound medical-scientific evidence* if:

(a) the information:

- (i) is consistent with material relating to medical science that has been published in a medical or scientific publication and has been, in the opinion of the Repatriation Medical Authority, subjected to a peer review process; or
- (ii) in accordance with generally accepted medical practice, would serve as the basis for the diagnosis and management of a medical condition; and

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

11 See Bradford Hill, A 1965, 'the Environment and Disease: Association or Causation?', Proceedings of the Royal Society of Medicine Section of Occupational Medicine, Meeting January 14, pp. 295 - 300.

24. 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'.
25. A copy of the Council's list of the pool of information, as forwarded to the Applicant and the Commissions, which the Council decided is the final pool, is attached at **Appendix E, Table 1.**

APPENDIX D – SUBMISSIONS TO THE COUNCIL

26. The Council received submissions from the Applicant and from the Commissions.

APPLICANT'S SUBMISSION

27. The Applicant stated that the information provided with his application of 9 August 2011, together with his letter dated 19 August 2011, comprised his written submission, all of which were taken into account by the Council.¹² The Applicant subsequently advised that he did not want to make an oral submission to complement his written submission.

28. The Applicant contended that the Statements of Principles:

..do not 'provide for people who drank, washed in, slept in sheets and wore clothes washed in, and ate food cooked in water contaminated by 245T (Agent Orange) for the whole time they were deployed as crew members on HMAS Sydney'.

29. He submitted that:

these people were not just cleaning spray equipment but were completely immersed in water contaminated by Agent Orange, which was stored in ships' tanks that were not decontaminated since 1952 during atomic testing.

30. The Applicant submitted that he served in the Royal Australian Navy during the Vietnam war. He submitted that:

the feed tanks were maintained with sufficient water for the boilers when the ship was stationed in Vung Tau harbour during the Vietnam War,

31. He submitted that there were two types of water (on board) - the first being 'too pure for drinking and was made specifically for use in the ship's boilers', the second being tank water for domestic use.

32. The Applicant contended that while in Vung Tau harbour, the ship's tanks were regularly topped up with water distilled from the muddy estuarine... and were not scrubbed or flushed out to remove contamination.

33. He contended that in their current form the Statements of Principles:

would appear to specifically exclude water contaminated with dioxins.

34. The Applicant contended that people who served on HMAS Sydney or her escorts, were exposed to the toxins distilled in an operational area long after the ships had left the area, and while they were exposed for a sufficient time to meet this SoP, they were not necessarily deployed on what is defined as operational service.

35. He contended that while a person:

would be exposed to contamination from toxins from the first time they showered or ingested the water carried in these tanks they may not necessarily have spent the required time within the operational area to meet the SoP.

36. He contended that the section of the Statement of Principles¹³:

12 The information upon which the Applicant relied, being information which the RMA advised was available to (before) the RMA at the relevant times, is listed in Appendix E Table 2

13 Referring to factors (b)(vii) and (j)(vii) of instrument 89 of 2011

Leaves too many imponderables in it raises the Question of whether bathing, drinking and being immersed in water contaminated by dioxin is included in this definition or does the definition specifically exclude water contaminated by dioxin.

37. The Applicant cited a National Research Centre for Environmental Toxicology (NRCET) report¹⁴ which he claimed was previously used by the RMA and is reflected in Statements of Principles allowed for personnel who served on ships which used distilled estuarine waters within 100 miles of Vung Tau. The report was published in 2002 for the Department of Veterans' Affairs.

38. He contended that the RMA has inconsistently applied the findings detailed in the NRCET study across various Statements of Principles.

The NERCAT[sic] report has been previously used by the RMA as is reflected in other SoPs which allows for personnel who served on ships which distilled estuarine waters within 100 nautical miles of Vung Tau

39. He referred to Statements of Principles for Malignant Neoplasm of the Larynx and Malignant Neoplasm of the Lung Malignant Neoplasm of the Prostate Provisions which allow for contamination

on land in Vietnam, or

at sea in Vietnamese waters¹⁵, or

on board a vessel and consuming potable water supplied on that vessel: when the water supply had been produced by evaporative distillation of estuarine Vietnamese waters.

He contended:

..this leaves no doubt as to who is covered or is it the contention of the RMA that this contamination is of no significance.

40. He also submitted:

The SoP supports my theory as it has factor which allows that a person who washes out spray equipment could conceivable [sic] be contaminated through skin absorption.

..This being a fact then a person who bathes in water contaminated by dioxin and drinks it in his coffee, tea, and other water based drinks (limers etc) even the ice used to cool drinks is made from the same supply. His food is cooked in it the utensils off which he eats have been washed in the same water supply as the clothes he wears or sleeps in, even the soft serve ice cream is mixed with contaminated water. Without his knowledge the silly sailor is being contaminated at every turn.

What no person has taken into consideration is that the sailor is not only contaminated during his operational service but that contamination continues every time the ship is using the feed tanks where water [is] from her tanks and not on shore supply. This contamination was not just switched on when they left port to go to Vietnam but every time she disconnected from shore supply.

41. The Applicant made no comment on the Council's proposed scope of review and proposed pool of information decisions.

14 Mueller J, Gaus C, Alberts V, Moore M. [2002] Examination of the potential exposure of Royal Australian Navy (RAN) personnel to polychlorinated dibenzodioxins and polychlorinated dibenzofurans via drinking water. A Report to the Department of Veteran Affairs, Australia. The National Research Centre for Environmental Toxicology (ENTOX) [NRCET] . RMA ID 27791

15 The location of Vietnam waters is set out in the Veteran's Entitlement Act.

COMMISSIONS' SUBMISSIONS

42. The Commissions made a written submission dated **25 June 2012**. A Medical Officer with the Department of Veterans' Affairs, representing the Commissions, made an oral submission complementing the Commissions' written submission at the Council's meeting on **22 November 2013**¹⁶

The Commissions posited that the application for this review:

largely concerns an evidentiary matter about whether (and if so how much) exposure to TCDD could have resulted from consuming potable water made by evaporative distillation on RAN ships during the Vietnam War.

Commissions' general comments on TCDD and diabetes

43. The first part of the Commissions' written submission describes the history of herbicide use in Vietnam, detailing background TCDD exposure, without specific reference to potentially contaminated waters. This part of the submission refers to a number of articles which were available to the RMA. (see Appendix **E Table 2**). The Commissions conclude that the main evidence in support of an association between TCDD and diabetes mellitus comes from the Ranch Hand cohort study¹⁷ but notes that the 'dose-dependent risk was not seen in the more highly exposed but smaller NIOSH¹⁸ cohort'.
44. The Commissions submitted that several herbicides used were named by colour – Agent Orange as well as Agents Purple, Pink and Green, all contained 2,4,4-trichlorophenoxyacetic acid (2,4,5-T), which was inadvertently contaminated during manufacture with TCDD.¹⁹
45. The Commissions submitted that this contamination and its health effects have been the source of much controversy and the subject of a large volume of medical scientific literature.
46. The Commissions contended that the Australian forces on the ground used herbicides that contained other chemicals, including picloram and 2,4-dichlorophenoxyacetic acid (2,4-D), that 'were not contaminated by TCDD'. The Commissions noted that Australian forces in Vietnam made 'almost no direct use of TCDD contaminated herbicides'.
47. The Commissions also submitted a brief description of the biology and background epidemiology to TCDD exposure. They stated that 'estimates of TCDD half-life in humans range from around 7-10 years'. and that .. 'Human exposure has declined

16 The information upon which the Commissions relied, being information which the RMA advised was available to (before) the RMA at the relevant times, is listed in Appendix E.

17 Henriksen GL, Ketchum NS, Michalek J, Swaby JA (1997). Serum dioxin and diabetes mellitus in Veterans of Operation Ranch Hand. *Epidemiology*, 8(3): 252-8. RMA ID 15064 & 14331

Michalek JE, Pavuk M (2008). Diabetes and cancer in veterans of Operation Ranch Hand after adjustment for calendar period, days of spraying, and time spent in Southeast Asia. *J Occup Environ Med*, 50: 330-40. RMA ID 56845

18 Steenland K, Calvert G, Ketchum N, Michalek J (2001). Dioxin and diabetes mellitus: an analysis of the combined NIOSH and Ranch Hand data. *Occupational & Environmental Medicine*, 58(10): 641-8. RMA ID 28532 & 56828

19 p5 of the Commissions' written submission

very substantially since the 1970s... noting that limited information is available on background exposure in Australian populations.

48. The Commissions contended that the two principal studies to have examined the association between TCDD exposure and diabetes mellitus are:
 - i) the Air Force Health Study²⁰, and
 - ii) A US National Institute for Occupational Safety and Health (NIOSH)²¹.
49. The Commissions submitted that Henriksen et al 1997²² reported results of the former after adjusting for known confounders, and found increased prevalence of diabetes in those Ranch Hand veterans whose estimated serum TCDD level at the end of service, was above the estimated background level at the time of testing. (page 6-7 written sub).
50. Michalek and Pavuk in 2008²³ followed up on the same cohort and found,
 - the prevalence of diabetes had increased to 17.6% in the Ranch Hand subjects and 17.9% in the comparison group.
51. The Commissions submitted that a stratified analysis in that paper found that serum TCDD level was positively associated with spraying for 90 days or more and also with service before the end of 1969.
 - Risk of diabetes was again lower in the comparison group relative to the group but significantly elevated in both the low and high exposure groups.²⁴
52. The NIOSH study relied on by the Commissions was a cross-sectional study of diabetes in workers who made 2,4,5-T, Agent Orange and other TCDD contaminated products in two US plants from the 1950s to the early 1970s. While the Commissions noted that the original study was not available to the RMA at the relevant time, 'details were available from a later re-analysis of the combined NIOSH and Ranch Hand data²⁵ as well as from the series of Institute of Medicine – Veterans and Orange biennial report'.²⁶
53. The Commissions submitted that TCDD exposure in the workers was substantially higher than in the Ranch Hand veterans. The Commissions noted that no dose-response trend was observed with either current serum or calculated TCDD exposure levels²⁷

20 The series of studies known as 'Operation Ranch Hand'

21 The original study was not available to the RMA.

22 Henriksen et al 1997, op cit

23 Michalek & Pavuk , 2008, op cit

24 Page 7 of the Commissions' written submission

25 Steenland et al (2001), op cit.

26 Institute of Medicine (2000). Herbicide/dioxin exposure and type 2 diabetes. Veterans and Agent Orange, National Academies Press - Washington, DC. RMA ID 19992

Institute of Medicine (2002). Veterans and Agent Orange Update 2002, National Academy Press, Washington, D.C. RMA ID 29493

Institute of Medicine (2009). Committee to review the health effects in Vietnam veterans of exposure to herbicides. Veterans and Agent Orange Update 2008, Seventh biennial update, The National Academies Press, Washington DC. RMA ID 56717

27 See p. 8 and table in Commissions written submission. The table appears to be derived from the earlier NIOSH study by Calvert study, which was not available to the RMA at the relevant times.

54. The Commissions contended that when the Ranch Hand and NIOSH data were re-analysed by Steenland et al, using a uniform approach, the odds ratio of prevalent diabetes in the combined exposed group versus the combined non-exposed group was 1.17 (95% CI 0.92 to 1.48); and that a 'significantly increased risk was found only in the highest (top 8%) exposure category in the Ranch Hand subjects.
55. The Commissions also cited
- Kang et al study (2006) who reported on 1499 US Army Chemical corps veterans who had sprayed defoliants in Vietnam. 'Diagnosis was based on self-report plus a few medical records'. The adjusted odds ratio for diabetes for Vietnam veterans versus non-Vietnam veterans was 1.16 (95%CI 0.91 to 1.49) 'For Vietnam sprayers vs Vietnam non-sprayers, the OR was 1.49 (95% CI 1.10 to 2.02).²⁸
 - Vena et al (1998) who found exposure to TCDD or HCB was associated with a non-statistically significant increased risk of mortality from diabetes' and no significant trend with duration of exposure'...'non-statistically significant'
 - Bertazzi et al 1998 who followed long-term a highly exposed population. Results 'were as per the table'.²⁹
56. The Veterans and Agent Orange study Update (2008) which summarised evidence on dioxins. The Commissions noted that the study concluded: that the evidence for an association between TCDD exposure and diabetes is in the limited/suggestive category.
57. The Commissions also submitted that self-reported diabetes in Australian Vietnam veterans exceeded expected rates in a 1998 study, but that validation studies indicated that prevalence across a range of diseases was substantially lower than self-reported prevalence.
58. The Commissions concluded that the main evidence in support of the association came from the Ranch Hand cohort, and that the reason for the discrepancy between the Ranch hand results and that of the NIOSH is not clear.
59. With regard to the first part of the submission, the Commissions concluded:³⁰
- The available evidence indicates that risk is increased in persons who have had long-term direct contact with liquid TCDD, from handling and spraying contaminated herbicides, sufficient to result in serum TCDD levels that remain elevated decades after the exposure. Commissions' comments on the potable water issue
60. In the next part of their submission, the Commissions focussed on the contended 'potable water' issue.
61. The Commissions submitted that there are Statements of Principles that have been issued by the RMA for other diseases that contain different factors for TCDD exposure, or that are in effect proxy factors for TCDD exposure. One such factor, found in a number of Statements of Principles, takes the following form:

28 p10 of the Commissions' written submission

29 The Commissions included in their submission at p11, a Table showing mortality from diabetes, extracted from the Bertazzi et al (1998) study

30 p13 of the Commissions' written submission

being on board a vessel and consuming potable water supplied on that vessel, when the water supply had been produced by evaporative distillation of estuarine Vietnamese waters, for a cumulative period of at least thirty days, at least five years before the clinical onset of (disease X);³¹ where

"estuarine Vietnamese waters" means at least one of the waterways or harbours in the relevant areas described in Items 4 and 8 of Schedule 2 of the VEA;

62. The Commissions submitted that the Applicant was evidently seeking to have a 'potable water' factor of this type included in the diabetes SOPs.
63. From the information that was available to the RMA at the relevant times, the Commissions identified the NRCET³¹ report (on which the Applicant also relies).
64. The Commissions submitted that this 'laboratory-based experimental study examined the potential exposure of RAN personnel serving in Vietnam to dioxins and furans via potable water'.
65. The Commissions submitted that the level of TCDD in the source water used to make potable water on RAN ships during the war is unknown.
66. The Commissions submitted details of the methods used in the NRCET study, contending that:

the NRCET report estimate although not explicitly stated, is effectively an attempt to estimate TCDD exposure on HMAS Sydney from potable water made in Vung Tau harbour [between 1965 and 1972].

Levels of TCDD in fish used in the NRCET calculation came from a paper by Baughman and Meelson (1973)

the NRCET report included the TCDD levels from the inland river fish in estimating the water TCDD level in Vung Tau Harbour. Those levels were up to nine-fold higher than the maximum level reported in the fish caught in the Vung Tau harbour area

The next step... seems to involve an assumption that the TCDD in the fish.. came from the water rather than from sediment or the food chain.

TCDD in waterways is photodegraded by sunlight, volatilises or binds to suspended solids and settles in sediment.....would have led to a substantial overestimate of the TCDD level in the water.

67. The Commissions contended that the estimate of the source water concentration in the NRCET report 'may be two or more orders of magnitude too high.'³² (p17)
68. The Commissions contended that there were a number of other uncertainties and variables around the estimate of TCDD exposure from evaporative distillations
69. On the basis of this analysis of the available literature, the Commissions concluded that:

31 Muller J, Gaus C, Alberts V, Moore M [2002]. Examination of the potential exposure of Royal Australian Navy (RAN) personnel to polychlorinated dibenzodioxins and polychlorinated dibenzofurans via drinking water. A Report to the Department of Veteran Affairs, Australia. The National Research Centre for Environmental Toxicology (ENTOX) [NRCET]. RMA ID 27791

32 p17 of the Commissions' written submission.

the minimum requirement of 500 hours (in the reasonable hypotheses of direct contact via handling or spraying with TCDD-contaminated herbicides, or other like exposure... is compatible with the sound-medical-scientific evidence...

the issue [of TCDD via potable water made on RAN ships] ... primarily relate to dose and to evidentiary matters about the level of exposure via this pathway, rather than questions of causation.

The level of exposure...in areas such as Vung Tau harbour on RAN ships cannot be determined with accuracy. However it is possible to give some consideration to the potential magnitude of that exposure relative to that of the Ranch Hand subjects

..based on limited evidence from serum TCC testing in RAN veterans, the potable water pathway would not have approached that experienced by personnel who directly handled and sprayed and had skin contact with TCDD-contaminated herbicides over extended periods of time. Further...could have been below contemporary background levels...

The evidence differs for every disease. The inclusion of a potable water factor in one SOP is not a basis for its inclusion in another SOP for a different disease.

70. To further conclude, the Commissions submitted:³³
 - ... the inclusion of additional SOP factors, or the amendment of existing SOP factors, to cover exposure to potable water made by evaporative distillation of estuarine Vietnamese waters is not warranted
71. The Commissions additionally submitted that a previous factor relating to having a specified serum dioxins, was in earlier versions of the diabetes mellitus the SoPs, but was removed from the SoPs in 2011 'on the basis of its impracticality', based on results of an unpublished NRCET report on serum TCDD testing, carried out for the Department, and is included in the information available to the RMA.³⁴

³³ p 20 of the Commissions' written submission.

³⁴ p 19 of the Commissions' written submission.

APPENDIX E – EVIDENCE BEFORE THE COUNCIL

TABLE 1

Council's Pool of Information

Table 1 – The Council's Pool of Information

RMA ID	Reference
61193	Batterman AR, Cook PM, Lodge KB, Lothenbach DB, Butterworth BC (1989). Methodology used for a laboratory determination of relative contributions of water, sediment and food chain routes of uptake for 2,3,7,8-TCDD bioaccumulation by lake trout in Lake Ontario. Chemosphere vol. 19 issue 1-6 1989. p. 451-458
61194	Baughman R, Meleson M (1973). An analytical method for detecting TCDD (dioxin): Levels of TCDD in samples from Vietnam. Environ Health Perspect, 5: 27-35.
56848	Everett CJ, Frithsen IL, Diaz VA, Koopman RJ, et al (2007). Association of a polychlorinated dibenzo-p-dioxin, a polychlorinated biphenyl, and DDT with diabetes in the 1999-2002 National Health and Nutrition Examination Study. Environ Res, 103: 413-8.
15064 14331	Henriksen GL, Ketchum NS, Michalek J, Swaby JA (1997). Serum dioxin and diabetes mellitus in Veterans of Operation Ranch Hand. Epidemiology, 8(3): 252-8.
19992	Institute of Medicine (2000). Herbicide/dioxin exposure and type 2 diabetes. Veterans and Agent Orange, National Academies Press, Washington, DC.
29493	Institute of Medicine (2002). Veterans and Agent Orange Update 2002. National Academy Press, Washington, D.C.
56717	Institute of Medicine (2009). Committee to review the health effects in Vietnam veterans of exposure to herbicides. Veterans and Agent Orange Update 2008, Seventh biennial update. The National Academies Press, Washington DC.
61195	Institute of Medicine (2011). Committee on Blue Water Navy Vietnam Veterans and Agent Orange Exposure; Summary. Blue Water Navy Vietnam Veterans and Agent Orange Exposure. National Academies Press - Washington, DC.
56849	Kang HK, Dalager NA, Needham LL, Patterson DG Jr, et al (2006). Health status of Army Chemical Corps Vietnam veterans who sprayed defoliant in Vietnam. Am J Ind Med, 49: 875-84.
56850 56575	Lee DH, Lee IK, Song K, Steffes M, et al (2006). A strong dose-response relation between serum concentrations of persistent organic pollutants and diabetes. Results from the National Health and Examination Survey 1999-2002. Diabetes Care, 29(7): 1638-44.
58496	Lee D-H, Steffes MW, Sjodin A, Jones RS, et al (2010). Low dose of some persistent organic pollutants predicts type 2 diabetes: a nested case-control study. Environ Health Perspect, 118(9): 1235-42.

Table 1 – The Council’s Pool of Information

RMA ID	Reference
56845	Michalek JE, Pavuk M (2008). Diabetes and cancer in veterans of Operation Ranch Hand after adjustment for calendar period, days of spraying, and time spent in Southeast Asia. <i>J Occup Environ Med</i> , 50: 330-40.
573234	Mueller JF, Toms LM, Aylward L (2009). Levels of 2,3,7,8-tetrachlorodibenzo-p-dioxin in Australian Vietnam veterans compared to the Australian population. Final Report to Australian Government Department of Veterans' Affairs, National Research Centre for Environmental Toxicology.
28532 56828	Steenland K, Calvert G, Ketchum N, Michalek J (2001). Dioxin and diabetes mellitus: an analysis of the combined NIOSH and Ranch Hand data. <i>Occupational & Environmental Medicine</i> , 58(10): 641-8.
27791	Muller J, Gaus C, Alberts V, Moore M.[2002] Examination of the potential exposure of Royal Australian Navy (RAN) personnel to polychlorinated dibenzodioxins and polychlorinated dibenzofurans via drinking water. A Report to the Department of Veteran Affairs, Australia. The National Research Centre for Environmental Toxicology (ENTOX) [NRCET] .
56846	Uemura H, Arisawa K, Hiyoshi M, Satoh H, et al (2008). Associations of environmental exposure to dioxins with prevalent diabetes among general inhabitants in Japan. <i>Environ Res</i> , 108: 63-8.
14332	Vena J, Boffetta P, Becher H, Benn T, Bueno-de-Mesquita HB, et al (1998). Exposure to dioxin and nonneoplastic mortality in the expanded IARC international cohort study of phenoxy herbicide and chlorophenol production workers and sprayers. <i>Environmental Health Perspective</i> . Apr 1998, 106 (Suppl 2), 645-653

TABLE 2

Information sent by the RMA to the SMRC in Accordance With Section 196k of the VEA. This table also identifies the information that the Applicant and the Commissions relied on from this list.

RMA ID	Reference	Relied upon by Applicant or Commissions
58633	Aarnisalo J, Veijola R, Vainionpaa R, Simell O, et al (2008). Cytomegalovirus infection in early infancy: risk of induction and progression of autoimmunity associated with type 1 diabetes. <i>Diabetologia</i> , 51: 769-72.	
2643	Abu-Bakare A, Gill GV, Taylor R, Alberti KG (1986). Tropical or Malnutrition-Related Diabetes: A Real Syndrome? <i>Lancet</i> , 1(8490): 135-8.	
58580	Access Medicine (2008). Diabetes mellitus. Chapter 338, Retrieved 22 September 2010, from http://proxy14.use.hcn.com.au/popup.aspx?aID=2891139&print=yes_chapter	
58424	Adams LA, Waters OR, Knuiman MW, Elliott RR, Olynyk JK (2009). NAFLD as a risk factor for the development of diabetes and the metabolic syndrome: an eleven-year follow-up study. <i>Am J Gastroenterol</i> , 104: 861-7.	
57570	Afridi HI, Kazi TG, Kazi N, Jamali MK, et al (2008). Evaluation of status of toxic metals in biological samples of diabetes mellitus patients. <i>Diabet Res Clin Pract</i> , 80: 280-8.	
58221		
26614	Ajani UA, Hennekens CH, Spelsberg A, Manson JE (2000). Alcohol consumption and risk of type 2 diabetes mellitus among US male physicians. <i>Arch Intern Med</i> , 160: 1025-30.	
15199	Ajlouni K, Jaddou H, Batieha A (1998). Diabetes and impaired glucose tolerance in Jordan: prevalence and associated risk factors. <i>Journal of Internal Medicine</i> , 244: 317-23.	
29572	Akbar DH (2003). Diabetes mellitus and viral hepatitis: the unsolved mystery. <i>Acta Diabetol</i> , 40(2): 77-9. Retrieved 10 December 2003, from 77-9	
56857	Al Lawati NM, Patel SR, Ayas NT (2009). Epidemiology, risk factors, and consequences of obstructive sleep apnea and short sleep duration. <i>Prog Cardiovasc Dis</i> , 51(4): 285-93.	

Table 2 The Information**Relied upon by
Applicant or
Commissions**

RMA ID	Reference
56855	Alaei M, Negro F (2008). Hepatitis C virus and glucose and lipid metabolism. <i>Diabetes & Metabolism</i> , 34: 692-700.
15450	Albanese RA (1991). The chemical 2,3,7,8-tetrachlorodibenzo-p-dioxin and U.S. Army Vietnam-era Veterans. <i>Chemosphere</i> , 22(5-6): 597-603.
57561	Albertsen PC (2010). [Comment] Does the benefit justify the risk? <i>JNCI</i> , 102(1): 4-5. Comment on ID: 57560.
56863	Alderman MH (2008). New onset diabetes during antihypertensive therapy. <i>Am J Hypertens</i> , 21: 493-9.
28711	Aldosary AA, Ramji AS, Elliott TG, Sirrs SM, Thompson DM, et al (2002). Post-liver transplantation diabetes mellitus: an association with hepatitis C. <i>Liver Transplantation</i> , 8(4): 356-61.
58309	Alibegovic AC, Sonne MP, Hojbjerg L, Bork-Jensen J, et al (2010). Insulin resistance induced by physical inactivity is associated with multiple transcriptional changes in skeletal muscle in young men. <i>Am J Physiol Endocrinol Metab</i> , : [Epub ahead of print
15106	Al-Mahroos F, McKeigue PM (1998). High prevalence of diabetes in Bahrainis. Associations with ethnicity and raised plasma cholesterol. <i>Diabetes Care</i> , 21(6): 936-42.
43833	Altobelli E, Petrocelli R, Verrotti A, Valenti M (2003). Infections and risk of type I diabetes in childhood: A population-based case-control study. <i>European Journal of Epidemiology</i> , 18: 425-30.
56966	Amarapurkar DN, Choksi M (2007). Genotype III - HCV infection. <i>Tropical Gastroenterology</i> , 28: 58-63.
15062	Amini M, Afshin-Nia F, Bashardoost N, et al (1997). Prevalence and risk factors of diabetes mellitus in the Isfahan city population (aged 40 or over) in 1993. <i>Diabetes Research and Clinical Practice</i> , 38(3): 185-90.
52864	Anderson RJ, Grigsby AB, Freedland K, De Groot M, et al (2002). Anxiety and poor glycemic control: A meta-analytic review of the literature. <i>Int J Psychiatry Med</i> , 32(3): 235-47.

Table 2 The Information**Relied upon by
Applicant or
Commissions**

RMA ID	Reference
43884	Andreoletti L, Hober D, Hober-Vandenberghe C, Fajardy I, et al (1998). Coxsackie B virus infection and B cell autoantibodies in newly diagnosed IDDM adult patients. <i>Clinical and Diagnostic Virology</i> , 9(2-3): 125-33.
2670	Anonymous (1994). <i>Guide to the Assessment of Rates of Veterans' Pensions</i> , 4th Edition,,: 10-7. Australian Government Publishing Service, Canberra.
15247	Anonymous (1997). Diabetes, protease-inhibitor link unproved: directorate. <i>CMAJ</i> , 157(5): 502-3.
57419	Arroyo C, Colditz GA, Hu FB, Speizer FE, et al (2004). Depressive symptoms and risk of type 2 diabetes in women. <i>Diabetes Care</i> , 27: 129-33.
58439	Athyros VG, Tziomalos K, Karagiannis A, Mikhailidis DP (2010). Lipid-lowering agents and new onset diabetes mellitus. <i>Expert Opin Pharmacother</i> , 11(12): 1965-70.
13837	Attvall S, Fowelin J, Lager I, von Schenck H, Smith U (1993). Smoking induces insulin resistance - a potential link with the insulin resistance syndrome. <i>Journal of Internal Medicine</i> , 233: 327-32.
58502	Australian Institute of Health and Welfare and National Heart Foundation of Australia (2004). <i>The relationship between overweight, obesity and cardiovascular disease. Cardiovascular Disease Series Number 23.</i> Australian Institute of Health and Welfare, Can
14328	Axelsson O, Persson B, Wingren G (1998). Dioxin and diabetes mellitus. <i>Epidemiology</i> , 9(3): 358-9.
58423	Aytaman A, McFarlane SI (2006). Hepatitis C and the risk of cardiovascular disease: an evolving epidemic? <i>Expert Rev Cardiovasc Ther</i> , 4(4): 439-42.
2644	Bajaj JS, Agrawal R (1984). <i>Malnutrition Diabetes. Recent Knowledge on Aetiology. Complication and Treatment.</i> S Baba, MK Gould, P Zimmet (Eds). <i>Diabetes Mellitus</i> , Chapter 9: 73-86. Academic Press, Sydney.
57422	Baker KS, Ness KK, Steinberger J, Carter A, et al (2007). Diabetes, hypertension, and cardiovascular events in survivors of hematopoietic cell transplantation: a report from the bone marrow transplantation survivor study. <i>Blood</i> , 109: 1765-72.

Table 2 The Information

RMA ID	Reference	Relied upon by Applicant or Commissions
58615	Balakrishnan V (2002). Fibrocalculous pancreatopathy. <i>International Journal of Diabetes in Developing Countries</i> , 22(3): 81-90.	
8122	Balakrishnan V, Sauniere JF, Hariharan M, Sarles H (1988). Diet, pancreatic function, and chronic pancreatitis in South India and France. <i>Pancreas</i> , 3(1): 30-5.	
13393	Baranski S, Czernski P (1976). Safe exposure limits and prevention of health hazards. <i>Biological Effects of Microwaves</i> , Chapter 6: 170-87. Dowden, Hutchinson and Ross, Pennsylvania, USA.	
57411	Basaria S (2008). Androgen deprivation therapy, insulin resistance, and cardiovascular mortality: an inconvenient truth. <i>J Andrology</i> , 29(5): 534-9.	
61193	Batterman AR, Cook PM, Lodge KB, Lothenbach DB, Butterworth BC (1989). Methodology used for a laboratory determination of relative contributions of water, sediment and food chain routes of uptake for 2,3,7,8-TCDD bioaccumulation by lake trout in Lake Onta Chemosphere vol. 19 issue 1-6 1989. p. 451-458	Commissions
15120	Batty D (1998). [Comment] Measurement of physical activity exposure. <i>International Epidemiological Association</i> , 27(2): 335.	
61194	Baughman R, Meleson M (1973). An analytical method for detecting TCDD (dioxin): Levels of TCDD in samples from Vietnam. <i>Environ Health Perspect</i> , 5: 27-35.	Commissions
57581	Baz-Hecht M, Goldfine AB (2010). The impact of vitamin D deficiency on diabetes and cardiovascular risk. <i>Curr Opin Endocrinol Diabetes Obes</i> , 17: 113-9.	
2645	Beardsley G, Goldstein MG (1993). Psychological Factors Affecting Physical Condition. <i>Endocrine disease Literature Review. Psychosomatics</i> , 34(1): 12-9.	
15365 15579	Bell PM (1997). Dietary and lifestyle factors contributing to insulin resistance. <i>Proceedings of the Nutrition Society</i> , 56(1B): 263-72.	
2646	Bengtsson C, Blohme G, Lapidus L, Lissner L, et al (1992). Diabetes incidence in users and non-users of antihypertensive drugs in relation to serum insulin, glucose tolerance and degree of adiposity: a 12-year prospective population study of women in Goth.	

Table 2 The Information

RMA ID	Reference	Relied upon by Applicant or Commissions
58482	Ben-Haroush A, Yogeve Y, Fisch B (2004). Insulin resistance and metformin in polycystic ovary syndrome. <i>Eur J Obstet Gynecol Reprod Biol</i> , 115: 125-33.	
28738	Benjamin AL (2001). Community screening for diabetes in the National Capital District, Papua New Guinea: is betelnut chewing a risk for diabetes? <i>PNG Med J</i> , 44(3-4): 101-7.	
14329	Bertazzi PA, Bernucci I, Brambilla G, Consonni D, Pesatori AC (1998). The Seveso studies on early and long-term effects of dioxin exposure: a review. <i>Environmental Health Perspectives</i> , 106(Suppl 2): 625-33.	Commissions
58432	Bhatia L, Byrne CD (2010). There is a slight increase in incident diabetes risk with the use of statins, but benefits likely outweigh any adverse effects in those with moderate-to-high cardiovascular risk. <i>Evid Based Med</i> , 15(3): 84-5.	
2647	Black HR (1994). Hypertension1994. RE Rakel (Ed). <i>Conn's Current Therapy</i> , Section 4: 283-95. WB Saunders Co. Philadelphia.	
26610	Blackburn D,Hux J, Mamdani M (2002). Quantification of the risk of corticosteroid-induced diabetes mellitus among the elderly. <i>Journal of the General Internal Medicine</i> , 17: 717-20.	
43780	Blom L, Nystrom L, Dahlquist G (1991). The Swedish childhood diabetes study. Vaccinations and infections as risk determinants for diabetes in childhood. <i>Diabetologia</i> , 34(3): 176-81.	
56838	Bodziak KA, Hricik DE (2009). New-onset diabetes mellitus after solid organ transplantation. <i>Transplant International</i> , 22: 519-30.	
58311	Bolland MJ, Bacon CJ, Horne AM, Mason BH, et al (2010). Vitamin D insufficiency and health outcomes over 5 y in older women. <i>Am J Clin Nutr</i> , 91: 82-9.	
265	Bookman JJ, Drachman SR, Schaefer LE, Adlersberg D (1953). Steroid diabetes in man: the development of diabetes during treatment with cortisone and corticotropin. <i>Diabetes</i> , 2(2): 100-11.	

Table 2 The Information**Relied upon by
Applicant or
Commissions**

RMA ID	Reference
24368	Boscarino JA (1996). Posttraumatic stress disorder, exposure to combat, and lower plasma cortisol among Vietnam Veterans: findings and clinical implications. <i>Journal of Consulting & Clinical Psychology</i> , 64(1):191-201.
49509	Boscarino JA (2004). Posttraumatic stress disorder and physical illness. <i>Ann NY Acad Sci</i> , 1032: 141-53.
48930	Boscarino JA (2008). A prospective study of PTSD and early-age heart disease mortality among Vietnam Veterans: implications for surveillance and prevention. <i>Psychosomatic Medicine</i> , 70: 668-76.
24365	Boscarino JA, Chang J (1999). Higher abnormal leukocyte and lymphocyte counts 20 years after exposure to severe stress: research and clinical implications. <i>Psychosomatic Medicine</i> , 61: 378-86.
15516	Bouchard PH, Sai P, Reach G, Caubarrere I, Ganeval D, Assan R (1982). Diabetes mellitus following pentamidine-induced hypoglycemia in humans. <i>Diabetes</i> , 31: 40-5.
58613	Boule NG, Haddad E, Kenny GP, Wells GA, Sigal RJ (2001). Effects of exercise on glycemic control and body mass in type 2 diabetes mellitus. <i>JAMA</i> , 286(10): 1218-27.
57416	Brown LC, Newman SC, Majumdar SR, Johnson JA (2005). History of depression increases risk of type 2 diabetes in younger adults. <i>Diabetes Care</i> , 28: 1063-7.
56577	Brown TT (2008). Approach to the human
56826	immunodeficiency virus-infected patient with lipodystrophy. <i>J Clin Endocrinol Metab</i> , 93(8): 2937-45.
56865	Buchanan TA, Xiang A, Kjos SL, Watanabe R (2007). What is gestational diabetes? <i>Diabetes Care</i> , 30(Suppl: 2): S105-11.
56502	Burns CJ, Collins JJ, Humphry N, Bodner KM, et al (2010). Correlates of serum dioxin to self-reported exposure factors. <i>Environ Res</i> , 110: 131-6.
28280	Buse JB, Cavazzoni P, Hornbuckle K, Hutchins D, Breier A, Jovanovic L (2003). A retrospective cohort study of diabetes mellitus and antipsychotic treatment in the United States. <i>J Clin Epidemiol</i> , 56(2): 164-70.
43727	Cainelli F, Manzaroli D, Renzini C, Casali F, Concia E, Vento S (2000). Coxsackie B virus-induced autoimmunity to GAD does not lead to type 1 diabetes. <i>Diabetes Care</i> , 23(7): 1021-2.

Table 2 The Information

RMA ID	Reference	Relied upon by Applicant or Commissions
58431	Cannon CP (2010). [Comment] Balancing the benefits of statins versus a new risk - diabetes. <i>The Lancet</i> , 375: 700-1. Comment on ID: 58429.	
15163	Carey VJ, Walters EE, Colditz GA, Solomon CG, et al (1997). Body fat distribution and risk of non-insulin-dependent diabetes mellitus in women. <i>American Journal of Epidemiology</i> , 145(7): 614-19.	
15204	Carey VJ, Walters EE, Colditz GA, Solomon CG, et al (1997). Body fat distribution and risk of non-insulin-dependent diabetes mellitus in women. <i>American Journal of Epidemiology</i> , 145(7): 614-9.	
28705	Carlsson S, Hammar N, Efendic S, Persson PG, Ostenson CG, Grill V (2000). Alcohol consumption, type 2 diabetes mellitus and impaired glucose tolerance in middle-aged Swedish men. <i>Diabet Med</i> , 17(11): 776-81.	
57417	Carnethon MR, Biggs ML, Barzilay JI, Smith NL, et al (2007). Longitudinal association between depressive symptoms and incident type 2 diabetes mellitus in older adults. <i>Arch Intern Med</i> , 167: 802-7.	
28691	Carnethon MR, Kinder LS, Fair JM, Stafford RS, Fortmann SP (2003). Symptoms of depression as a risk factor for incident diabetes: findings from the National Health & Nutrition Examination Epidemiologic Follow-Up Study, 1971-1992. <i>American Journal of Epide.</i>	
28284	Caro JJ, Ward A, Levinton C, Robinson K (2002). The risk of diabetes during olanzapine use compared with risperidone use: a retrospective database analysis. <i>J Clin Psychiatry</i> , 63(12): 1135-9.	
56964	Carpenter DO (2008). Environmental contaminants as risk factors for developing diabetes. <i>Reviews on Environmental Health</i> , 23(1): 59-74.	Commissions
26603	Cassidy F, Ahearn E, Carroll BJ (1999). Elevated frequency of diabetes mellitus in hospitalized manic-depressive patients. <i>Am J Psychiatry</i> , 156: 1417-20.	
58523	Chan JCN, Cockram CS, Critchley JAJH (1996). Drug-induced disorders of glucose metabolism. Mechanisms and management. <i>Drug Safety</i> , 15(2): 135-57.	
58314	Chan NN, Osaki R, et al; Molazowski (2002). [Comments] Drug-related hyperglycemia. <i>JAMA</i> , 287(6): 714; Author's reply: 715. Comments on ID: 58313.	

Table 2 The Information

RMA ID	Reference	Relied upon by Applicant or Commissions
55298	Chang J-W, Chen H-L, Su H-J, Liao P-C, et al (2010). Dioxin exposure and insulin resistance in Taiwanese living near a highly contaminated area. <i>Epidemiology</i> , 21(1): 56-61.	
8119	Chari ST, Jayanthi MV, Snehalatha C, Malathi S, et al (1992). Comparative study of the clinical profiles of alcoholic chronic pancreatitis and tropical chronic pancreatitis in. <i>Tamil Nadu, South India. Pancreas</i> , 7(1): 52-8.	
15113	Chasan-Taber L, Willett WC, Stampfer MJ, Hunter DJ, et al (1997). A prospective study of oral contraceptives and NIDDM among US women. <i>Diabetes Care</i> , 20(3): 330-5.	
7976	Chattopadhyay PS, Gupta SK, Chattopadhyay R, Kundu PK, Chakraborti R (1995). Malnutrition-related diabetes mellitus (MRDM), not diabetes-related malnutrition. A report on genuine MRDM. <i>Diabetes Care</i> , 18(2): 276-77.	
56864	Chen CJ, Wang SL, Chiou JM, Tseng CH, et al (2007). Arsenic and diabetes and hypertension in human populations: A review. <i>Toxicol Appl Pharmacol</i> , 222(3): 298-304.	
56852	Chen HL, Su HJ, Guo YL, Liao PC, et al (2006). Biochemistry examinations and health disorder evaluation of Taiwanese living near incinerators and with low serum PCDD/Fs levels. <i>Sci Total Environ</i> , 366: 538-48.	Commissions
59788	Cheng P, Neugaard B, Foulis P, Conlin PR (2011). Hemoglobin A as a predictor of incident diabetes. <i>Diabetes Care</i> , Epub ahead of print.	
58506	Chern JPS, Lin K-H, Lu M-Y, Lin D-T, et al (2001). Abnormal glucose tolerance in transfusion-dependent B-thalassemic patients. <i>Diabetes Care</i> , 24(5): 850-4.	
58426	Chitturi S, Farrell GC (2007). [Comment] Fatty liver now, diabetes and heart attack later? The liver as a barometer of metabolic health. <i>J Gastroentero Hepatol</i> , 22: 967-9. Comment on ID: 58425.	
56960	Choquette M, Goebel JW, Campbell KM (2010). Nonimmune complications after transplantation. <i>Pediatr Clin North Am</i> , 57: 505-21.	
2648	Chou P, Chen HH, Hsiao KJ (1992). Community-based epidemiological study on diabetes in Pu-Li, Taiwan. <i>Diabetes Care</i> , 15(1): 81-9.	

Table 2 The Information**Relied upon by
Applicant or
Commissions**

RMA ID	Reference
56965	Choudhuri G, Lakshmi CP, Goel A (2009). Pancreatic diabetes. <i>Tropical Gastroenterology</i> , 30(2): 71-5.
15156	Chronister CL, Gurwood AS (1998). Type 2 diabetes in association with HIV-1 protease inhibitors in HIV-infected patients. <i>Journal of the American Optometric Association</i> , 69(11): 695-8.
52928	Chrousos GP (1995). The hypothalamic-pituitary-adrenal axis and immune-mediated inflammation. <i>The New England Journal of Medicine</i> , 332(20): 1351-62.
57577	Chu SY, Kim SY, Lau J (2009). [Comment] Prepregnancy BMI and the risk of gestational diabetes: a systematic review of the literature with meta-analysis. <i>Obesity Reviews</i> , 10: 487-8. Comment on ID: 57576.
8125	Clark A, deKoning EJP, Hattersley AT, Hansen BC, et al (1995). Pancreatic pathology in non-insulin dependent diabetes (NIDDM). <i>Diabetes Research and Clinical Practice</i> , 28(S): S39-47.
2649	Clark CG, Mitchell PE (1961). Diabetes mellitus and primary carcinoma of the pancreas. <i>BMJ</i> , 2(5262): 259-62.
43774	Classen JB, Classen DC (1999). [Comment] Immunisation and type 1 diabetes mellitus. Is there a link? <i>Drug Safety</i> , 21(5): 423-5.
44026	Classen JB, Classen DC (2002). Clustering of cases of insulin dependent diabetes (IDDM) occurring three years after hemophilus influenza B (HiB) immunization support causal relationship between immunization and IDDM. <i>Autoimmunity</i> , 35(4): 247-53.
43848	Classen JB, Classen DC (2003). Clustering of cases of type 1 diabetes mellitus occurring 2-4 years after vaccination is consistent with clustering after infections and progression to type 1 diabetes mellitus in autoantibody positive individuals. <i>Journal o</i>
44025	Classen JB; Montgomery SM (2004). [Comments] Pertussis infections, vaccines and type 1 diabetes. <i>Diabet Med</i> , 21(4): 397-9.
58422	Clore JN, Thurby-Hay L (2009). Glucocorticoid-induced hyperglycemia. <i>Endocr Pract</i> , 15: 469-74.

Table 2 The Information

RMA ID	Reference	Relied upon by Applicant or Commissions
58508	Colagiuri S, Davies D, Girgis S, Colagiuri R (2009). National Evidence Based Guideline for Case Detection and Diagnosis of Type 2 Diabetes, . Diabetes Australia and the NHMRC, Canberra.	
15201	Colditz GA, Coakley E (1997). Weight, weight gain, activity, and major illnesses: the nurses' health study. International Journal of Sports Medicine, 18(Suppl 3): S162-70.	
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57572	Coronado-Gonzalez JA, Del Razo LM, Garcia-Vargas G, et al (2007). Inorganic arsenic exposure and type 2 diabetes mellitus in Mexico. Environ Res, 104: 383-9.	
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2651	Dahlquist G (1993). Etiological aspects of insulin-dependent diabetes mellitus: an epidemiological perspective. <i>Autoimmunity</i> , 15(1): 61-5.
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58485	Fukui M, et al; Abbott J, et al; Spyer, et al; Cutfield WS, et al (2000). [Comments] Growth-hormone treatment and risk of diabetes. <i>The Lancet</i> , 355: 1912-3.
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56839	Garcia-Compean D, Jaquez-Quintana JO, Maldonado-Garza H (2009). Hepatogenous diabetes. Current views of an ancient problem. <i>Ann Hepatol</i> , 8(1): 13-20.
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29980	Gentile S, Loguercio C, Marmo R, Carbone L, Del Vecchio Blanco C (1993). Incidence of altered glucose tolerance in liver cirrhosis. <i>Diabetes Res Clin Pract</i> , 22(1): 37-44.

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43792	Gibbon C, Smith T, Egger P, Betts P, Phillips D (1997). Early infection and subsequent insulin dependent diabetes. <i>Arch Dis Child</i> , 77(5): 384-85.
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57418	Golden SH, Williams JE, Ford DE, Yeh HC, et al (2004). Depressive symptoms and the risk of type 2 diabetes. The atherosclerosis risk in communities study. <i>Diabetes Care</i> , 27: 429-35.
52863	Goodwin RD, Davidson JR (2005). Self-reported diabetes and posttraumatic stress disorder among adults in the community. <i>Preventive Medicine</i> , 40: 570-74.
15187	Goodyear LJ, Kahn BB (1998). Exercise, glucose transport, and insulin sensitivity. <i>Ann Rev Med</i> , 49: 235-61.
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43891	Green J, Casabonne D, Newton R (2004). Cocksackie B virus serology and type 1 diabetes mellitus: a systematic review of published case-control studies. Diabetic Medicine, 21(6): 507-14.
56579 56825	Greenberg JA, Boozer CN, Geliebter A (2006). Coffee, diabetes, and weight control. Am J Clin Nutr, 84: 682-93.
2667	Grendell JH, Cello JP (1993). Chronic Pancreatitis. Sleisenger & Fordtran (Eds.). Gastrointestinal Disease, 5th Edition, 2 81: 1654-81. Saunders, Philadelphia.
2668	Gries FA, Kleophas W (1990). Effects of diuretics on insulin and glucose disposal. Horm Metab Res, 22(Suppl): 33-8.
56842 56578	Grinspoon S (2009). [Comment] Diabetes mellitus, cardiovascular risk, and HIV disease. Circulation, 119: 770-2. Comment on ID: 56840.
15089	Grodzicki T, Palmer A, Bulpitt CJ (1997). Incidence of diabetes and gut in hypertensive patients during 8 years of follow-up. Journal of Human Hypertension, 11: 583-85.
58440	Gronbaek H, Thomsen KL, Rungby J, Schmitz O, Vilstrup H (2008). Role of nonalcoholic fatty liver disease in the development of insulin resistance and diabetes. Expert Rev Gastroenterol Hepatol, 2(5): 705-11.
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58312	Gulati R, Bhatia V, Agarwal SS (2000). Early onset of endocrine abnormalities in B-Thalassemia major in a developing country. <i>J Pediatr Endocrinol Metab</i> , 13: 651-6.
2671	Gullo L, Pezzilli R, Morselli-Labate AM and the Italian Pancreatic Cancer Study Group (1994). Diabetes and the risk of pancreatic cancer. <i>NEJM</i> , 331(2): 81-4.
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58571	Guyton JR (2007). Niacin in cardiovascular prevention: mechanisms, efficacy, and safety. <i>Curr Opin Lipidol</i> , 18: 415-20.
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15202	Haffner SM, Miettinen H, Stern MP (1997). Are risk factors for conversion to NIDDM similar in high and low populations? <i>Diabetologia</i> , 40: 62-6.
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15112	Harris MI, Eastman RC, Cowie CC, Flegal KM, Eberhardt MS (1997). Comparison of diabetes diagnostic categories in the US population according to 1997 American Diabetes Association and 1980-1985 World Health Organization diagnostic criteria. <i>Diabetes Care</i> .
60877	Harrison's Online (2008). Diabetes Mellitus. Chapter 338, . Retrieved 6 August 2010, from http://proxy14.use.hcn.com.au/popup.aspx?aID=2891139&print=yes_chapter
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26604 28707	Hayashi T, Tsumura K, Suematsu C, Endo G, Fujii S, Okada K (1999). High normal blood pressure, hypertension, and the risk of Type 2 diabetes in Japanese men. <i>Diabetes Care</i> , 22(10): 1683-7.
56869	Hayashino Y, Fukuhara S, Okamura T, Yamato H, et al (2008). A prospective study of passive smoking and risk of diabetes in a cohort of workers. The high-risk and population strategy for Occupational Health Promotion (HIPOP-OHP) study. <i>Diabetes Care</i> , 31(4).
59062	Healy GN, Dunstan DW, Salmon J, Cerin E, et al (2008). Breaks in sedentary time: beneficial associations with metabolic risk. <i>Diabetes Care</i> , 31(4): 661-6.
15121	Helmrich SP, Ragland DR, Leung RW, Paffenbarger RS (1991). Physical activity and reduced occurrence of non-insulin dependent diabetes mellitus. <i>NEJM</i> , 325: 147-52.
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43773	Hiltunen M, Lonrot M, Hyoty H (1999). Immunisation and type 1 diabetes mellitus. Is there a link? <i>Drug Safety</i> , 20(3): 207-12.	
43810	Hindersson M, Elshebani A, Orn A, Tuvemo T, Frisk G (2005). Simultaneous type 1 diabetes onset in mother and son coincident with an enteroviral infection. <i>Journal of Clinical Virology</i> , 33(2): 158-67. Erratum, 34(2): 160.	
58521	Hober D, Sauter P (2010). Pathogenesis of type 1 diabetes mellitus: interplay between enterovirus and host. <i>Nature Reviews Endocrinology</i> , 6: 279-89.	
8301	Hodge AM, Dowse GK, Alberti GMM, et al (1996). Relationship of insulin resistance to weight gain in non-diabetic Asian Indian, Creole, and Chinese Mauritians. <i>Metabolism</i> , 45(5): 627-33.	
8304	Hodge AM, Montgomery J, Dowse GK, Mavo B, et al (1996). A case-control study of diet in newly diagnosed NIDDM in the Wanigela people of Papua New Guinea. <i>Diabetes Care</i> , 19(5): 457-62.	
57571	Hoffmeister PA, Storer BE, Sanders JE (2004). Diabetes mellitus in long-term survivors of pediatric hematopoietic cell transplantation. <i>J Pediatr Hematol Oncol</i> , 26(2): 81-90.	
28713	Holbrook TL, Barrett-Connor E, Wingard DL (1990). A prospective population-based study of alcohol use and non-insulin-dependent diabetes mellitus. <i>American Journal of Epidemiology</i> , 132(5): 902-9.	

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26686	Mason AL, Lau JYN, Hoang N, Qian K, et al (1999). Association of diabetes mellitus and chronic hepatitis C virus infection. <i>Hepatology</i> , 29: 328-33.
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28352	Mehta SH, Brancati FL, Strathdee SA, Pankow JS, Netski D, Coresh J, Szklo M, Thomas DL (2003). Hepatitis C virus infection and incident type 2 diabetes. <i>Hepatology</i> , 38(1): 50-6.	
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58501	Meliker JR, Wahl RL, Cameron LL, Nriagu JO (2007). Arsenic in drinking water and cerebrovascular disease, diabetes mellitus, and kidney disease in Michigan: a standardized mortality ratio analysis. <i>Environ Health</i> , 6: 4.	
58616	Meslier N, Gagnadoux F, Giraud P, Person C, et al (2003). Impaired glucose-insulin metabolism in males with obstructive sleep apnoea syndrome. <i>Eur Respir J</i> , 22: 156-60.	
18818	Michalek JE, Akhtar FZ, Kiel JL (1999). Serum dioxin, insulin, fasting glucose, and sex hormone-binding globulin in veterans of operation ranch hand. <i>The Journal of Clinical Endocrinology & Metabolism</i> , 84(5): 1540-3.	Commissions

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2695	Modan M, Karasik A, Halkin H, Fuchs Z, et al (1986). Effect of past and concurrent body mass index on prevalence of glucose intolerance and Type 2 (non-insulin-dependent) diabetes and on insulin response. The Israel study of glucose intolerance, obesity a	
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15063	Mohan V, Vijayaprabha R, Rema M, et al (1997). Clinical profile of lean NIDDM in South India. <i>Diabetes Research and Clinical Practice</i> , 38(2): 101-8.	
44024	Montgomery SM, Ehlin AGC, Ekbom A, Wakefield AJ (2002). Pertussis infection in childhood and subsequent type 1 diabetes mellitus. <i>Diabet Med</i> , 19(12): 986-993.	
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15119	Mooy JM, Groothenhuis PA, Vries HD, Valkenburg HA, et al (1995). Prevalence and determinants of glucose intolerance in a Dutch caucasian population. <i>Diabetes Care</i> , 18(9): 1270-3.	
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15209	Nadler JL, Balon TW, Rude R (1997). [Comment] Fibre intake and risk of developing non-insulin-dependent diabetes mellitus. <i>JAMA</i> , 277(22): 1761-2.	
26613	Nakanishi N, Nakamura K, Matsuo Y, Suzuki K, & tatar K (2000). Cigarette smoking and risk for impaired fasting glucose and type 2 diabetes in middle-aged Japanese men. <i>Ann Intern Med</i> , 133: 183-91.	
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28282	Nakanishi N, Suzuki K, Tatar K (2003). Alcohol consumption and risk for development of impaired fasting glucose or type 2 diabetes in middle-aged Japanese men. <i>Diabetes Care</i> , 26(1): 48-54.	
7956	Narendranathan M, Cheriyan A (1994). Lack of association between cassava consumption and tropical pancreatitis syndrome. <i>Journal of Gastroenterology & Hepatology</i> , 9(30): 282-5.	
2734	Nathan DM (1993). Diabetes Mellitus. E Rubenstein and DD Federman (Eds). <i>Scientific American Medicine</i> , Vol 2 Section 9, Chap VI: 1-27. Scientific American Inc, New York.	
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17995	National Coding Centre (NCC) (1996). Clinical Modification (ICD-9-CM). Australian Version of The International Classification of Diseases, 9th Edition, Vol i, ii, iii & iv: (ICD-9-CM), Second Edition. Faculty of Health Sciences, University of Sydney, NSW.	

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TABLE 3

New Information

Information cited by the Commission or noted by the Council, that was not included in the information available to the RMA at the relevant time, and so could not be used by the Council in making its decision.

Table 3 New Information

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