

The Senate

Community Affairs
References Committee

Growing evidence of an emerging tick-borne
disease that causes a Lyme-like illness for
many Australian patients

Final report

November 2016

© Commonwealth of Australia 2016

ISBN 978-1-76010-484-9

Secretariat

Ms Jeanette Radcliffe (Committee Secretary)

Ms Natasha Rusjakovski (Principal Research Officer)

Dr Josh Forkert (Senior Research Officer)

Ms Megan Jones (Research Officer)

Ms Carol Stewart (Administrative Officer)

PO Box 6100
Parliament House
Canberra ACT 2600

Phone: 02 6277 3515

Fax: 02 6277 5829

E-mail: community.affairs.sen@aph.gov.au

Internet: www.aph.gov.au/senate_ca

This document was produced by the Senate Community Affairs Committee Secretariat and printed by the Senate Printing Unit, Parliament House, Canberra.

This work is licensed under the Creative Commons Attribution-NonCommercial-NoDerivs 3.0 Australia License.



The details of this licence are available on the Creative Commons website:

<http://creativecommons.org/licenses/by-nc-nd/3.0/au/>

MEMBERSHIP OF THE COMMITTEE

45th Parliament

Members

Senator Rachel Siewert, Chair	Western Australia, AG
Senator Jonathon Duniam, Deputy Chair	Tasmania, LP
Senator Sam Dastyari (from 10 October 2016)	New South Wales, ALP
Senator the Hon Don Farrell (to 10 October 2016)	South Australia, ALP
Senator Louise Pratt	Western Australia, ALP
Senator Linda Reynolds	Western Australia, LP
Senator Murray Watt	Queensland, ALP

Substitute members

Senator Claire Moore for Senator Murray Watt (from 2 November 2016 to 2 November 2016)	Queensland, ALP
--	-----------------

Participating members for this inquiry

Senator Jacqui Lambie	Tasmania, JLN
Senator Claire Moore	Queensland, ALP

44th Parliament

Members

Senator Rachel Siewert, Chair	Western Australia, AG
Senator Zed Seselja, Deputy Chair	Australian Capital Territory, LP
Senator Catryna Bilyk	Tasmania, ALP
Senator Carol Brown	Tasmania, ALP
Senator Katy Gallagher	Australian Capital Territory, ALP
Senator the Hon Bill Heffernan (from 4 February to 15 March 2016)	New South Wales, LP
Senator Joanna Lindgren (to 4 February 2016)	Queensland, LP
Senator James Paterson (from 15 March 2016)	Victoria, LP

Participating members for this inquiry

Senator Scott Ludlam

Western Australia, AG

Senator John Madigan

Victoria, IND

Senator Claire Moore

Queensland, ALP

Senator Linda Reynolds

Western Australia, LP

Senator Zhenya Wang

Western Australia, PUP

TABLE OF CONTENTS

Membership of the Committee	iii
Abbreviations	vii
List of Recommendations	ix
Chapter 1	
Patients first	1
Inquiry background	1
Interim report	2
Conduct of the inquiry	4
Structure of the report	4
Acknowledgements	4
Chapter 2	
Testing for infection	7
Lyme, or Lyme-like?	7
Diagnosing Lyme disease	13
What is in our ticks?	22
More research is needed	26
Chapter 3	
Treating the illness	31
Existing treatment pathways	32
First do no harm	32
Establishing a treatment protocol	38
Committee view and conclusion	41
Appendix 1	
Submissions and additional information received by the Committee	45

Appendix 2

Public hearings..... 105

ABBREVIATIONS

ACIIDS	Australian Chronic Infectious and Inflammatory Disease Society
AHPRA	Australian Health Practitioner Regulation Agency
AMA	Australian Medical Association
CDC	US Centers for Disease Control and Prevention
DAkKS	Deutsche Akkreditierungsstelle
Department	Department of Health
ELISA	Enzyme-linked immunosorbent assay
IDSA	Infectious Diseases Society of America
ILADS	International Lyme and Associated Diseases Society
KMF	Karl McManus Foundation
LB	Lyme Borreliosis
MBA	Medical Board of Australia
MCNSW	Medical Council on New South Wales
MSIDS	Multiple Systemic Infectious Disease Syndrome
NATA	National Association of Testing Authorities
NHMRC	National Health and Medical Research Council
NSRL	National Serology Reference Laboratory
NSW	New South Wales
PCR	Polymerase Chain Reaction
POTS	Postural orthostatic tachycardia syndrome
QCMD	Quality Control Molecular Diagnostics
US	United States of America

LIST OF RECOMMENDATIONS

Recommendation 1

2.90 The committee recommends that the Australian Government Department of Health engage with stakeholders following the publication of the National Serology Reference Laboratory review to discuss the findings of the review and any bearing those may have on testing for Lyme disease in Australia.

Recommendation 2

2.91 The committee recommends that the Australian Government increase funding for research into tick-borne pathogens as a matter of urgency. This funding should include:

- **funding for research on pathogens which may cause infection;**
- **funding for research on whether newly-identified pathogens can cause illness in humans; and**
- **funding for the development of diagnostic tests which can detect infection by any newly-identified pathogens endemic to Australia.**

Recommendation 3

3.54 The committee recommends that government medical authorities, in consultation with stakeholders including the Australian Chronic Infectious and Inflammatory Diseases Society (ACIIDS) and the Karl McManus Foundation, establish a clinical trial of treatment guidelines developed by ACIIDS with the aim of determining a safe treatment protocol for patients with tick-borne illness.

Recommendation 4

3.55 The committee recommends that the Australian Government allocate funding for research into medically-appropriate treatment of tick-borne disease, and that medical authorities measure the value of treatment in terms of patient recovery and return to health. The best treatment options must then be developed into clinical treatment guidelines.

Recommendation 5

3.56 The committee recommends that the Australian Government Department of Health facilitate, as a matter of urgency, a summit to develop a cooperative framework which can accommodate patient and medical needs with the objective of establishing a multidisciplinary approach to addressing tick-borne illness across all jurisdictions.

Recommendation 6

3.57 The committee recommends that federal, state and territory health agencies, through the Council of Australian Governments Health Council, develop a consistent, national approach to addressing tick-borne illness.

Recommendation 7

3.58 The committee recommends that the Australian Government Department of Health urgently undertake an epidemiological assessment of the prevalence of suspected tick-borne illness in Australia, the process and findings of which are to be made publicly available.

Recommendation 8

3.59 The committee recommends that the Australian Government Department of Health establish the prevalence and geographical distribution of overseas-acquired Lyme disease in Australia.

Recommendation 9

3.60 The committee recommends that Australian medical authorities and practitioners addressing suspected tick-borne illness:

- consistently adopt a patient-centric approach that focusses on individual patient symptoms, rather than a disease label; and
- remove 'chronic Lyme disease', 'Lyme-like illness' and similar 'Lyme' phrases from diagnostic discussions.

Recommendation 10

3.61 The committee recommends that, to help the referral of patients for guided and comprehensive pathology testing, medical practitioners work with pathologists, especially microbiologists, immunologists, chemical pathologists and haematologists to optimise diagnostic testing for each patient.

Recommendation 11

3.62 The committee recommends that the Australian Government Department of Health work closely with the Australian Medical Association and Royal Australian College of General Practitioners to ensure that general practitioners have a better understanding of how to treat patients who present with complex symptoms.

Recommendation 12

3.63 The committee recommends that treatment guidelines developed by Australian medical authorities emphasise the importance of a multidisciplinary, case conference approach to patient care, involving consultation between general practitioners and specialists with expertise in neurology, psychiatry, rheumatology, immunology, infectious diseases and microbiology.

Chapter 1

Patients first

People often say to me that I have coped with my situation with bravery and an astonishing amount of grace, but it is not really true. It is just that my fury has made me quiet.¹

1.1 The existence of tick—or other vector—borne, Lyme-like illness endemic to Australia is a controversial, polarising question. The committee considered evidence provided by many qualified professionals articulating considered, plausible, yet contradictory views. This evidence, presented over the course of two parts to this inquiry, mirrored the tangled public discourse which has been going around in circles for years: do pathogens responsible for Lyme disease exist in Australia, which pathology results are reliable, who do we believe?

1.2 The committee heard many moving personal accounts from patients over the course of this inquiry: eroding health, excruciating pain, complex manifestations, desperation, exasperation—in a few cases, even death. Ordinary, previously high-functioning members of the community rendered helpless and exhibiting symptoms many say are consistent with tick-borne illness. Years—sometimes decades—spent struggling just to get up and get on with life. It is undeniable that people are suffering.

1.3 Given that the committee accepts that the human toll is real, it is clearly necessary to go back to first principles—people are unwell, and they must be helped. It is therefore the committee's primary objective, in this, its final report on this inquiry, to put the patients first.

1.4 With this in mind, this report builds on the committee's interim report, tabled in May 2016, and seeks to define why there is so much confusion and disagreement. The committee hopes to establish how some progress can be made by cutting through the controversy and identifying areas of agreement. Put simply, why don't we know exactly what these patients have, and how do we help people suffering from an unrecognised, unidentified, but real illness?

1.5 These are the questions at the core of this inquiry.

Inquiry background

1.6 The inquiry into emerging evidence of a tick-borne disease was first referred to the committee on 12 November 2015, with a reporting date of 20 June 2016.²

1 Ms Fiona Caskie, *Committee Hansard*, Sydney, 2 November 2016, p. 32.

2 [*Journals of the Senate*](#), No. 126–12 November 2015, p. 3380.

- 1.7 The terms of reference for the inquiry were:
- a. the prevalence and geographic distribution of Lyme-like illness in Australia;
 - b. methods to reduce the stigma associated with Lyme-like illness for patients, doctors and researchers;
 - c. the process for diagnosis of patients with a Lyme-like illness, with a specific focus on the laboratory testing procedures and associated quality assurance processes, including recognition of accredited international laboratory testing;
 - d. evidence of investments in contemporary research into Australian pathogens specifically acquired through the bite of a tick and including other potential vectors;
 - e. potential investment into research to discover unique local causative agents causing a growing number of Australians debilitating illness;
 - f. the signs and symptoms Australians with Lyme-like illness are enduring, and the treatment they receive from medical professionals; and
 - g. any other related matters.³

1.8 Due to the federal election, however, the inquiry lapsed at the dissolution of the Senate on 9 May 2016, by which time the committee had held three hearings, in Perth, Brisbane and Canberra. Given the large volume of evidence received, the committee tabled a comprehensive interim report on 4 May 2016, just prior to the dissolution of the Senate.⁴

Interim report

1.9 The committee's interim report was a wide-ranging analysis of the evidence presented, and recognised that there is considerable debate in Australia and internationally about what constitutes Lyme disease and Lyme-like illness.

1.10 A large number of submissions were made by individuals detailing their personal experience, or that of others close to them. Many submissions were also received from doctors treating patients and researchers looking at tick-borne pathogens. The report detailed this experience, the trajectory of illness, access to medical treatment, and, in some cases, journey to recovery. For clarity, patients were divided into four clear groups:

- those who acquired and were diagnosed with classical Lyme disease in an endemic area overseas;
- those who acquired their illness overseas but weren't diagnosed;

3 *Journals of the Senate*, No. 126–12 November 2015, p. 3380.

4 Senate Community Affairs References Committee, *Growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients*, [Interim report](#), May 2016.

-
- those who became ill following a tick or other insect bite in Australia; and
 - those who have experienced a long-term chronic illness in Australia and may or may not have been bitten by a tick or other insect.⁵

1.11 The committee noted the weight of evidence on the relationship between tick bites and people becoming ill.

1.12 The committee was concerned by reports of stigma attached to Lyme-like illness and the treatment of those patients potentially suffering the illness, and noted that more could be done to educate the public and medical professionals about the risk of tick bites and tick-borne illnesses in Australia, as well as classical Lyme disease acquired overseas.⁶

1.13 The committee also looked at diagnostic testing processes for Lyme disease and the recommended protocol for laboratory testing of patients with suspected Lyme disease. Testing, evidence suggested, was at the centre of the heated debate on whether or not Lyme disease itself can be contracted in Australia. Discordant laboratory results between accredited laboratories in Australia and non-accredited Australian and overseas laboratories, the committee concluded, were the cause of considerable confusion and frustration for patients.⁷

1.14 Although the committee's interim report was comprehensive and examined key evidence in detail, the committee identified a number of issues warranting further investigation.

1.15 Three recommendations were made:

Recommendation 1

4.52 The committee recommends that the Community Affairs References Committee continue its inquiry into this matter in the 45th Parliament.

Recommendation 2

4.56 The committee recommends that the Department of Health further develop education and awareness strategies for:

- the public about the prevention of tick bites and seeking medical attention; and

5 Senate Community Affairs References Committee, *Growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients*, Interim report, May 2016, p. 19.

6 Senate Community Affairs References Committee, *Growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients*, Interim report, May 2016, p. 31.

7 Senate Community Affairs References Committee, *Growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients*, Interim report, May 2016, p. 58.

- the medical profession about how to diagnose and treat classical Lyme disease acquired overseas and known tick-borne illnesses acquired in Australia.

Recommendation 3

4.58 The committee recommends that the Chief Medical Officer continue to consult with the medical and patient communities through mechanisms such as the Clinical Advisory Committee on Lyme Disease, and for the Department of Health to continue to facilitate meetings with medical and patient representatives.⁸

Conduct of the inquiry

1.16 In light of the truncating effect the dissolution of Parliament had on the committee's inquiry, on 13 September 2016 the Senate agreed to re-adopt the inquiry with the same terms of reference and a reporting date of 30 November 2016.⁹

1.17 The committee did not call for further evidence upon re-adoption of this inquiry, having already received and considered over 1200 submissions prior to tabling its interim report. The committee did, however, hold an additional public hearing on 2 November 2016, in Sydney.

Structure of the report

1.18 This report is divided into three chapters:

- **Chapter 1** provides a background to the committee's inquiry and overview of evidence considered by the committee in its interim report.
- **Chapter 2** looks at diagnostic testing processes for Lyme disease, with the objective of establishing why these processes and test results are so controversial.
- **Chapter 3** examines treatment options available for patients suffering Lyme-like illness. The chapter examines the evidence around non-mainstream treatment, the position Australia's medical authorities take on such treatment, and how the existing impasse might be breached.

Acknowledgements

1.19 The committee thanks witnesses and submitters for their engagement with this inquiry, and recognises that a number of witnesses attended hearings at short notice on more than one occasion. The committee thanks them for their time, professionalism and evident commitment to acting in the best interests of the community.

8 Senate Community Affairs References Committee, *Growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients*, Interim report, May 2016, p. ix.

9 See inquiry homepage, available at: http://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/Lyme_like_illness45 (accessed 14 November 2016).

1.20 The committee also extends particular gratitude and recognition to the individuals who came forward to relate their difficult personal experiences. The committee was deeply moved by these accounts, and by the patients' determination in having their voices heard and contributing in a positive way to the wider community's understanding of tick-borne disease.

Chapter 2

Testing for infection

Scientific folk want evidence of causative agents to enable disease; patients want focus on their symptoms, their illness, while science works on the details. Both groups make equally valid points, but lives are at risk and people are suffering.¹

2.1 The question of pathology testing is perhaps the most contentious issue to emerge from this inquiry, and is at the root of the frequently-posed and incessantly debated question: can Lyme disease be contracted in Australia? The committee explored this issue at length in its interim report but found that conclusive answers were elusive. In this, its final report, the committee aims to identify a few areas where some progress may be made.

2.2 Evidence presented to the committee over the course of this inquiry suggests three principal points of contention:

1. A lack of an agreed definition and understanding of what constitutes Lyme-like illness and how, if at all, it differs from Lyme disease.
2. Disagreement over laboratory testing protocols and results when looking for the pathogens responsible for Lyme disease.
3. The lack of conclusive, accepted scientific evidence linking tick bites in Australia to Lyme-like illness.

2.3 This chapter will examine all three.

Lyme, or Lyme-like?

2.4 The illnesses discussed throughout this inquiry are Lyme disease, chronic Lyme disease and Lyme-like illness. The terms are often used interchangeably, and generate considerable disagreement.

Classical Lyme disease

2.5 In its interim report, the committee outlined known epidemiological facts about Lyme disease in detail.² Classical Lyme disease, or Lyme borreliosis, is a tick-borne disease caused by a number of closely related species of *Borrelia* bacteria. Lyme disease is recognised as one of the most common tick-borne diseases in

1 Ms Elaine Kelly, Secretary, Sarcoidosis Lyme Australia, *Committee Hansard*, 14 April 2016, p. 9.

2 Senate Community Affairs References Committee, *Growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients*, Interim report, May 2016, p. 3.

humans, and is known to be present in parts of the United States of America (US), Europe and Asia. Lyme disease is named after the town of Lyme in Connecticut where it was first recognised in the early 1970s.³

2.6 There are a number of common species of *Borrelia* known to cause Lyme disease. In the US, the most common of these is *Borrelia burgdorferi*. Different species of *Borrelia* have been identified as Lyme pathogens in Europe and Northern Asia, such as *Borrelia afzelii* and *Borrelia garinii*. Although different, these species are related and referred to as the '*Borrelia burgdorferi sensu lato complex*'.⁴

Chronic Lyme disease

2.7 If classical Lyme disease is understood to be an acute infection, one that is treated with readily available antibiotics,⁵ the concept of chronic Lyme disease, on the other hand, is a controversial one. This is in part because the symptoms some patients experience after an acute Lyme infection are not easily defined. As put by the Department of Health (department):

In some patients, a post-treatment late Lyme disease syndrome occurs, with patients experiencing non-specific symptoms like headache, fatigue, and muscle and joint pain. These symptoms are generally not regarded as persistence of active infection but more as post infectious problems.⁶

2.8 There is much debate about whether post-infection symptoms constitute chronic Lyme disease, whether such a disease even exists. This debate, as set out in the committee's interim report, is not unique to Australia. Disagreement revolves around whether an ongoing *Borrelia* infection can manifest as chronic, debilitating illness once the acute state of infection has subsided:

The department is aware of the controversy in endemic areas overseas about the diagnosis of chronic Lyme disease. That controversy which focuses on persistent infection rather than post infectious sequelæ as the cause of ongoing symptoms is relevant to the Australian context because the Australian advocacy groups for a Lyme disease-like illness support the concept of persistent infection.⁷

3 Senate Community Affairs References Committee, *Growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients*, Interim report, May 2016, p. 3. Department of Health, *Submission 495*, p. 2.

4 See Senate Community Affairs References Committee, *Growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients*, Interim report, May 2016, p. 3. The committee notes that there are other, known *Borrelia* species which cause different illnesses in humans and animals, but not Lyme disease.

5 Department of Health, *Submission 495*, p. 3.

6 Department of Health, *Submission 495*, p. 2.

7 Department of Health, *Submission 495*, p. 2.

2.9 Australian medical authorities do not support the use of the term 'chronic Lyme disease', nor do they accept that its associated symptoms are the result of ongoing *Borrelia* infection:

The issue of chronic Lyme disease assumes that there is persistent, active infection. That is what is so contentious. The mainstream conventional position is that the sequelae that we see after an infection is post-infectious and not active infection ... So, in Australia, like in many other countries that we would be like-minded with in terms of medicine, the experts in microbiology and infectious disease will not readily accept that there is chronic Lyme disease or chronic persistent active infection. So, for that reason, and because of the association between what is happening in Australia with chronic Lyme disease, most of the medical profession expert in this field do not accept that it is Lyme disease.⁸

2.10 This view was, however, challenged by submitters such as Dr Mualla McManus, a scientist with credentials and expertise in immunology, pharmacology, pharmacy, neuroscience and molecular biology:

The significance of *Borrelia* infection is that once you are infected with it, you have to be treated early so that it does not disseminate. Once disseminated, it becomes chronic. It is very hard to eradicate...after 20 years of antibiotic treatment on a patient, they took the samples from the synovium, the knee joint, and they could actually identify the *Borrelia burgdorferi*—after 20 years of treatment. So you are looking at a unique pathogen that is emerging, but the problem with this pathogen is that it is emerging very slowly.⁹

2.11 The notion of chronic Lyme disease is also important to understanding the debate around laboratory testing results, to be discussed later in this chapter.

Lyme-like illness

2.12 Whereas Lyme disease is caused by known pathogens, and later stages of infection are sometimes referred to as chronic Lyme disease, the term 'Lyme-like illness' has been used to describe a constellation of symptoms thought to be caused by a variety of tick-borne pathogens. As these symptoms are closely connected to those exhibited by patients with classical Lyme disease, the terms 'Lyme disease', 'Lyme-like illness' and 'chronic Lyme disease' are often used interchangeably by patients and their advocates.

2.13 Public discourse on Lyme-like illness is problematic in part due to a lack of agreement or understanding around terminology:

The department [Department of Health WA] notes that there is no widely published or accepted definition of Lyme-like illness. It is not possible, therefore, to determine the prevalence or geographical distribution of

8 Dr Gary Lum, Principal Medical Adviser, Office of Health Protection, Department of Health, *Committee Hansard*, Canberra, 20 April 2016, p. 10.

9 Dr Mualla McManus, Director, Karl McManus Foundation, University of Sydney, *Committee Hansard*, 15 April 2016, p. 28.

Lyme-like illness in Australia or even to be certain that different groups discussing Lyme-like disease are referring to the same concept.¹⁰

2.14 Patient advocacy groups, such as the Lyme Disease Association of Australia, similarly recognise the lack of clear definition. From their perspective, however, the semantic debate is unhelpful:

There is considerable contention around these two simple words ‘Lyme’ and ‘disease’. On their own they do not offend, used together they invoke very powerful, often emotive shifts in the demeanour, language and behaviours of others. Depending on your perspective, we either have it in Australia or we don’t – it’s binary.

It is impossible to find a precise and consistent definition of the term in Australia. It is used by the medical community to describe a very specific strain of a biological organism, or sometimes organisms; even they can’t decide. It is used by the rest of the world to describe a suite of symptoms and infections caused by a number of organisms.

...We don’t know what people have. We do know that some people become seriously ill, sometimes after the bite of a tick, and that their symptoms closely resemble that of internationally defined Lyme disease.¹¹

2.15 Given that the pathogens which cause Lyme disease overseas are known, Australian authorities are firm in the view that the term ‘Lyme disease’ is misused in the local context. This is because the pathogens responsible for Lyme disease overseas were identified some time ago, and have not been identified locally:

The term is used to describe a variety of symptoms and clinical features ranging from well-defined illnesses to non-specific chronic symptoms. However, there is no evidence to indicate that infection with *Borrelia burgdorferi* sensu lato, resulting in Lyme disease, has been acquired within Australia. In addition, there is no convincing scientific evidence to date that tick bites from native Australian ticks result in Lyme-like disease.¹²

2.16 Critics of this position, however, challenge both the assertion that a) *Borrelia* known to cause Lyme disease have not been found in Australia, and b) only bacteria known to be part of the *Borrelia burgdorferi* sensu lato complex can cause Lyme disease.

10 Professor David Forbes, Office of the Chief Medical Officer, Department of Health Western Australia, *Committee Hansard*, Perth, 14 April 2016, p. 1.

11 Lyme Disease Association of Australia, *Submission 528*, p. 5.

12 Professor David Forbes, Office of the Chief Medical Officer, Department of Health Western Australia, *Committee Hansard*, Perth, 14 April 2016, p. 1.

Lack of consensus on the name or the cause

2.17 If symptoms of Lyme-like illness in Australia lack clear definition, its cause is similarly very poorly understood and in dispute. As put by Dr McManus, exclusive focus on *Borrelia burgdorferi* as a causative agent for Lyme-like disease may be counterproductive:

We need to change our view. The government only thinks of Lyme disease, and follows the CDC [US Center for Disease Control] criteria. I have an explanation for *Borrelia*...There is *Borrelia burgdorferi* sensu lato group, and a subset of that is Lyme disease *Borrelia*. There is relapsing fever, which has over 20 genospecies known today. We have reptilian *Borrelia*, but the infection has not yet been found in humans. So if we concentrate on Lyme disease we are missing out on 80 per cent of other *Borrelia* infections, and that is really dangerous. We are being short-sighted. Some of the relapsing fever genospecies can produce 80 per cent of their infections neurologically, but there is no research, because relapsing fever is a poor-country disease. It is endemic in Africa, Asia, India, Indonesia and Vietnam. All the focus is in Lyme disease; everyone makes such a fuss about it. Lyme disease, *Borrelia burgdorferi* sensu stricto, is much easier to treat than relapsing fever. This is something that has not been understood.¹³

2.18 Dr Richard Horowitz, who spoke to the committee in a private capacity, suggested that Lyme disease itself is far more complex than first imagined. The fact that Lyme disease is still poorly understood, Dr Horowitz believes, contributes in large part to the controversy over its diagnosis and treatment:

I think some of the controversy is happening because we are not understanding the definition of what Lyme disease really is. The patients that I see with Lyme disease do not just have *Borrelia burgdorferi* sensu lato. What they end up having is many other species of bacteria, viruses and parasites because the ticks are now containing many of these different species and are rapidly spreading.¹⁴

2.19 The evidence supplied by Dr Horowitz is not easily dismissed. He is one of the founding members, as well as past president, of the International Lyme and Associated Diseases Society (ILADS), has published a large number of peer-reviewed articles on the subject and has engaged with a number of governments—including the US, Chinese, UK, French and Belgian—on the subject of Lyme and related diseases.¹⁵

2.20 On the basis of his own research and that of others cited in his submission, Dr Horowitz in fact advocates a move away from the term "Lyme disease", submitting that the Lyme diagnosis fails to capture the chronic symptoms and multiple infections exhibited by many patients:

One of the first and most basic problems we face is in helping Australian patients is defining "chronic Lyme disease" or "Lyme-like illness". Patients

13 Dr Mualla McManus, *Committee Hansard*, 15 April 2016, p. 29.

14 Dr Richard Horowitz, *Committee Hansard*, 2 November 2016, p. 1.

15 Dr Richard Horowitz, *Submission 936*, pp. 25–33.

with chronic symptoms who see me, either before or after classical treatment for Lyme disease, have multifactorial causes for their illness. I call this syndrome Lyme-MSIDS. MSIDS stands for Multiple Systemic Infectious Disease Syndrome, and represents sixteen potential overlapping medical problems contributing to persistent symptoms in the Lyme patient.

...

The first point on the MSIDS map is infections. Ticks are now containing multiple bacterial, viral and parasitic infections which can be transmitted simultaneously with *Borrelia burgdorferi*, the agent of Lyme disease. Patients infected with Lyme disease and associated co-infections are much sicker and resistant to standard therapies.¹⁶

2.21 Dr McManus similarly pointed to multiple infections as an impediment to straightforward diagnosis and treatment:

The scientific community is not in a state to understand the multiple infections. Over 100 years ago, Koch's postulates were formulated to say, 'You have one infection, one specific set of symptoms—we give you one antibiotic.' That was the treatment. But then you come to something with four or five infections—which one do you treat first? Which is the prominent one that produced the symptoms?

Doctors do not know, we do not know. There are no clinical trials, no investigations into it, because most of the research community thinks that it is too hard to handle. Most of the research on Lyme disease or any species of *Borrelia* looks at acute disease because it is easier to follow. You have got one tick bit, you have got history and you can detect it because the immune system is competent and you can follow it through and treat it. But when it comes to chronic—I have talked to IDSA members; they do not know what to do. ILADS try to treat with long-term antibiotics.¹⁷

Where to from here?

2.22 Despite considerable disagreement around most aspects of tick-borne illness in Australia, this inquiry also highlighted important areas of agreement. The committee chose to focus on these, as they are a clear indication that progress on the issue is possible.

2.23 Importantly, the committee noted a promising level of interest in further research and examination of the issues from authorities, such as this statement from the department indicating its preparedness to work towards broadening and deepening understanding of tick-borne illness:

We acknowledge that the cause of these tick-bite-associated, chronic debilitating symptoms may not be limited to a single bacterial species. Parasitic and viral causes as well as environmental toxins should also be investigated.

16 Dr Richard Horowitz, *Submission 936*, p. 2.

17 Dr Mualla McManus, *Committee Hansard*, 15 April 2016, p. 29.

As part of the department's work in communicable diseases in states and territories, we are developing an awareness of newer genomic technology that is using specimens from patients to look for bacterial and viral nucleic acid, in an attempt to find commonalities in patient specimens. It may reveal a common pathogen or pathogens which can be further considered.¹⁸

Committee view

2.24 The committee notes that the term 'Lyme-like illness' is in use to describe a constellation of symptoms and what may very well be a number of different illnesses. In the committee's view debate around what to call tick-borne illness in Australia has impeded progress on establishing its cause and optimising treatment. The scope of what scientists and clinicians are grappling with—tick-borne infections, co-infections and post-infection symptoms—is not yet well defined, but appears to be considerable. Australia's understanding of what is in our ticks, and how it might be making some people sick, is clearly at a very nascent stage.

2.25 The committee notes the department's commitment to exploring tick-borne illness and identifying the pathogens involved:

Through regular communication and correspondence, the department has gained a deeper appreciation and real concern for those Australians experiencing these chronic debilitating symptoms, which they associate with a tick bite. The department remains engaged with the patient and medical community to continue to find, share and understand the evidence associated with this medical conundrum. The department hopes our work with diagnostic pathology and research communities will result in answers and relief for patients and their families.¹⁹

2.26 The committee is encouraged by this and calls on medical authorities to engage with the research presented during the course of this inquiry.

Diagnosing Lyme disease

2.27 Diagnostic testing of samples—usually blood—taken from patients suspected of having Lyme-like illness is perhaps the most controversial issue to emerge from this inquiry, and one that evidence returned to time and again.

2.28 Much—if not most—of the evidence presented was contradictory, and most of it was confidently articulated by qualified, experienced and respected professionals. It is therefore necessary to establish from the outset that the committee is not in a position to arbitrate a scientific debate. Instead, the committee's objective is to broadly define the parameters of the disagreement around laboratory testing, and identify how some progress can be made.

2.29 As outlined in the committee's interim report, a number of prominent and experienced doctors have questioned the reliability of laboratory tests used to

18 Department of Health, *Submission 495*, p. 2.

19 Department of Health, *Submission 495*, pp. 1–2.

diagnose or rule out Lyme-like illness—classical and chronic Lyme disease or other Lyme-like illnesses. Broadly, the question can be seen from two perspectives:

1. Classical Lyme disease, caused by *Borrelia* bacteria, cannot be contracted in Australia. This position is held by the Australian medical authorities and many experts in relevant fields, and supported by the fact that accredited Australian laboratories return negative results when testing for Lyme disease.
2. An illness with considerable similarities to Lyme disease can and has been contracted in Australia, and pathogens which cause Lyme disease do exist here. This position is held by some doctors and scientists, and supported by the fact that patients who have not travelled overseas have had positive laboratory test results when tested for Lyme disease by some Australian and overseas laboratories.

2.30 A key part of the matter is the issue of test quality—understanding which testing protocol is optimal and how test results are to be interpreted.

2.31 This section will build on evidence already explored by the committee's interim report. Evidence already examined by the interim report is only referred to again where necessary.

The two-tier testing protocol

2.32 As previously described, classical Lyme disease is caused by a number of known, closely related species of *Borrelia* bacteria. The *Borrelia* strains known to cause Lyme disease in Europe, for example, are different to the strains responsible for Lyme disease in the United States (US)—together the bacteria make up the *Borrelia burgdorferi* sensu lato complex. It is antibodies to these bacteria that most laboratories test for when doctors send patients for pathology tests, looking to diagnose or rule out Lyme disease.

2.33 The committee's interim report detailed the protocol used for testing and diagnosis.²⁰ In brief, most Australian laboratories accredited with the National Association of Testing Authorities (NATA)²¹ use a two-tier serological diagnostic protocol, as is also the case with accredited US and European laboratories.

2.34 The first tier is most commonly an enzyme-linked immunosorbent assay (ELISA). If the ELISA test returns a positive result, laboratories will then conduct a Western blot test. The committee understands that laboratories can, but will rarely run a Western blot test in the absence of a positive ELISA result.

2.35 This testing protocol is considered to be world-class and reliable. Accredited laboratories using the protocol in Australia have only returned positive results for

20 For details, see Chapter 3 of Senate Community Affairs References Committee, *Growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients*, Interim report, May 2016.

21 NATA Australia provides assessment, accreditation and training services to laboratories. Accreditation with NATA provides assurance of laboratory competence. See www.nata.com.au (accessed 16 November 2016).

Lyme disease acquired overseas, reinforcing the understanding that the pathogens responsible for Lyme disease are not endemic to Australia.²²

2.36 Seeking to understand the logic behind the two-tier testing system, the committee questioned why the ELISA test was routinely performed first. Professor Stephen Graves, spokesman on Lyme disease for the Royal College of Pathologists Australasia, described how and why the two tiers of testing ensure accuracy:

The Western Blot assay is more “reliable” than the ELISA in that it is more specific, at least when the IgG class of antibodies is being tested for. This means it is less likely to give a false-positive result. i.e. mis-call some other illness as Lyme Disease.

The ELISA assay is more sensitive than the Western Blot and will detect almost all patients with antibodies to the Lyme bacteria, but it is less specific and some of the antibodies it detects are not the result of Lyme Disease. These are cross-reacting antibodies. The ELISA assay can therefore give false-positive results.

By going straight to a Western Blot assay, there is a possibility that some Lyme cases could be missed, as it is a less sensitive assay than the ELISA.

The logic for this serological testing pattern is that the ELISA is a “screening” assay that will detect all cases of Lyme Disease [and some non-case also] and the Western Blot is a “specific” assay and will differentiate the true Lyme cases from the non-Lyme cases, as it is a more specific assay than the ELISA.

In practice however, both assays can give false positive results and also false-negative results. By having the 2 assays the lab is more likely to obtain the correct result.

If a lab went straight to the Western Blot assay they are likely to miss some genuine cases of Lyme Disease.²³

2.37 However, a considerable number of submitters and witnesses questioned the reliability of the protocol. These ranged from patients and their advocates, to respected members of the medical and scientific community—each provided evidence in stark contrast to that presented by Professor Graves. Their positions can be broadly divided into two categories:

- those who hold that the ELISA test is not sensitive enough, can therefore only detect antibodies to Lyme disease in some patients, and cannot rule infection out; and

22 Senate Community Affairs References Committee, *Growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients*, Interim report, May 2016, pp. 47–49.

23 Professor Stephen Graves, Spokesman on Lyme Disease, Royal College of Pathologists of Australasia, answer to question on notice, received 15 November 2016.

- those who hold that Lyme-like illness is in Australia caused by an as-yet unidentified pathogen, perhaps a species of *Borrelia* unique to Australia, and therefore testing for *Borrelia* which are endemic overseas is redundant.

2.38 A small sample of the evidence presented in support of a move away from ELISA-led testing is cited below.

ELISA sensitivity

2.39 Dr Peter Dobie, Secretary of the Australian Chronic Infectious and Inflammatory Disease Society (ACIIDS), told the committee that Lyme disease and Lyme-like illness were underdiagnosed in Australia due to over-reliance on ELISA, which in his experience is not sensitive enough to detect the presence of infection:

[M]ost Australian pathology laboratories are doing the wrong blood test for Lyme disease. This is one reason why Lyme disease and Lyme-like illness are underdiagnosed in Australia. Most laboratories are using a test called the ELISA test. This test is not sensitive enough to detect most cases of this illness. There is a large body of scientific opinion that this test should be abandoned because of the high rate of false negatives.²⁴

2.40 Mr Christopher Walker, Acting Chief Executive Officer of the Karl McManus Foundation, was unequivocal in his assessment of the two-tier protocol:

The complicated nature of *Borrelia* infections makes it highly possible for laboratory tests to miss an infection, for multiple reasons. One of the biggest flaws in the current Australian *Borrelia* or Lyme disease testing is the singularity presumption—that is, a presumption that a negative test result is a positive confirmation that one does not have a *Borrelia* infection. Permit me to repeat that: there is a presumption that a negative test result is a positive confirmation that one does not have a *Borrelia* infection.²⁵

2.41 Dr Richard Horowitz similarly questioned the logic behind the protocol, concluding that ELISA lacks the necessary sensitivity to detect ongoing infection:

According to these guidelines, an immunoblot is not to be performed if the ELISA is negative, despite the poor sensitivity of ELISA tests ranging from 34 to 70.5%.²⁶

The problem with that is if you look at the scientific literature carefully, the scientific literature is supporting that the ELISA test is not reliable...these organisms can persist. I think the literature is there.²⁷

24 Dr Peter Dobie, Secretary, Australian Chronic Infectious and Inflammatory Disease Society (ACIIDS, formerly the Australian Chronic Infectious Disease Society, ACIDS), *Committee Hansard*, 15 April 2016, p. 19.

25 Mr Christopher Walker, Acting Chief Executive Officer, Karl McManus Foundation, *Committee Hansard*, 2 November 2016, p. 45.

The Karl McManus Foundation is a charity funding research into tick-borne diseases.

26 Dr Richard Horowitz, *Submission 936*, p. 10.

27 Dr Richard Horowitz, *Committee Hansard*, 2 November 2016, p. 4.

2.42 Dr McManus concurred, describing *Borrelia* as complex and possessing a considerable capacity for mutation which makes testing difficult:

The testing is problematic because the bacteria *Borrelia* has got very variable, hypervariable genomes. Basically, it can mutate inside you. If I had a rat injected in one leg with one genome species of *Borrelia* and I took blood from the other leg, I can get a different genospecies. That is not normal; you do not normally find that. If I inject a rat with a *staph. aureus*, or a golden staph, I get the golden staph, but a different strain, not a different genospecies. The reason for this is that this bacteria: (1) can mutate a lot; and (2) it has a lot of phages, or bacterial viruses. I can give you an example. Golden staph has got only one phage, and it is very difficult to eradicate from hospitals because of the way it develops a tolerance to all the treatment protocols. You have a *Borrelia*, the *burgdorferi* one in the US has 21 phages. That means it can dress itself in so many different ways that it can hide in your body—it can change from vector to vector; it can be in a tick; it can be in a deer; it can be in a human—because it has the capacity to change itself so enormously. I do not think that is really understood by the scientific community or by the clinicians.²⁸

2.43 The committee put this to Professor Graves. He indicated that having hypervariable genomes was not particular to *Borrelia*, but instead could be said of all microbes. He reiterated that the accuracy of the two-tiered protocol in use by the majority of laboratories is not impeded by the hypervariable genomes:

This problem doesn't apply to serological assays that detect antibodies, as a wide variety of antibodies of different specificities that are produced by a patient in response to an infectious agent.

Those persons who believe that Lyme Disease occurs in Australia can always point to minor defects in certain assays that may result in the assay not detecting the occasional patient with Lyme Disease due to a rare variability in the patient or the bacterium. But this would not be the case for the majority of patients and the fact that no genuine patients have been detected, by a variety of laboratory assays, strongly points to the conclusion that this infection [Lyme Disease] does not occur naturally in Australia.

The patients who claim to have Lyme Disease have something else wrong with them, whether an infection transmitted by tick bite or not remains to be seen. They clearly need help but giving them the wrong diagnosis does not help them!²⁹

2.44 The committee noted the contradictory evidence.

2.45 Dr Richard Schloeffel, Chairperson of ACIIDS, challenged the role which has been ascribed to laboratory testing, making the point that pathology should only be used to confirm a doctor's clinical assessment, not the other way around. The tests

28 Dr Mualla McManus, *Committee Hansard*, 15 April 2016, p. 28.

29 Professor Stephen Graves, answer to question on notice, received 15 November 2016.

most commonly used, Dr Schloeffel, stated, were of little use in patients who are immunosuppressed:

The tests are not good enough. The bugs are varied. There are viruses, parasites and bacteria. Pathology is very secondary. Sure, do no harm, but do not lie to your patient that they are not sick because the test was negative.³⁰

2.46 This was supported by Ms Jennie Burke, Director of Australian Biologics, who clarified how the devastating effect *Borrelia* has on patients' immune system makes detection through ELISA, which looks for an immune response, uncertain:

With tests that rely on an immune response, again *Borrelia* is difficult, as it has a devastating effect on the patient's immune system, which may lead to abhorrent effects in tests. With other infections you would expect the patient to produce IgM antibodies in the initial stage and, three to six months later, the antibodies to seroconvert to IgG antibodies. With *Borrelia*, however, patients may show no antibodies at all. They may not seroconvert and can remain IgM positive for greater lengths of time than usual.³¹

2.47 Australian Biologics does not use the two-tier protocol to detect *Borrelia* infection. This is explored below.

Other testing protocols

2.48 There are a number of laboratories which do not use the two-tier testing protocol, and which have reported positive results for Australian patients who have never travelled to known Lyme-endemic areas overseas. The laboratories most 'Lyme-literate'³² doctors prefer to use are:

- Australian Biologics Testing Services, a Sydney-based laboratory which is not yet accredited with NATA;³³
- ArminLabs, a German laboratory with a focus on Lyme disease which is in the process of accreditation with the German accreditation body, Deutsche Akkreditierungsstelle (DAkkS);³⁴

30 Dr Richard Schloeffel, Chairperson, ACIIDS, *Committee Hansard*, 2 November 2016, p. 55.

31 Ms Jennie Burke, Director, Australian Biologics, *Committee Hansard*, 2 November 2016, p. 12.

32 The term 'Lyme-literate' is used by some clinicians, patients and advocacy groups to denote doctors who have expertise in Lyme disease and Lyme-like illness beyond that of the mainstream medical establishment. For more see Chapter 2 of the committee's interim report.

33 It is important to note that discussion of laboratory competence should not be linked to discussion of NATA accreditation. NATA has stated that it makes no judgement about the competence of non-accredited laboratories. The committee understands that Australian Biologics is aiming to secure NATA accreditation in the near future. See Mrs Nicole Bailey, Assistant Stakeholder Relations Manager, NATA, *Committee Hansard*, 2 November 2016, p. 10; Dr Hugh Derham, *Submission 453*, p. 2; Dr Adam Nuttall, *Submission 601*, p. 2.

34 <http://www.arminlabs.com/en>. See Dr Hugh Derham, *Submission 453*, p. 2; Dr Adam Nuttall, *Submission 601*, p. 2.

- Infectolab in Germany, which is accredited by DAkkS;³⁵ and
- IGeneX, a US-based laboratory which specialises in Lyme Disease and associated tick-borne diseases.³⁶

2.49 Australian Biologics offers three types of testing for *Borrelia*—DNA testing, or Polymerase Chain Reaction (PCR), an immunoblot test imported from Germany, and EliSpot testing, also from Germany. Australian Biologics uses these tests because of a perceived lack of sensitivity of ELISA testing:

Earlier ELISA testing was known to have poor sensitivity whereas the newer ImmunoBlot assays using recombinant antigens have a much higher level of sensitivity. The EliSpot Lymphocyte Transformation Test is useful to show if an infection is active.³⁷

2.50 A submission from Australian Biologics explains that the PCR test is the gold standard for the detection of bacterial infection:

PCR is one of the most sensitive methods utilised to detect microbial pathogens in clinical specimens. This is particularly necessary when specific pathogens, difficult to culture in vitro or are known to be of low level in blood, tissue and other samples, are to be detected. The diagnostic value of PCR is known to be significant.³⁸

False positives vs false negatives

2.51 The committee held an additional public hearing partly with the aim of clarifying the apparent discordance in test results obtained from different laboratories, however this failed to provide conclusive answers.³⁹ In short, evidence on the presence of *Borrelia* in Australia was once again contradictory. However, two laboratories testing for the same infection but getting different results cannot both be right—it is an issue of false positives versus false negatives.⁴⁰

2.52 When asked about the rate of false negatives of ELISA, Professor Graves assured the committee the tests have a high degree of sensitivity and are not likely to miss infections. On the contrary, it appears ELISA is more likely to return a false positive than false negative:

35 See Dr Hugh Derham, *Submission 453, Attachment 1*, p. 11; Dr Adam Nuttall, *Submission 601*, p. 2.

36 www.igenex.com. See Dr Richard Schloeffel, *Submission 2, Attachment 1*, p. 7.

37 Australian Biologics Testing Services, *Submission 545*, p. 1.

38 Australian Biologics, *Submission 545*, p. 2.

39 A detailed discussion of alternative testing protocols, including arguments presented for and against their use, is contained in the committee's interim report and is not repeated here.

40 A 'false positive' is a test result that indicates that a person has an illness when they do not; a 'false negative' is a test result that indicates that a person does not have a particular disease when they in fact do.

Probably close to zero as it is a very sensitive assay and won't miss many cases. However, many of the "positive" results will not be genuine Lyme Disease as the assay has poor specificity.

In my lab, the Australian Rickettsial Reference Laboratory, the genuine cases of Lyme Disease that we have diagnosed [all in travellers returning from overseas and infected in endemic countries] the ELISA assay has always been positive.⁴¹

2.53 Professor Graves suggested that Australian Biologics must be getting false positive results:

I would never refer a specimen to a nonaccredited laboratory so I never refer specimens to Jenny because I do not think that her laboratory is doing the tests properly. I think she is getting a lot of false positives. That is where the difference is. I hear everybody laughing but that is the bottom line. I think that she is putting out a lot of false positives for Lyme disease, mycoplasma and whatever so I do not have confidence in her testing; therefore, I would not refer to her.⁴²

2.54 However, the committee noted that there is no concrete evidence to support the conclusion that Australian Biologics is returning false positives.⁴³

2.55 The committee sought to clarify, through a question taken on notice, whether testing protocols used by Australian Biologics were peer reviewed:

Yes, we have swapped samples (both positives and negatives) with the Reference Laboratory for Borreliosis in the Czech Republic. We detected all the samples they sent us and they detected all the samples we sent them. The six research papers on *Borrelia* to which we contributed used our PCR testing and the same samples were also tested by Prof Eva Sapi at New Haven University. Prof. Sapi is well known for her work on *Borrelia*. We have also had correlations in PCR testing with Professor Vett Lloyd at Mt. Alison University and since 2012 we have participated in a Quality Assurance Programme offered by QCMD (Quality Control Molecular Diagnostics), based at Glasgow University. We now have 5 years of results showing 100% correct detection of *Borrelia* through QCMD. Dr. Peter Mayn published "Clinical Determinants of Lyme Borreliosis, babesiosis, bartonellosis, anaplasmosis, and ehrlichiosis in an Australian cohort" in 2014 (paper is attached) which compared our testing to that of Igenex. Our positivity rate for *Borrelia* was given as 59% and Igenex as 58%. This is very good confirmation of both laboratories' testing.⁴⁴

2.56 Professor Graves suggested that his laboratory and Ms Burke's might do well to compare the assays they use in order to ascertain why they are getting different results:

41 Professor Stephen Graves, answer to question on notice, received 15 November 2016.

42 Professor Stephen Graves, *Committee Hansard*, 2 November 2016, p. 16.

43 *Committee Hansard*, 2 November 2016, pp. 16–17.

44 Australian Biologics, answer to question on notice, received 17 November 2016, pp. 2–3.

What usually happens in a situation like this is that different labs will compare their assays so we would take a common QAP, quality assurance process, sample. They would go to different laboratories and be tested to see whether or not they are getting the same results. That is how we normally do it. There may be, say, just for argument's sake, six or seven different assays for detecting antibodies for Lyme disease used in Australian laboratories. They will all have slightly different sensitivities and specificities but on the whole most of them will give the same answer—positive if it is truly positive or negative if it is truly negative. That is how we do it. Strictly speaking, what we should do is Jennie [Ms Burke, Director, Australian Biologics] and I should exchange specimens and methodologies and see why we are not getting the same results.⁴⁵

2.57 Representatives of the Karl McManus Foundation suggested that some of the confusion could be alleviated if laboratories stated the parameters and limitations of their results when these are provided.⁴⁶

2.58 Clarity around these issues may be within reach, however. As noted in the committee's interim report, the department has contracted the National Serology Reference Laboratory (NSRL) to conduct a review of serological assays used to diagnose Lyme disease. The review is looking at assays used in Australia and overseas.⁴⁷

2.59 The NSRL provided an update on the status of the review:

- We have received approximately 650 specimens from the collaborators in UK, Germany, US and Australia, along with the results the collaborators obtained for those specimens.
- We have collected 308 specimens prospectively from Australian blood donors who have not travelled outside Australia.
- The collaborators have informed us of the serology assays they use to test for Lyme Disease.
- NRL has purchased sufficient of each of these assays to test all collaborator and blood donor specimens on all assays.
- We are in the process of testing the specimens now.
- The specimens are being tested in a blind manner. By that I mean that the specimens are labelled with an NRL identifier, not the identifier from the collaborator. Therefore we do not know the origin of the specimens or the results obtained by the collaborators

45 Professor Stephen Graves, *Committee Hansard*, 2 November 2016, p. 17.

46 Mr Christopher Walker, *Committee Hansard*, 2 November 2016, p. 45.

47 Senate Community Affairs References Committee, *Growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients*, Interim report, May 2016, p. 57.

as we are testing them. Therefore we cannot say anything at the moment about what the results are showing.⁴⁸

Committee view

2.60 This inquiry has highlighted what is now decades-old disagreement on whether classical Lyme disease can be contracted in Australia. The committee acknowledges evidence provided by Australian medical authorities indicating that accredited laboratories—following established best-practice testing processes—have not found classical Lyme disease in Australian patients, with the exception of those who most likely contracted the disease overseas. This is what leads many in the medical profession to the conclusion that classical Lyme disease is not endemic to Australia.

2.61 However, while ever the issue of test quality remains contentious, the committee warns against ruling out the possibility that these bacteria are endemic to Australia. The committee is not satisfied that enough has been done to examine testing processes used by laboratories such as Australian Biologics. In the absence of such examination, the committee does not support an *a priori* conclusion that those test results are false positives.

2.62 Furthermore, the very fact that the reliability of the two-tiered testing protocol for Lyme disease is being questioned by respected doctors and scientists is, in the committee's view, reason enough for authorities to give careful consideration to these doctors' concerns. This notwithstanding, acknowledging the controversy does not in itself constitute proof of the inadequacy of the two-tiered testing protocol. The committee notes that work on developing new tests for Lyme disease is underway overseas and urges Australian medical authorities to remain apprised of the development of these tests.

2.63 The committee notes the NSRL review currently underway with interest. It is the committee's hope that this review will be conducted in a transparent manner and its findings published as anticipated. The committee expects that this review will provide some much-needed, conclusive answers, and enable the discourse on testing protocols to progress beyond the current impasse.

What is in our ticks?

2.64 Ticks in Australia, like ticks elsewhere, harbour a microcosm of bacteria, viruses and other pathogens. To reiterate, the department states that bacteria responsible for Lyme disease have not been identified in Australian ticks, and discovering such a bacterium is necessary before an evidence-based conclusion about the existence of Lyme disease in Australia—or a related illness—can be made:

The conclusive finding of a bacterium that could cause Lyme disease or a Lyme disease-like illness in Australia has yet to be made. Such a finding

48 National Serology Reference Laboratory, answer to question on notice, received 18 November 2016, p. 1.

would put beyond doubt the existence of Lyme disease, or a Lyme disease-like illness in Australia.⁴⁹

2.65 Many submitters and witnesses concurred with this position, and suggested an alternative explanation: that another, as yet unidentified pathogen, may be the likely cause of tick-borne illness in Australia.

2.66 Others however challenged the assertion that bacteria causing Lyme disease were not present in Australian ticks, providing evidence to support their views.

2.67 Both positions are explored below.

Is Lyme Borreliosis endemic in Australia?

2.68 The committee was provided with excerpts from doctoral research dating back to the early 1990s which alludes to the likely presence in Australian ticks of *Borrelia* associated with Lyme disease. The objectives of the research were as follows:

1. To determine whether Australian ticks carry and transmit spirochaetes related to *Borrelia burgdorferi*.
2. To develop a specific and sensitive sero-diagnostic test to assess whether or not there is a correlation between clinical illness and the presence of *Borrelia burgdorferi* specific antibodies in likely Australian LB [Lyme Borreliosis] candidates.
3. To assess the distribution of LB along the East Coast of Australia.⁵⁰

2.69 The research project was initiated in 1989 and concluded in 1994. It began with a focus on the Manning Valley in New South Wales (NSW), but expanded to include the Sydney and Hunter Valley regions of NSW as well.

2.70 The paper concluded that Lyme Borreliosis does exist indigenously in Australia, because patients who had never left Australia tested positive for *Borrelia* antigens and displayed corresponding clinical symptoms.⁵¹ Based on these findings, Dr Wills called for further research into:

1. Development of suitable cultural conditions for the growth and maintenance of Australian *B. burgdorferi*.
2. The molecular characteristics of Australian strains of *B. burgdorferi* so that a taxonomical comparison with existing genospecies can be obtained.
3. A more exact definition of the clinical manifestations of Australian Lyme disease and the immunological responses of patients.

49 Department of Health, *Submission 495*, p. 2.

50 Dr Stuart King, *Submission 1289, Attachment 1*, p. 1.

51 Lyme Disease Association of Australia, *Submission 528.1*, pp. 7–9

4. Determination of epizootiology of LB in Australia, and the importance of LB in Australian wild and domestic animal populations.⁵²

2.71 It is unknown to what extent this research has been pursued or reviewed. The department did, however, address this research in a scoping study conducted in 2013, concluding that the results were unable to be replicated:

To this date, there has only been one report of *Borrelia* species being found in *I. holocyclus* ticks, but the cultures were not confirmed and were unsustainable (Wills and Barry 1991)... Spirochaetes morphologically similar and antigenically related to *Borrelia burgdorferi* were cultured from the gut contents of *I. holocyclus* and *Haemophysalis spp.* ticks by Wills and Barry (1991), but the cultures weren't sustainable and these results have not been able to be repeated from ticks collected more recently.⁵³

2.72 The committee notes that the department does not conclusively rule out the presence of classical Lyme disease in Australia. Instead, the department expresses a more nuanced position, stating that there is no evidence to suggest the presence of the bacteria:

[T]he likelihood that Australia has an indigenous form of classical Lyme disease is questionable, given that a causative micro-organism with a competent vector is yet to be found. Whether a form of tick-borne human borreliosis exists in Australia is yet to be determined.⁵⁴

A different Borrelia?

2.73 Some witnesses suggest that—accepting that Lyme disease is caused by members of the *Borrelia burgdorferi* sensu lato complex which have not been found in Australia—a different species of *Borrelia* might be present in Australia:

On that basis, I would like to say that as far as I can see—from the patients' clinical symptoms, from the scientific research and from the preliminary results from the tick-borne disease unit—we do not have *Borrelia burgdorferi*, or Lyme disease, in Australia. What we have is a unique *Borrelia* infection. The problem with this disease is the symptoms are non-specific, so not every single Lyme patient ends up with the same set of symptoms. It is very hard to diagnose clinically. You can check the literature: every single publication will say the same thing. In the US they ask for a history of tick bite, and in certain areas like Connecticut it is common to have an EM rash, or the 'bull's-eye' rash, so diagnosis is easier. But in Australia the symptomology is much broader, and there are a lot more neurological symptoms. So you will end up with patients having seizures, patients having MS-like symptoms, patients having atypical Parkinson—atypical. Most of their symptoms are atypical, so a classical

52 Lyme Disease Association of Australia, *Submission 528.1*, p. 7.

53 Department of Health, *Submission 495, Attachment D*, pp. 8–14.

54 Dr Gary Lum, Department of Health, *Committee Hansard*, 2 November 2016, p. 58.

neurologist cannot put them in the perfect box of multiple sclerosis or whatever they are familiar with.⁵⁵

2.74 The plausibility of this theory is supported by other evidence. Dr Horowitz pointed out that identification of new strains of *Borrelia* is progressing at a rapid rate, suggesting that there may be far more species of *Borrelia* than are currently identified:

So with inadequate diagnostic testing, and with the multiple species of bacteria and parasites that are spreading with environmental toxins, the problem is that with over 100 strains of Lyme borreliosis in the United States and 300 strains worldwide, although most of them are not pathogenic, we are finding new species every two years. There have been 15 new *Borrelia* species discovered in the last 20 years. The problem is that the testing has a difficult time keeping up with it.⁵⁶

2.75 The committee notes that, as Dr Horowitz states above, most of the new species found are not pathogenic, they will not cause illness in humans. However, the identification of new strains of *Borrelia*, as well as other bacteria, in ticks around the world, including Australia, is of considerable significance to this inquiry, as it is possible that some will be found to be pathogenic.

2.76 The department noted the recent discovery of new *Borrelia* species in some Australian ticks, but cautioned against premature conclusions in the absence of thorough research:

The department welcomes the finding of new *Borrelia* species from ticks found on echidnas. This new *Borrelia* probably represents a new clade.⁵⁷ It is different from the *Borrelia* in the Lyme disease group, the relapsing fever group and the reptile group. While this is a significant finding, it is important not to jump to conclusions. Whether these micro-organisms cause disease in humans requires research into transmission and human pathogenicity. The same research group has been able to readily identify *Borrelia burgdorferi* sensu lato species in ticks collected from endemic areas overseas. This demonstrates that, to date, with state-of-the-art technology, there remains no evidence of a cause of classical Lyme disease in Australian ticks. The Australian government has previously highlighted, in the scoping study it commissioned, the importance of research not only in ticks but also in patients, and of the need to draw evidence-based connections, if they exist.⁵⁸

2.77 The committee looks at research underway in the next section.

55 Dr Mualla McManus, *Committee Hansard*, 15 April 2016, p. 28.

56 Dr Richard Horowitz, *Committee Hansard*, 2 November 2016, p. 2.

57 A clade is a group of organisms, usually species, more closely related to one another than any group, implying a shared recent ancestor.

58 Dr Gary Lum, Department of Health, *Committee Hansard*, 2 November 2016, p. 59.

Committee view

2.78 The committee notes contradictory evidence received on the subject of *Borrelia* in Australian ticks, and reiterates that it is beyond the scope of this inquiry to establish whether *Borrelia* species which may cause Lyme disease are to be found in Australian ticks. The committee acknowledges the prevailing view that contracting Lyme disease in Australia is not possible, that our ticks have been studied and found not to harbour known Lyme disease-causing pathogens.

2.79 However, the committee also notes that evidence challenging this position has been presented during this inquiry. The committee refers particularly to the research of Dr Michelle Wills, which has been provided in evidence by more than one submitter, with consent from Dr Wills. The committee is persuaded that steps should be taken by the medical authorities to conduct a review of this evidence afresh if this has not already been done. To be authoritative and conclusive, such a review must be conducted by an independent, qualified team of scientists, with its methodology and results published in full.

More research is needed

2.80 Scientific research will play a critical part in identifying the pathogen, or pathogens, responsible for tick-borne illness in Australia. The committee's interim report outlined research currently underway. This was explored further at an additional hearing, with new evidence presented by Professor Peter Irwin, representing the Vector- and Water-borne Pathogen Research Group at Murdoch university, on recently discovered potential pathogens:

Since the appearance of Professor Ryan and Dr Oskam before the committee, we have further characterised a number of bacteria which, in our opinion, represent potential candidates for tick-borne pathogens in Australia. These include *Neoehrlichia*, *Anaplasma*, *Ehrlichia* and *Borrelia*. Our work with *Borrelia* has confirmed that it is a unique Australian species. It is distinct from both the Lyme disease group and the relapsing fever disease group. Similar work with other bacterial species also reveals a unique phylogeny. Our conclusion, based on the evidence so far, is that Australian ticks harbour a relatively unique set of bacteria and therefore these are unknown to medical science in terms of their capacity to cause disease.⁵⁹

2.81 Professor Irwin has emphasised that it is not appropriate to link these newly identified bacteria to illness in humans.⁶⁰ The next logical step in this research, Professor Irwin advised, will be to look at which, if any, of the newly identified organisms found in Australian ticks can be transmitted to humans. This, Professor Irwin concludes, is critical to determining causation.⁶¹ Professor Irwin further

59 Professor Peter Irwin, Principal, College of Veterinary Medicine, Murdoch University, *Committee Hansard*, 2 November 2016, p. 25.

60 Department of Health, *Submission 495*, p. 4.

61 Professor Peter Irwin, *Committee Hansard*, 2 November 2016, p. 25.

explained that after potential pathogens are identified, work will need to be done to assess the impact these may have on humans:

There are several phases in this research. Ours is to form the building blocks of what is here in the ticks. The whole determination of disease causation by which of those bugs could cause disease in people is a further set of work that will require quite significant epidemiological type studies.

We are actually intending to start work in that space. We intend to apply for an NHMRC grant next year—in the next main funding round—to support this work. We are starting to gather together collaborators—doctors in various parts of Australia who see patients with tick bites. We want to investigate them in a longitudinal fashion to follow those patients into the future.⁶²

2.82 Professor Irwin reported having received a new grant which will fund some studies over the next three years, but called for an urgent increase in funding through the National Health and Medical Research Council (NHMRC):

The NHMRC is the most relevant funding agency. However, an understanding of the importance, or relevance, of research into Lyme-disease-like illness may not be appreciated by all the reviewers and independent experts. We are aware of a grant application on this topic that was recently rejected by the NHMRC that scored relatively poorly for the category of 'significance'. I note also that Professor Kelso explained the NHMRC funding process in her submission to the committee in April, and I am encouraged by her comments that the NHMRC is putting in place targeted calls for research, which may recognise the priorities of not only government but also the wider Australian community. I believe that funding for research into tick-borne diseases in Australia is urgently needed.⁶³

2.83 Research is also underway at the tick-borne diseases unit at Sydney University, which is currently conducting a study looking at whether ticks in Australia carry *Borrelia* or similar bacteria. The committee notes that the research has not been published yet, but that conclusive, direct evidence of *Borrelia* known to cause Lyme disease has not been found, but that other *Borrelia* have been found.⁶⁴

2.84 Professor Irwin and Dr Ann Mitrovic⁶⁵ both extrapolated a further conclusion from the research already conducted: serological testing currently available, discussed earlier in this chapter, is quite likely ill-equipped to identify infection by the pathogens most likely at play in Australia:

I heard the end of the discussion previously on serological testing, and, to my mind, it somewhat completely misses the point—that all the tests that are available at the moment are developed against known bacteria and

62 Professor Peter Irwin, *Committee Hansard*, 2 November 2016, p. 26.

63 Professor Peter Irwin, *Committee Hansard*, 2 November 2016, p. 25.

64 See discussion, *Committee Hansard*, 2 November 2016, pp. 25–26.

65 Dr Ann Mitrovic is a Research Fellow with the Tick-Borne Diseases Unit, School of Medical Sciences (Pharmacology), University of Sydney.

disease. That is what they are designed for. I believe the Australian situation is completely different. We have organisms here that may be causing disease—we do not know what they are yet; we are working on that. In order to develop tests that are going to be more specific for what we have going on here, we need to isolate those organisms and develop tests from them.⁶⁶

2.85 In making the same point, Dr Mitrovic brought the committee back to the issue of laboratory testing. In the US and Europe, where new strains of *Borrelia* are being discovered, these are not able to be detected by tests looking for infection with the *Borrelia burgdorferi* sensu lato complex.⁶⁷

2.86 The committee notes evidence indicating that international bodies are expanding definitions around Lyme disease to include more than one strain of *Borrelia* and a number of co-infections.⁶⁸

Committee view

2.87 The committee notes evidence outlined above indicating that unique pathogens have already been identified in Australian ticks, and that pathology tests currently conducted in Australia are not designed to look for those newly-identified pathogens. The committee is of the view that funding should be made available for this research to continue and be expanded as a matter of priority.

2.88 The committee is persuaded that it is possible that these unique pathogens may be causing Lyme-like illnesses and therefore further work is urgently needed to identify these pathogens and links to Lyme-like illnesses.

2.89 The committee however urges caution against extrapolating too much from the discovery of possible new pathogens, supporting the department's view that nothing should be assumed without further research.⁶⁹

Recommendation 1

2.90 The committee recommends that the Australian Government Department of Health engage with stakeholders following the publication of the National Serology Reference Laboratory review to discuss the findings of the review and any bearing those may have on testing for Lyme disease in Australia.

Recommendation 2

2.91 The committee recommends that the Australian Government increase funding for research into tick-borne pathogens as a matter of urgency. This funding should include:

- **funding for research on pathogens which may cause infection;**

66 Professor Peter Irwin, *Committee Hansard*, 2 November 2016, p. 27.

67 Dr Ann Mitrovic, *Committee Hansard*, 2 November 2016, p. 27.

68 Ms Sharon Whiteman, President, Lyme Disease Association of Australia, *Committee Hansard*, 2 November 2016, p. 43.

69 See Department of Health, *Submission 495*, p. 4.

- **funding for research on whether newly-identified pathogens can cause illness in humans; and**
- **funding for the development of diagnostic tests which can detect infection by any newly-identified pathogens endemic to Australia.**

Chapter 3

Treating the illness

My father taught me to swim with the rip, and that is how my children and I have survived. I am treading water, holding up two children. The medical system is stuck on the rocks. Way before Lyme I learnt that the medical profession does the best it can, but they are swamped and they do not know everything. I see the responses from authorities added to the inquiry. They are debating if the rip exists, how they can test if it is a true rip and who has the accreditation required to tell if it is a rip. I am so relieved to see people on the beach now, but I need to know that you are not just going to write a report about what you see. I need decisions to be made that will save my children from sinking. I want my children and I to please receive the critical, effective and timely treatment that we need.¹

3.1 It will be some time before scientists are able to conclusively identify the pathogen, or pathogens, responsible for tick-borne illness in Australia. This is a critical step in the evolution of our understanding and response to tick-borne illness in Australia. For this reason, in the previous chapter the committee recommended that funding for research into tick-borne disease be prioritised. But the answers that research will bring may be years away, and people need action now.

3.2 Despite continued disagreement around the science, two important facts have emerged over the course of this inquiry: there is considerable evidence indicating that the illness we are looking at is tick-borne, and almost unanimous agreement that people with this illness must be helped.

3.3 The experiences patients have described are of great concern to the committee. Many report being dismissed by general practitioners and infectious disease specialists. Some report being turned away from hospitals and denied treatment upon mentioning the words 'Lyme disease'. Others report being shuttled from misdiagnosis to misdiagnosis over a number of years, eventually only to be told 'it's all in your head'.

3.4 This inquiry shows that there are too many people presenting with tangible symptoms for this assessment to be accurate. While the committee cannot independently verify patients' accounts, it has no reason to doubt their veracity. Put simply, this many people cannot be making themselves this sick.

3.5 Throughout this inquiry, the committee has sought to place patients who are unwell and in need of treatment front and centre.

1 Ms Julianne Hansen, *Committee Hansard*, 15 April 2016, p. 42.

Existing treatment pathways

Exactly seven years ago today I was in a hospital bed with my daughters at my side. Under my pillow was a letter telling them how much I love them and what good girls they were in case I died. Six months earlier I had over 20 nymph tick bites. I had fevers and sweats all night, and the next day the doctor gave one course of antibiotics. One week later, with heart symptoms, I was sent home from the hospital, told I had anxiety and given Valium, which I refused. After seeing every doctor and natural therapist I could for six months, barely able to walk, sleep or eat, I spent one week in hospital. Again, I was told I had anxiety and was sent home with Xanax. It was living hell.²

3.6 In its interim report the committee described treatment pathways available for people who acquired Lyme disease overseas, and treatment pathways for illness acquired in Australia. The committee recognised that many people, like the witness quoted above, felt let down by the health system, and that more should be done to educate the public and medical professionals about the risk of tick bites and tick-related illness.³

3.7 The committee also noted that Australia's health care system could be improved to better meet the needs of people with chronic illness, and that the illness in question would benefit from greater attention from the medical authorities.

3.8 The committee heard that a lack of treatment options and the resulting desperation was driving many Australian sufferers to seek treatment for Lyme-like illness overseas. On top of this, treatment locally and abroad is often expensive, and may leave vulnerable patients open to financial exploitation.⁴

3.9 Given the number of people suffering the chronic, debilitating symptoms associated with Lyme-like illness, it is clear that more must be done.

3.10 The following section of this report will look at evidence presented on treatment recommended by doctors who have diagnosed patients with Lyme-like illness, and who are at the frontline in the management of this disease.

First do no harm

3.11 As with most aspects of this inquiry, appropriate treatment for patients with Lyme-like illness was a contentious issue.

3.12 The Australian Medical Association (AMA), the nation's foremost membership organisation representing medical practitioners, explained that doctors

2 Ms Dianne Ellis, *Committee Hansard*, 2 November 2016, p. 34.

3 Chapter 2, Senate Community Affairs References Committee, *Growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients*, Interim report, May 2016.

4 Chapter 2, Senate Community Affairs References Committee, *Growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients*, Interim report, May 2016.

have a responsibility to rely on evidence to determine a diagnosis and treatment plan. The AMA set out its position in a submission to the committee:

Medical practitioners do their utmost to accurately diagnose the cause of an illness and provide an appropriate treatment. Doctors support the patient in understanding their condition and what they might expect, define circumstances when patients' symptoms could have several causes, identify and advise on appropriate treatment or preventive options. A doctor's duty of care is to make an accurate diagnosis or state that there is insufficient evidence for a specific diagnosis...

...To date there has been no evidence to support the existence of *Borrelia burgdorferi* (*Borrelia*) in Australia...In the absence of a conclusive aetiology of an indigenous vector for Lyme disease or a Lyme-like disease, diagnosis remains difficult and patients are frustrated when their illness is not easily diagnosed or treated. The AMA understands that this sentiment is genuine and that a failure to reach a conclusive diagnosis can be stressful, however the medical profession's role is to make clinically appropriate treatment recommendations based on the best available evidence. It is ethically and legally appropriate for doctors to refuse demands by patients, patients' family members or other third parties for tests, treatments or procedures that are not clinically appropriate.⁵

3.13 The committee did not receive any submissions disputing the call for medical treatment to be ethical and safe. The question of what constitutes clinically appropriate treatment for an illness with an undefined causative agent, however, can be seen from a number of perspectives. On one hand, there is a risk of misdiagnosis, as there is with any illness. On the other, denial of treatment in the absence of certainty around the diagnosis may arguably also contribute to an adverse outcome.

The risk of misdiagnosis

3.14 As seen above, the AMA highlights the responsibility of doctors to make evidence-based diagnoses. This is echoed by other organisations, such as the Medical Council of New South Wales (MCNSW). The MCNSW expressed concern about the harm caused by misdiagnosis and drew the committee's attention to complaints from the public and medical professionals about the performance of some doctors who have diagnosed Lyme-like illness in the absence of confirmation from an accredited laboratory:

Additionally, in those patients with serious underlying diseases, including cancers, misdiagnosed as "Lyme-like illness" and treated for long periods with repeated courses of antibiotics there has been progression of the underlying disease in the absence of the patient receiving timely and appropriate therapy.⁶

3.15 A submission from the Medical Board of Australia (MBA) and the Australian Health Practitioner Regulation Agency (AHPRA) similarly indicated that medical

5 Australian Medical Association, *Submission 456*, p. 1.

6 Medical Council of New South Wales, *Submission 935*, p. 2.

authorities are aware of concerns about treatment being administered for Lyme-like illness. Specifically, there is a concern that the diagnosis might be premature and as such may preclude more appropriate treatment for other conditions:

There is a concern that patients may be deprived of the opportunity to have more appropriate treatment for another condition because the alternative condition is not considered once Lyme-like illness has been diagnosed. Treating Lyme-like illness with long-term antibiotic treatment, in the absence of an identified infection, is of concern. This management is at odds with advice from public health authorities regarding the dangers of antibiotic resistance. We understand that some practitioners are prescribing and administering antibiotics for years (whereas the treatment of Lyme disease is for weeks).⁷

3.16 A submission from the Infectious Diseases Department at Austin Health, Melbourne, describes work and treatment undertaken with a cohort of patients who believe they have Lyme-like illness and who were referred to Austin Health for assessment. It was determined that, of these patients:

- 30-50% have potentially serious medical conditions that have either been previously undiagnosed, diagnosed but inappropriately treated, or diagnosed but denied by the patient such that no treatment was sought.
- 10-20% have a serious defined psychiatric illness that requires specialist care
- 80-90% have undergone substantial financial hardship paying for investigations from unaccredited laboratories and, in some cases, prolonged antibiotic treatment that has had no (or minimal) objective evidence of benefit.
- The current specialty-based medical approach to managing these patients is inappropriate. Instead, a multi-disciplinary approach is required to better assess these patients, including specialist physicians (e.g. infectious diseases, rheumatology and oncology), psychiatrists (with a special expertise in so-called conversion disorders) and primary care physicians (GPs) with an interest in the long-term care of patients with chronic disease. A specific funding model should be considered since the current system is inhibitory to this approach.⁸

3.17 It is unclear how the sample of patients referred to Austin Health was selected; however, the conclusions infer a considerable instance of inappropriate diagnosis and treatment.

3.18 The committee's interim report discussed the stigma feared by doctors who treat tick-borne disease in Australia, citing numerous reports of threats and

7 Medical Board of Australia and Australian Health Practitioner Regulation Agency, *Submission 533*, p. 3.

8 Infectious Disease Department, Austin Health, *Submission 820*, p. 2.

intimidation by the medical authorities. Patients reported feeling anxious that their doctors would have complaints made against them or be sanctioned for attempting to treat the illness.

3.19 The committee discussed complaints against practitioners who treat Lyme disease or Lyme-like illness with AHPRA and the MBA, and was informed that the vast majority of complaints do not result in regulatory action. Only three doctors currently 'have conditions on their practice relating to Lyme or Lyme-like illness.'⁹

3.20 The committee notes that despite these statistics, there are claims of intimidation by AHPRA.¹⁰

The risk of inaction

3.21 A number of medical practitioners with experience in treating the tick-borne illness in question discussed the risk of medical inaction and over-reliance on pathology tests. They argued that chronically ill patients need safe, appropriate treatment even when a definitive pathological cause is elusive. Medicine, as pointed out by the Karl McManus Foundation, 'is not static but constantly changing':¹¹

In a situation where the causative agent is not well characterised treatment protocols are not likely to be within the realm of mainstream medicine.¹²

3.22 Dr Richard Schloeffel, chairperson of the Australian Chronic Infectious and Inflammatory Diseases Society (ACIIDS), argued that diagnosis should begin with observation, which in this case is that Australian ticks are making people sick:

We have to recognise there are things in our ticks that we have not fully identified yet. When you make an observation, what happens is the evidence will follow the observation. But chance favours only the prepared mind. If the mind is not prepared, you will not make that A equals B equals Z. You cannot join the dots if you are not able to make that transition. That is why it has not moved forward with the doctors. I do not think they are hearing the patient. This is a clinical diagnosis before anything else.¹³

3.23 Dr Schloeffel highlighted the importance of clinical diagnosis, making the point that pathology should be used to verify, not guide a doctor's clinical diagnosis:

A pathology test should only confirm your thought process, not the other way around. We are clinicians. Doctors are properly trained, hard thinking and intelligent people who make a decision clinically, and then the test verifies our thought process. The tests are inadequate because the patient is immunosuppressed. The tests are not good enough. The bugs are varied.

9 Associate Professor Stephen Bradshaw, Practitioner Member, Medical Board of Australia, *Committee Hansard*, 2 November 2016, p. 60.

10 Karl McManus Foundation, answer to question on notice, received 18 November 2016, p. 4.

11 Karl McManus Foundation, answer to question on notice, received 18 November 2016, p. 1.

12 Karl McManus Foundation, answer to question on notice, received 18 November 2016, p. 1.

13 Dr Richard Schloeffel, Chairperson, Australian Chronic Infectious and Inflammatory Diseases Society, *Committee Hansard*, 2 November 2016, p. 50.

There are viruses, parasites and bacteria. Pathology is very secondary. Sure, do no harm, but do not lie to your patient that they are not sick because the test was negative. It is not helpful; it is not good medicine.¹⁴

The most important thing when you have patients who are sick is to listen to the patient. If you do not listen to the patient you will not make a diagnosis. Forget about ELISA test versus Western Blot and all these other things. These patients come to me, referred to me by other specialists, other doctors. I have 800 people on a waiting list. I have letters like this one from people telling me their child is going to die if they do not have treatment.¹⁵

3.24 Dr Schloeffel described the magnitude of the situation and the urgent need for action, estimating that 40 000 to 50 000 Australians may have this illness.¹⁶ He explained that diagnosis is neither quick, nor simple, and is evidence-based:

I started looking at this disease 20 years ago. I have become very interested in it of late because we seem to have more and more patients with this. People are coming forward with motor neurone disease, chronic fatigue syndrome, fibromyalgia, autism spectrum disorder, dementia, multiple sclerosis, Parkinson's disease. I have seen all of those patients multiple times. I have had 17 of my patients die and I have three of them dying at the moment. They will die from this illness. They got a tick bite and they are going to die. Most of them talked to 20 or 30 doctors before they got to us. We diagnosed them with Australian testing and overseas testing and developed what we called levels of evidence. But it was in the clinical diagnosis and the absence of other disease that we decided this was this disease.¹⁷

3.25 Dr Richard Horowitz discussed tick-borne illness in Australia in a wider, international context, describing Lyme disease as a worldwide epidemic:

The National Science Foundation and the World Health Organization consider Lyme disease to be one of the pandemic diseases that is spreading worldwide right now.¹⁸

3.26 Dr Christopher Walker, representing the Karl McManus Foundation, a charity funding research into tick-borne diseases, suggested that medical authorities' lack of focus on tick-borne illness and debates around terminology in the absence of an agreed causative agent were having an adverse effect on progress in terms of diagnosis and treatment for patients. This inaction and dearth of support from medical authorities in some cases leaves patients looking for a diagnosis themselves, making them vulnerable to misinformation and exploitation:

14 Dr Richard Schloeffel, *Committee Hansard*, 2 November 2016, p. 55.

15 Dr Richard Schloeffel, *Committee Hansard*, 2 November 2016, p. 48.

16 Dr Richard Schloeffel, *Committee Hansard*, 2 November 2016, p. 49.

17 Dr Richard Schloeffel, *Committee Hansard*, 2 November 2016, p. 48.

18 Dr Richard Horowitz, *Committee Hansard*, 2 November 2016, p. 1.

Currently health practitioners are being discouraged from diagnosis and treatment of tick-borne diseases. This appears to be linked to the Lyme disease terminology and has seen a significant reduction in treating doctors. This reduction of available medical practitioners is forcing desperate people to turn to the likes of 'Dr Google' for answers. It must be said that 'Dr Google' presents one of the most disruptive and destructive forces in diagnosis and treatment of any tick-borne disease. There exists a plethora of individuals and organisations who are quick to reproduce and repost advice without any qualification or validation. One of the most extreme, misguided 'Dr Google' discourses identified is the claim that Lyme disease can be contracted from eating too much kale. A claim of nonsense in the extreme, but nonetheless published in a women's health magazine, readily available on 'Dr Google' and easily believed by those who know no better. We need our medical profession to be actively involved in the diagnosis and treatment of these diseases, even at this confounding juncture, and put paid to such subterfuge ignorance and outright incompetence.¹⁹

3.27 Mr Mike Pym, Director of the Karl McManus Foundation, called for action based on current best practice, telling the committee that waiting for research to be conclusive would cause harm:

[W]e have to have a treatment protocol for this 'new name' set of symptoms now. We cannot wait for more science. We have to work out what is best practice now, draw a line in the sand, acknowledge that that is what is good enough and then move on—but get all of the doctors using best practice now. We all know that it will not be perfect, but it is better than watching people die. Simply doing nothing is not doing no harm; it is letting people suffer and die on your watch.²⁰

Committee view

3.28 The committee notes concerns expressed by medical authorities about the potential for misdiagnosis and inappropriate treatment in a situation where the cause of illness is not entirely clear. The committee shares these concerns.

3.29 At the same time, however, the committee recognises that complex, emerging diseases require treatment even in the absence of definitive research. As put by Dr Schloeffel, 'the science has not caught up, but the compassion needs to be there.'²¹

3.30 Recognising that it is not a medical body, the committee agrees in principle that in situations where other causes have been appropriately considered and ruled out, doctors should have access to the best available treatment guidelines for Lyme-like, tick-borne disease.

19 Dr Christopher Walker, Acting Chief Executive Officer, Karl McManus Foundation, *Committee Hansard*, 2 November 2016, p. 46.

20 Mr Mike Pym, Director, Karl McManus Foundation, *Committee Hansard*, 2 November 2016, p. 47.

21 Dr Richard Schloeffel, *Committee Hansard*, 15 April 2016, p. 23.

3.31 The committee acknowledges the work and experience of medical professionals treating this illness, and supports calls for the treatment options they have developed to be trialled more broadly in consultation with medical authorities.

Establishing a treatment protocol

3.32 Aware of the need for medical professionals to balance the risks involved in addressing an unknown or emerging disease, the committee sought evidence on how patients can receive treatment in a safe environment.

3.33 To this end, the committee held an additional hearing on 2 November 2016, at which treatment was discussed with a number of witnesses. To establish what is current best practice, the committee consulted representatives from the Karl McManus Foundation, Dr Schloeffel representing ACIIDS, and Dr Horowitz, a US-based practitioner specialising in the treatment of Lyme disease and related infections. The evidence they presented was discussed with the department, the MBA and AHPRA.

3.34 The committee invited the AMA and Royal Australian College of General Practitioners to participate in this discussion, however representatives were not available at the time of the hearing.

Effective treatment

3.35 The Karl McManus Foundation described the lack of agreement in the medical community on how best to address tick-borne disease:

Generally doctors in Australia are also split into two groups, the mainstream who will consider acute treatment and offer palliative care for chronic TBDs (ie: post Lyme syndrome). While holistic doctors are aware that when pathogens have disseminated into other tissues a broad approach may be needed which may require not only prolonged treatment of disseminated infections but also supporting the immune system and providing the right nutrients for patient recovery.²²

3.36 Holistic doctors treat what they refer to as chronic illness. This, the committee heard, is because tick-borne disease is complex and often involves more than just one single, acute infection:

The patients that I see with Lyme disease do not just have *Borrelia burgdorferi* sensu lato. What they end up having is many other species of bacteria, viruses and parasites because the ticks are now containing many of these different species and are rapidly spreading.²³

3.37 In Australia, doctors treating the disease frequently see patients presenting with symptoms consistent with relapsing fever. Dr Schloeffel postulated that research would ultimately confirm this to be the case:

Borreliosis is from a spirochete organism. It can cause all sorts of symptoms. It can go anywhere. There are multiple species. There is one in America called Lyme disease, but what we have here—I am sure a lot of

22 Karl McManus Foundation, answer to question on notice, received 18 November 2016, p. 4.

23 Dr Richard Horowitz, *Committee Hansard*, 2 November 2016, p. 1.

the patients I see have a relapsing fever type of *Borrelia*. That would be consistent with what Peter Irwin is finding in those ticks. We just have to join the dots between what he finds in echidna ticks and what I see in my patients.²⁴

3.38 The committee heard that the co-infections Dr Horowitz and Dr Schloeffel describe can in some cases lead to death if not adequately treated.²⁵ Treatment, however, is not simple, and involves more than fighting infection with antibiotics. Patients first of all need to be stabilised before antibiotics can be used to fight infection:

Treatment is not throwing antibiotics at people. I totally agree with my colleagues about the overuse or the difficulty of giving just antibiotics. You have to resuscitate the patient. These people are sick. They get brain fog, fits and seizures. Some of them are psychotic and some of them are depressed. They get pounding, vice-like headaches, seizures, twitches, body pain and POTS [postural orthostatic tachycardia syndrome²⁶]. Their blood pressure is really low and they cannot do anything—they stand up and they collapse. Their bowels do not work and they have racking pain in their body. Their body temperature is often 34—three degrees below normal—because their thyroids are failing and they get adrenal failure. If you give someone like that antibiotics to start with, they are just going to get much sicker. So we have to resuscitate the patients.²⁷

3.39 The committee understands that Dr Schloeffel, together with colleagues Dr Peter Dobie and Dr Hugh Durham, is in the process of drafting new evidence-based guidelines for diagnosis and treatment of tick-borne illness in Australia:

It will have no authority except we will try and get some backing from infectious disease specialists. I will show it to the chief medical officer and Gary Lum, because it is important that they have a look at it. But it will go out irrespective of how they think about it. It is not a dangerous document. It is a factual document based on evidence that we will present. It will be a guideline and it will be up to the individual doctors to make a decision but at least it is a guideline. If we start treating patients who get a tick bite, or something that bites, in the first instance they may not end up like this lot of people who have suffered.²⁸

3.40 The committee understands that the guidelines will move away from the term 'Lyme' and refer instead to tick-borne illness as 'Multiple Systemic Infectious Disease

24 Dr Richard Schloeffel, *Committee Hansard*, 15 April 2016, p. 49.

25 Dr Richard Schloeffel, *Committee Hansard*, 15 April 2016, p. 49.

26 Postural orthostatic tachycardia syndrome (POTS) is a condition in which sufferers experience an abnormal heart rate increase when they change from a supine to an upright position.

27 Dr Richard Schloeffel, *Committee Hansard*, 15 April 2016, p. 49.

28 Dr Richard Schloeffel, *Committee Hansard*, 15 April 2016, p. 50.

Syndrome, as suggested by Dr Horowitz.²⁹ They will be peer reviewed by two infectious disease specialists, then forwarded to the department.³⁰

3.41 The committee discussed these guidelines with the department, and was advised the department was aware of the draft and engaging with Dr Schloeffel on the content:

In discussion with Dr Schloeffel, the department provided information on how he can modify the ACIIDS guidelines which he is currently writing to be included in the National Health and Medical Research Council's clinical guidelines portal. The department will also continue to encourage Dr Schloeffel, along with his ACIIDS members, to work with academic units in medical schools to develop NH&MRC grant applications for patient based research.³¹

3.42 The committee understands the new treatment guidelines will be complete and ready for dissemination by the end of 2016 or early 2017.³²

3.43 The committee also approached the Karl McManus Foundation on the topic of treatment guidelines, and was informed that the Foundation had not validated any treatment protocols as yet and therefore could not recommend a particular protocol. The Foundation did, however, recognise that different treatment protocols may be required for acute and chronic disease:

Keen to see current best practise to be implemented immediately the KMF recognise that the Infectious Diseases Society of America (IDSA) present best practise treatment protocol for treatment of ACUTE forms of Lyme disease while International Lyme and Associated Diseases Society (ILADS) have developed best practise protocol for CHRONIC conditions. It is noted that the ILADS practice of long term antibiotic therapy is disputed by some and the two societies are split over TBDs treatment.³³

3.44 A submission from ACIIDS states that their views are closely aligned with those of ILADS and provided the committee with current treatment guidelines—the committee notes that these advocate cautious use of antibiotics where needed.³⁴

3.45 ACIIDS reports a considerable patient recovery rate, with peer review of this treatment conducted in Europe and the US:

In relation to the recovery rate of patients, of which the ACIIDS group of doctors have treated over 4,000, the general consensus is that 60-80% of

29 Dr Richard Horowitz, see *Submission 936*, p. 1.

30 ACIIDS, answer to question on notice, received 17 November 2016, p. 2.

31 Dr Gary Lum, Principal Medical Adviser, Office of Health Protection, Department of Health, *Committee Hansard*, 2 November 2016, p. 59.

32 ACIIDS, answers to questions on notice, received 17 November 2016, p. 3.

33 Karl McManus Foundation, answer to question on notice, received 18 November 2016, p. 3.

34 ACIIDS, *Submission 370, Attachment 24*. ILADS treatment guidelines can be found at <http://www.ilads.org/lyme/treatment-guideline.php> (accessed 23 November 2016).

our patients have considerable or complete recovery with appropriate treatment.³⁵

3.46 The committee asked the department about its consultations with ACIIDS. The department provided the following on its engagement with the organisation:

The department has met with medical practitioners who are treating patients. This has included meetings with members of the Australian Chronic Infectious and Inflammatory Diseases Society, separate meetings with Dr Richard Schloeffel and a treatment roundtable which brought together nine treating general practitioners along with other specialist medical practitioners to consider treatment options. Dr Lum has also attended a two-day meeting of the International Lyme and Associated Diseases Society.³⁶

3.47 The committee welcomes this engagement, and notes Dr Schloeffel's call for government support:

I am happy to have doctors sit in with me and I will teach them how to diagnose, treat and help these patients, but then someone else has to take them on. So we need funding for hospitals. We need an intellectual and a committed effort from the health departments, national and state, in our public system to help everybody who thinks they might have this illness...I do not think I am right or wrong; I am just seeing clinical evidence of a disease that needs to be managed...[I]t has got to come from the health minister, the Department of Health and the senior colleagues who direct policy and thought process, who have to say, 'Stop! We've got to stop. We've got to go over here. Maybe we got it wrong.' Admit you are wrong and come and talk to us. Actually make something happen. Support a pilot program with the Karl McManus Foundation. Let's look at 100 patients straight-up. Let's fund that. Let's do some proper medicine. Let's study that. Then we get 100 more. Then you will have 10,000 waiting in the queue. But they can be treated in all these peripheral hospitals, and doctors with interest and skill can start treating them. It is a process. I think that is the answer.³⁷

Committee view and conclusion

3.48 The committee concludes its inquiry without clarity on diagnosis or treatment of this illness. Given the magnitude of the dispute around tick-borne illness in Australia this is perhaps unsurprising.

3.49 What is clear, however, is that potentially infectious pathogens are being transmitted by Australian ticks, and treatment for the ensuing illnesses is currently suboptimal. The committee therefore returns to its starting premise: people are sick, and they must be helped. That people report avoiding engagement with medical staff at Australian hospitals for fear of being branded 'crazy' is concerning. That some

35 ACIIDS, answer to question on notice, received 17 November 2016, p. 1.

36 Department of Health, answer to question on notice, received 21 November 2016, p. 5.

37 Dr Richard Schloeffel, *Committee Hansard*, 2 November 2016, p. 51.

patients are contemplating suicide as a result, in part, of their distress at not receiving what they believe to be proper medical attention and care, is profoundly disquieting. The committee has no cause to doubt the veracity of these accounts.

3.50 Any suggestion that doctors should only treat patients if and when they have pinpointed the cause of illness is troubling—whilst not being comprised of medical professionals, the committee is persuaded that emerging diseases require safe and responsible treatment even when the science is in progress. Notwithstanding the absence of definitive answers on what the responsible pathogens are, it is the committee's view that medical authorities and doctors have a responsibility to address and treat illness. The patients are not responsible for the absence of vital research establishing which pathogens carried by which vectors are responsible for Lyme-like illness—this evidence is needed, and urgently, but so is treatment for patients who are unwell now.

3.51 The best possible treatment protocols need to be established as a matter of priority, and medical professionals educated on their use. The committee urges medical authorities to take advantage of the momentum created by this inquiry and consult extensively with researchers and clinicians focusing on tick-borne disease. With the right commitment from medical professionals and authorities, these treatment protocols will be refined and improved over time.

3.52 For this reason, the committee is recommending that treatment guidelines currently in use by doctors who claim significant recovery rates in their patients be assessed and a clinical trial conducted to determine their effectiveness. In parallel with scientific research into possible pathogens which is currently underway, this clinical trial of treatment protocols will serve to inform an evolving, evidence-based response to tick-borne disease. The committee urges medical authorities to act on this recommendation without delay and in consultation with relevant stakeholders including the Karl McManus Foundation and ACIIDS.

3.53 Patients cannot be asked to wait. The science will catch up, and it is critical that funding be made available for this to happen.

Recommendation 3

3.54 The committee recommends that government medical authorities, in consultation with stakeholders including the Australian Chronic Infectious and Inflammatory Diseases Society (ACIIDS) and the Karl McManus Foundation, establish a clinical trial of treatment guidelines developed by ACIIDS with the aim of determining a safe treatment protocol for patients with tick-borne illness.

Recommendation 4

3.55 The committee recommends that the Australian Government allocate funding for research into medically-appropriate treatment of tick-borne disease, and that medical authorities measure the value of treatment in terms of patient recovery and return to health. The best treatment options must then be developed into clinical treatment guidelines.

Recommendation 5

3.56 The committee recommends that the Australian Government Department of Health facilitate, as a matter of urgency, a summit to develop a cooperative framework which can accommodate patient and medical needs with the objective of establishing a multidisciplinary approach to addressing tick-borne illness across all jurisdictions.

Recommendation 6

3.57 The committee recommends that federal, state and territory health agencies, through the Council of Australian Governments Health Council, develop a consistent, national approach to addressing tick-borne illness.

Recommendation 7

3.58 The committee recommends that the Australian Government Department of Health urgently undertake an epidemiological assessment of the prevalence of suspected tick-borne illness in Australia, the process and findings of which are to be made publicly available.

Recommendation 8

3.59 The committee recommends that the Australian Government Department of Health establish the prevalence and geographical distribution of overseas-acquired Lyme disease in Australia.

Recommendation 9

3.60 The committee recommends that Australian medical authorities and practitioners addressing suspected tick-borne illness:

- consistently adopt a patient-centric approach that focusses on individual patient symptoms, rather than a disease label; and
- remove 'chronic Lyme disease', 'Lyme-like illness' and similar 'Lyme' phrases from diagnostic discussions.

Recommendation 10

3.61 The committee recommends that, to help the referral of patients for guided and comprehensive pathology testing, medical practitioners work with pathologists, especially microbiologists, immunologists, chemical pathologists and haematologists to optimise diagnostic testing for each patient.

Recommendation 11

3.62 The committee recommends that the Australian Government Department of Health work closely with the Australian Medical Association and Royal Australian College of General Practitioners to ensure that general practitioners have a better understanding of how to treat patients who present with complex symptoms.

Recommendation 12

3.63 The committee recommends that treatment guidelines developed by Australian medical authorities emphasise the importance of a multidisciplinary, case conference approach to patient care, involving consultation between general practitioners and specialists with expertise in neurology, psychiatry, rheumatology, immunology, infectious diseases and microbiology.

Senator Rachel Siewert

Chair

APPENDIX 1

Submissions and additional information received by the Committee

Submissions

- 1** Mrs Alexandra Patsan
- 2** Dr Richard Schloeffel (plus twelve attachments)
- 3** Confidential
- 4** Name Withheld
- 5** Ms Marie Corby
- 6** Confidential
- 7** Name Withheld
- 8** Name Withheld
- 9** Mr Greg Watts
- 10** Mr Charlie Cohen
- 11** Name Withheld
- 12** Name Withheld
- 13** Confidential
- 14** Mr Jeremie Smith
- 15** Miss Emily O'Sullivan
- 16** Confidential
- 17** Confidential
- 18** Name Withheld

- 19 Name Withheld
- 20 Ms Bev McMillan
- 21 Confidential
- 22 Name Withheld
- 23 Name Withheld
- 24 Mr Nick Knottenbeld
- 25 Confidential
- 26 Ms Sara Franzoni
- 27 Mr Paul Fenwick
- 28 Name Withheld
- 29 Ms Kylie Gilbert
- 30 Ms Trudi Bareham
- 31 Ms Nell Anderson
- 32 Name Withheld
- 33 Confidential
- 34 Name Withheld
- 35 Chris Wilson
- 36 Name Withheld
- 37 Name Withheld
- 38 Ms Kamisha Seale-Woodberry
- 39 Mr John Woodberry
- 40 Mr Alan Williams
- 41 Confidential

- 42 Name Withheld
- 43 Ms Angela Muzzin
- 44 Confidential
- 45 Name Withheld
- 46 Confidential
- 47 Mr Sean O'Donoghue
- 48 Confidential
- 49 Name Withheld
- 50 Name Withheld
- 51 Ms Kathy Brierley
- 52 Ms Samantha Coates
- 53 Name Withheld
- 54 Name Withheld
- 55 Name Withheld
- 56 Confidential
- 57 Name Withheld
- 58 Name Withheld
- 59 Confidential
- 60 Name Withheld
- 61 Name Withheld
- 62 Name Withheld
- 63 Name Withheld
- 64 Name Withheld

- 65 Mr Brad Shepherd
- 66 Confidential
- 67 Name Withheld (plus seven attachments)
- 68 Name Withheld
- 69 Confidential
- 70 Ms Christine Linigen
- 71 Ms Gail Petherick
- 72 Name Withheld
- 73 Ms Emily Miklovic
- 74 Ms Marie Saurine
- 75 Mr Glenn Gilbert
- 76 Mr Mathew Gilbert
- 77 Name Withheld
- 78 Name Withheld
- 79 Name Withheld
- 80 Name Withheld
- 81 Mrs Bronwyn Bungey (plus two attachments)
- 82 Name Withheld
- 83 Ms Cate Moloney
- 84 Name Withheld
- 85 Mr Mark O'Meara (plus an attachment)
- 86 Name Withheld
- 87 Confidential

- 88** Confidential
- 89** Name Withheld
- 90** Ms Sharon King
- 91** Name Withheld
- 92** Ms Jill Marley
- 93** Confidential
- 94** Name Withheld
- 95** Name Withheld
- 96** Name Withheld
- 97** Name Withheld
- 98** Country Women's Association of NSW (plus an attachment)
- 99** Name Withheld
- 100** Confidential
- 101** Name Withheld
- 102** Confidential
- 103** Ms Cornelia Mortimer
- 104** Ms Tiffany Cameron
- 105** Name Withheld
- 106** Mr Brendan Witham
- 107** Confidential
- 108** Mr Ross Floate
- 109** Ms Karin Floate
- 110** Name Withheld

- 111 Name Withheld
- 112 Name Withheld
- 113 Confidential
- 114 Name Withheld
- 115 Confidential
- 116 Name Withheld
- 117 Confidential
- 118 Mr Daniel Larking
- 119 Confidential
- 120 Confidential
- 121 Name Withheld
- 122 Name Withheld (plus five attachments)
- 123 Name Withheld
- 124 Name Withheld
- 125 Name Withheld
- 126 Name Withheld
- 127 Mr Chris Willis
- 128 Ms Dona Stobie
- 129 Ms Michelle Wood (plus an attachment)
- 130 Name Withheld
- 131 Ms Val Wright
- 132 Ms Tammorae Williamson
- 133 Name Withheld

- 134 Mr Lachlan Monks
- 135 Mrs Sue Monks
- 136 Name Withheld
- 137 Confidential
- 138 Name Withheld
- 139 Name Withheld
- 140 Ms Natalie Young (plus three attachments)
- 141 Ms Krystle Krenske
- 142 Ms Di Ellis
- 143 Ms Heidi Adams
- 144 Name Withheld
- 145 Mrs Christina Sinnamon
- 146 Name Withheld
- 147 Ms Vicki Hain
- 148 Ms Angela Milroy
- 149 Ms Margaret Adams
- 150 Ms Steph Hammersley (plus an attachment)
- 151 Ms Georgina Burston
- 152 Name Withheld
- 153 Name Withheld
- 154 Name Withheld
- 155 Name Withheld
- 156 Name Withheld

157 Mrs Neeva Stephen

158 Confidential

159 Name Withheld

160 Name Withheld

161 Ms Anita Morrison

162 Name Withheld

163 Name Withheld

164 Name Withheld

165 Name Withheld

166 Confidential

167 Confidential

168 Name Withheld

169 Name Withheld

170 Name Withheld

171 Confidential

172 Name Withheld

173 Confidential

174 Name Withheld

175 Name Withheld

176 Name Withheld

177 Confidential

178 Name Withheld

179 Name Withheld

- 180 Confidential
- 181 Mr Marcus Hewitt
- 182 Name Withheld
- 183 Name Withheld
- 184 Name Withheld (plus four attachments)
- 185 Name Withheld
- 186 Name Withheld
- 187 Name Withheld
- 188 Confidential
- 189 Name Withheld
- 190 Mr Kim Rhodes
- 191 Name Withheld (plus an attachment)
- 192 Confidential
- 193 Confidential
- 194 Name Withheld
- 195 Name Withheld
- 196 Name Withheld
- 197 Name Withheld
- 198 Name Withheld
- 199 Name Withheld
- 200 Name Withheld
- 201 Name Withheld
- 202 Name Withheld

203 Name Withheld

204 Confidential

205 Name Withheld

206 Name Withheld

207 Confidential

208 Confidential

209 Confidential

210 Confidential

211 Name Withheld

212 Name Withheld

213 Name Withheld

214 Name Withheld

215 Name Withheld

216 Name Withheld

217 Confidential

218 Name Withheld

219 Name Withheld

220 Name Withheld

221 Name Withheld

222 Name Withheld

223 Name Withheld

224 Confidential

225 Name Withheld

- 226 Name Withheld
- 227 Name Withheld
- 228 Confidential
- 229 Confidential
- 230 Confidential
- 231 Name Withheld
- 232 Name Withheld
- 233 Name Withheld
- 234 Name Withheld
- 235 Name Withheld
- 236 Name Withheld
- 237 Name Withheld
- 238 Confidential
- 239 Name Withheld
- 240 Mr Des O'Sullivan
- 241 Name Withheld
- 242 Confidential
- 243 Name Withheld
- 244 Mrs Carolyn O'Sullivan
- 245 Confidential
- 246 Name Withheld (plus an attachment)
- 247 Name Withheld
- 248 Name Withheld

249 Confidential

250 Confidential

251 Name Withheld

252 Name Withheld

253 Name Withheld

254 Name Withheld

255 Confidential

256 Name Withheld

257 Name Withheld

258 Confidential

259 Name Withheld

260 Name Withheld

261 Ms Linda Jones

262 Name Withheld

263 Name Withheld

264 Name Withheld

265 Name Withheld

266 Name Withheld

267 Name Withheld

268 Name Withheld

269 Name Withheld

270 Confidential

271 Name Withheld

272 Name Withheld

273 Name Withheld

274 Confidential

275 Name Withheld

276 Name Withheld

277 Name Withheld

278 Mr Max Russell

279 Name Withheld

280 Name Withheld

281 Name Withheld (plus an attachment)

282 Name Withheld (plus an attachment)

283 Confidential

284 Name Withheld

285 Name Withheld

286 Confidential

287 Name Withheld

288 Name Withheld

289 Name Withheld

290 Name Withheld

291 Name Withheld

292 Name Withheld

293 Ms Lynn Rees

294 Confidential

- 295 Name Withheld (plus an attachment)
- 296 Name Withheld
- 297 Confidential
- 298 Name Withheld
- 299 Name Withheld
- 300 Ms Nickey Carroll
- 301 Name Withheld
- 302 Name Withheld
- 303 Name Withheld
- 304 Name Withheld
- 305 Name Withheld
- 306 Name Withheld
- 307 Name Withheld
- 308 Name Withheld (plus an attachment)
- 309 Name Withheld
- 310 Name Withheld
- 311 Mr Chris Hain (plus four attachments)
- 312 Confidential
- 313 Name Withheld
- 314 Mr Stephen Bloomer
- 315 Ms Melissa Pym
- 316 Name Withheld
- 317 Mr Ryan O'Dea

- 318 Name Withheld
- 319 Name Withheld
- 320 Mr Allen Main
- 321 Confidential
- 322 Name Withheld
- 323 Ms Alison Veitch
- 324 Name Withheld (plus a supplementary submission)
- 325 Name Withheld
- 326 Confidential
- 327 Name Withheld
- 328 Name Withheld
- 329 Name Withheld
- 330 Name Withheld
- 331 Name Withheld
- 332 Name Withheld
- 333 Name Withheld
- 334 Name Withheld
- 335 Name Withheld
- 336 Name Withheld
- 337 Name Withheld (plus an attachment)
- 338 Name Withheld
- 339 Name Withheld
- 340 Name Withheld

- 341 Name Withheld
- 342 Name Withheld
- 343 Name Withheld
- 344 Name Withheld
- 345 Name Withheld
- 346 Ms Karen Winter
- 347 Name Withheld
- 348 Name Withheld
- 349 Name Withheld
- 350 Name Withheld
- 351 Mr John Curnow
- 352 Ms Connie Conlon
- 353 Name Withheld
- 354 Name Withheld
- 355 Name Withheld
- 356 Name Withheld
- 357 Ms Nancy Weir
- 358 Name Withheld
- 359 Name Withheld
- 360 Name Withheld
- 361 Name Withheld
- 362 Name Withheld
- 363 Confidential

364	Confidential
365	Confidential
366	Confidential
367	Name Withheld
368	Name Withheld
369	Name Withheld
370	Australian Chronic Infectious and Inflammatory Disease Society (plus forty one attachments)
371	Confidential
372	Name Withheld
373	Confidential
374	Name Withheld
375	Confidential
376	Name Withheld
377	Name Withheld
378	Mr Shane Moloney
379	Name Withheld
380	Name Withheld
381	Name Withheld
382	Ms Joanne Cassam
383	Name Withheld
384	Ms Jasmin Moran
385	Name Withheld

- 386 Name Withheld
- 387 Name Withheld
- 388 Ms Lara Coleman
- 389 Ms Allison Alexander
- 390 Name Withheld
- 391 Ms Susie Brown
- 392 Name Withheld (plus six attachments)
- 393 Name Withheld
- 394 Name Withheld
- 395 Name Withheld
- 396 Name Withheld
- 397 Name Withheld
- 398 Name Withheld
- 399 Mr Michael Reid
- 400 Name Withheld
- 401 Name Withheld
- 402 Name Withheld
- 403 Name Withheld
- 404 Name Withheld
- 405 Name Withheld
- 406 Mr Alex Lange
- 407 Ms Emily Rosner
- 408 Name Withheld

- 409** Name Withheld
- 410** Name Withheld
- 411** Name Withheld
- 412** Name Withheld
- 413** Name Withheld
- 414** Name Withheld
- 415** Mrs Marie Huttley-Jackson
- 416** Mr Carl Jackson
- 417** Ms Chrissy Carter
- 418** Ms Lynne Hogan
- 419** Ms Beki Seekamp
- 420** Ms Vikki Seekamp
- 421** Ms Claire O'Dea
- 422** Name Withheld
- 423** Ms Tahlia Smith
- 424** Name Withheld
- 425** Name Withheld
- 426** Name Withheld
- 427** Name Withheld
- 428** Mr Ray Pignataro
- 429** Ms Sarah Belmomte
- 430** Name Withheld
- 431** Mrs Christine Humphries

- 432 Mr Stephen Humphries
- 433 Name Withheld
- 434 Name Withheld
- 435 Ms Tracey Payne
- 436 Ms Roz Moore
- 437 Mr Terry Rowlands
- 438 Ms Ronda Rowlands
- 439 Name Withheld
- 440 Name Withheld
- 441 Name Withheld
- 442 Ms Jacqui Judd
- 443 Name Withheld (plus a supplementary submission)
- 444 Name Withheld
- 445 Ms Robyn Williams
- 446 Ms Betty Quick
- 447 Name Withheld
- 448 Name Withheld
- 449 Ms Lauren and Ms Sarah Parker (plus an attachment)
- 450 Ms Margaret Stewart
- 451 Dr Margaret Hardy
- 452 Dr Lance Sanders (plus two attachments)
- 453 Dr Hugh Derham (plus two attachments)
- 454 Public Health Laboratory Network

-
- 455 Australasian College of Dermatologists
- 456 Australian Medical Association
- 457 NSW Health
- 458 Professor Peter Collignon AM (plus six attachments)
- 459 Australian Rickettsial Reference Laboratory Foundation
- 460 Name Withheld
- 461 Name Withheld (plus an attachment)
- 462 Name Withheld
- 463 Name Withheld
- 464 Name Withheld
- 465 Name Withheld
- 466 Name Withheld
- 467 Name Withheld
- 468 Name Withheld
- 469 Name Withheld
- 470 Confidential
- 471 Dr Ivan Hooper (plus twelve attachments)
- 472 Ms Dale Ryan
- 473 Name Withheld
- 474 Name Withheld
- 475 Name Withheld
- 476 Name Withheld
- 477 Confidential

478	Confidential
479	Confidential
480	Name Withheld
481	Ms Violet Moloney
482	Name Withheld
483	Name Withheld
484	Name Withheld
485	Name Withheld
486	Name Withheld
487	Confidential
488	Name Withheld
489	Name Withheld
490	Name Withheld
491	Name Withheld
492	Name Withheld
493	Mr Anthony Docherty
494	Ms Kerry Mathews
495	Australian Government Department of Health (plus fourteen attachments)
496	Australasian Society for Infectious Diseases Inc (plus three attachments)
497	Murdoch University
498	Name Withheld
499	Confidential
500	Name Withheld

- 501 Name Withheld
- 502 Name Withheld
- 503 Name Withheld
- 504 Name Withheld
- 505 Name Withheld
- 506 Name Withheld
- 507 Confidential
- 508 Name Withheld
- 509 Name Withheld
- 510 Name Withheld
- 511 Name Withheld
- 512 Name Withheld
- 513 Name Withheld
- 514 Ms Isabelle Ghetti
- 515 Name Withheld
- 516 Name Withheld
- 517 Name Withheld
- 518 Name Withheld
- 519 Name Withheld
- 520 Mrs Valmae Price
- 521 Confidential
- 522 Name Withheld
- 523 Ms Annette Pollard (plus an attachment)

- 524 Ms Hellene Burling
- 525 Ms Diane Walker
- 526 Name Withheld
- 527 Country Women's Association of Australia
- 528 Lyme Disease Association of Australia (plus two supplementary submissions)
- 529 Western Australian Department of Health
- 530 Karl McManus Foundation
- 531 Communicable Diseases Network Australia
- 532 Royal College of Pathologists of Australasia
- 533 Medical Board of Australia and Australian Health Practitioner Regulation Agency
- 534 Dr Philip Stowell
- 535 Ms Carol Adams
- 536 Ms Michelle Nettle (plus two attachments)
- 537 Name Withheld
- 538 Mrs Linda Bourne
- 539 Name Withheld
- 540 Name Withheld
- 541 Ms Leanne Barsby
- 542 Name Withheld (plus an attachment)
- 543 Name Withheld
- 544 Name Withheld
- 545 Australian Biologics Testing Services Pty Ltd (plus a supplementary submission)

546	Professor Edward Holmes
547	Victorian Department of Health and Human Services
548	Name Withheld
549	Confidential
550	Name Withheld
551	Name Withheld
552	Name Withheld
553	Name Withheld
554	Confidential
555	Name Withheld
556	Confidential
557	Confidential
558	Name Withheld
559	Confidential
560	Name Withheld
561	Name Withheld
562	Name Withheld
563	Name Withheld
564	Name Withheld
565	Name Withheld
566	Name Withheld
567	Name Withheld
568	Name Withheld

569 Name Withheld

570 Name Withheld

571 Name Withheld

572 Name Withheld

573 Name Withheld

574 Dr Clare Middle

575 Name Withheld

576 Name Withheld

577 Name Withheld

578 Name Withheld

579 Confidential

580 Name Withheld

581 Mrs Daphne Bunt

582 Name Withheld

583 Name Withheld

584 Name Withheld

585 Confidential

586 Name Withheld

587 Name Withheld

588 Name Withheld

589 Name Withheld

590 Name Withheld

591 Name Withheld

592	Confidential
593	Name Withheld (plus a supplementary submission)
594	Confidential
595	Name Withheld
596	Confidential
597	Confidential
598	Name Withheld
599	Name Withheld
600	Confidential
601	Dr Adam Nuttall
602	Name Withheld
603	Ms Lisa Chatwin
604	Ms Jennifer Hall
605	Name Withheld
606	Name Withheld
607	Ms Jill Willis
608	Mr Ross McLagan
609	Ms Diane McLagan
610	Name Withheld
611	Ms Michelle Bowry
612	Ms Ellen Bailey
613	Name Withheld
614	Name Withheld

- 615** Name Withheld
- 616** Name Withheld
- 617** Name Withheld
- 618** Name Withheld
- 619** Ms Charlotte Markwick
- 620** Miss Amanda Petrie
- 621** Confidential
- 622** Name Withheld
- 623** Name Withheld
- 624** Mr Turker Sen
- 625** Name Withheld
- 626** Mr Philip Gardiner
- 627** Mrs Therese Perez
- 628** Name Withheld
- 629** Name Withheld
- 630** Mr Malcolm Gully
- 631** Name Withheld
- 632** Name Withheld
- 633** Ms Pam Rudd
- 634** Name Withheld
- 635** Dr Clifford Hawkins
- 636** Name Withheld
- 637** Name Withheld

638 Ms Jennifer Taylor

639 Name Withheld

640 Name Withheld

641 Ms Linda Epton

642 Ms Janine Clark

643 Name Withheld

644 Name Withheld

645 Name Withheld

646 Mr Anthony Jones

647 Name Withheld

648 Confidential

649 Name Withheld

650 Name Withheld

651 Name Withheld

652 Confidential

653 Ms Michele Mora

654 Ms Noeleen Mora

655 Name Withheld

656 Confidential

657 Name Withheld

658 Ms Coreena Chenhall

659 Ms Belinda Mears

660 Mr Greg Haylen

661 Mr Rod Chenhall

662 Name Withheld

663 Name Withheld

664 Name Withheld

665 Name Withheld

666 Confidential

667 Name Withheld

668 Name Withheld

669 Name Withheld

670 Name Withheld

671 Name Withheld

672 Mrs Roberta Verey

673 Mrs Tanya Chapman

674 Name Withheld

675 Confidential

676 Name Withheld

677 Name Withheld

678 Name Withheld

679 Name Withheld

680 Name Withheld

681 Name Withheld

682 Name Withheld

683 Ms Patricia Davies

684	Dr Ariane Kersting (plus three attachments)
685	Confidential
686	Name Withheld
687	Name Withheld
688	Name Withheld
689	Name Withheld
690	Name Withheld
691	Name Withheld
692	Name Withheld
693	Confidential
694	Name Withheld
695	Ms Janice Foster Response from Department of Health Response from Health Care Complaints Commission Response from NSW Health Response from Australian Medical Association
696	Confidential
697	Name Withheld
698	Name Withheld
699	Confidential
700	Name Withheld
701	Ms Deborah Davis
702	Confidential
703	Name Withheld
704	Name Withheld

- 705** Name Withheld
- 706** Name Withheld
- 707** Confidential
- 708** Ms Trudi Marchant
- 709** Name Withheld
- 710** Ms Josie Downes
- 711** Name Withheld
- 712** Ms Carolyn Ford
- 713** Name Withheld
- 714** Name Withheld
- 715** Name Withheld
- 716** Name Withheld
- 717** Name Withheld (plus a supplementary submission)
- 718** Name Withheld
- 719** Name Withheld
- 720** Name Withheld
- 721** Confidential
- 722** Confidential
- 723** Ms Pamela Connellan
- 724** Name Withheld (plus an attachment)
- 725** Name Withheld
- 726** Confidential
- 727** Ms Natalie Ross

728 Name Withheld

729 Name Withheld

730 Confidential

731 Name Withheld

732 Name Withheld

733 Name Withheld

734 Confidential

735 Name Withheld

736 Name Withheld

737 Name Withheld

738 Name Withheld

739 Name Withheld

740 Name Withheld

741 Name Withheld

742 Name Withheld

743 Name Withheld

744 Name Withheld

745 Name Withheld

746 Name Withheld

747 Name Withheld

748 Name Withheld

749 Name Withheld

750 Name Withheld

751	Confidential
752	Confidential
753	Name Withheld
754	Royal Australasian College of Physicians
755	Name Withheld
756	Name Withheld
757	Confidential
758	Mr Lindsay Neil
759	Combined Caravan Club of Victoria
760	Name Withheld
761	Name Withheld
762	Confidential
763	Name Withheld
764	Name Withheld
765	Confidential
766	Name Withheld
767	Name Withheld
768	Confidential
769	Confidential
770	Name Withheld
771	Confidential
772	Confidential
773	Confidential

774	Confidential
775	Confidential
776	Name Withheld
777	Name Withheld
778	Name Withheld
779	Name Withheld
780	Confidential
781	Australian Society for Microbiology
782	Confidential
783	Confidential
784	Name Withheld
785	Confidential
786	Name Withheld
787	Confidential
788	Name Withheld
789	Name Withheld
790	Confidential
791	Name Withheld
792	Name Withheld
793	Name Withheld
794	Confidential
795	Confidential
796	Name Withheld

797	Name Withheld
798	Confidential
799	Confidential
800	Name Withheld
801	Name Withheld
802	ME/CFS and Lyme Association of WA Inc
803	Name Withheld
804	Wildlife Health Australia
805	Name Withheld
806	Name Withheld
807	Name Withheld
808	Confidential
809	Name Withheld
810	Confidential
811	Confidential
812	Name Withheld
813	Name Withheld
814	Name Withheld
815	Name Withheld
816	Name Withheld
817	Name Withheld
818	Confidential
819	Name Withheld

-
- 820 Infectious Diseases Department, Austin Health
Response from Australian Biologics Testing Services
- 821 Mr Nigel Say
- 822 Lyme Australia Recognition and Awareness; and Global Lyme and Invisible
Illness Organisation Inc (plus three attachments)
- 823 Name Withheld
- 824 Name Withheld
- 825 Name Withheld
- 826 Name Withheld
- 827 Confidential
- 828 Confidential
- 829 Name Withheld (plus an attachment)
- 830 Name Withheld
- 831 Confidential
- 832 Name Withheld
- 833 Name Withheld
- 834 Name Withheld
- 835 Name Withheld
- 836 Name Withheld
- 837 Name Withheld
- 838 Name Withheld
- 839 Name Withheld
- 840 Name Withheld (plus an attachment)
- 841 Confidential

842 Confidential

843 Name Withheld

844 Name Withheld

845 Name Withheld

846 Confidential

847 Name Withheld

848 Name Withheld

849 Name Withheld

850 Name Withheld

851 Name Withheld

852 Name Withheld

853 Name Withheld

854 Ms Jen Thwaites

855 Confidential

856 Confidential

857 Confidential

858 Name Withheld

859 Name Withheld

860 Name Withheld

861 Name Withheld

862 Confidential

863 Name Withheld

864 Name Withheld

865 Name Withheld

866 Confidential

867 Confidential

868 Name Withheld

869 Confidential

870 Name Withheld

871 Name Withheld

872 Name Withheld

873 Confidential

874 Confidential

875 Name Withheld

876 Name Withheld

877 Confidential

878 Confidential

879 Name Withheld

880 Name Withheld

881 Name Withheld (plus an attachment)

882 Confidential

883 Name Withheld

884 Name Withheld

885 Name Withheld

886 Ms Magic Barclay

887 Name Withheld

888 Confidential

889 Name Withheld

890 Name Withheld

891 Name Withheld

892 Name Withheld

893 Name Withheld

894 Name Withheld (plus two attachments)

895 Name Withheld

896 Confidential

897 Name Withheld

898 Name Withheld

899 Confidential

900 Confidential

901 Name Withheld

902 Mr Ben Cavenagh

903 Name Withheld (plus an attachment)

904 Confidential

905 Name Withheld

906 Name Withheld

907 Name Withheld

908 Name Withheld

909 Confidential

910 Confidential

- 911 Confidential
- 912 Confidential
- 913 Name Withheld
- 914 Name Withheld
- 915 Name Withheld (plus four supplementary submissions)
- 916 Name Withheld
- 917 Dr David Weedon (plus two attachments)
- 918 Ms Janice Kruger
- 919 Name Withheld
- 920 Name Withheld
- 921 Ms Gillian Jones
- 922 Name Withheld
- 923 Ms Melitta Marr
- 924 Ms Melissa Turner
- 925 Mr Ryan Hollings
- 926 Name Withheld
- 927 Dr Joseph Dunn
- 928 Mr David Meyrick
- 929 Mrs Lesley Peterson
- 930 Ms Rochelle Meyrick (plus an attachment)
- 931 Ms Giovanna Triana Cuellar
- 932 Mr Dennis Johnson
- 933 Ms Colette Geier

- 934 Name Withheld
- 935 Medical Council of NSW
- 936 Dr Richard Horowitz
- 937 Ms Christina Cassar
- 938 Mr John Miller
- 939 Ms Leanne Bennie
- 940 Name Withheld
- 941 Confidential
- 942 Name Withheld
- 943 Name Withheld
- 944 Ms Jennifer Taylor (plus a supplementary submission)
- 945 Mr Donald Taylor
- 946 Ms Gloria Reddy
- 947 Name Withheld
- 948 Name Withheld (plus an attachment)
- 949 Confidential
- 950 Ms Marilyn Oldfield
- 951 Mr Joel Lange
- 952 Mr Rowen Privett
- 953 Mr John Eldred
- 954 Mrs Lisa Willis
- 955 Ms Lisa Oats
- 956 Ms Amanda Hogg

957 Confidential

958 Confidential

959 Mrs Vicki Ferguson

960 Name Withheld

961 Mrs Holly Sanders

962 Name Withheld

963 Name Withheld

964 Name Withheld

965 Ms Julieanne Ditchfield

966 Ms Janet Burgin

967 Name Withheld

968 Name Withheld

969 Name Withheld

970 Ms Naomi Hart

971 Name Withheld

972 Name Withheld

973 Name Withheld

974 Name Withheld

975 Name Withheld

976 Name Withheld

977 Name Withheld

978 Name Withheld

979 Name Withheld

- 980 Confidential
- 981 Ms Jenny Spencer
- 982 Name Withheld
- 983 Confidential
- 984 Confidential
- 985 Confidential
- 986 Name Withheld
- 987 Name Withheld
- 988 Name Withheld
- 989 Name Withheld
- 990 Name Withheld
- 991 Name Withheld
- 992 Australian Red Cross Blood Service
- 993 Name Withheld
- 994 Name Withheld
- 995 Ms Rhonda Johnson
- 996 Name Withheld
- 997 Name Withheld
- 998 Name Withheld
- 999 Confidential
- 1000 Confidential
- 1001 Name Withheld (plus an attachment)
- 1002 Ms Amanda Bramwell

1003	Confidential
1004	Confidential
1005	Name Withheld (plus a supplementary submission)
1006	Name Withheld
1007	Name Withheld
1008	Name Withheld
1009	Name Withheld
1010	Name Withheld
1011	Name Withheld
1012	Name Withheld
1013	Confidential
1014	Name Withheld
1015	Ms Sarah Limbrick
1016	Ms Elise Searson
1017	Confidential
1018	Name Withheld
1019	Name Withheld
1020	Name Withheld
1021	Name Withheld
1022	Name Withheld
1023	Name Withheld
1024	Name Withheld
1025	Confidential

1026 Name Withheld

1027 Name Withheld

1028 Name Withheld

1029 Name Withheld

1030 Mr Barry Gray

1031 Name Withheld

1032 Confidential

1033 Name Withheld

1034 Ms Emma Monteiro

1035 Name Withheld

1036 Name Withheld

1037 Name Withheld

1038 Name Withheld

1039 Confidential

1040 Confidential

1041 Name Withheld

1042 Name Withheld

1043 Name Withheld

1044 Name Withheld

1045 Name Withheld

1046 Ms Leanne Collingwood

1047 Mr Andrew Vilder

1048 Name Withheld

1049	Mr Jim Luxford
1050	Mr David Ellett
1051	Ms Karen New
1052	Ms Monika Gotthardt-Marshall
1053	Name Withheld
1054	Name Withheld
1055	Name Withheld
1056	Name Withheld
1057	Ms Ingeborg Kuiper
1058	Ms Tracey Pritchett
1059	Name Withheld
1060	Ms Julie Mills
1061	Name Withheld
1062	Confidential
1063	Name Withheld
1064	Ms Catherine Monteiro
1065	Name Withheld
1066	Name Withheld
1067	Ms Moira Martin
1068	Name Withheld
1069	Name Withheld
1070	Ms Deanne Powell
1071	Mr Michael and Ms Mary O'Neill

- 1072 Name Withheld
- 1073 Name Withheld
- 1074 Name Withheld
- 1075 Mr Phil Shaw
- 1076 Ms Emily Campbell
- 1077 Name Withheld
- 1078 Mr Frank Kipling
- 1079 Mr Alex Silva
- 1080 Name Withheld
- 1081 Ms Ailsa Burgess
- 1082 Ms Marian Slusny
- 1083 Name Withheld
- 1084 Ms Carole Adele (plus a supplementary submission)
- 1085 Name Withheld (plus an attachment)
- 1086 Name Withheld
- 1087 Ms Michelle Wheeler
- 1088 Mr Trevor Ryan
- 1089 Dr Karina Kennedy
- 1090 Ms Aydah Silva
- 1091 Mr Dave Main
- 1092 Name Withheld
- 1093 Name Withheld
- 1094 Name Withheld

1095	Ms Amanda Loren
1096	Mrs Lisette Studdert
1097	Ms Zowie Tydeman
1098	Name Withheld
1099	Mr Robert Cooper
1100	Name Withheld
1101	Name Withheld
1102	Name Withheld
1103	Name Withheld
1104	Ms Noela Hamilton
1105	Mr Simon Bremner
1106	Ms Kylie Hutcheon
1107	Ms Agnieszka Toole
1108	Dr Rachel Wells
1109	Name Withheld
1110	Name Withheld
1111	Ms Victoria Meyer
1112	Name Withheld
1113	Name Withheld
1114	Name Withheld
1115	Name Withheld
1116	Name Withheld
1117	Name Withheld

- 1118 Name Withheld
- 1119 Name Withheld
- 1120 Name Withheld
- 1121 Name Withheld
- 1122 Name Withheld
- 1123 Name Withheld
- 1124 Ms Elisha Parker
- 1125 Mr Laurie Seekamp
- 1126 Name Withheld (plus an attachment)
- 1127 Name Withheld
- 1128 Name Withheld
- 1129 Name Withheld
- 1130 Ms Molly Hannebery
- 1131 Mr Gerard Siero
- 1132 Name Withheld
- 1133 Ms Kristine Maunder
- 1134 Name Withheld
- 1135 Name Withheld
- 1136 Ms Clare Henry
- 1137 Name Withheld
- 1138 Name Withheld
- 1139 Ms Lisa-Jane Hunt
- 1140 Name Withheld (plus an attachment)

- 1141 Name Withheld
- 1142 Ms Kathy Nastov
- 1143 Ms Belinda Elliott
- 1144 Mr Lee Salman
- 1145 Ms Rachael Brice
- 1146 Ms Deborah Gleeson
- 1147 Name Withheld
- 1148 Name Withheld
- 1149 Name Withheld
- 1150 Ms Margaret Wilson
- 1151 Ms Kate Miljons
- 1152 Name Withheld
- 1153 Name Withheld
- 1154 Ms Tara Stevens
- 1155 Confidential
- 1156 Name Withheld
- 1157 Ms Mandy Stevens
- 1158 Mr Glen Wilkie
- 1159 Name Withheld
- 1160 Confidential
- 1161 Ms Shekinah Yammacoona
- 1162 Name Withheld
- 1163 Name Withheld

- 1164 Name Withheld
- 1165 Name Withheld
- 1166 Ms Bronwyn Smith
- 1167 Name Withheld
- 1168 Name Withheld
- 1169 Name Withheld
- 1170 Name Withheld
- 1171 Name Withheld
- 1172 Name Withheld
Response from NSW Health
- 1173 Name Withheld
- 1174 Name Withheld
- 1175 Name Withheld
- 1176 Confidential
- 1177 Name Withheld
- 1178 Name Withheld
- 1179 Confidential
- 1180 Confidential
- 1181 Name Withheld
- 1182 Name Withheld
- 1183 Name Withheld
- 1184 Name Withheld
- 1185 Name Withheld

1186 Name Withheld
1187 Name Withheld
1188 Confidential
1189 Confidential
1190 Confidential
1191 Confidential
1192 Confidential
1193 Confidential
1194 Confidential
1195 Confidential
1196 Confidential
1197 Confidential
1198 Confidential
1199 Confidential
1200 Confidential
1201 Confidential
1202 Confidential
1203 Confidential
1204 Confidential
1205 Confidential
1206 Name Withheld
1207 Name Withheld
1208 Name Withheld

- 1209** Name Withheld
- 1210** Name Withheld
- 1211** Name Withheld
- 1212** Mrs Sue Fuller
- 1213** Name Withheld
- 1214** Name Withheld
- 1215** Name Withheld
- 1216** Name Withheld
- 1217** Ms Suzanne Clementi
- 1218** Ms Sue McFarlane
- 1219** Name Withheld
- 1220** Name Withheld
- 1221** Mr Brett Jones
Response from Professor Stephen Graves
- 1222** Name Withheld
- 1223** Name Withheld
- 1224** Name Withheld
- 1225** Name Withheld
- 1226** Name Withheld
- 1227** Name Withheld
- 1228** Name Withheld
- 1229** Name Withheld
- 1230** Name Withheld

1231	Name Withheld
1232	Name Withheld
1233	Name Withheld
1234	Name Withheld
1235	Name Withheld
1236	Name Withheld
1237	Name Withheld
1238	Name Withheld
1239	Name Withheld
1240	Name Withheld
1241	Name Withheld
1242	Name Withheld
1243	Name Withheld
1244	Mr Kevin Bryant
1245	Name Withheld
1246	Dr James Read
1247	Name Withheld
1248	Ms Michelle Curry
1249	Ms Jan Curry
1250	Name Withheld
1251	Name Withheld
1252	Name Withheld
1253	Name Withheld

- 1254 Name Withheld
- 1255 Name Withheld
- 1256 Confidential
- 1257 Name Withheld
- 1258 Name Withheld
- 1259 Name Withheld (plus an attachment)
- 1260 Name Withheld
- 1261 Name Withheld
- 1262 Name Withheld
- 1263 Name Withheld
- 1264 Name Withheld
- 1265 Name Withheld
- 1266 Name Withheld
- 1267 Name Withheld
- 1268 Name Withheld (plus an attachment)
- 1269 Confidential
- 1270 Confidential
- 1271 Confidential
- 1272 Confidential
- 1273 Confidential
- 1274 Revd. Nikki Coleman
- 1275 Confidential

1276	Confidential
1277	Confidential
1278	Confidential
1279	Confidential
1280	Confidential
1281	Professor Noel Campbell
1282	Pluslife Perth Bone and Tissue Bank
1283	Confidential
1284	Confidential
1285	Confidential
1286	Confidential
1287	Confidential
1288	Confidential
1289	Dr Stuart King (plus two attachments)

Additional Information

- 1** Information, from Multiple Systemic Infectious Disease Syndrome Inc, received 9 May 2016
- 2** The Use of Dapsone as a Novel "Persister" Drug in the Treatment of Chronic Lyme Disease/Post Treatment Lyme Disease Syndrome, journal article, from Dr Richard Horowitz, received 31 October 2016
- 3** Are Mycobacterium Drugs Effective for Treatment Resistant Lyme Disease, Tick-Borne Co-Infections, and Autoimmune Disease, journal article, July 2016, from Dr Richard Horowitz, received 31 October 2016
- 4** Does Lyme disease exist in Australia?, from Dr Gary Lum, received 1 November 2016

- 5 Transhemispheric Exchange of Lyme Disease Spirochetes by Seabirds, journal article, from Dr Ann Mitrovic, received 24 November 2016

Answers to Questions on Notice

- 1 Answers to Questions taken on Notice during 14 April public hearing, received from Australasian College of Dermatologists, 14 April 2016
- 2 Answers to Questions taken on Notice during 14 April public hearing, received from Australasian College of Dermatologists, 14 April 2016
- 3 Answers to Questions taken on Notice during 14 April public hearing, received from Professor John Mackenzie, 21 April 2016
- 4 Answers to Questions taken on Notice during 14 April public hearing, received from WA Department of Health, 22 April 2016
- 5 Answers to Questions taken on Notice during 14 April public hearing, received from WA Department of Health, 27 April 2016
- 6 Answers to Questions taken on Notice during 14 April public hearing, received from Lyme Disease Association of Australia, 27 April 2016
- 7 Answers to Questions taken on Notice during 15 April public hearing, received from Australian Health Practitioner Regulation Agency, 26 April 2016
- 8 Answers to Questions taken on Notice during 20 April public hearing, received from National Association of Testing Authorities Australia, 26 April 2016
- 9 Answers to Questions taken on Notice during 20 April public hearing, received from Department of Health, 6 May 2016
- 10 Answers to written Questions on Notice, received from Professor Peter Collignon, 2 May 2016
- 11 Answers to written Questions on Notice, received from Department of Health, 6 May 2016
- 12 Answers to Questions taken on Notice during 14 April public hearing, received from Multiple Systemic Infectious Disease Syndrome Inc, 9 May 2016
- 13 Answers to Questions taken on Notice during 2 November public hearing, received from Royal College of Pathologists of Australasia, 15 November 2016
- 14 Answers to Questions taken on Notice during 2 November public hearing, received from Australian Chronic Infections and Inflammatory Diseases Society, 17 November 2016
- 15 Answers to Questions taken on Notice during 2 November public hearing, received from National Serology Reference Laboratory, 17 November 2016

-
- 16 Answers to Questions taken on Notice during 2 November public hearing, received from Australian Biologics Testing Services, 17 November 2016
 - 17 Answers to Questions taken on Notice during 2 November public hearing, received from Karl McManus Foundation, 18 November 2016
 - 18 Answers to Questions taken on Notice during 2 November public hearing, received from National Association of Testing Authorities, Australia, 18 November 2016
 - 19 Answers to Questions taken on Notice during 2 November public hearing, received from Department of Health, 21 November 2016

Correspondence

- 1 Response from Professor Peter Collignon to adverse comments made during the public hearing on 2 November 2016

Tabled Documents

- 1 Information, tabled by Lyme Disease Association of Australia, at Brisbane public hearing 15 April 2016
- 2 Diagram explaining Borrelia, tabled by Karl McManus Foundation, at Brisbane public hearing 15 April 2016
- 3 Journal article: Effects of Borrelia on host immune system: Possible consequences for diagnostics, tabled by Karl McManus Foundation, at Brisbane public hearing 15 April 2016
- 4 Information, tabled by Australian Biologics Testing Services, at Brisbane public hearing 15 April 2016
- 5 Opening statement, tabled by Department of Health, at Canberra public hearing 20 April 2016
- 6 Scientific papers, tabled by Department of Health, at Canberra public hearing 20 April 2016
- 7 Scientific papers, tabled by Department of Health, at Canberra public hearing 20 April 2016
- 8 Scientific papers, tabled by Department of Health, at Canberra public hearing 20 April 2016
- 9 Scientific papers, tabled by Department of Health, at Canberra public hearing 20 April 2016
- 10 Scientific papers, tabled by Department of Health, at Canberra public hearing 20 April 2016

- 11** Scientific papers, tabled by Department of Health, at Canberra public hearing
20 April 2016

APPENDIX 2

Public hearings

Thursday, 14 April 2016

International on the Water Hotel, Perth

Witnesses

Department of Health, Western Australia

MAK, Dr Donna, Public Health Physician, Communicable Disease Control
Directorate

FORBES, Professor David Alan, Senior Clinical Adviser, Office of the Chief Medical
Officer

Multiple Systemic Infectious Disease Syndrome Inc.

DANIELS, Ms Kathryn Mary (Kate), Chairperson

Sarcoidosis Lyme Australia

KELLY, Ms Elaine, Secretary

ME/CFS and Lyme Association of WA Inc.

LE PAGE, Mr Stephen George, Committee Member

Lyme Disease Association of Australia

VARY, Ms Rebecca Ellen, Volunteer

ASH, Ms Judith, Private capacity

BOWER, Ms Joanne, Private capacity

BROWN, Ms Natalie, Private capacity

BOOL, Ms Rebecca, Private capacity

DOWNIE, Mrs Leanne, Private capacity

EBDEN, Ms Linda, Private capacity

HAMERSLEY, Ms Stephanie, Private capacity

MONKS, Ms Sue, Private capacity

STEPHEN, Ms Melinda, Private capacity

STEPHEN, Ms Neeva, Private capacity

STEVEN, Mrs Meg, Private capacity

WEBB, Ms Leanne, Private capacity

WHITE, Ms Vicki, Private capacity

Australasian College of Dermatologists

ZAGARELLA, Associate Professor Samuel, Fellow

COLLIGNON, Professor Peter, Private capacity

DERHAM, Dr Hugh, Private capacity

NUTTALL, Dr Adam, Private capacity

ADAMS, Ms Carol, Private capacity

NETTLE, Ms Michelle, Private capacity

ERSEK, Ms Nikki, Private capacity

GUERINI, Ms Nicole, Private capacity

HUTTLEY-JACKSON, Ms Marie, Representative, Lyme Disease Association of Australia

KENT, Ms Jan, Private capacity

KURET, Ms Gabrielle, Private capacity

LIDDELL, Ms Carol, Private capacity

LIM, Mr Nick, Private capacity

SHEPHERD, Ms Val, Private capacity

WILLIAMS, Ms Amy, Private capacity

Vector and Waterborne Pathogens Group, Murdoch University

RYAN, Professor Una, Professor, Vector and Waterborne Pathogens Group, Murdoch University

OSKAM, Dr Charlotte, Lecturer, Murdoch University

MACKENZIE, Professor John Sheppard, Private capacity

Friday, 15 April 2016

Royal on the Park Hotel, Brisbane

Witnesses**Lyme Disease Association of Australia**

WHITEMAN, Ms Sharon Lee, President

Global Lyme & Invisible Illness Organisation Inc; and Lyme Australia Recognition & Awareness

SMITH, Ms Karen Ann, Co-President; and Founder

CHANT, Mr Mathew William, Private capacity

SULLIVAN, Mrs Meaghan, Private capacity

Australian Chronic Infectious and Inflammatory Disease Society

SCHLOEFFEL, Dr Richard John, Chairperson

DOBIE, Dr Peter, Secretary

Karl McManus Foundation, University of Sydney

McMANUS, Dr Mualla, Director

CURNOW, Mr John Arthur, Veterinarian

HARDY, Dr Margaret, Private capacity

BAKER, Mrs Wanda, Private capacity

BALLARD, Ms Ailsa Victoria, Private capacity

BARSBY, Ms Leanne Bridget, Private capacity

BRADLEY, Mrs Rhonda Ruth, Private capacity

CHAPMAN, Mrs Wendy, Private capacity

ELLIS, Ms Dianne Elizabeth, Private capacity

EVANS, Ms Yvonne Denise, Private capacity

GRAY, Mr Barry, Private capacity

HANSEN, Ms Julieanne, Private capacity

SEEKAMP, Ms Vikki, Private capacity

SIMONSEN, Mr Jason Andrew, Private capacity

Public Health Laboratory Network

BATES, Mr John Robert, Chair

Royal College of Pathologists of Australasia; and Australian Rickettsial Reference Laboratory

GRAVES, Professor Stephen Roger, Spokesman on Lyme Disease

Australian Biologics Testing Services Pty Ltd

BURKE, Ms Jennie Maree, Director

Australian Health Practitioner Regulation Agency

FLETCHER, Mr Martin, Chief Executive Officer

Medical Board of Australia

BRADSHAW, Associate Professor Stephen, Practitioner Member

Wednesday, 20 April 2016

Parliament House, Canberra

Witnesses

Department of Health

LUM, Dr Gary David, Principal Medical Adviser, Office of Health Protection

APPLEYARD, Ms Sharon, First Assistant Secretary, Office of Health Protection

BARDEN, Mr Graeme, Assistant Secretary, Health Protection Policy Branch, Office of Health Protection

National Health and Medical Research Council

KELSO, Professor Anne, Chief Executive Officer

National Association of Testing Authorities, Australia

STYZINSKI, Mr John, General Manager, Operations and Technical

MITCHELL, Mr John Cameron, Manager, Government Relations

GRIFFIN, Mr Andrew James, Deputy Sector Manager, Legal and Clinical Services

Wednesday, 2 November 2016

Portside Centre, Sydney

Witnesses

HOROWITZ, Dr Richard, Private capacity

Australian Biologics Testing Services Pty Ltd

BURKE, Ms Jennie, Director

Royal College of Pathologists of Australasia

GRAVES, Professor Stephen Roger, Spokesman on Lyme Disease

National Association of Testing Authorities

GRIFFIN, Mr Andrew, Deputy Sector Manager, Legal and Clinical Services

MITCHELL, Mr John Cameron, Manager, Government Relations

BAILEY, Mrs Nicole, Assistant Stakeholder Relations Manager

National Serology Reference Laboratory

BEST, Ms Susan, Director

IRWIN, Professor Peter, Principal, College of Veterinary Medicine

MITROVIC, Dr Ann, Research Fellow, Tick-borne Diseases Unit, School of Medical Sciences (Pharmacology), University of Sydney

CASKIE, Ms Fiona, Private capacity

ELLIS, Ms Dianne, Private capacity

FITT, Ms Megan, Private capacity

FLOATE, Mr Ross, Private capacity

FOSTER, Ms Janice, Private capacity

GUMIENIUK, Ms Lisa, Private capacity

HAFOURI, Ms Rita, Private capacity

HUTTLEY-JACKSON, Ms Marie, Private capacity

KELLY, Ms Elaine, Private capacity

KNEVITT, MS Rachel, Private capacity

PARKINSON, Ms Dayna, Private capacity

STEVENS, Ms Tara, Private capacity

ATTWOOD, Ms Lani, Private capacity

CHADWICK, Mr Jesse, Private capacity

CLULOW, Mr Adrian, Private capacity

CONNELLAN, Ms Pamela, Private capacity

DAVIS, Mrs Deborah, Private capacity

DAVIS, Mr Peter, Private capacity

HOLBEN, Mrs Tania, Private capacity

KERMODE, Miss Vivienne, Private capacity

MOTT, Mr Bruce, Private capacity

NASH, Ms Joanne, Private capacity

PEPPER, Mrs Roanna, Private capacity

PYM, Mr Michael, Private capacity

TOOLE, Mr Daniel, Private capacity

WINNER, Miss Tracey, Private capacity

Lyme Disease Association of Australia

WHITEMAN, Ms Sharon, President

Karl McManus Foundation

WALKER, Mr Christopher Peter, Acting Chief Executive Officer

PYM, Mr Mike, Director

Australian Chronic Infections and Inflammatory Diseases Society

SCHLOEFFEL, Dr Richard John, Chairperson

Department of Health

LUM, Dr Gary, Principal Medical Adviser, Office of Health Protection

Australian Health Practitioner Regulation Agency

HARDY, Mr Matthew, National Director, Notifications

Medical Board of Australia

BRADSHAW, Associate Professor Stephen, Practitioner Member