
The Parliament of the Commonwealth of Australia

Living with the pain of adhesive arachnoiditis

Report on the roundtable into adhesive arachnoiditis

House of Representatives
Standing Committee on Health and Ageing

February 2013
Canberra

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Foreword

There is no doubting the debilitating effects of chronic and severe pain. Sufferers of adhesive arachnoiditis and their families know this first hand. The impact on quality of life can be catastrophic, extracting a physical, social and emotional toll, not only on the person but also on his or her family.

That adhesive arachnoiditis is a little known condition, even among health professionals, means getting a diagnosis can be a lengthy and frustrating ordeal. The stress of living with this painful condition, for which there is currently no cure, is increased for some who attribute their adhesive arachnoiditis to medical procedures that were in fact intended to relieve their suffering.

By holding the roundtable and presenting this report to the Parliament, the Committee aims to raise the profile of adhesive arachnoiditis, highlight the challenges facing sufferers and identify some practical means of assistance for this group.

On behalf of the Committee, I extend thanks to all of the roundtable participants.

Ms Jill Hall MP
Chair



Terms of reference

The House of Representatives Standing Committee on Health and Ageing has resolved to conduct an inquiry by roundtable into adhesive arachnoiditis. The Committee's inquiry will focus on the aetiology, diagnosis, treatment and prognosis of adhesive arachnoiditis.



List of recommendations

Recommendation 1

In the context of corporate social responsibility the Committee encourages GlaxoSmithKline to consider establishing a charitable foundation to assist sufferers of adhesive arachnoiditis.

The foundation could operate as a flexible means of assisting those affected by adhesive arachnoiditis. Priorities for support would need to be established in consultation with sufferers of adhesive arachnoiditis and their families, but could include activities to:

- raise awareness of the condition;
- support research into adhesive arachnoiditis;
- coordinate adhesive arachnoiditis support groups;
- make representations to government;
- establish and maintain an Australian case register; and
- provide top-up funding for home modifications or other practical assistance.

Recommendation 2

The Royal Australian College of General Practitioners and Medicare Locals provide general practitioners with educational and training opportunities aimed at raising awareness of the diagnosis, symptoms and treatment of chronic adhesive arachnoiditis. The Australian and New Zealand College of Anaesthetists advise pain units and its membership of the likely incidence of adhesive arachnoiditis in the community.

Recommendation 3

Medicare Locals, and other health providers, actively engage with local communities and health professionals to determine the needs of people living with adhesive arachnoiditis and chronic pain, to develop strategies to assist sufferers optimise management of chronic pain and achieve the best possible quality of life.

Recommendation 4

The Australian Government, through the Australian Research Council and National Health and Medical Research Council, support research projects in relation to adhesive arachnoiditis, in particular areas that can be leveraged to a wider patient base, such as chronic pain management, particularly neuropathic pain.

Introduction

The disease

- 1.1 Chronic and clinically significant adhesive arachnoiditis is a painful condition caused by long term scarring of the arachnoid membrane, one of the membranes that surround and protect the nerves of the spinal cord and spinal nerves. Inflammation from medical intervention or infection can lead to the formation of scar tissue, which causes the spinal nerves to 'stick' together, hence the descriptive term 'adhesive' arachnoiditis which is used in this report. This 'tethering' of the spinal nerves can prevent them from moving freely as an individual moves, triggering pain and other symptoms.
- 1.2 Sufferers of adhesive arachnoiditis experience a range of symptoms, including:
 - pain, particularly affecting the lower back and legs, often intense and leading to decreased mobility or in severe cases paralysis;
 - bladder and bowel dysfunction; and
 - impaired sexual function.
- 1.3 There are no reliable data on the prevalence or incidence of adhesive arachnoiditis in Australia (or apparently elsewhere) as the necessary clinical data do not exist.¹ However, it was clear to the Committee at the roundtable that the impact of adhesive arachnoiditis on the lives of sufferers and their families can be devastating.

1 P Day, *Arachnoiditis: A brief summary of the literature*, (2001) New Zealand Health Technology Assessment, pp. 7-9.

- 1.4 The aetiology (i.e. clinical cause) of adhesive arachnoiditis is complex. Causes and risk factors associated with the development of adhesive arachnoiditis include:
- complications of bacterial and viral infections;
 - degenerative back conditions such a disc herniation or spinal stenosis;
 - trauma to the back or spine due to injury or multiple surgical procedures; and
 - exposure of the spinal cord and surrounding membranes to a range of therapeutic and diagnostic agents.
- 1.5 Reports on the relative contribution of these factors to the development of adhesive arachnoiditis vary. It is often very difficult to establish a single causative event for individuals with adhesive arachnoiditis, as many sufferers will have experienced more than one risk factor.
- 1.6 For those with a diagnosis with adhesive arachnoiditis, treatment options are limited and the prognosis is poor. There is no cure for adhesive arachnoiditis and treatment is primarily pain management and assistance with functional impairment.

Context of the Committee's inquiry

- 1.7 Adhesive arachnoiditis was first brought to the attention of the House of Representatives Standing Committee on Health and Ageing (the Committee) by a member of the Committee in the context of constituent concerns raised by affected individuals and/or their carers.
- 1.8 On 19 September 2011, during the grievance debate, the Committee's deputy Chair Mr Steve Irons MP, called for the Committee to inquire into specific matters associated with adhesive arachnoiditis. A key issue raised by Mr Irons was the extent to which certain diagnostic agents, specifically the oil-based contrast media marketed as Myodil by the UK product manufacturers and Pantopaque by the USA product manufacturers², caused adhesive arachnoiditis. These oil-based contrast media, containing iophendylate dye as the main active ingredient, were used to help clinicians determine the causes of chronic back conditions in affected individuals. The contrast media were injected into the cerebrospinal fluid (CSF) in a process known as myelography. This allowed details of the spinal cord and spinal nerves to be visualised by X-ray.

2 In the UK Myodil was produced by Glaxo (now GlaxoSmithKline) and in the USA Pantopaque was produced by Lafayette Pharmacal.

- 1.9 The oil-based contrast media Myodil and Pantopaque were used in myelography from the 1950s to the 1980s in Australia and elsewhere, including the UK and USA. As a consequence, often many years post-procedure, some individuals have developed adhesive arachnoiditis.
- 1.10 A number of those affected have subsequently litigated seeking compensation from the product manufacturers. The basis of many of their claims for compensation is that the product manufacturers provided insufficient warnings about product safety and did not appropriately react to the evolving scientific literature. While the outcomes of litigation have varied according to individual circumstances, it is clear that some individuals in Australia and overseas have received out of court settlements from product manufacturers.³ These out of court settlements were made by the product manufacturers without admission of guilt. The Committee comments further on litigation in Chapter 2 of the report.
- 1.11 Mr Irons' speech is not the first time that adhesive arachnoiditis has been debated in the House. In 2002 several Members of Parliament debated the condition, and matters relating to adhesive arachnoiditis were subject to questions on notice directed to the then Minister for Health.⁴ While all speakers on the issue acknowledged the seriousness of the condition and its impact on sufferers, opinions differed on whether a committee inquiry into adhesive arachnoiditis was warranted.⁵

Scope and conduct of the inquiry

- 1.12 On 22 May 2012 the Committee resolved to investigate the issue of adhesive arachnoiditis further.⁶ To assist the Committee to determine the nature and scope of its investigations it initially received a private briefing on 14 August 2012 from a clinical neurologist and a representative of the Therapeutic Goods Administration. On the basis of information from that

3 Commonwealth, *Parliamentary Debates*, House of Representatives, 19 September 2011, 10707 (Steve Irons).

4 See: Commonwealth, *Parliamentary Debates*, House of Representatives, 16 September 2002, 6267 (Jennie George); Commonwealth, *Parliamentary Debates*, House of Representatives, 16 September 2002, 6270 (Mal Washer); and Commonwealth, *Parliamentary Debates*, House of Representatives, 16 September 2002, 6273 (Andrew Southcott).

5 See: Commonwealth, *Parliamentary Debates*, House of Representatives, 16 September 2002, 6267 (Jennie George); Commonwealth, *Parliamentary Debates*, House of Representatives, 16 September 2002, 6270 (Mal Washer); and Commonwealth, *Parliamentary Debates*, House of Representatives, 16 September 2002, 6273 (Andrew Southcott).

6 The Committee has a general power to inquire into the annual reports of Commonwealth agencies under Standing Order 215(c).

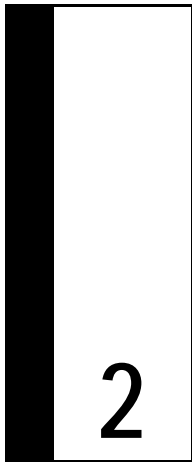
briefing the Committee undertook to focus on the aetiology, diagnosis, treatment and prognosis of adhesive arachnoiditis.

- 1.13 As noted, the Committee is aware of litigation relating to exposure to Myodil and/or Pantopaque and the development of adhesive arachnoiditis. In conducting its inquiry into adhesive arachnoiditis the Committee is of course mindful that the courts are independent of the Parliament. The Committee also emphasises that it does not have the authority to order compensation with respect to the use of Myodil or Pantopaque. Individuals who are considering such legal action should obtain their own independent medical assessment and legal advice. It is in this context that the Committee has sought to investigate issues associated with adhesive arachnoiditis with a view to assisting sufferers by raising the profile of the condition and considering practical options for support.
- 1.14 To progress its investigations into adhesive arachnoiditis the Committee resolved to hold a public roundtable in Canberra on 21 September 2012. The Committee invited a range of participants with experience of adhesive arachnoiditis. The roundtable opened with introductory statements by teleconference from Professor Marcus Stoodley, Professor of Neurosurgery, Macquarie University in New South Wales (NSW) and from Professor Michael Cousins, Royal Australasian College of Physicians. Other participants at the roundtable were:
- Ms Ruth Ahrens, Vice President, Australian Arachnoiditis Sufferers Association and sufferer;
 - Professor Chris Baggoley, Chief Medical Officer, Department of Health and Ageing;
 - Ms Bernadette Clarke, sufferer;
 - Dr Tony Gill, Acting Principal Medical Adviser, Therapeutic Goods Administration;
 - Mr Joern Hagemann, sufferer;
 - Ms Maureen McLean, President/Secretary, Australian Arachnoiditis Sufferers Association (NSW) and sufferer;
 - Professor Michael Sage, Royal Australian and New Zealand College of Radiologists;
 - Mr Max Scott, sufferer (teleconference); and
 - Mrs Erika Zorzit, daughter and carer of Mr Hagemann.
- 1.15 Following the roundtable, the Committee also took 'in-camera' evidence from representatives of GlaxoSmithKline (GSK), the product manufacturer of Myodil. On the same day as the roundtable GSK posted a press release on its website outlining its position on the use of Myodil and the

development of adhesive arachnoiditis (at Attachment A). Subsequently GSK also provided the Committee with a range of information in correspondence to the Committee, including product information sheets for Myodil from the 1970s.⁷

- 1.16 The Committee very much appreciates the contributions of all participants to its inquiry. The roundtable made clear to the Committee how debilitating adhesive arachnoiditis can be to sufferers. The Committee very much sympathises and hopes that the recommendations in the report will help to improve quality of life for sufferers, and their families and carers.

⁷ Correspondence to the Standing Committee on Health and Ageing from GlaxoSmithKline, dated 12 October 2012.



Issues and conclusions

Aetiology

A product of spinal inflammation

2.1 Broadly, aetiology is the clinical cause of a disease or condition. The general cause of adhesive arachnoiditis is 'anything that causes inflammation in the spinal-fluid space or [the spinal] membranes.'¹ Professor Marcus Stoodley and Professor Michael Cousins outlined the specific causes of adhesive arachnoiditis as including:

- meningitis;
- tuberculosis;
- spinal injury;
- spinal surgery;
- bleeding from blood vessel abnormalities;
- chronic lumbosacral nerve root compression; and
- oil-based contrast media used in myelography, such as Myodil and Pantopaque.²

1 Professor Marcus Stoodley, *Official Committee Hansard*, Canberra, 21 September 2012, p. 2.

2 Professor Marcus Stoodley and Professor Michael Cousins, *Official Committee Hansard*, Canberra, 21 September 2012, pp. 2, 6.

2.2 A roundtable witness also suggested that epidural blocks could also cause arachnoiditis, but Professor Cousins expressly stated that there is no evidence for this.³

2.3 Some of the sufferers who participated in the roundtable stated that they had developed the condition through myelography using either Myodil or Pantopaque. It is now widely accepted that the use of these oil-based contrast media resulted in adhesive arachnoiditis in some patients.⁴ Professor Stoodley summarised the figures as follows:

For people who undergo myelography now with the water based dyes ... it would be negligible. Even for those patients who have had the oil-based myelograms, the minority develop arachnoiditis and certainly the minority who develop arachnoiditis that is clinically significant. I have read one paper from the UK from I think the 1950s or 1960s where they looked at over 100 patients who had oil-based myelograms where the oil was not removed and about 10 per cent of those patients developed significant arachnoiditis. Even where the oil is not removed, it is still the minority and I think if the oil has been effectively removed it is a very low number. For all the patients who have had myelograms, which is a very large number of patients, it is a small percentage where arachnoiditis has happened.⁵

2.4 A 1978 paper concluded that the figure was 1 per cent.⁶ This is the same figure as provided by the previous Government in 2002 in a response to a question on notice.⁷

2.5 Nevertheless, the most common cause of adhesive arachnoiditis has been myelography using Myodil or Pantopaque. Professor Michael Sage, a radiologist, stated:

I believe that the most common cause of chronic arachnoiditis is Myodil, and most people have been suffering for 40 years ... These people have suffered, mainly because we were using a dye, Myodil, with no alternative. This was used until the early 1970s in the British-trained areas like Australia, New Zealand and Britain –

3 Mrs Maureen McLean, AASA, *Official Committee Hansard*, Canberra, 21 September 2012, p. 12; Professor Michael Cousins, *Official Committee Hansard*, Canberra, 21 September 2012, p. 7.

4 Professor Marcus Stoodley, *Official Committee Hansard*, Canberra, 21 September 2012, p. 3.

5 Professor Marcus Stoodley, *Official Committee Hansard*, Canberra, 21 September 2012, p. 3.

6 M D M Shaw, J A Russell, K W Grossart, 'The changing pattern of spinal arachnoiditis,' *Journal of Neurology, Neurosurgery and Psychiatry*, 1978, vol 41, pp. 97-107.

7 The Hon Kevin Andrews MP, Minister representing the Minister for Health and Ageing, *House of Representatives Hansard*, 14 May 2003, p. 14,594.

Myodil was left in. Then there was a gradual recognition – with poor literature, I might say – that there was a problem. A needle was introduced to allow us to suck it out; the problem was that it was often impossible to suck it all out anyway. The bottom line was that, if there was some alternative, we should not have been putting it in. I was very concerned about this.⁸

- 2.6 In other words, most people who have adhesive arachnoiditis these days will have been subject to myelography. However, for the majority of people it seems that myelography itself has not resulted in chronic and clinically significant adhesive arachnoiditis.

Committee comment

- 2.7 It appears that medical practitioners were subjecting patients to risk through myelography, but the Committee heard evidence that at the time there was little alternative to investigating patients' spinal cord and spinal nerves. Injecting patients with contrast media allowed X-rays to pick up details of the spinal cord and spinal nerves.
- 2.8 Professor Stoodley stated in evidence that, 'Prior to magnetic resonance imaging being used, myelography was the main mechanism for imaging spinal problems.' He also stated that, 'If you take an X-ray without a [contrast medium], you cannot differentiate between the fluid and the spinal cord or the nerves.'⁹
- 2.9 Some of the alternatives to myelography with an oil-based contrast medium were to use water-based ionic contrast media or air. Both were used in Sweden, but they also carried significant risks:

... there were two problems you had [with water based contrast media]: one was that the carrying agent you used for your iodine, was toxic – methylglucamine or sodium; and the other one was that it was hypertonic, and if you introduce a hypertonic solution into the CSF, that has an osmotic effect on the spinal cord and the nerves and causes a very severe acute reaction.

The Swedes did two things: they would either give you a [general anaesthetic] and use the ionic contrast media, which had a risk of producing a seizure and other things so it was quite a major operation, or they would do what was called an air myelogram, which is where, to produce the contrast with the CSF, instead of

8 Professor Michael Sage, *Official Committee Hansard*, Canberra, 21 September 2012, p. 10.

9 Professor Marcus Stoodley, *Official Committee Hansard*, Canberra, 21 September 2012, p. 2.

putting in something that is more dense, you put air in ... But that was terrible, because you had to put the patient upside down and suck all the CSF out and put air in, and post-operatively the patient had enormous headaches.¹⁰

- 2.10 It is clear that, in Australia by the 1970s, the benefits, risks and trade-offs of myelography with Myodil and Pantopaque were well understood. An Australian paper in 1976 stated:

It is a general principle in medicine that a certain incidence of complications must be accepted in a procedure provided that the incidence is low in relation to the seriousness of the condition and that the procedure is essential. Because of complications with Myodil, water-soluble contrast media have been used. These agents, however, produced their own undesired effects and are at present rarely used.

At present it appears that, despite the considerable morbidity associated with its use, [Myodil] is the best agent available for contrast studies at all levels of the subarachnoid space. It is important for the clinician to appreciate the dangers in its use and to use it only when the investigation is essential.¹¹

- 2.11 The Committee accepts that clinicians were generally making decisions in the best interests of patients within the confines of the existing technology and the body of knowledge that was available at the time. But the fact that adhesive arachnoiditis was an infrequent side effect of a procedure that generally assisted patients, has affected how the medical profession has responded to it. In particular, it appears that is a low level of awareness of the condition among health professionals, including GPs who are likely to be a person's first point of contact when seeking diagnosis and treatment for chronic pain. The low level awareness is also compounded by inadequate research and a poor scientific literature base. These issues are considered in more detail and addressed later in the report.

Changing scientific knowledge about Myodil and Pantopaque

- 2.12 One of the themes to emerge during the roundtable was that medical knowledge about the risks attached to Myodil and Pantopaque developed over time, as did the way in which medical and scientific experts responded to them. Professor Sage stated in evidence that the literature in
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10 Professor Michael Sage, *Official Committee Hansard*, Canberra, 21 September 2012, p. 10.

11 W Ward, M Matheson, A Gonski, 'Three Cases of Granulomatous Arachnoiditis after Myelography,' *Medical Journal of Australia*, 28 August 1976, vol 2(9), p. 335.

this area has been 'poor'¹² and this may account for the delays in progress in the field.

2.13 An early indication of the risks in myelography was an article by F L Davies in 1956 in *The Lancet*, which followed up 119 patients for an average of three years after their myelography. Removal of the Myodil had only been attempted in six patients and the study found long term symptoms occurring in 43 cases, the most common being persistent pain and aches in the head, neck, back and legs. The paper recommended that Myodil and similar agents should be removed from patients after their X-rays.¹³

2.14 Although with hindsight this paper looks like conclusive evidence of the risks of oil-based contrast media, it does not appear to have shaped the subsequent literature and knowledge in the field, at least in the UK and Australia. For example, a 1960 paper in the *Proceedings of the Royal Society of Medicine* stated that Myodil 'does not cause a significant arachnoiditis.' In referring to a 1951 paper by F.L. Davies, the author further states:

The author is therefore in agreement with Davies (1951), who stated that he did not consider it necessary to remove the Myodil. The author would go farther and considers it positively undesirable to remove the Myodil because of the additional trauma which may occur to the subarachnoid space and the possibility of Myodil pulmonary embolism.¹⁴

2.15 The Committee received evidence that the traditional approach of leaving the agent *in situ* remained standard practice in Commonwealth countries until the early 1970s, when the view developed that the Myodil or Pantopaque should be aspirated (removed by suction). Referring to his own experience, Professor Sage explained:

I trained initially in Adelaide and Melbourne, and the idea was that you put the Myodil in and did not suck it out. Then I went to the UK, where again the same thing was done. Then in 1971 there was concern in the UK that there may be some problems with Myodil ... So we started trying to aspirate it ...¹⁵

12 Professor Michael Sage, *Official Committee Hansard*, Canberra, 21 September 2012, p. 10.

13 F L Davies, 'Effect of Unabsorbed Radiographic Contrast Media on the Central Nervous System,' *The Lancet*, 13 October 1956, pp. 747-48.

14 G F Swann, 'Technique of Positive Contrast Myelography,' *Proceedings of the Royal Society of Medicine*, June 1960, vol 53(6), pp. 448-54.

15 Professor Michael Sage, *Official Committee Hansard*, Canberra, 21 September 2012, pp. 13-14.

2.16 It appears that there was greater recognition of the risks of oil-based myelography in the USA and that the move to aspirating the contrast media occurred earlier there. A 1963 paper noted that the American literature preferred to remove the oil-based contrast media, whereas the British literature took the opposite view. In line with the American studies, this paper recommended that the agent be removed.¹⁶ A 1966 paper by the same authors states, 'There are numerous reports in the literature of this occurrence [adhesive arachnoiditis] with operative or autopsy confirmation of severe meningeal inflammation.' It refers to the removal of Pantopaque as if this were a routine procedure.¹⁷

2.17 In 1969, the Food and Drug Administration in the United States recommended that the producer of Pantopaque, Lafayette Pharmacal, state on its product that the agent should be removed after the X-ray.¹⁸ GlaxoSmithKline (GSK) took the same action for Myodil in 1971 in Australia. The product information for clinicians stated:

Occasionally arachnoiditis has been reported, but that type of reaction has not been associated with a specific disease or technique of investigation. The literature contains references to adhesions and fibrous exudate being found on operation in patients who had at some time undergone myelography with iophendylate. The sporadic nature of these reports, and sometimes the sparseness of information about the patient's condition prior to myelography, make it difficult to evaluate the role of iophendylate. However, these reports probably add weight to the case for removing as much Myodil as possible at the time of investigation.¹⁹

2.18 In 1973, GSK changed the last sentence of the product information to read, 'However, these reports emphasise the importance of removing as much Myodil as possible at the time of investigation.'²⁰ There is no evidence that GSK further updated this product warning at any time subsequently. A

16 W J Howland, J L Curry, A K Butler, 'Pantopaque Arachnoiditis: Experimental Study of Blood as a Potentiating Agent,' *Radiology*, March 1963, vol 80(3), pp. 489-91.

17 W J Howland, J L Curry, 'Experimental Studies of Pantopaque Arachnoiditis,' *Radiology*, August 1966, vol 87(2), pp. 253-60.

18 Correspondence dated 14 April 1969 from the Food and Drug Administration to Lafayette Pharmacal, viewed 12 November 2012 at <http://www.myodilaction.info/fda_warning_1969.html>.

19 Correspondence to the Standing Committee on Health and Ageing from GSK, dated 12 October 2012.

20 Correspondence to the Standing Committee on Health and Ageing from GSK, dated 12 October 2012.

general perusal of the literature of the 1970s indicates that, by this time, the risks attached to oil-based contrast media were well known and that myelography should only be performed when necessary.²¹

- 2.19 Removing the Myodil or Pantopaque was not a simple process and it was not always possible to remove it all.²² Patients were sometimes recalled to have it removed, but additional interventions in the spine of themselves increased the risk of adhesive arachnoiditis, as well as low pressure headaches. Professor Sage advised the Committee that:

... one of the observers mentioned how she got a very severe headache the following day after the myelogram. What happens if you puncture the thecal sac too much is that the CSF leaks out and you get what is called a low pressure headache. It has nothing to do with the Myodil. But if you try to go back the next day and repuncture and you could not get the Myodil out the first day sometimes you did get them back the next day and have another go ...²³

- 2.20 However, removing the Myodil or Pantopaque did not provide complete protection to patients. For example, an Australian study found that patients could still develop adhesive arachnoiditis under these circumstances.²⁴ The breakthrough came with the release in Australia in 1976 of the much safer non-ionic water based contrast medium, Metrizamide, and the Australian trials around that time.²⁵ Professor Sage was the lead author for one of the papers from the Metrizamide trial. He stated in evidence:

Ahlem came up with the idea of non-ionic contrast, which could be introduced. The first paper in his research was in 1968. In the mid-1970s, I started writing to the government saying, 'Can we do a trial of Metrizamide?' That was eventually done in Adelaide, and Metrizamide was released in, probably, the late 1970s. After the 1970s I never used Myodil; it was sometimes, perhaps, used by neurosurgeons when they did [an X-ray of the brain].²⁶

21 For example, J Jorgensen, P H Hansen, V Steenskov, N Ovesen, 'A Clinical and Radiological Study of Chronic Lower Spinal Arachnoiditis,' *Neuradiology*, 1975, vol 9, pp. 139-44.

22 Professor Michael Sage, *Official Committee Hansard*, Canberra, 21 September 2012, p. 11.

23 Professor Michael Sage, *Official Committee Hansard*, Canberra, 21 September 2012, p. 15.

24 W Ward, M Matheson, A Gonski, 'Three Cases of Granulomatous Arachnoiditis after Myelography,' *Medical Journal of Australia*, 28 August 1976, vol 2(9), pp. 333-35.

25 Dr Anthony Gill, Therapeutic Goods Administration (TGA), *Official Committee Hansard*, Canberra, 21 September 2012, p. 11.

26 Professor Michael Sage, *Official Committee Hansard*, Canberra, 21 September 2012, p. 10.

- 2.21 Professor Sage's 1981 paper states that, 'Metrizamide is well tolerated, gives good anatomical demonstration and should replace iophendylate (Myodil) in this region.'²⁷ Another Australian paper in 1981 corroborated these results. It did note that Metrizamide had more negative short term effects on patients than Myodil, such as nausea, vomiting, pain, headaches, spasms, tremors, and in a few cases difficulty in voiding urine and convulsions. However, these side effects stopped within a week and the study noted that adhesive arachnoiditis 'has never been demonstrated with Metrizamide in clinical practice.' It also stated that Metrizamide 'represents the best contrast medium for myelography currently available.'²⁸
- 2.22 The Committee received evidence that the changeover from oil-based contrast media to water based agents 'was not straightforward'.²⁹ The Committee heard that some medical practitioners continued to use Myodil and Pantopaque even after the clinical trials for Metrizamide had indicated that it provided a suitable and safer alternative.³⁰
- 2.23 Pantopaque was withdrawn from sale in the 1980s by the product manufacturers and Myodil was no longer sold in both Australia and the UK in 1987. An important factor here is that Magnetic Resonance Imaging (MRI) and computed tomography (CT) had been introduced by this time, providing alternative and better diagnostic capability. As a result there was little demand anymore for contrast media.³¹

The regulatory approach in Australia

- 2.24 Prior to 1970, the regulatory system for medical drugs and agents in Australia was limited and was focussed on quality assurance. The *Therapeutic Goods Act 1966* commenced in 1970 and restricted the supply of therapeutic goods through the Commonwealth's powers to legislate on

27 M R Sage, G T Benness, L V Perrett, J Mansfield, 'Lumbar myelography today. Experience with metrizamide, a water-soluble, non-ionic contrast medium.' *Medical Journal of Australia*, 21 February 1981, pp. 175-76.

28 C C McCormick, H T ApSimon and T M Chakera, 'Myelography with Merizamide - An Analysis of the Complications Encountered in Cervical, Thoracic and Lumbar Myelography,' *Australian and New Zealand Journal of Medicine*, October 1981, vol 11(5), pp. 645-50.

29 Professor Marcus Stoodley, *Official Committee Hansard*, Canberra, 21 September 2012, p. 2.

30 Professor Michael Sage, *Official Committee Hansard*, Canberra, 21 September 2012, p. 11.

31 Dr Anthony Gill, TGA, *Official Committee Hansard*, Canberra, 21 September 2012, p. 10; D. Brahams, 'UK Myodil arachnoiditis claims settled out of court,' *The Lancet*, 5 August 1995, vol. 346(8971), p. 368; The Hon Kevin Andrews MP, Minister representing the Minister for Health and Ageing, *House of Representatives Hansard*, 14 May 2003, p. 14,594.

imports and interstate trade. The Act put in place a framework for the development of Australian standards to regulate products.

2.25 In the absence of an Australian standard, then the Act applied the *British Pharmacopoeia*, which is also used by many other countries. Products were banned if they did not comply with the applicable requirements. If there was neither a standard nor an entry in *British Pharmacopoeia*, then the product was not regulated, apart from laboratory tests on its quality. The *Health Acts Amendment Act 1981* added the requirement for a National Register of Therapeutic Goods.

2.26 As GSK noted in correspondence to the Committee, the regulation of therapeutic goods has significantly changed since Myodil was first introduced in the 1950s.³² The legislation for comprehensive national regulation of medical products in Australia was reviewed and replaced with the *Therapeutic Goods Act 1989*.

2.27 The Committee did not receive a great deal of evidence at the roundtable on the extent to which the Australian authorities reviewed Myodil or Pantopaque. However, in a 2003 response to a question on notice, the then Government stated:

In the late 1970s, the Therapeutic Goods Administration's predecessor, the Therapeutic Goods Branch of the then Department of Health, evaluated an application to register Pantopaque, for general marketing in Australia. This application was approved in October 1979.³³

2.28 An audit report in 1984 found there had been little progress in implementing the *Therapeutic Goods Act 1966*. The development of Australian standards was virtually dormant and the Therapeutic Goods Standards Committee, which inquired into the standards and advised the Minister on them, had only met three times since 1972. Further, there had been no progress on the National Register of Therapeutic Goods.³⁴

2.29 Given these findings and the lack of information about what actually occurred in any assessment of Pantopaque or Myodil, the Committee is not in a position to draw any conclusions about what actions the Commonwealth took to regulate or evaluate these products.

32 Correspondence to the Standing Committee on Health and Ageing from GSK, dated 12 October 2012.

33 The Hon Kevin Andrews MP, Minister representing the Minister for Health and Ageing, *House of Representatives Hansard*, 14 May 2003, p. 14,594.

34 Australian Audit Office, *Report of the Auditor-General upon audits, examinations and inspections under the Audit and Other Acts*, March 1984, pp. 96-99.

Was Myodil banned in Sweden?

- 2.30 A statement made during the roundtable discussion was that Myodil was banned in Sweden in the 1950s.³⁵ This was potentially very important because it could indicate that there may have been officially sanctioned, scientific evidence that the side effects of Myodil should have prevented its wider use.
- 2.31 The claim that Myodil was banned in Sweden has been made before. In 1992, the Queensland Supreme Court accepted that Myodil was banned in Sweden in 1948 in the case of *Wood v Glaxo Australia*.³⁶ The court relied on material written in 1990 by an American academic and clinician, Dr C V Burton to determine that this was the case.³⁷
- 2.32 However, GSK advised the Committee that Sweden did not ban Myodil and tendered correspondence to the Committee to this effect. In 1993, the Swedish Medical Products Agency wrote to GSK in the United Kingdom with the following findings:
- Myodil has never been widely used in Sweden, mainly due to therapeutic tradition.
 - The use of radiological contrast mediums in Sweden was not subject to any registration until 1964, when they were required to be registered as pharmaceutical preparations.
 - Myodil was never submitted for registration by the manufacturer, neither in 1964 nor later ...
 - No verification of the claims that Myodil at some time was banned by drug regulatory authorities in Sweden has been found in our records.³⁸
- 2.33 On the basis information available to the Committee, it is evident that there are contrasting views as to whether Myodil was actually banned in Sweden or not. The alternative explanation is that oil-based contrast media were not used by Swedish medical practitioners as they were pursuing a different diagnostic approach involving the use water-based ionic contrast media or air myelography, which in themselves had significant but different risks for patients.³⁹
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35 Professor Michael Sage, *Official Committee Hansard*, Canberra, 21 September 2012, p. 10.

36 *M E Wood v Glaxo Australia P/L*, Supreme Court of Queensland, J Cooper, 33 of 1990, 28 February 1992, BC9202281, p. 18.

37 The case cited C V Burton, 'Adhesive Arachnoiditis,' 1990, Ch. 97, pp. 2859-61, in J Youmans (ed), *Neurological Surgery*, 3rd edn, Philadelphia: W B Saunders.

38 Correspondence from the Swedish Medical Products Agency to Glaxo Research Group Ltd, 16 July 1993, provided to the Standing Committee on Health and Ageing by GSK.

39 Professor Michael Sage, *Official Committee Hansard*, Canberra, 21 September 2012, p. 15.

- 2.34 As the Committee is not with any degree of confidence able to substantiate the veracity of claims or counter claims that Myodil was banned in Sweden in the late 1940s or early 1950s, it is not in a position to reach a conclusion on the reasons that Myodil was not used in Sweden.

Legal proceedings and compensation

Background

- 2.35 In discussing the legal consequences of using Myodil and Pantopaque for myelography, the Committee wishes to make clear that it has no legal power to require the payment of compensation. The courts are independent of the Parliament and the Committee cannot investigate individual cases. The main direction of this inquiry is to make recommendations to the Government with the aim to improve the quality of life for all sufferers of adhesive arachnoiditis. Any sufferer contemplating litigation must obtain their own medical assessment and legal advice.

- 2.36 A number of individuals who believe they have contracted adhesive arachnoiditis through the use of Myodil or Pantopaque in myelography have conducted litigation, although almost all of the cases have been settled out of court. The bulk of the litigation in Australia was resolved in 2000 in a class action. GSK summarised its position on the litigation as follows:

GSK has received around 140 claims in relation to Myodil, the first in around 1989. GSK has responded in good faith to these claims. GSK believes that it had managed the product responsibly and therefore did not admit fault.

The overwhelming majority of those claims were handled by Cashman and Partners (as it was then called), a well-known plaintiff law firm. All those claims were resolved in around 2000 on terms acceptable to those injured persons, and their lawyers. Those settlements were confidential, and GSK did not determine the ultimate individual claimant allocations.⁴⁰

- 2.37 Although there is little information publicly available about the Australian cases, there is some detail about the cases in the United Kingdom, which were also settled out of court. In 1995, 426 plaintiffs agreed to settle with

40 Correspondence to the Standing Committee on Health and Ageing from GSK, dated 12 October 2012.

GSK for £7 million, or an average amount of £16,000. Their claims were that GSK failed to adequately research the safety of the product and did not provide sufficient warnings about its use. However it should be noted that the great majority of the initial 3,600 plaintiffs were excluded from participating in this class action because complicating factors such as spinal surgery meant it was difficult for them to prove that Myodil was in fact the cause of their condition.⁴¹

- 2.38 One of the few examples of judicial comment about Myodil in Australia comes from the litigation commenced in 1990 by Mrs Mary Wood, who was had a myelography in Cairns in 1972. Much of the case concerned whether Mrs Wood could use the legislative exemption to the limitations period, given that she commenced her litigation 18 years after the event. This partly depended on the strength of her case.
- 2.39 The single judge in the Queensland Supreme Court found that her doctors and GSK complied with best practice at the time. However, one of the judges in the Queensland Court of Appeal found that the product warning in 1972 should have been more specific. Another found there were doubts about whether GSK had sufficiently tested the product or had appropriately reacted when the scientific literature started to raise concerns about it. The Queensland Court of Appeal found that Mrs Wood was not barred by the limitations period. GSK applied to the High Court for special leave to appeal this decision, which was refused.⁴² There is no further information about this case on the public record.
- 2.40 Mrs Wood and GSK both had some judicial support for their respective cases. Further, each plaintiff would have their particular circumstances which would have to be argued and considered by a court. Settling would reduce legal costs and risk for both sides. It would also allow sufferers to gain some benefit and closure.

41 D Brahams, 'UK Myodil arachnoiditis claims settled out of court,' *The Lancet*, 5 August 1995, vol. 346(8971), p. 368. See also: E Jellinek, 'Myodil arachnoiditis: Iatrogenic and forensic illness,' *Practical Neurology*, August 2002, vol 2, pp. 237-39.

42 *M E Wood v Glaxo Australia P/L*, Supreme Court of Queensland, J Cooper, 28 February 1992, 33 of 1990, BC9202281; *M E Wood v Glaxo Australia P/L*, Supreme Court of Queensland - Court of Appeal, C J Macrossan, J Davies, J Ambrose, 30 March 1993, 37 of 1992. *Glaxo Australia P/L v M E Wood*, High Court of Australia, J Toohey, J Gaudron, J McHugh, 2 July 1993, B18 of 1993. The High Court did not give detailed reasons for refusing special leave. It simply stated that it 'is not persuaded that the actual decision of the Court of Appeal is attended with sufficient doubt to warrant a grant of special leave to appeal.' J Toohey at p. 22.

Committee comment

- 2.41 It has been around 25 years since the use of Myodil and Pantopaque in Australia was discontinued. Over this period, up until the present day, a number of adhesive arachnoiditis sufferers who had myelography using these oil-based contrast media have sought compensation from the product manufacturers. Some have pursued individual litigation, while others have been involved in class action. The Committee understands that additional financial resources provided through compensation could assist sufferers to more readily access a range of therapies and practical aids to better manage their condition. Importantly, for some sufferers, the Committee also understands that compensation for pain and suffering will give closure and/or a sense of justice.
- 2.42 However, there is currently no cure for adhesive arachnoiditis, and no amount of compensation will alter this circumstance. Professor Sage put this view in evidence, saying:
- Money is not going to cure the pain; support is. By that I mean, sure, you can litigate, and certain people will win and other people will lose. Let us agree that there is a problem here. We must get the diagnosis.
- ... I am not saying people cannot litigate, but you will get certain people who will get payouts: some will get £400,000; other people get £7,000 – and we support the people with it with diagnosis and support, like ramps et cetera, and pain relief and treatment ...⁴³
- 2.43 As noted previously, the Committee is not in a position to advise individuals on whether to pursue litigation or not. Rather, the Committee's focus is on determining what can be done to provide practical benefit to sufferers of adhesive arachnoiditis, regardless of the cause of their condition.
- 2.44 While government remains responsible for provision of health care, the Committee is aware that the private sector is increasingly recognising the value of establishing business models that incorporate an ethical framework to underpin activities and promote perceptions of good corporate citizenship. This is frequently referred to as corporate social responsibility (CSR).
- 2.45 One practical suggestion considered by the Committee would involve provision of additional and flexible support for sufferers of adhesive arachnoiditis through a charitable foundation established specifically for

43 Professor Michael Sage, *Official Committee Hansard*, Canberra, 21 September 2012, p. 23.

that purpose. While the Committee, and indeed the Australian Government, cannot direct private enterprise to commit to such an undertaking, the Committee encourages GSK in the context of CSR, to consider establishing a charitable foundation to assist sufferers of adhesive arachnoiditis and their families.

- 2.46 If established, priorities for a charitable foundation would need to be determined in consultation with those affected by the condition. Examples of the kind of support that might be provided include assistance with raising awareness of adhesive arachnoiditis; support for research; coordination of support/advocacy groups; establishing and maintaining a case register; and top-up funding for home modifications, treatments or other practical assistance.

Recommendation 1

- 2.47 **In the context of corporate social responsibility the Committee encourages GlaxoSmithKline to consider establishing a charitable foundation to assist sufferers of adhesive arachnoiditis.**

The foundation could operate as a flexible means of assisting those affected by adhesive arachnoiditis. Priorities for support would need to be established in consultation with sufferers of adhesive arachnoiditis and their families, but could include activities to:

- **raise awareness of the condition;**
- **support research into adhesive arachnoiditis;**
- **coordinate adhesive arachnoiditis support groups;**
- **make representations to government;**
- **establish and maintain an Australian case register; and**
- **provide top-up funding for home modifications or other practical assistance.**

- 2.48 The Committee would also like to acknowledge that there may be potential in the future for the National Disability Insurance Scheme (NDIS) to assist people who are experiencing significant levels of disability as a consequence of chronic pain. The intent of the NDIS is to provide lifelong and broad ranging support for people with a significant

and permanent disability. An important aspect of the NDIS is that it supports choice for people with a disability, their families and carers, giving them more of a say on the care and support they receive.⁴⁴ The greater flexibility of funding provided through the NDIS means that may be used to meet costs of therapies and practical aids to assist with their conditions (eg mobility assistance aids and home modifications).

- 2.49 The Australian Government has committed \$1 billion over four years to support the first stage of an NDIS from July 2013 to operate initially in five states/territories.⁴⁵ While the Committee is aware that the details of NDIS implementation are yet to be finalised, and indeed the definition of 'disability' is still under discussion, the NDIS represent a significant reform to the way in which people with disabilities can be supported.
- 2.50 It is unclear at this time precisely how the NDIS will operate in conjunction with supports and services available through the aged care system to people over 65 years of age. However, adhesive arachnoiditis is not confined to people aged over 65 years and may occur as a result of spinal trauma and/or surgery in anyone and at any time of life. Therefore, for eligible individuals suffering the debilitating effects of adhesive arachnoiditis, the NDIS has the potential to improve access to a range of supports and services.

Symptoms and diagnosis

An intense but inconsistent pain

- 2.51 The first symptom that most patients notice in adhesive arachnoiditis is pain, which can present in a wide variety of ways. Professor Cousins gave the following description to the Committee:

The pain is often described as stinging, burning, gnawing, and there are often pins and needles. There can be electricity sensations, like bolts of electricity running from one area to another. The pain is often continuous, or, if it is not at the start, it becomes continuous. But it can have spikes of pain on top of that which can be triggered by movement – jarring, straining, even coughing or sneezing. In some of the most severe patients I have

44 Commonwealth of Australia 2013 website, National Disability Insurance Scheme, viewed 4 January 2013 at <<http://www.ndis.gov.au/>>.

45 South Australia, Tasmania, ACT, the Hunter in NSW and the Barwon area of Victoria.

seen, just moving the end of the bed a little bit can be enough to trigger a paroxysm of pain. There can be cramping sensations and painful muscle spasms, and this sometimes means that, in addition to the nerve roots that go into the spinal cord that are associated with sensation, there is involvement of the nerve roots in the front of the cord that are associated with muscle function. There can be damage to the spinal cord itself that can cause changes in sensation and motor function.⁴⁶

2.52 Patients can also experience loss of muscle function, which can result in weakness extending to paraplegia, and incontinence. Further, a loss of myelin coating on a nerve can result in dysesthesias (unpleasant abnormal sensations such as ants walking on the skin or having hot water poured on one's legs).⁴⁷

2.53 Mr Maxwell Scott spoke to the Committee about his experience. He underwent myelography in 1977 and has since suffered from intense pain. His condition has deteriorated to such an extent that he is now a paraplegic:

I now exist on an electric wheelchair and a bed, transferring from one to the other by means of slide-boards. My only outings now are to go shopping once a fortnight, by means of a maxi-taxi. For hygiene, ladies from Amana Living, with some help from the state government, come to shower and dress me six days a week. My wife, now in her 80th year, attends to me on Sundays and puts me to bed at night and gets me out of bed in the morning. She prepares meals and keeps the garden and the house in order. Also, she handles the very uncomfortable situation of toilet duties. These are things she did not envisage when she married me, some 54 years ago.⁴⁸

2.54 The Committee often heard during the roundtable that adhesive arachnoiditis is difficult to diagnose and this adds to patients' suffering. Professor Cousins stated, 'In my experience of seeing patients with arachnoiditis for over 40 years, they come with a story very often that there was a lot of doubt about the effects that they were describing.'⁴⁹ He noted that the pain does not present in a straightforward way. He stated

46 Professor Michael Cousins, *Official Committee Hansard*, Canberra, 21 September 2012, p. 5

47 Professor Michael Cousins, *Official Committee Hansard*, Canberra, 21 September 2012, p. 5.

48 Mr Maxwell Scott, *Official Committee Hansard*, Canberra, 21 September 2012, p. 13.

49 Professor Michael Cousins, *Official Committee Hansard*, Canberra, 21 September 2012, p. 5.

that, 'the pain is so widespread, is poorly localised and can be inconsistent from week to week.'⁵⁰

- 2.55 Mrs Maureen McLean, President of the Australian Arachnoiditis Sufferers Association, who had her first injection of Myodil in 1971, told the Committee that her adhesive arachnoiditis was initially 'diagnosed' by her work colleagues:

But I found out in 2002 when it was on the front page of the *Daily Telegraph* for three days. All my workmates were coming in and saying, 'Mrs Mac, look, this is what you've got.' They recognised the symptoms just from me being at work. I said to my husband, 'I'm going to go and see [my surgeon] and ask him.' I said to him, 'Have I got arachnoiditis?' He said, 'Bloody papers.' He said, 'No.' About two months later he called me in and said: 'I'm sorry, I shouldn't have done that. You have got arachnoiditis and I'll show you where it is.'⁵¹

- 2.56 Another witness, Ms Bernadette Clarke, advised the Committee that she was treated for 'fatigue and pain' for 10 years and fibromyalgia for 25 years. It was only after the media coverage in 2002 generated after a speech in the House by Ms Jennie George, the then Member for Throsby, that Ms Clarke was able to obtain a correct diagnosis.⁵²

- 2.57 As might be expected from such a debilitating condition, adhesive arachnoiditis places a great deal of strain on marriages. The AASA advised the Committee that many marriages break up and sufferers often live by themselves:

... we have so many men where their wives have just had it – they walk out and they take the kids, or they take the house as well. We have quite a few male members like that. We have a lot of members that live on their own.⁵³

Committee comment

- 2.58 For many sufferers, adhesive arachnoiditis is a debilitating condition that means they cannot do many of the things that people take for granted. For them, adhesive arachnoiditis has meant that they cannot hope to live a

50 Professor Michael Cousins, *Official Committee Hansard*, Canberra, 21 September 2012, p. 5.

51 Mrs Maureen McLean, Australian Arachnoiditis Sufferers Association (AASA), *Official Committee Hansard*, Canberra, 21 September 2012, p. 11.

52 Ms Bernadette Clarke, *Official Committee Hansard*, Canberra, 21 September 2012, p. 20.

53 Mrs Maureen McLean, AASA, *Official Committee Hansard*, Canberra, 21 September 2012, p. 20.

normal life. In addition, many sufferers were misdiagnosed for decades, which has compounded their trauma. The Committee expresses its greatest sympathy for these people.

Knowledge among the medical profession

2.59 The Committee received two broad messages during the roundtable about the medical profession's level of awareness about adhesive arachnoiditis. The first is that GPs, who act as the gateway to the medical system, have a low level of knowledge about the condition. Secondly, sufferers are not attending pain management clinics when they should do so, and the clinics themselves are not aware of how many sufferers there are. The AASA put the patients' perspective to the Committee:

Most GPs do not know. You have got to go through your GP to get to a neuro or orthopaedic to have an MRI. If they cannot get one, I have got members in all states and I ring them and say: 'Look, I have got a new member. Which specialist do you go to or can I give them your phone number? They can talk to you and you can tell them what you think of your specialist or pain management clinic.' I really recommend pain management clinics. Not enough people are going to pain management clinics, or they do not know that is a resource that they can go to at their public hospital.⁵⁴

2.60 Professor Sage made a similar argument:

The real problem is diagnosis ... This group is a group of people who have ... such a variation in neurological symptoms and signs that they need someone with great experience to sort out if it is due to chronic arachnoiditis and give them a label ... the public system should be supporting pain relief. A lot of pain units have not recognised that there is a great number of people out there with chronic arachnoiditis, which we now should recognise, and they need help.⁵⁵

2.61 It appears to the Committee that this matter needs to be addressed on two fronts. Firstly, there needs to be greater awareness among GPs of the condition and its effects on sufferers. The Committee accepts that the ultimate diagnosis often needs to be made by an experienced specialist, but GPs need to be aware of adhesive arachnoiditis so that they can make suitable referrals in the first instance.

54 Mrs Maureen McLean, AASA, *Official Committee Hansard*, Canberra, 21 September 2012, p. 19.

55 Professor Michael Sage, *Official Committee Hansard*, Canberra, 21 September 2012, p. 22.

- 2.62 Secondly, if GPs are made more aware of adhesive arachnoiditis and of the appropriate treatments, there will be an increase in diagnoses and an increase in referrals to pain units, both for those who already know they have the condition and for sufferers who are newly diagnosed. Pain units and the specialists who supervise them should be made aware of the true level of incidence of adhesive arachnoiditis.

Recommendation 2

- 2.63 **The Royal Australian College of General Practitioners and Medicare Locals provide general practitioners with educational and training opportunities aimed at raising awareness of the diagnosis, symptoms and treatment of chronic adhesive arachnoiditis. The Australian and New Zealand College of Anaesthetists advise pain units and its membership of the likely incidence of adhesive arachnoiditis in the community.**

Treatment and prognosis

Pain relief and chronic pain management

- 2.64 Since there is currently no cure for adhesive arachnoiditis, approaches to treatment largely revolve around pain relief and management of chronic pain. As described by the Chief Medical Officer, 'treatments are not curative and prognosis is not optimistic.'⁵⁶ The condition generates a neuropathic pain and there is a range of medications that have been developed for these conditions. Professor Cousins stated that, 'they can be effective for neuropathic pain of the arachnoiditis type.'⁵⁷
- 2.65 A number of sufferers at the roundtable indicated that they needed to use strong pain medication, including opiate-based medications, to cope with their condition. Mr Joern Hagemann raised the question of the lack of subsidy for Lyrica. This is a medication for neuropathic pain that has the generic name of pregabalin. Mr Hagemann stated that it cost him up to \$400 a month, depending on the dose he needed. He noted that members of the armed forces could obtain the equivalent medication for \$5.80.

56 Professor Christopher Baggoley, Australian Government Department of Health and Ageing, *Official Committee Hansard*, Canberra, 21 September 2012, p. 10.

57 Professor Michael Cousins, *Official Committee Hansard*, Canberra, 21 September 2012, p. 6.

- 2.66 The Department of Health and Ageing responded that pregabalin was going through the required assessments for listing on the Pharmaceutical Benefit Scheme:

The Pharmaceutical Benefits Advisory Committee gave pregabalin a positive recommendation in March this year for an authority required listing for neuropathic pain, when other treatments had failed, I think ... This is a high-cost medicine and is subject to the memorandum of understanding with Medicines Australia. The government is committed to use its best endeavours for a six-month consideration and decision by the cabinet after pricing is agreed between the department and the sponsors.⁵⁸

- 2.67 Some research has been conducted into whether spinal cord stimulation might help sufferers. This involves sending electrical impulses into the spinal cord. Professor Michael Cousins advised the Committee that, although he has been experimenting with the technology for an extended period without much progress, there have been some recent advances:

I have not found the existing spinal cord stimulation methodology to be terribly useful in many people's arachnoiditis. I have been trying to use it for over 30 years. The news is that for the very first time we are able to measure compound action potentials from the spinal cord of people with neuropathic pain ... I believe this will allow us to understand much better what are the underlying mechanisms of problems such as neuropathic pain of arachnoiditis ... we are well down the track in developing specific new-age technology which will be able to exploit this treatment of neuromodulation. I think this holds some hope for neuropathic pain sufferers and also arachnoiditis sufferers.⁵⁹

- 2.68 A treatment that can supplement pain relief medication and electrical pain relief is cognitive behavioural therapy. This does not directly reduce the symptoms, but can change the way in which sufferers perceive and manage their pain. One witness stated that, by combining opiate pain relief and cognitive behavioural therapy (CBT), she has been able to run her own business from home:

Probably from when I sustained the back injury, in 1989, up until 2001 I was in and out of hospital for chronic pain relief. In between that I suffered a breakdown ... But, with the help of my GP, I was

58 Professor Christopher Baggoley, Australian Government Department of Health and Ageing, *Official Committee Hansard*, Canberra, 21 September 2012, p. 24.

59 Professor Michael Cousins, *Official Committee Hansard*, Canberra, 21 September 2012, p. 7.

introduced to cognitive therapy, and it has been a positive for me. It is not for everyone, but it has been for me. Today I swim and walk, but I am still on opiate medication. I can live a reasonable life, and I started my own business some years ago. I work from home.⁶⁰

Committee comment

- 2.69 The Committee recognises that chronic pain has a significant effect on adhesive arachnoiditis sufferers. While the Committee accepts that veterans have access to an enhanced range of medical products and services in recognition of their service to Australia, it is concerned to hear that the sufferers of adhesive arachnoiditis may not have reasonable access to equivalent pain relief medications. In relation to this, since holding the roundtable in September 2012, the Committee is pleased to note the Minister for Health's 16 November 2012 announcement that pregabalin (Lyrica), the pain medication specifically referred to by Mr Hagemann, is soon to be listed on the Pharmaceutical Benefits Scheme. This means that pregabalin will be subsidised making it more affordable for people with chronic nerve pain, including sufferers of adhesive arachnoiditis.⁶¹
- 2.70 With regard to other approaches to pain management, the Committee understands that CBT in conjunction with pain relief medication may assist some sufferers. Also, while Professor Cousins' comments on spinal stimulation are promising, the Committee notes that there will probably be a significant delay until a proven technology is developed.
- 2.71 Although not considered in detail at the roundtable, the Committee believes that the new Medicare Locals have significant potential to enhance strategies for the management of chronic pain in the primary health care setting. A good example of how this may be achieved is provided by the Perth North Metro Medicare Local. The Perth Metro Medical Local which has introduced the innovative Self Training Educative Pain Sessions (STEPS) program.⁶²
- 2.72 The STEPS program is a broad approach to the management of chronic pain problem, with the emphasis on involving the patient in each step of their care by providing them with accurate information about the

60 Mrs Ruth Ahrens, *Official Committee Hansard*, Canberra, 21 September 2012, p. 12.

61 The Hon Tanya Plibersek, Minister for Health, Media Release dated 16 November 2012, *Medicine Subsidy for Sufferers of Chronic Nerve Pain*. Lyrica will be listed from March 2013.

62 Medicare Local Perth North Metro, Self Training Educative Pain Sessions, viewed 26 November 2012 at: < <http://www.pnml.com.au/index.php/Article/self-training-educative-pain-program.html>>.

management of pain. The program involves patients attending a series of group education sessions run by a behavioural medicine specialist, a physiotherapist and a pain specialist over two days. Following the group education sessions, patients are seen individually and an individual pain management plan is developed for them to take to their primary practitioner. Outcomes from the program seem promising, with a significant number of participants being able to reduce their pain relief medication.

Recommendation 3

- 2.73 Medicare Locals, and other health providers, actively engage with local communities and health professionals to determine the needs of people living with adhesive arachnoiditis and chronic pain, to develop strategies to assist sufferers optimise management of chronic pain and achieve the best possible quality of life.**

Future directions

- 2.74 The Committee observed during the roundtable that there is a low level of knowledge about the condition. The Professor Sage described the literature as 'poor'.⁶³ A comprehensive literature review of adhesive arachnoiditis in 2001 also noted that research has been patchy. In particular, it stated:

A notable weakness of this report is the reliance on the work of several key authors.

... From an evidence based perspective the quality of evidence is lacking in the topic areas reviewed because of the lack of specific material, the study types and small case series. There is a major need for further research and the development of clinical trials.⁶⁴

- 2.75 It would appear to the Committee that this state of the literature is partly due to the condition's low profile, which may of itself be due to its iatrogenic character (ie caused by medical interventions). While the Committee considers that there is scope for further research into adhesive

63 Professor Michael Sage, *Official Committee Hansard*, Canberra, 21 September 2012, p. 10.

64 P Day, *Arachnoiditis: A brief summary of the literature*, November 2001, New Zealand Health Technology Assessment Clearing House, p. vii.

arachnoiditis, it is also mindful that, compared with other conditions the prevalence is likely to be relatively low and future incidence is likely to be limited, particularly now that Myodil and Pantopaque are no longer used. Therefore, the Committee believes that the most appropriate avenue for future research in relation to the condition would be in areas that are also applicable to other circumstances, such as chronic pain management, particularly neuropathic pain.

Recommendation 4

- 2.76 **The Australian Government, through the Australian Research Council and National Health and Medical Research Council, support research projects in relation to adhesive arachnoiditis, in particular areas that can be leveraged to a wider patient base, such as chronic pain management, particularly neuropathic pain.**

Conclusions

- 2.77 The Committee would like to extend its greatest sympathies to the sufferers of adhesive arachnoiditis, including those that have developed it as a result of myelography using Myodil or Pantopaque. This debilitating condition can cause intense pain and deny sufferers any chance of a normal life. What has compounded their difficulties is poor levels of awareness of the condition and challenges with diagnosis, meaning that sufferers may have struggled for decades to be correctly diagnosed. For some this has meant they may not have received the optimal treatment. The lack of a diagnosis or misdiagnosis has also prevented some sufferers from readily achieving a way in which they can frame their condition and better cope with its consequences.
- 2.78 The Committee has made a number of recommendations that it hopes will assist sufferers. These cover diagnosis and treatment, both in terms of new therapies, as well as making sure that sufferers can make full use of current knowledge and expertise.
- 2.79 This roundtable has reminded the Committee of some basic truths about medicine and health care. It is apparent that many medications, diagnostic agents and medical interventions are not totally without risk. On the other hand, doctors swear under the Hippocratic Oath to do no harm. A key responsibility for governments, health care professionals and the health

care industry is how to balance these competing factors. An important consideration is the extent to which patients are involved in making decisions about medical intervention and how best to communicate so they are prepared for any adverse consequences should these eventuate. The Committee's impression from the roundtable was that in the past medical intervention decisions were more likely to be 'imposed' on patients by health care professionals, albeit with good intent. The trend to improve communication so that patients are well informed and more actively involved in the decision making process is of benefit to all in these circumstances.

- 2.80 Although it was not discussed at length during the roundtable, this inquiry is also very much about the changes in how drugs and therapies are evaluated and tested. There is little doubt that nowadays, if a treatment or diagnostic approach generated the sort of data in F.L. Davies' 1954 paper, it would not be approved for use. This inquiry has vindicated the more thorough approach that governments now take in approving drugs and therapies, both in Australia and internationally.

Ms Jill Hall MP
Committee Chair

8 February 2013



Appendix A - GlaxoSmithKline press release

21 Sep 2012 - Public roundtable Arachnoiditis

GlaxoSmithKline (GSK) provided information to the Standing Committee on Health and Ageing's public roundtable on Arachnoiditis through an 'in-camera' basis.

GSK has the utmost sympathy for the people who have been, and are, afflicted by arachnoiditis. Arachnoiditis is a complex condition that may be caused by a number of conditions such as spinal infections, surgery and trauma.

Myodil was an injectable dye used by doctors as a contrast medium for x-ray purposes in myelography and supplied by Glaxo from 1950.

Although a causal link between Myodil and arachnoiditis was not established, when the company became aware of a possible association, it included a precautionary warning in the Myodil product information sheet that there was a possible risk of arachnoiditis from the use of this medicine.

Myodil was not withdrawn from the market in Australia but discontinued in 1987 when newer diagnostic radiographic techniques became available.

All pharmaceutical products have side-effects, which doctors have to take into account by weighing them against the benefit to be gained by using the products.

In Australia, a court action around Myodil was launched against Glaxo and in 1999 Glaxo reached a settlement with claimants. The settlement was without admission of guilt. GSK is not at liberty to divulge the details of the settlement as these are confidential.

GSK believes that it acted responsibly at all times in relation to the supply of Myodil. Glaxo supplied this diagnostic product with the information available at that time to meet the needs of a very knowledgeable and specialist medical

profession for many years, until it was superseded by newer products and technology.

GlaxoSmithKline is a global research-based pharmaceutical and healthcare company with a proud history in Australia dating back to 1886. Our mission is to improve the quality of human life by enabling people to do more, feel better and live longer.