

REPATRIATION MEDICAL AUTHORITY

STATEMENT OF REASONS

RE: INVESTIGATION INTO GULF WAR SYNDROME

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PART I INTRODUCTION

- 1. The Repatriation Medical Authority (the Authority) has decided not to make Statements of Principles (SoPs) under subsections 196B (2) or (3) of the *Veterans' Entitlements Act 1986* (the Act) in respect of Gulf war syndrome, following notice of an investigation gazetted on 14 January 2009 in the *Commonwealth of Australia Gazette*.
- 2. The Authority declares that Gulf war syndrome is not a disease or injury for the purposes of the *Veterans' Entitlements Act 1986* and hence is not a condition for which a Statement of Principles could be determined.

PART II BACKGROUND TO THE INVESTIGATION

- 3. At its meeting of 29 July 2003 the Authority, following an investigation pursuant to subsection 196B(4) of the Act, concluded that Gulf War syndrome was not a disease or injury for the purposes of the *Veterans' Entitlements Act 1986* and hence was not a condition for which a Statement of Principles could be determined. The Authority's decision was published in the *Commonwealth of Australia Gazette* of 20 August 2003.
- 4. On 17th November 2008, the Congressionally-mandated US Research Advisory Committee on Gulf War Veterans' Illnesses released a 454 page report on Gulf War Illness (the Binns Report). That report is publically available on the internet at http://sph.bu.edu/insider/index.php?option=com_content&task=view&id=1579&Itemid=150.
- On 28th November 2008 the Authority received a request (dated 20 November 2008) from the National Secretary, Defence Force Welfare Association. The request asked the Authority to review its 2003 decision not to determine a Statement of Principles concerning Gulf War Syndrome. The Binns Report was cited as the new available sound medical-scientific evidence.
- 6. At its meeting of 9 December 2008, the Authority, pursuant to subsection 196B(7) of the Act, decided to investigate whether a Statement of Principles may be determined in respect of Gulf War syndrome.
- 7. An investigation Notice was signed by the Authority Chairperson on 19 December 2008 and was gazetted in accordance with section 196G of the Act in the *Commonwealth of Australia Gazette* on 14 January 2009. Submissions were invited from persons and organisations wishing to do so. The closing date for submissions as noted in the Gazette Notice was 29 May 2009.
- 8. The Authority notes that the Notice, as gazetted on 14 January 2009, incorrectly stated that the investigation was being conducted pursuant to subsection 196B(4). The investigation concerned a review of the Authority's 2003 decision above not to determine Statements of Principles with respect to Gulf War Syndrome and the investigation notice should have stated "pursuant to subsection 196B(7)". The Authority has concluded that no action is necessary to correct this typographical error as the Notice complied in all respects with section 196G of the Act.

PART III SUBMISSIONS RECEIVED BY THE AUTHORITY PURSUANT TO SECTION 196F

- 9. Following notification of its investigation, the Authority received six further submissions from persons or organisations eligible to make submissions pursuant to section 196F as follows:
 - 9.1. A request for investigation was received on 21 January 2009 from an exserviceman on behalf of his nephew who has Alzheimer's disease. He attached a letter in which he stated his belief that radiation might be a cause of Gulf War syndrome, which might in turn be contributing to his nephew's illness because "he had very high radium levels in his blood tests."
 - 9.2. A request for investigation was received on 2 February 2009 from a Gulf War veteran who stated that he served on HMAS Darwin and has PTSD.
 - 9.3. A letter was received on 28 May 2009 from a Gulf War veteran, stating that he has had a number of health problems since his Gulf service, of sufficient severity to make him unfit for work.
 - 9.4. A submission was received on 29 May 2009 from the Allergy and Environmental Sensitivity and Research Association Inc (AESSRA). The submission provided an abstract of an article on multiple chemical sensitivity, a summary of a book authored by Pall (2007)¹ which has a chapter on Gulf War syndrome (including a list of the 58 references cited in this chapter), and a new, soon-to-be-published review on multiple chemical sensitivity by the same author. The chapter on Gulf War syndrome was obtained for further review, but the material on multiple chemical sensitivity was not obtained because it only has indirect relevance to this investigation.
 - 9.5. A letter was received on 2 June 2009 from the National President of the Defence force Welfare Association, stating that the Association believes that, since the publication of the Binns Report, there is sufficient evidence to determine Statements of Principles related to exposure to pyridostigmine bromide, the health effects of vaccines given to ADF members, and, particularly, the health effects of receiving multiple vaccines.
 - 9.6. A letter was received on 26 June 2009 from a veteran of Gulf War 1 and the Iraq war. He was exposed to multiple inoculations and pyridostigmine bromide tablets (one tablet three times a day for several days). In support of his letter, he submitted a letter from his general practitioner, who has diagnosed him with an unexplained allergic type reaction. He also provided a detailed chronological listing of his allergic episodes over the last 6 years

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¹ Pall ML (2007). Gulf War Syndrome: a combination of all four (CFS, MCS, FM, and PTSD). Explaining "Unexplained Illnesses". Disease Paradigm for Chronic Fatigue Syndrome, Multiple Chemical Sensitivity, Fibromyalgia, Post-Traumatic Stress Disorder, Gulf War Syndrome, and Others. Chapter 10: 159-69. Harrington Park Press, New York.

PART IV EVIDENCE/INFORMATION AVAILABLE TO THE REPATRIATION MEDICAL AUTHORITY

- 10. The following information was available to the Authority.
 - 10.1. Submissions and correspondence as detailed in Part III above.
 - 10.2. Literature searches were conducted using the Ovid search engine from 1950 to April Week 1 2010, limited to English language, using the search terms: Exp Persian Gulf Syndrome/. From these searches articles were selected for further study based on relevance, study quality, reliability and journal authority. The above search was supplemented by specific Pubmed searches for Gulf war illness and various factors of interest, as well as manual searches of reference lists, and reference to authoritative reviews such as those conducted by the US Institute of Medicine (including the 2010 update of the Health Effects of Serving in the Gulf War). Animal studies formed part of the evidence assessed by some of these reviews, but they were not separately examined in this investigation.
 - 10.3. Medical or scientific publications as set out in the bibliography attached hereto.
 - 10.4. Briefing paper prepared for presentation to the Authority by a research officer of the Secretariat.

PART V DISEASE AND INJURY

11. Section 5D of the Act defines disease and injury relevantly as follows:

disease means:

- (a) any physical or mental ailment, disorder, defect or morbid condition (whether of sudden onset or gradual development); or
- (b) the recurrence of such an ailment, disorder, defect or morbid condition;

but does not include:

- (c) the aggravation of such an ailment, disorder, defect or morbid condition; or
- (d) a temporary departure from:
 - (i) the normal physiological state; or
 - (ii) the accepted ranges of physiological or biochemical measures;

that results from normal physiological stress (for example, the effect of exercise on blood pressure) or the temporary effect of extraneous agents (for example, alcohol on blood cholesterol levels);

[and]

injury means any physical or mental injury (including the recurrence of a physical or mental injury) but does not include:

- (a) a disease; or
- (b) the aggravation of a physical or mental injury.
- 12. The proper meaning of what constitutes a disease or injury for the purposes of determining a Statement of Principles under the Act is to be determined by the Authority. In considering these terms, the Authority had regard to ordinary dictionary definitions, medical dictionaries, and its expert knowledge. In determining whether a condition is a disease as defined, the Authority is entitled to have regard to the connotations of the word 'disease' as used and understood in its ordinary meaning.²
- 13. Being familiar with the ordinary English meanings of the terms that are used in section 5D, the Authority considered whether Gulf War syndrome was within the ordinary meaning of these terms, and applied the ordinary meaning of those terms to its consideration of whether Gulf War syndrome is a disease. It also relied upon its expert medical knowledge and had regard to internationally agreed concepts in considering whether Gulf War syndrome may represent a disease state.

PART VI REASONS FOR THE DECISION

- 14. There is no consensus in the medical scientific literature as to what may constitute a unique syndrome among Gulf War veterans.
- 15. Numerous studies have been published on the health of Gulf War Veterans. These studies have been comprehensively reanalysed, and reviewed by the US Institute of Medicine (IOM) in a series of monographs published between 2000 and 2010.
- 16. These reviews noted that, compared to non-deployed veterans, Gulf War veterans personally reported an increased frequency of a range of symptoms including fatigue, memory loss, confusion, inability to concentrate, mood swings, somnolence, gastrointestinal symptoms, muscle and joint pain and skin or mucous membrane complaints.
- 17. The IOM and others have grouped the symptoms reported in the Gulf War investigations under the heading "Chronic Multisymptom Illness" (CMI) for the purpose of trying to determine whether they constitute a disease and investigating their relationship to potential causative factors.
- 18. Agents to which service personnel were exposed or potentially exposed during the Gulf War include pyridostigmine bromide, vaccines, pesticides, insect repellents, desert sand, endemic diseases, paints, solvents, diesel fumes, smoke from oil-well fires or burning waste and depleted uranium.³ There were also numerous psychosocial stressors, including combat and chemical and biological alerts. Military

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² Comcare v Mooi (1996) 42 ALD 495.

³ Sim M, Abramson M, Forbes A, Ikin J, et al (2003). Australian Gulf War Veterans' Health Study (Vol 1, p. 40), Commonwealth of Australia.

- personnel might have been exposed to various doses and combinations of these agents or stressors.⁴
- 19. The IOM assessed the published papers that investigated the relationship between specific exposures and CMI, and determined that there was inadequate evidence to support a relationship.
- 20. Researchers agree that there are numerous methodological problems inherent in investigating this relationship, including multiple comparisons (such that a number of positive associations will be found just by chance), a lack of specific associations (argues against a specific effect of any one agent), retrospective recall of exposures (which appears to be associated with levels of symptom reporting)⁵, lack of baseline health data, self-reporting of health outcomes, low response rates, and lack of specificity in the case definition.
- 21. The only report that has found a distinct illness, and supported the role of Gulf War service in contributing to this illness was the Binns Report which was released in November 2008, by the Research Advisory Committee on Gulf War Veterans' Illnesses (the RAC), a body established to advise the US VA on the issue. The report, like the IOM's monographs, was a review of existing information, but differed in that it paid less attention to the human studies, and focussed more on inferences from animal toxicology.
- 22. In reaching its conclusions, the Authority drew upon both the original research reports of Gulf War Veterans (primarily from the US, UK and Australia), as well as the IOM and RAC reports. The RMA's conclusions are consistent with the IOM's, based on the same body of information. Possible explanations for the differing conclusions reached by the RAC are:
 - The criteria used by the RAC for assessing causality, which were not made explicit in the report and therefore cannot be subject to rigorous scrutiny. In contrast, the IOM specified in its reports that it used the criteria described by Bradford Hill.
 - The apparently greater weight placed on animal studies by the RAC.
- 23. Long term follow up of personnel who served in the Gulf War has not revealed any evidence of a deterioration in health or new illnesses emerging in this cohort in the almost twenty years since the Gulf War, as one might expect if symptoms were associated with clinically significant pathology. In follow up studies, mortality is not increased except for a transient increase in deaths from motor vehicle accidents, consistent with a similar phenomenon after other conflicts. There is a lack of

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⁴ Sim M, Abramson M, Forbes A, Ikin J, et al (2003). Australian Gulf War Veterans' Health Study (Vol 1, p. 40), Commonwealth of Australia.

 $^{^{5}}$ Wessely S, Unwin C, Hotopf M, Hull L, Ismail K, Nicolaou V & David A. (2003) Stability of recall of military hazards over time. Evidence from the Persian Gulf War of 1991. BMJ Vol 183 pp 314-22.

⁶ Brewer NT. Hallman WK. Kipen HM. (2008) The symmetry rule: a seven-year study of symptoms and explanatory labels among Gulf War veterans. Risk Analysis. 28(6):1737-48.

⁷ Iversen A, Chalder T, Wessely S (2007). Gulf War illness: lessons from medically unexplained symptoms. Clinical Psychology Review, 27: 842-54.

- documented physical abnormalities in veterans with symptoms, and no consistent evidence of a higher incidence of any cancer in Gulf War veterans.^{8 9 10 11 12 13 14}
- 24. In one of its reports, the IOM concluded that there was "limited and suggestive evidence of an association" between military service generally and later development of motor neurone disease¹⁵, although in a more recent study of mortality from specified neurological illnesses in Gulf War veterans, this association was not confirmed ¹⁶.
- 25. One hypothesis that has been investigated is that the increased reporting of CMI type symptoms may be related to higher levels of psychiatric illness in Gulf War Veterans. While Australian, US and UK troops experienced significantly higher rates of PTSD, major depressive disorder, anxiety disorders and substance use disorders than non-deployed comparison groups^{17 18 19}, and veterans with CMI had higher rates of psychiatric illnesses ^{20 21}, an increase in psychiatric comorbidity seen in those with CMI could arise from an overlap between criteria for both conditions, or to common underlying exposures. Nevertheless, both Wessely et al (2009) and the IOM (2010) have concluded that clinically diagnosable psychiatric illnesses are *not* the most plausible explanation for the unexplained medical symptoms reported by deployed Gulf War veterans.^{22 23} Although the rates of psychiatric illness were probably at least

⁸ Lee H, Jones E (2007). War and Health: Lessons from the Gulf War. Chapter 6. John Wiley & Sons Ltd, West Sussex, England

⁹ Hotopf M, David AS, Hull L, Nikalaou V, Unwin C, Wessely S. (2003) Gulf war illness--better, worse, or just the same? A cohort study. BMJ. Dec 13;327(7428):1370.

¹⁰ Sim M, Abramson M, Forbes A, Ikin J, et al (2003). Australian Gulf War Veterans' Health Study (Vol 2), Commonwealth of Australia.

¹¹ Macfarlane GJ, Hotopf M, Maconochie N, Blatchley N, Richards A, Lunt M. (2005) Long-term mortality amongst Gulf War Veterans: is there a relationship with experiences during deployment and subsequent morbidity? Int J Epidemiol. Dec;34(6):1403-8. Epub 2005 Oct 26.

¹² Gray G, and Kang H (2006) Healthcare utilisation an mortality among veterans of the Gulf War. Phil. Trans. R. Soc. B. Vol 361, pp. 553-569.

¹³ Pessler F. Chen LX. Dai L. Gomez-Vaquero C. Diaz-Torne C. Paessler ME. Scanzello C. Cakir N. Einhorn E. Schumacher HR. (2008) A histomorphometric analysis of synovial biopsies from individuals with Gulf War Veterans' Illness and joint pain compared to normal and osteoarthritis synovium. Clinical Rheumatology. 27(9):1127-34.

¹⁴ Committee on Gulf War and Health (2010) Gulf War and Health, Volume 8. Update of Health Effects of Serving in the Gulf War, p 78. National Academies Press, Washington DC.

¹⁵ Committee on Gulf War and Health (2010) Gulf War and Health, Volume 8. Update of Health Effects of Serving in the Gulf War, p 129. National Academies Press, Washington DC.

 $^{^{16}}$ Barth SK, Kang HK, Bullman TA, Wallin MT. (2009) Neurological Mortality Among US Veterans of the Persian Gulf War: 13-year Follow-up. Am J Ind Med. 2009 Sep;52(9):663-70.

¹⁷ Sim M, Abramson M, Forbes A, Ikin J, et al (2003). Australian Gulf War Veterans' Health Study (Vol 2), p. 270-271. Commonwealth of Australia.

¹⁸ Unwin C, Blatchley N, Coker W, Ferry S, Hotopf M, Hull L, Ismail K, Palmer I, David A, Wessely S. (1999) Health of UK servicemen who served in Persian Gulf War. Lancet. Jan 16;353(9148):169-78.

¹⁹ Committee on Gulf War and Health (2010) Gulf War and Health, Volume 8. Update of Health Effects of Serving in the Gulf War, p 106. National Academies Press, Washington DC.

²⁰ Blanchard MS, Eisen SA, Alpern R, Karlinsky J, Toomey R, Reda DJ, Murphy FM, Jackson LW, Kang HK. (2006) Chronic multisymptom illness complex in Gulf War I veterans 10 years later. Am J Epidemiol. Jan 1;163(1):66-75.

²¹ Kelsall HL, McKenzie DP, Sim MR, Leder K, Forbes AB, Dwyer T. Physical, psychological, and functional comorbidities of multisymptom illness in Australian male veterans of the 1991 Gulf War. Am J Epidemiol. 2009 Oct 15;170(8):1048-56.

²²Wessely S, Greenberg N, Woodhead C, Fear NT. (2009) Gulf war illnesses. Lancet. Feb 7;373(9662):462.

- doubled in Gulf veterans when compared to the non-deployed groups, the absolute rate of illness was low (around 3% for PTSD)²⁴, and the brief ground war meant that exposure to combat was relatively short for most Gulf veterans.
- 26. It is still a matter of debate as to the extent to which symptoms experienced by Gulf war veterans could be due to exposure to psychological stressors, and the extent to which increased reporting of symptoms is psychological, or at least has a psychological contribution. An absence of a characterised physiological mode of action does not, in itself, prove that the cause must be psychological. It is possible that more than one mode of action may be involved in producing the range of symptoms associated with Gulf War service.
- 27. In summary, the available body of sound medical-scientific evidence shows a lack of a specific pattern of symptoms, a lack of pathological signs or emerging illnesses or deaths, insufficient support for a plausible biological mechanism and insufficient support for a link to specific exposures.
- 28. On this basis the Authority has concluded that there is insufficient evidence to support a unique Gulf War syndrome.

PART VII DECISION

29. At its meeting on 2 June 2010 the Authority decided not to make a Statement of Principles in respect of Gulf war syndrome for the purposes of subsection (2) or (3) of section 196B of the Act as the Authority concluded, for the reasons set out above, that it is not a disease within the meaning of section 5D of the Act.

²³ Committee on Gulf War and Health (2010) Gulf War and Health, Volume 8. Update of Health Effects of Serving in the Gulf War, p 109. National Academies Press, Washington DC.

²⁴ Greenberg and Wessely (2008) Gulf War syndrome: an emerging threat or a piece of history? Emerging Health Threats Journal. Vol 1:e10. Available at http://www.eht-forum.org/ehtj/journal/v1/pdf/ehtj08010a.pdf. Accessed 8-9-09.

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