LYME DISEASE
ASSOCIATION OF AUSTRALIA
For Lyme Disease Awareness & Action

A patient perspective

Supplementary Submission to the Senate Inquiry on the Growing Evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients

Lyme Disease Association of Australia

November 2016

"In the fullness of time, the mainstream handling of chronic Lyme disease will be viewed as one of the most shameful episodes in the history of medicine because elements of academic medicine, elements of government and virtually the entire insurance industry have colluded to deny a disease. This has resulted in needless suffering of many individuals who deteriorate and sometimes die for lack of timely application of treatment or denial of treatment beyond some arbitrary duration".

Dr Kenneth B. Leigner

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Background

On 12 November 2015, the Senate referred the following matter to the Senate Community Affairs References Committee for inquiry and report:

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

The terms of reference are:

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.

Introduction

The Lyme Disease Association of Australia (LDAA) has provided a submission published as #528 prior to the suspension of the Inquiry.

As the Senate Committee has resumed its work under this Inquiry, following the election of a new Senate in the 45Th Parliament of Government, the LDAA provides a Supplementary Submission that covers:

- historical evidence not previously submitted as part of this inquiry;
- the LDAA's proposal for a Targeted Call for Research made on 16 September 2016 to the National Medical Health and Research Council;
- a statistical analysis of 432 of the submissions made to this Committee; and
- responses to Questions on Notice arising from the Senate Committee hearings.

Executive summary

Recommendations

In our previous submission #528, we proposed recommendations outlined below. In addition to those recommendations we draw the Committee's attention to further recommendations as a result of the Committee's Interim report, the considerable evidence we heard during the hearing and the additional papers and answers to questions on notice provided to the Committee. For simplicity these are separated.

Initial recommendations

We call upon the committee to recommend:

- the Council of Australian Governments (COAG) Health Council address a coordinated national response to Lyme-like disease as a matter of urgency
- a study of the prevalence and incidence of Lyme-like illness in Australia, including a clinical study of patients
- the National Health and Medical Research Council (NHMRC) provide funding to support the research set out by the Department of Health
- a legislative response be developed to ensure that Australian Lyme-patients receive the care they need in a safe and non-discriminatory health system
- the establishment of specialist, multi-disciplinary Lyme treatment clinics with services for patients
- expediting a solution to the diagnostic and testing issues outlined
- amendments to the diagnostic case definition to address the issues raised
- a broad education campaign be developed and rolled out, that includes:
    - mandatory education for all health professionals concerning Lyme and tick-borne infection that includes diagnosis, signs, symptoms and types of treatment with requirements for continuing education as more research emerges;
    - public dissemination for prevention and awareness;
    - occupational education for outdoor workers; and
    - prioritisation of funding and fellowships for researchers.
- the Government acknowledge the evidence of Lyme-like disease found in the overseas Lyme specialist laboratories that operate under the Mutual Recognition Arrangement (MRA). Advice to clinicians should be immediately updated to inform them about retrospectively accepting overseas testing results
- a progressive and contemporary approach to research that harnesses next generation sequencing and new molecular techniques to better understand the pathogens that reside in Australian ticks and how they can infect humans. This could be achieved by prioritising the following:
    - research into the potential pathogens that Australian ticks carry;
    - an epidemiological study that examines the habitant of vectors and hosts and how they come to be in contact with humans;
    - immediate development of diagnostic tests that recognise the pathogens being discovered; and
    - a tick borne disease research centre or Cooperative Research Centre (CRC).

Supplementary recommendations:

We further call upon the Committee to recommend:

- The systemic discrimination encountered by Australian patients of Lyme disease and Lyme-like illness is referred to the Australian Human Rights Commission for investigation and action, on behalf of all Australian patients.
- An independent investigation into:
    - the liability of pathology laboratories who report a false negative test result that delays proper diagnosis and treatment and appears to be based on fallacious circular reasoning; and the systemic failure to disseminate advice to the medical community that many Australians become unwell after tick bites and that existing pathology tests are unreliable;
    - the pathology accreditation process, that may be limiting available evidence of Australian tick borne pathogens;
    - the financial and professional interests of the many professionals associated with Lyme disease and Lyme-like illness who are outspoken opponents of the debate; there appears too many levels of conflict that remain undisclosed;
    - whether the state and federal health departments and associated medical bodies are acting in the interests of the patients or engaging in obscuration;
    - the culture and regulation of the medical profession that has facilitated the denial that there is a problem in Australia;
- The Department of Health develop an interim definition of Australian Lyme-like illness based on current world's best practice while the nation waits for the gap in knowledge to be addressed.
- That Australian Lyme-like illness is referred to the COAG agenda for collective resolution. This will highlight the gaps in the Australian health administration particularly between federal and state governments that has denied thousands of patients effective diagnostic tests and treatment for more than 20 years.
- The urgent need to alert the medical profession that the onset of tick borne chronic illness can, in many instances, be prevented by the prescription of readily available antibiotics within the first few weeks after a tick bite.
- That a full accounting of the decision making that determined the NSW Health Department's assertion there is 'no Lyme here' following the outcomes of the 1994 Russell & Doggett study, be obtained under Freedom of Information request. The Committee should seek to understand why the Wills & Barry research was not considered, or if it was, why it was discounted.
- That the NHMRC provide historical evidence of the funding application that supported the Russell & Doggett research project in 1992.

The Lyme Disease Association of Australia (LDAA) represents the interests of the Australian patient community and is passionate about achieving a result from the Senate inquiry into tick-borne disease that actually helps patients. We have endured years of seemingly good intentions that have not resulted in any significant change to the desperate plight of patients with Lyme-like illness.

As the Committee has heard, with the exception of a series of 'discussions,' there has been little action in the four years since we first provided a submission to the Department of Health's Scoping Study. That Submission provided a highly detailed Strategic Action Plan[1] that set out the action that the health departments could initiate in a patient focused way, if only they were motivated to do so.

What is even more distressing to the patient community is the emergence of historical research data and evidence that has been both buried, and ignored for more than 24 years. Imagine our dismay to find an ABC 7:30 Report story from 1992 and associated newspaper articles that are identical to ones we see today? And the revelation that the same diagnostic testing issues that we have heard about through the course of this Inquiry are neither new nor previously unknown.

It's no surprise that the international medical world are perplexed by the 'dysfunctional politics' and 'political-scientific quagmire' that exists here in relation to Lyme-like illness. The complete and known inadequacy of the diagnostic and medical system for Australia patients with Lyme-like illness has already left an unnecessary legacy of suffering and disability, and will likely be the subject of a future class action.

It's a travesty that the combined health departments have enabled this situation to emerge, while precious scientific egos are protected at the expense of thousands of sick Australians. In the words of patient Ms Elaine Kelly, "Shame on you".[2]

[1] See: http://www.lymedisease.org.au/wp-content/uploads/2010/11/20140129LDAAPatientStrategicActionPlan.pdf

[2] Elaine Kelly, Proof Committee Hansard, 2 Nov 2016, p 33

(A) ToR the prevalence and geographic distribution of Lyme-like illness in Australia

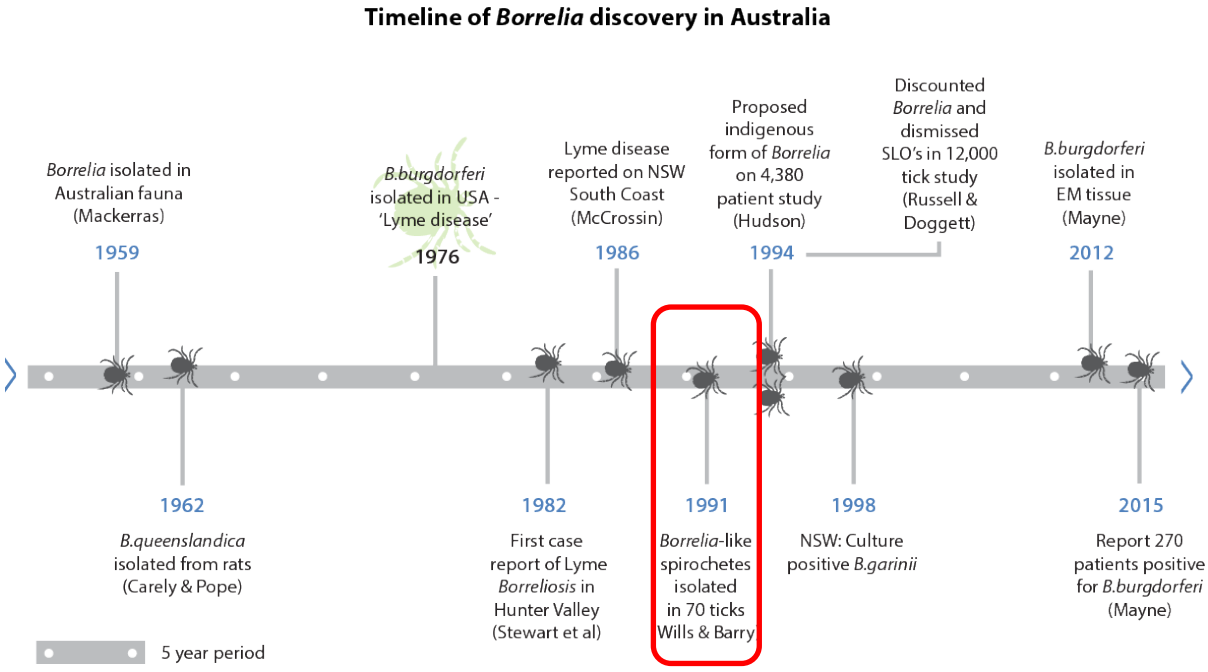
Historical evidence is ignored

The LDAA has previously asserted that the governments of Australia have systematically ignored all historical attempts to classify and count patients, have ignored scientific evidence of the presence of *Borrelia* in Australian ticks and have failed to conduct any real investigation or surveillance on the issue.

We have consistently provided referenced evidence that includes research conducted by Prof Richard Barry and Dr Michelle Wills of Newcastle University. We'd like to draw the Committee's attention to that research. Dr Wills qualifications and experience are provided in APPENDIX 1.

As indicated in our submission #528, the timeline of discovery of Borrelia in Australia was presented in Figure 1; we've reproduced it here for simplicity. It shows the Wills & Barry research of 1991 which predates the Russell & Doggett research that was funded by the NHMRC. Additional evidence will be added to this timeline to report the sero-epidemiological study conducted by Wills & Barry between 1993- 94, in collaboration with Dr Bernie Hudson that found and internationally validated *Borrelia* antibodies in 210 patients from tick infested areas of NSW eastern coast.

FIGURE 1: ILLUSTRATION OF THE TIMELINE OF *BORRELIA* DISCOVERY IN AUSTRALIA



We've previously established that the 'no Lyme here' findings of the 1994 Russell & Doggett Study (detailed in ToR D of our submission #528) effectively halted all research on tick-borne human pathogens for the next twenty years, and dismissed the existence and presence of *Borrelia burgdorferi* (Bb.) and an indigenous strain that had been isolated in 1991 and confirmed in 210

Australian patients in 1993-94. With the new evidence we present here, we recommend the Committee inquire further into this issue.

Conclusive proof of the existence of *Borrelia* in Australia

In 1989 Dr Michelle Wills, a microbiologist, observed a Lyme disease-like syndrome in her local district and commenced study into the phenomena. Under the supervision of Professor Richard Barry, microbiologist and immunologist, Dr Wills produced a series of research papers which led to her PhD thesis titled "Lyme Borreliosis, The Australian Perspective". Dr Wills' thesis is lodged in the Auchmerty Library of Newcastle University, and marked 'not for loan'.

Following the Committee's hearing in Sydney on 2 November 2016, Dr Wills contacted the LDAA and shared her story, her thesis, and her research. She provided evidence that we were previously unaware of.

Dr Wills concludes Lyme Borreliosis exists indigenously in Australia in 1994

Dr Wills' study commenced in 1989 and concluded in December 1994. The objectives of the study were to:

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 candidates.*
3. *To access the distribution of LB along the East Coast of Australia."*

Dr Wills, in her synopsis alluded to the controversy of her findings. Citing (reproduced here as the thesis is available to us in hard copy only):

> *"Despite modest success in the isolation of fragile spiral shape organisms, using conventional Borrelia culture methods (Wills and Barry, 1991), a controversy subsequently developed as to the true nature of these agents, because it was claimed that they were artefacts, probably aggregates of bacterial flagellae (Russell et al., 1994). From experiments based on improvements in culture conditions and examination of the ultrastructure of antibacterially treated cultures of B. burgdorferi, it was concluded that the spiral shaped organisms detected in this study were mostly dead spirochaetes. Subsequent studies using monoclonal antibodies directed against the major structural proteins, as well as polymerase chain amplification of microbial DNA, provided evidence that B. burgdorferi - like spirochaetes are likely to occur in Australian ticks."*

Wills went on to address these 'controversies' and progressed a study that correlated patients with Lyme disease-like symptoms AND specific *Borrelia* antibodies in their blood. This study commenced in 1992 and was conducted with Dr Bernie Hudson, an Infectious Disease Specialist at the Royal North Shore Hospital in Sydney. They set about developing a specific serological test. Wills reported:

> *"Using stringent criteria for the clinical diagnosis of LB, Dr Hudson subdivided candidate LB patients into three categories based on the decreasing likelihood of LB specific illness.* ***A correlation was established between the likelihood of clinical illness and positive serology****. An unexpected finding to emerge was that the diagnostic specificity of the immunoblot test varied*

according to which genospecies of B. burgdorferi was used as antigen. Sera from Australian patients were most likely to be reactive to Osp A of B. garinii, with reactivity to B. afielii Osp A less common. They were least likely to be reactive to B. burgdorferi sensu stricto."

Together they were able to establish that the clinical presentation of Lyme Borreliosis (LB) in Australia mostly resembled that described in Europe, and their serological test proved that Australian patients reacted more frequently with the European strain *B.garinii (Bg).* Wills' research supported the conclusion *"**that LB exists indigenously in Australia** and provides a reasonable explanation for the controversy created by previous Australian studies."*

In 1994, more than 22 years ago, Wills raised a significant issue of public health concern. She collaborated with other researchers, all experts in their respective medical fields, and was supported in her findings. Yet her conclusions have been systematically discounted and dismissed by entomologists, not medical experts in bacteria causing organisms, who were funded by the NHMRC.

Wills raised the need for:

"Further research is needed concerning several issues arising from this study:

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

Wills' Lyme Borrelia serological test development & sero-epidemiological study

Through her research, Wills disproves the conclusions made by Russell & Doggett in 1994 that "there is no Lyme borreliosis in Australia," which was based on the search for a single strain of Borrelia known to cause Lyme disease, *Borrelia burgdorferi senso stricto*. She was able to detect *Borrelia* antibodies in a number of patients through a serological test she had developed as part of her study. Wills developed the test in response to demand from medical practitioners who were seeing increased presentation of patients with similar Lyme-like symptoms; Dr Bernie Hudson was one of them.

In Wills' PhD thesis she reported that *"a steady demand has developed for LB diagnostic WB serology, based partly on increased physician awareness of the LB illness, but also because of increased expectation from the community."*

In response to demand, she developed a Western Blot (WB) using antigens from all known *Borrelia* species causing Lyme disease; *B.burgdorferi senso stricto (Bb), B.afzellii (Ba)* and *B.garinii (Bg)*. She had standardised the diagnostic procedure and was effectively offering serological testing addressing a growing need from the medical community, for which **no commercial laboratory entity could satisfy**.

The criterion that determined positive result was the **presence of the antibody to OspA (31Kda Band on a WB)** and flagellin. The study proved that *"the sensitivity and specificity of the WB test indicated that it not only had value as a diagnostic procedure, but that it might shed light on the community prevalence of the disease."* What emerged from Wills' research was a statistically significant pattern of seropositivity to *Borrelia* in patients with *"under-diagnosed musculo-skeletal pain who live and work in regions that are tick infested."*

In 1994 Wills presented statistical evidence of the results of this study. She records it as a "pilot sero-epidemiological survey" made up of samples collected in 1993 and 1994, comprising a total sample of 1043 patients residing on the eastern coast of NSW. 210, or 20% of the samples tested were positive to *Borrelia* antibodies to OspA. Table 5.1 from Wills' thesis is reproduced here with permission.

Table 5.1 Percentage of serologically positive patients in each region studied

*Genospecies of *B. burgdorferi*	Region 1		Region 2		Region 3		Region 4		Region 5	
	No. +ve	[1]% +ve	No. +ve	[1]% +ve	No. +ve	[1]% +ve	No. +ve	[1]% +ve	No. +ve	[1]% +ve
B. afzelii	0	0	9	16.7	6	5.7	6	5	37	5.4
B. garinii	4	4.8	17	31.5	9	8.7	8	6.8	59	8.6
B. burgdorferi sensu stricto	2	2.4	2	3.7	2	1.9	2	1.7	10	1.5
B. burgdorferi sensu stricto & *B. afzelii*	1	1.2	2	3.7	1	1	1	0.8	9	1.3
B. burgdorferi sensu stricto & *B. garinii*	0	0	2	3.7	1	1	2	1.7	3	0.4
B. afzelii & *B. garinii*	2	2.4	1	1.9	1	1	2	1.7	4	0.6
B. burgdorferi sensu stricto & *B. afzelii* & *B. garinii*	0	0	0	0	0	0	0	0	5	0.7
Total number tested in each region	83		54		104		117		685	
% of Total tested in each region with positive serology	10.8		61.2		19.3		17.7		18.5	

Region 1 = Far North Coast Region 2 = Mid North Coast Region 3 = Hunter Valley Region 4 = Central Coast Region 5 = Sydney

* Strains of genospecies used
B. afzelii ACA-1
B. garinii NBS-16
B. burgdorferi sensu stricto B31

[1] % positive in relation to the number tested in each region

Wills noted:

> *"Of a total of 210 seropositive samples, 173 (83%) reacted with only a single genospecies Osp A; the remaining 37 samples (18%), reacted with more than one Osp A antigen, and **were considered to be either mixed infections or multiple infections**. The predominant positive sero-reaction was to B garinii, for which 97 positives were detected. Next most frequent were positive reactions to B. afzelii (58) and then B.burgdorferi sensu stricto (18). The predominance of B. garinii positive reaction over that of other serotypes was found to occur in each of the survey regions."*

Importantly, Wills highlighted the significance of a positive result to Osp A and flagellin, combined with clinical symptoms and history consistent with a Lyme-like illness. She proved that a positive WB was associated with more than 50% of those patients with Lyme like illness compared to control subjects.

Wills noted the intent of the study was to *"obtain a preliminary estimate of the possible burden of illness, and some guidance as to the likely B. burgdorferi genotype involved."* She concluded that *"an*

*indigenous Lyme Borrelia like illness, associated with tick bite and Lyme Borrelia seroconversion, occurs annually throughout tick-infested areas**. As such it becomes a matter of public health concern and deserves further detailed investigation.”***

Wills recommended the design and implementation of a conventional sero-epidemiology study to detect the overall incidence and prevalence of disease in Australia. It’s now 21 years later and we are still waiting.

Alarmingly, Wills’ research reports significant sero-prevalence in samples from the NSW Mid North Coast which correlates with LDAA’s data of today. Dr Bernie Hudson continued this research and was taught by Wills to perform her WB test as part of the commercial offer of the Pacific Laboratory Medicine Service (PaLMS) at Royal North Shore Hospital. Dr Hudson also went on to report positive responses to both *Bg* and *Ba*, which have also been discounted. If we were to model the sero-prevalence of the positive samples against today’s resident population of the regions outlined in Wills’ research, without question **we would be describing a pandemic**. Accordingly, the **NSW Health Department is complicit in its ignorance of the significance of this data and its impact on public health in the past 20 years**.

ABC’s 7:30 Report – Lyme Ticks 1992

As part of this submission we include, at APPENDIX 2, a media file ‘Title: Lyme Ticks’, produced by the ABC’s 7:30 Report and aired on 24 February 1992. (See Figure 2: Production screen ABC's 7:30 Report on Lyme Ticks -1992 The report has eerie reflections of the same reports we see now nearly 25 years later. It highlights the conflict and controversy that existed in 1992, and remains today.

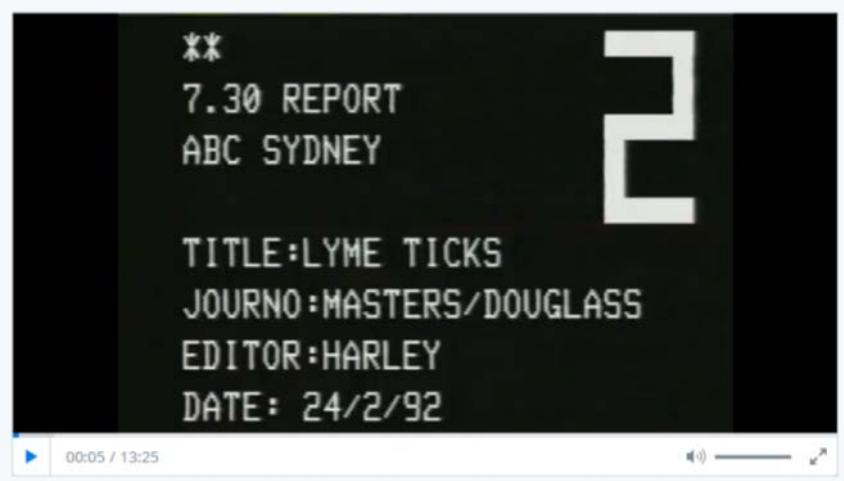


FIGURE 2: PRODUCTION SCREEN ABC'S 7:30 REPORT ON LYME TICKS -1992

An interview with Dr Wills (2016) on her 1994 research

As part of our preparation for this supplementary submission we contacted Dr Wills, who agreed to allow the taping of an audio interview for submission. Dr Wills asserts that the patients she tested as part of the study had not left the country. They showed conclusive evidence that they had come into contact with a *Borrelia* species, because they had developed antigens to it in their blood and had corresponding clinical symptoms.

An audio copy of our interview with Dr Wills is included at APPENDIX 3 of this Supplementary Submission.

Dr Wills tells a story of 20 years of neglected patients who she hopes will obtain the medical treatment they need. Dr Wills calls out a systemic issue in the way scientific research is funded, its scarcity and the competition this creates. Speaking candidly about her own experience Dr Wills relays being threatened with losing her job if she spoke out about scientific misconduct. Dr Wills spoke out regardless, and subsequently did lose her job.

When asked about her opinion of the controversy surrounding her own research and its dismissal by other researchers, Dr Wills notes that after her thesis was submitted, all funding and interest in the science of Lyme disease was halted. The scientific community were led by the powerful group funded by NHMRC, as part of the NSW Government's Institute for Clinical Pathology and Medical Research (ICPMR) Laboratory at Westmead Hospital. She asserts that there was likely significant embarrassment in that a small, minimally funded, research group could find spirochaetes when a large lab with considerably more resources and official government funding could not.

In reference to the ABC's 7:30 Report, Dr Wills told us that the ABC was faced with legal action initiated by the competing research group over the airing of their story. She alludes that this became a major issue based on hurt scientific ego. Dr Wills notes that the funding provided to the Westmead/Sydney University group of researchers was for work that overlapped with her findings. By the time the Sydney University group had received their funding, Dr Wills had already reported the presence of *Borrelia* in Australia. There was little left to 'discover', so the team could only discount it or agree.

Dr Wills reports having her findings of spirochaetes and their isolates validated as positive *Borrelia* species by the Department of Microbiology at the University of Texas. This is significant as Professor Alan Barbour, now Prof of Microbiology & Molecular Genetics in School of Medicine at the University of California, and an international expert on Lyme disease, was the one to validate Wills' research findings. Through his laboratory at University of Texas, his intern Dr Virginia Bundoc communicated with Wills and Barry, confirming their isolates in 1992 and then in collaborating in their research. A copy of their communications is included at APPENDIX 4.

In response to our question about Dr Wills' assertion regarding developing a test to determine Lyme disease in a matter of months, Dr Wills noted that her test was a laboratory test, focused on a time-intensive WB which would be difficult to commercialise. Nevertheless, following her research submission, she and Prof Barry tried to get funding to develop a commercial test, but noted that the

well-publicised findings of the Sydney University group that there was 'no Lyme here' made it impossible to attract investors or funding to test for a supposedly non-existent disease.

Competition and conflicts in the field of medical research

The Wills research and its outcomes raise a significant issue in medical research competition and highlight the dire public health consequences of a conflict of interest.

In competition to the Wills research was the Department of Medical Entomology in Sydney University. The Department of Medical Entomology resides within the ICPMR at Westmead Hospital. The ICPMR provides specialist pathology services and is the main referral lab for the Pathology West Network, which covers 70% of NSW. Its remit is to foster excellence in clinical care, public health, training and medical research. It is funded by the NSW Government and is part of the NSW Department of Health.

According to ICPMR, it is unique as it provides the State referral centre for a range of organisms and communicable diseases such as tuberculosis, pneumococcal disease, influenza, arboviruses and other emerging infections. It also operates the only hospital-based Medical Entomology laboratory in Australia, which provides research and advice about the impact of insect-borne diseases on human health. Additionally, it is involved in collaborative research with the Westmead Millennium Institute, the Marie Bashir Institute for Infectious Diseases and Biosecurity, NSW Health, the National Health and Medical Research Council, and a range of national and international research programs.

The primary researchers involved in the 1994 study that concluded 'no Lyme here' were employees of the Department of Medical Entomology or the ICPMR Laboratory. Interestingly, their research (Russell & Doggett 1994) reported "in 1988, a serological diagnostic service for Lyme disease was initiated at Westmead Hospital in Sydney, N.S.W." This laboratory was providing commercial laboratory services by way of an indirect fluorescent antibody test (IFAT) and enzyme linked immunosorbent ELISA using antigens derived from a North American strain (B31) of Borrelia burgdorferi. The research further reports that from "1988 through 1992, specimens from 2,446 patients were referred with suspected clinical Lyme disease and were tested."

We know from previous evidence submitted as part of our response to the Department of Health's Scoping Study, that the ICPMR laboratory only conducted testing against the *B.burgdorferi senso stricto* strain, not *B.afzelii* or *B.garinii* as asserted in the NSW Government Health advice. In fact, until 1994, when Dr Wills had developed and proven the utility and validity of her WB, ICPMR did not even offer an immunoblot test.

In 1994, off the back of the results provide by Dr Wills, the ICPMR laboratory developed an in-house whole cell lysate immunoblot test as their second tier test. This is supported by evidence provided by Dickeson in a presentation provided by the National Serology Reference Laboratory (NRL) on an

'Evaluation of four commercial Lyme Borreliosis EIA antibody screening kits compared to immunoblots' shown in Figure 3.[3]

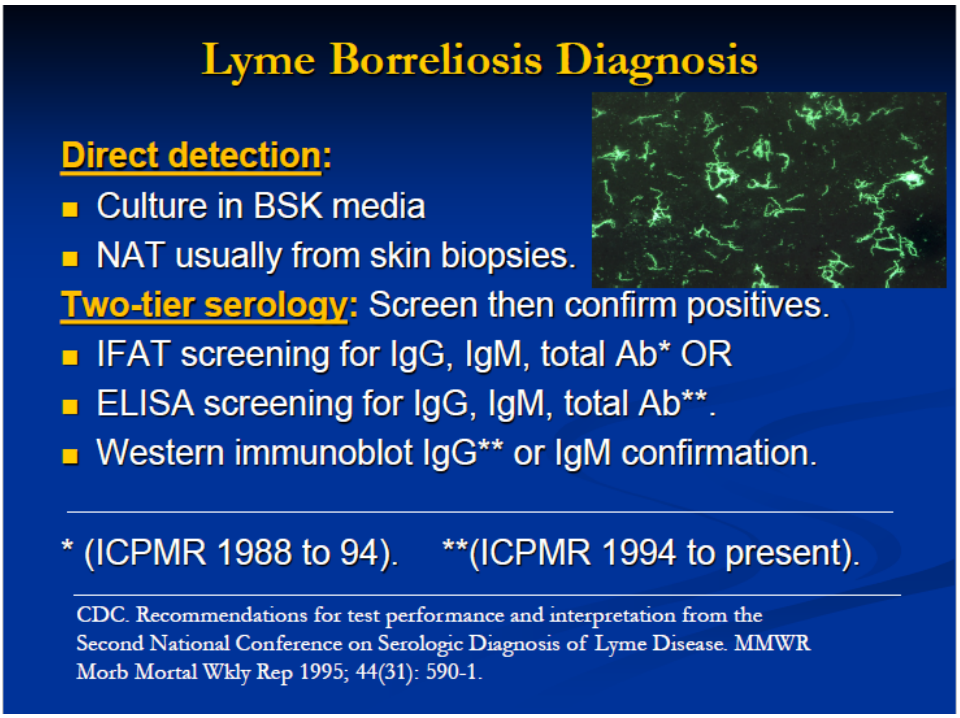


FIGURE 3: SLIDE FROM ICPMR ON SCREENING

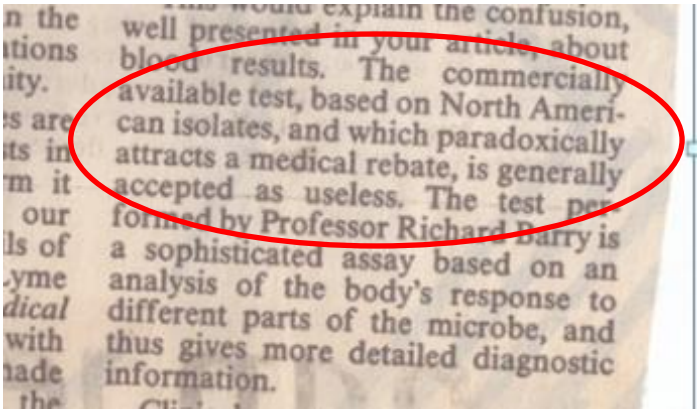
This occurred at the same time this very laboratory was asserting that there is 'no Lyme here'. It's difficult to understand the commercial justification to initiate in 1988 a commercial laboratory testing process for a disease that was not present, yet continue to test thousands of people. Even more puzzling is that off the back of their 1994 findings of 'no Lyme here', ICPMR progressed to develop their own in-house immunoblot using the scientific knowledge and work of Dr Wills and Dr Hudson. How could this have been justified from a business case perspective?

A newspaper article dating back to February 1995, provided by Dr Wills, highlights the controversy that surrounded Dr Wills' research and calls out the paradoxical situation that existed more than 20 years ago, surrounding the commercially available test that was based upon North American strains of *Borrelia* and attracts the medical rebate, but which is accepted as useless. It serves as proof of the ridiculous argument that has ensued for 20 years while people suffer. The original article titled '*Lyme disease: the tick-borne epidemic the experts can't agree on',* was published in the Sydney Morning Herald of February 4 1995. It articulated the same issues that we face today. A full copy of the article is included at APPENDIX 5.

[3] David Dickeson - http://www.nrl.gov.au/CA25782200833499/All/B6B1467B023EF562CA257A63000084BB/$file/David_Dickeson.pdf

It is a revelation, to us at least, that these same testing issues were well described and understood in 1995, yet here we are 21 years later debating the same issues. A subsequent Letter to the Editor, titled *'Clarifying the confusion around Lyme disease',* was written by Prof Clancy, Professor of Pathology of Newcastle University, and published on February 7 1995. It is included at

APPENDIX 6. An excerpt is included below.



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well presented in your article, about blood results. The commercially available test, based on North American isolates, and which paradoxically attracts a medical rebate, is generally accepted as useless. The test performed by Professor Richard Barry is a sophisticated assay based on an analysis of the body's response to different parts of the microbe, and thus gives more detailed diagnostic information.

It's also important to understand the relationships and role of the participants of ICPMR and the Department of Medical Entomology, and the 'expert' roles they assume in the fabric of government committees that consistently rely upon outdated research. These same researchers are the authors of multiple papers, most specifically the 1994 paper asserting 'no Lyme here'.

The Russell & Doggett study conducted between 1990 and 1992 attempted to isolate spirochaetes in Australian ticks and focused on *B. burgdorferi*. They asserted this would "provide unequivocal evidence for the local existence of an etiological agent for the disease. Local spirochaetes could then be used as antigen to improve serological tests and disease diagnosis. This would allow a more accurate assessment of the public health importance of the disease".

Their study was limited by its sole focus on *B.burgdorferi.* While their study did find spirochaete-like objects(SLOs), the researchers discounted them as non-specific artefacts. They did "recognise that the monoclonal antibodies and PCR primers used in this study **may not have been appropriate to detect an indigenous Australian spirochaete** but, notwithstanding this concession, the SLOs were ultimately shown by electron microscopy not to be spirochaetes."

The acknowledgements section of the 1994 Russell & Doggett study cites "the investigations were supported by a project grant from the National Health and Medical Research Council, and by a grant-in-aid from the Ramaciotti Foundations."

So we have a government reference laboratory and university research department funded by the NHMRC to conduct research into a causative agent under the auspices of the NSW Health Department. It is not difficult to speculate upon how the Wills research outcomes might have challenged the perceived supremacy of the ICPMR researchers and enabled the dire public health situation we find ourselves in 25 years later.

There is no doubt that the government of the day were faced with a conundrum; two pieces of scientific evidence - one that isolated antibodies to *Borrelia* in 55% of the patients it studied AND could link the antibody reaction to clinical symptoms, against one that found spirochaetes in insects, not people, but discounted them as 'artefacts'. The most appropriate public health response should

have been to investigate further, but the NSW Department of Health did not. As a result, the Russell & Doggett research permeates every discussion about the presence of *Borrelia* in this country.

Despite many medical professionals urging the government to move away from the argument of a causative agent, we remain stuck in the quagmire of negligence all these years later. In the meantime, an increasing cohort of people are infected by otherwise preventable tick bites and accompanying illness simply because their government, in full awareness of the unanswered public health issues, chose to ignore credible and independently validated scientific evidence.

In 2013, as part of our response to the Scoping Study we raised the issue of legal liability in respect to the inefficient and inaccurate testing processes surrounding Lyme disease. We now raise the issue once again in respect to the conflicts of interest that underpin the public health assertion that there is 'no Lyme here'.

The LDAA recommends that the Committee seek a full accounting of the decision making that determined the NSW Health Department's assertion there is 'no Lyme here' following the outcomes of the Russell & Doggett study in 1994. The Committee should seek to understand why the Wills & Barry research was not considered, or if it was, why it was discounted.

Australia mired in a political-scientific quagmire, losing medical and scientific credibility

Following the Senate Inquiry hearing in Sydney on 2 November, Dr Richard Horowitz posted a very frank piece on social media, for simplicity it is reproduced here.

> *The Australian Senate recently held a hearing on tick-borne diseases in Sydney, and I provided testimony by teleconference with an associated scientific submission. Australia is mired in a political-scientific quagmire regarding Lyme, where some doctors "down under" are denying the existence of chronic tick-borne diseases.*
>
> *This has resulted in patients coming to me from Australia in wheelchairs, unable to get help in their own country. In fact, at the recent ILADS conference in Philadelphia, a man flew from Australia just to meet me in the lobby and discuss his wife's case because no one could help relieve her suffering!*
>
> ***The dire situation that some Australian citizens face is partly a result of the lack of adequate blood testing to diagnose the multiple strains of emerging tick-borne illnesses, and partly due to longstanding dysfunctional politics surrounding Lyme and associated diseases.***
>
> *New PCR technologies which are being developed will hopefully end the decades long scientific debate, however* ***if we continue to ignore the science which shows the inadequacy of standard two-tiered testing, as well as the science proving the persistence of borrelia and other tick-borne diseases, we will be leaving a health care legacy of suffering and disability for decades to come.***

While ever our medical and scientific funding is predicated upon a 'select' few who publish papers in 'credible' journals, without full disclose of their conflicts, we will continue to perpetuate the issues discovered over 20 years ago for which there has been no progress. In quotes of prominent editors of medical journals, sourced from submissions made to the Medical Complaints inquiry currently underway and due to report this week, we offer this:

> *"It is simply no longer possible to believe much of the clinical research that is published, or to rely on the judgment of trusted physicians or authoritative medical guidelines. I take no pleasure in this conclusion, which I reached slowly and reluctantly over my two decades as an editor of the New England Journal of Medicine."* – Dr. Marcia Angell, a physician and longtime editor-in-chief of the New England Medical Journal (NEMJ)

and

> *"The case against science is straightforward: much of the scientific literature, perhaps half, may simply be untrue. Afflicted by studies with small sample sizes, tiny effects, invalid exploratory analyses, and flagrant conflicts of interest, together with an obsession for pursuing fashionable trends of dubious importance, science has taken a turn towards darkness."* – Dr. Richard Horton, the current editor-in-chief of the Lancet – considered to be one of the most well respected peer reviewed medical journals in the world.

Significantly, the Senate Inquiry into the medical complaints process in Australia is likely to shed light on more of the issues that Dr Wills, hounded from her profession, experienced back in the mid 1990s. Appallingly, many of the researchers and doctors associated with Lyme disease in Australia have suffered a similar fate; worse still some have been inappropriately threatened and many have retired. It's time to shine a light into the dark corners of the medical and scientific misconduct, the undisclosed conflicts of interest and ego-fuelled research that exists here, especially surrounding Lyme-like illness.

International precedents in legislation around Lyme disease

In our submission to the Scoping Study, we raised the issue of inadequate serology testing and the controversy that surrounds the tests, the two tier testing process, the qualification of those performing the tests, the criteria used to determine a positive result and the subsequent reporting of outcomes. With the additional evidence presented in this paper, we can clearly establish that the issue of inaccurate and inappropriate diagnostic tests, paradoxically funded through the medical rebate system, were 'generally accepted as useless'[4] 20 years ago.

Through its various media efforts, the Royal College of Pathologists of Australia (RCPA), and their spokesperson Prof Stephen Graves, have successfully used the issue of NATA accreditation as the smokescreen to primarily focus the debate. It has diverted attention away from the serious conflicts of interest that exist in Australia and from the issue of test accuracy and reliability.

The Committee has been educated on the two-tier testing process, and understands that the first tier of testing is via an ELISA, using a commercially available test kit. In Australia, the in vitro diagnostic (IVD) test kits used for Lyme disease fall into the Class IV 'high public health risk' category, as specified in Regulation 3.1 of the Therapeutic Goods (Medical Devices) Regulations 2002[5].

Under our system, these devices are classified at the highest level of risk, which is determined by an assessment of the risk of an incorrect result arising from the use of an IVD. It should be noted that the 'class' is partly determined by the "manufacturer's intended use of the device". The product data accompanying commercial test kits state that "Negative results (either first or second-tier) should not be used to exclude Lyme disease[6]" (from the MarDX ELISA test kit routinely used at Westmead until 2013) and "the diagnosis of Lyme disease must include careful clinical evaluation and should not be based upon the detection of antibodies to *B. afzelii/garinii/burgdorferi* alone; a negative interpretation does not exclude the possibility of infection with *B. afzelii/garinii/burgdorferi*[7]" (from the Trinity Biotech Western Blot test kit).

On top of the test kit disclaimers, we have heard numerous times during the Committee's inquiry that the RCPA and its laboratories routinely dismiss positive result tests on the basis of low prevalence of disease in Australia, for which they apply some secret algorithm.

In the United States, where the same test kits are used, the State of Maine enacted legislation *An Act To Inform Persons of the Options for the Treatment of Lyme Disease, 2013,* requiring that the Maine Centre for Disease Control and Prevention update their website to include the following statement: "*A negative result for a Lyme disease test does not necessarily mean that Lyme disease is not present*".[8]

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[4] See APPENDIX 6
[5] http://www.tga.gov.au/industry/ivd-classification.htm#.UteEz_Lxvcc
[6] http://www.trinitybiotech.com/Product%20Documents/8696G,P,PJ-MS%20B.%20burgdorferi%20EIA%20Test%20System.pdf
[7] http://www.trinitybiotech.com/Product%20Documents/44-2020GV-29EN%20EU%20Lyme%20+VLsE%20IgG%20WB.pdf
[8] http://www.mainelegislature.org/legis/bills/bills_126th/chapters/PUBLIC340.asp

Similarly, the Virginia government introduced the *Lyme Disease Testing Information Disclosure Act*. It requires patients to be provided with written notification advising that "*If you are tested for Lyme disease, and the results are negative, this does not necessarily mean you do not have Lyme disease*".[9]

Sadly, many Australian patients are living with the results of the testing processes used in Australia and the inexplicable dismissal of their result if they ever return a positive. Which begs the question - who bears the liability for the inefficient, ineffective and inaccurate testing processes? For now, it is patients who are paying with their health. However, if these issues are not quickly resolved, the laboratories *and* governments that advocate for these processes (in full knowledge of their limitations) may well be found to be legally liable.

Additionally, in 2016, senators in Delaware became aware that some doctors were still ruling out Lyme disease based on negative laboratory test results. They passed legislation requiring medical staff to "learn more about Lyme disease as part of their continuing education." Senator Lopez said "this misdiagnosis issue...is a big concern, so having that awareness on the outset...is important"[10]

Liability surrounding Lyme disease is on the rise

In the past few weeks, a class action has been launched against five French companies marketing the ELISA test for Lyme disease. Reports state that 130 patients are claiming 500,000 euros compensation for damages related to delayed diagnosis of Lyme disease. Similarly to Australia, a patient must first receive a positive result on an ELISA test, in order to progress to an immunoblot test. Yet like Australia, the laboratories are not capable of guaranteeing the reliability of the tests they market. The government in Australia is complicit in that they have declared the test kits IVD Class IV, and yet provide payment under the MBS for these tests in full knowledge of their long standing unreliability.

In eerily similar circumstances, the French government has recognised the need to develop new diagnostic tests, yet like Australia, for 4 years they have not acted to address the situation. The Australian Department of Health finds itself in the same position. Although it can claim some mediocre action in commissioning the NRL to investigate testing discordance, we assert that they are complicit in the knowledge that they wilfully ignored the issues that were first raised with testing more than 20 years ago. In France, lawyers have also called upon the Health Department to create a compensation fund to support people who have a delayed diagnosis due to inaccurate testing.[11]

[9] https://lis.virginia.gov/cgi-bin/legp604.exe?131+sum+HB1933
[10] Source: Delaware Public Media, Lyme disease added to ongoing education for healthcare workers, 29 Aug 2016, http://delawarepublic.org/post/lyme-disease-added-ongoing-education-healthcare-workers
[11] http://stopru.org/lyme-disease-a-new-aquitaine-among-the-130-patients-who-claim-500000-euros-to-the-labs/20463

Conflicts of interests surrounding pathology

During the course of this inquiry, the Committee has heard from [redacted] multiple times.

[redacted]

[12] See APPENDIX 7 for information about the process of 'peer review' in relation to articles produced in the Medical Journal of Australia.

[redacted]

[redacted]

Analysis of Submissions made under this Inquiry

It has been asserted that the LDAA's data previously presented as part of 'Patient Situation' reports is somehow skewed and unreliable. To alleviate the concerns about skewed research, and as part of its ongoing statistical research, the LDAA analysed a subset of submissions made to this Senate Inquiry. We note that there are significant statistical patterns in the public submissions that require further investigation.

While the LDAA analysed the data provided in submissions to this inquiry, this data must not be interpreted as the 'complete' story for patients. As such our analysis is confined to the information that could be classified and counted. For example, a submitter who told the Committee that they have been diagnosed with a medical condition has been counted as suffering from that condition.

The LDAA and its volunteers analysed 432 (34%) of the 1268 submissions made to this Inquiry. Of those, 349 submissions were made by individuals who either provided their names, or withheld their names. The following charts and tables provide insight into the 349 (27.5%) individual submissions. **This is statistically relevant sample**.

Demographics

Of the 432 submissions analysed, 218 (50%) were made by individuals who may or may not be listed by name. A further 131 (30%) were published as 'Name Withheld'. For the purpose of this analysis we focused on submissions made by individuals and included those classified as 'name withheld'.

Of the 432 submissions, we analysed the type of submitter, these are shown in Figure 4: Submission Type . We further analysed the status of the submitter, classifying them as Patients, Carers, Doctors or Family making submissions on behalf of, or in support of a patient, or friends of patients. Some submitters did not disclose who they were, or it could not be determined, they are classified as 'unknown'. Confidential submissions could not be analysed.

Type	Carer	Doctor	Family	Friend	Patient	Unknown	Total
Confidential						48	48
Individual - name given	6	6	36	7	147	16	218
Missing						26	26
Organisation						9	9
Individual - name withheld	1	2	25	6	65	32	131
Total	**7**	**8**	**61**	**13**	**212**	**131**	**432**

FIGURE 4: SUBMISSION TYPE

Of the submitters, the seven who described themselves as a carer also noted that they were related to the patient. This provides the Committee with insights into the burden of illness on families; when a family member becomes the 'carer' in what should be a familial relationship. From the submissions we were unable to determine if those 'carers' were officially recognised and compensated as carers for people with Lyme-like illness.

Gender

Of the 349 individual submitters (218 whose names were given and 131 whose names were withheld), we were able to classify the gender of 160 people; 120 (75%) were female, 40 (25%) were male.

Mental Health

Of the 349 submissions we could analyse**, 21 submissions reported to the Committee they had had thoughts of, or frequently contemplated suicide.** Who is caring for these people as part of this Inquiry process?

Travel history

Of the 349 submitters, **47 (13%) reported they had never been overseas.**

Dismissal by Infectious Disease Specialist

Of the 349 submitters analysed, 101 (28%) reported dismissal by an Infectious Disease Specialist (IDS).

As the Committee heard from the testimony of Dr Gary Lum of the Australian Government's Department of Health, the recommendation is for patients suspected of a Lyme-like illness to be referred to an IDS. Yet submissions to this inquiry recount appalling stories of the disrespectful and discriminatory treatment suffered by those consulting with IDS.

Alarmingly, we recently witnessed the confusing Medical Journal of Australia article authored by an IDS and co-authored by Dr Gary Lum, asserting that "Clinicians and medical scientists in Australia are able to identify and fully characterise unexpected or previously unknown pathogens, as evidenced by the recent report of a Babesia infection." But they neglected to report that they were only able to find the Babesia organism after their patient died; that's hardly comforting for patients.

In the same paper, the very next paragraph provides an admission that "Some may have illnesses caused by tick-borne bacteria or viruses that are yet to be identified but which may be widely distributed in Australia." The LDAA are disappointed that given this (rather obvious) admission, the general IDS community have not been actively championing the need for urgent research, but instead, treating patients in an unprofessional, discriminatory and often distressing manner.

Acquisition

From the submissions we analysed, we recorded any documented place of acquisition of a Lyme-like illness and classified it by state. The results are reported in Figure 5.

199 (73%) stated they had acquired their illness in Australia, 37 (13%) stated they acquired their illness overseas and the location of acquisition for 37 (13%) was unknown.

Place of Acquisition	Total
NSW	75
VIC	19
QLD	58
SA	2
WA	26
NT	2
TAS	4
Australia (State unknown)	13
USA	16
Europe	8
Asia	6
Africa	2
Pacific	3
Unknown	37

FIGURE 5: PLACE OF ACQUISITION

Testing

Where a submitter provided information about the laboratories in which their samples had been tested, we recorded the laboratories' name. These are presented in Figure 6. **58% (203) reported testing in more than one laboratory.** Most people reported pursuing some kind of overseas laboratory testing, which we know to be expensive and not reimbursed by Medicare or private health insurers.

Laboratories used for testing	Total
Australian Laboratories	
Australian Biologics	64
Australian Ricksettsial Reference Lab	11
QML Pathology	2
St John of God Pathology	2
Westmead (ICPMR)	2
Western Diagnostics Pathology	1
Overseas Laboratories	
Armin Labs (Germany)	12
IGENEX (USA)	96
Infectolab (Germany/ Denmark)	42
Fry Labs (USA)	2
Unknown	48

FIGURE 6: LABORATORIES USED FOR TESTING

Treatment

Where a submitter reported that they had obtained treatment, we recorded the location of their treatment. 7% reported they had undergone treatment in more than one location. Worryingly, some reported that they had never been treated.

Location of treatment	
Australia	153
Belgium	1
India	1
Indonesia	1
USA	14
UK	2
None	9

FIGURE 7: TREATMENT LOCATIONS

Treatment type

Of the 349 individual submissions we analysed, where the type of treatment was reported, we captured it in Figure 8. Clearly, antibiotics are the most common type of treatment encountered by patients, followed by supplements and herbs, as described to the Committee as the gold standard in treatment by Dr Horowitz. 32% (113) report undertaking more than one type of treatment.

Type of treatment undertaken	
Antibiotics	101
Bio-resonance	2
Herbs	45
Hypothermia	15
Oils	3
Ozone	5
RIFE	2
Supplements	52
Other	34

FIGURE 8: TYPE OF TREATMENT

Differential diagnosis

We analysed the 349 individual submissions to determine if the submitter had a differential diagnosis provided at any time during their illness. We recorded any other diagnosis the submitter mentioned in their submission; Figure 9 reports the findings.

Diagnosis provided by medical professionals			
ADD/ADHD	8	Irritable Bowel Syndrome	12
Adrenal Fatigue	13	Lattice Degeneration	2
Anxiety	21	Lupus	11
Autonomic nervous system dysfunction	3	Meniere's	2
B12 Deficiency	2	Meningitis	5
Bipolar Disorder	3	Mental Disorder	18
Blood pressure low	5	Migraine	10
CCSVI	3	MS	28
CFS / ME	87	MSID	1
Coeliac disease	1	Osteoarthritis	5
Conversion Disorder	6	Pancreatitis	2
Costochondritis	4	Parkinson's	3
CREST	1	Peri-Menopausal	2
Cushing's disease	1	Post Viral Fatigue	13
Dengue Fever	2	Psoriasis	2
Depression	42	Psoriatic Arthritis	3
Diabetes	5	PTSD	5
EBV	16	Poly arthroplasty/myalgia	7
Fibromyalgia	42	Postural Tremors	2
Folliculitis	1	Pyrrole's Disorder	4
Gastritis	4	Reactive Arthritis	4
Hashimoto's	7	Rheumatic fever	1
Hernia	1	Ross River Fever	9
Hyperesthesia	1	Thyroiditis/Graves	8
Active imagination	3	Rheumatoid Arthritis	15

FIGURE 9: DIFFERENTIAL DIAGNOSIS

Type of infection or co-infection

Of those who reported or named an infection they have been diagnosed with, we recorded the name as provided. The most common infections reported are listed in Figure 10. 156 people reported having more than 1 infection; this makes their treatment much more complicated.

Infections reported	
Borrelia	118
Anaplasma	1
Babesia (unstated strain)	64
Babesia duncani	10
Babesia microti	1
Barmah Forest virus	5
Bartonella (henselae)	76
Blastocystis hominis	4
Brucella	1
CMV	5
Cocksackie virus	4
Coxiella burnetiae	1
CPN	23
Diantomeoba fragilis (parasite)	2
EBV	22
EMV	1
Ehrlichia	12
HSV / Zoster	3
Hashimoto disease	3
Mycoplasma	30
Mycoplasma fermentans	3
Parvo	3
Pyrroluria	3
Q Fever	5
Rickettsia Spotted fever group	50
Ross River Fever	12
Strep	3
Toxoplasmosis	3
Typhus	7
Other	22

FIGURE 10: INFECTIONS REPORTED

Number of people infected

36 of the individual submitters reported that more than one person in their family were affected with a Lyme-like illness. From the data, we note that four submitters reported four or more family members with Lyme-like illness.

In-utero infection

16 submitters report that their infection was acquired in-utero; their mothers had a *Borrelia* infection and passed it onto them. These people have lived their entire lives with Borrelia infection. Their long term prognosis is not known.

Costs

Of those who reported the cost of their treatment, the combined value of treatment reported is $2,725, 881. The average treatment cost reported is $42, 561.

Of those who reported any loss of income, the combined value of the reported loss is $1,768,031. The average loss of income was $43,122.

Noting this was a sample of 349 submitters, and only those who reported their actual costs, it is mindboggling to think of the entirety of cost that has been shifted onto the patient community due the political and scientific ignorance of this disease in this country. With this scale of financial loss, a class action is inevitable.

While the LDAA volunteers have only had the capacity to assess 432 of the submissions provided as part of this inquiry, the significant statistical data collected as part of this inquiry provides the first official evidence of the prevalence of an Australian Lyme disease. Yet the absence of a complete statistical analysis of the 1268 submissions by the Australian Government's Department of Health further illustrates the entrenched and ongoing ignorance that surrounds the issue of Lyme-like illness in Australia.

While LDAA volunteers were busy reading and classifying the 432 submissions, the Department of Health's Dr Gary Lum found time to author an article published in the Medical Journal of Australia, denying the existence of Lyme disease in Australia. We ask the Committee to refer the robust epidemiological data provided to this Inquiry to the Department of Health for complete and proper analysis and reporting, as is their role in protecting the health of the Australian public.

(E)ToR potential investment into research to discover unique local causative agents causing a growing number of Australians debilitating illness

A proposal for the National Health and Medical Research Council - Targeted Call for Research

As part of this inquiry Prof Anne Kelso, Chief Executive Officer of the NHMRC, gave evidence at a public hearing in Canberra on 20 April 2016. Prof Kelso outlined the Targeted Call for Research (TCR) concept and new online "mechanisms by which community and professional groups can assist NHMRC in identifying important under researched areas of unmet need."[18]

Prof Kelso went on to suggest that the recommendations of the committee would "assist NHMRC in rolling out a series of targeted calls for research to address significant government and community health needs which are not already being supported through our other funding schemes."

In response to Prof Kelso's comments the LDAA prepared and submitted a proposal to the NHMRC titled '*A proposal for the National Health and Medical Research Council - Targeted Call for Research*', to meet the 16 September deadline for the second round of research calls.

Proposals to the NHMRC are not public. [redacted]

[18] Prof Anne Kelso, *Committee Hansard*, Canberra, 20 April 2016, p. 4.

Response to Questions on Notice

Question 1: Could you please tell the committee, based on your experience with people who are affected with Lyme-like illness, what options are available to them in Australia?

In our experience, there are three primary options available for patients in Australia;

1. to consult an Australian 'Lyme-literate' doctor, such as a member of the Australian Chronic Infectious and Inflammatory Diseases Society (ACIIDS), for treatment that generally involves pharmaceutical antibiotic treatment, herbal antimicrobials and dietary supplements and rehabilitation recommendations/referrals. Pharmaceutical antibiotics are usually administered orally, although a small number of patients use a PICC if deemed appropriate by their doctor. Additional treatment is also provided as needed for any conditions experienced by the patient that may not be directly related to tick-borne disease.
2. to consult a Lyme-literate naturopath, for treatment as above, excluding pharmaceutical antibiotics. Some patients choose to use both a doctor and a naturopath.
3. to consult with a Lyme-literate doctor or naturopathic doctor located overseas via Skype. This doctor will work in conjunction with the patient's GP, who will prescribe the recommended pharmaceutical antibiotic treatment.

The details of these 'Lyme literate' professionals are provided to the LDAA by the existing patient community. We then share this information with new patients who contact us for assistance. This information is shared via email, not published on our website, to minimise the risk of harassment of practitioners, by those who do not recognise Lyme-like illness.

We do not provide reviews or make specific recommendations regarding the practitioners; we simply pass on their details.

Due to the small number of practicing Lyme-literate professionals, patients are unlikely to have one in their local area. Figure 20 in the LDAA's submission to this inquiry (#528) reveals that almost 44% of 862 survey respondents have travelled distances of greater than 101 kilometres in order to access treatment for Lyme-like illness within Australia. To counteract this, some practitioners offer follow up appointments via Skype or telephone. Unfortunately, such consultations cannot be claimed via Medicare or private health fund.

132 surveyed patients revealed that they are not currently undergoing treatment. Their free text answers include the below reasons:

> *I took antibiotics for 5 weeks, starting 14 days after the bite. My blood might still be positive but I don't have any symptoms anymore*
>
> *I have severe chemical sensitivities and am unable to tolerate medication or antibiotics*
>
> *I'm trying to find a doctor who will be able to treat me*

> *I had to go off them because I am the carer for my husband who has chronic Lyme disease and who is currently much sicker than me so we cannot afford the time or money for me to continue treatment at present*

Lack of available treating practitioners is certainly a problem. At the Sydney hearing for this inquiry, Dr Richard Schloeffel advised the Committee that he has 800 people on his waiting list.

Question 2: Some witnesses [Assoc. Prof. Samuel Zagarella, Australasian College of Dermatologists, Perth, 14 April] have suggested that non-mainstream treatment has not been proven to help. What is your view on this?

In his testimony, Assoc Prof Zagarella defines mainstream treatment for 'proven Lyme disease' as 'a two week course of antibiotics.' We assume that he is referring to the recommendations of the Infectious Diseases Society of America (IDSA). We note that the IDSA's guidelines have been considered controversial in America for many years.

In 2003, the International Lyme and Associated Diseases Society (ILADS) expressed concern, stating that the guidelines "*…fall short of meeting the needs for diagnosis and treatment of individuals with chronic Lyme disease. The latest IDSA Guidelines (2000) fail to take into account the compelling, peer-reviewed, published evidence confirming persistent, recurrent and refractory Lyme disease and, in fact, deny its existence.*"[19]

The IDSA reviewed their guidelines in 2006, but did not make any changes. Corruption within the IDSA was suspected, and an anti-trust investigation was launched. At its conclusion, Attorney General Richard Blumenthal reported that "*The IDSA's 2000 and 2006 Lyme disease panels refused to accept or meaningfully consider information regarding the existence of chronic Lyme disease, once removing a panellist from the 2000 panel who dissented from the group's position on chronic Lyme disease to achieve "consensus."*[20]

Despite this, the American federal government continued to promote the IDSA guidelines.

Some American state governments were so concerned by the perception that long term antibiotic treatment was inappropriate that they introduced 'doctor protection' legislation. These laws acknowledge the existence of chronic Lyme disease (CLD), and the right of doctors to treat it.

In New York, doctors using long-term antibiotic treatment were investigated by the Office of Professional Medical Conduct. In 2002, the New York Assembly discussed this issue. The related documentation recognises the existence of CLD by stating "*Patients in whom* [Lyme] *disease is not caught early and who are not treated adequately can progress to chronic disease with infection of*

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[19] International Lyme and Associated Diseases Society, *Evidence-based guidelines for the management of Lyme disease*, 2003, p4, http://www.ilads.org/lyme/ILADS_Guidelines.pdf

[20] Office of the Attorney-General, *Attorney General's Investigation Reveals Flawed Lyme Disease Guidelines Process, IDSA Agree to Reassess Guidelines, Install Independent Arbiter*, 1 May 2008, http://www.ct.gov/ag/cwp/view.asp?a=2795&q=414284

the central nervous system…" The Assembly voted that "*insurance companies and the Office of Professional Medical Conduct cease and desist from targeting* [these] *physicians."*[21]

Also in 2002, the Rhode Island General Assembly passed a 'doctor protection law'. This defined Lyme disease as "*the clinical diagnosis by a physician of the presence in a patient of signs and symptoms compatible with acute infection with Borrelia burgdorferi, or with late stage or chronic infection with Borrelia burgdorferi, or with complications related to such an infection."*[22] The law ruled that doctors couldn't be disciplined for treating CLD with long-term antibiotics. Five other states have since introduced similar legislation.[23]

(Six states out of 50 mightn't seem many, but Lyme disease is far more common in some states than others, due to varying tick populations.) All of the legislation recognises the existence of CLD, either directly or indirectly.

In 2003, the Rhode Island General Assembly introduced legislation requiring health insurers to cover long-term antibiotic treatment for CLD.[24] The legislation was trialled for a year. In 2004, it was made permanent.[25]

In 2010, the Commonwealth of Massachusetts passed legislation formally allowing long-term antibiotic therapy for Lyme disease.[26]

In August 2016, they passed further additional legislation requiring insurance policies that cover medical expenses to "*provide coverage for long-term antibiotic therapy for a patient with Lyme disease when determined to be medically necessary…"*[27]

All treatment guidelines endorsed by the American federal government are published on its National Guideline Clearinghouse (NGC) database. The NGC is managed by the Agency for Healthcare

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[21] State of New York, *Assembly Resolution 2155*, 2002, http://www.lymeinfo.net/nyresolution.html
[22] State of Rhode Island General Assembly, *Lyme disease diagnosis and treatment act*, 2002, http://webserver.rilin.state.ri.us/PublicLaws/law02/law02159.htm
[23] Legislative Council of the State of California, *Assembly Bill No. 592, Chapter 304*, 2005, http://www.leginfo.ca.gov/pub/05-06/bill/asm/ab_0551-0600/ab_592_bill_20050922_chaptered.pdf
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Maine State Legislature, *An Act To Improve Access to Treatments for Lyme Disease*, accessed Aug 2016, http://www.mainelegislature.org/legis/bills/bills_127th/billtexts/HP028901.asp
[24] State of Rhode Island General Assembly, *Lyme disease diagnosis and treatment Act*, 2003, http://webserver.rilin.state.ri.us/PublicLaws/law03/law03113.htm
[25] State of Rhode Island General Assembly News, *House passes Lyme disease bill*, 2004, http://www.rilin.state.ri.us/pressrelease/Lists/PressReleaseData/DispForm.aspx?ID=969
[26] The Commonwealth of Massachusetts, *Section 12DD Administration of long-term antibiotic therapy upon diagnosis of Lyme disease,* 2010, https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXVI/Chapter112/Section12DD
[27] The Commonwealth of Massachusetts, *Bill H4491 An Act relative to long-term antibiotic therapy for the treatment of Lyme disease*, accessed Oct 2016, https://malegislature.gov/Bills/189/House/H4491
Massachusetts Lyme Disease Legislative Task Force, *For Immediate Release*, 2 August 2016, https://www.lymediseaseassociation.org/images/NewDirectory/Government/State/Massachusetts/Lymelegislationpressreleasessaug22016.pdf

Research and Quality (AHRQ). The AHRQ describes the database as "*an Internet-based resource that contains evidence-based clinical practice guidelines and related documents...an accessible mechanism for obtaining objective, detailed information on clinical practice guidelines and to further their dissemination, implementation and use.*"[28]

In early 2016, the IDSA guidelines were removed from the NGC database. They failed to meet new 'Standards for Developing Trustworthy Clinical Practice Guidelines'.[29] The IDSA has estimated the development of its revised guidelines will take 2-5 years.[30]

It is important to note that the ILADS guidelines did meet the new standards. They are currently the only Lyme disease guidelines on the NGC database. The ILADS guidelines recommend long-term antibiotic treatment when short term regimes have proven insufficient.

The authors say "…*we moved away from designating a fixed duration for antibiotic therapy and instead encourage clinicians to tailor therapy based on the patient's response… We not only recommend that clinicians perform a deliberate and individualised assessment of the potential risks and benefits of various treatment options before making their initial selection, we also recommend careful follow-up because this allows them to adjust therapy as circumstances evolve. This patient-centred approach should reduce the risk of chronic illness due to inadequate antibiotic therapy.*"[31]

Unfortunately, other American government agencies have not yet updated their websites to reflect this. The Centres for Disease Control and Prevention, for example, still advises audiences to consult the IDSA guidelines for Lyme treatment.[32] Their definition of Post-Treatment Lyme Disease Syndrome also specifically mentions the outdated 2-4 week antibiotic regime.[33]

The National Institute of Allergy and Infection Diseases' (NIAID) page also refers to the IDSA antibiotic regime. The NSW Health Lyme disease fact sheet also refers to this outdated advice.

The LDAA believe that long term antibiotic treatment can be successful in treating both Lyme and Lyme-like illness. We have witnessed the significant and sustained improvement of health in patients who have undergone such treatment. We have heard from patients who have experienced regular Herxheimer reactions for months into antibiotic treatment; these reactions involve a short term intensification of symptoms as a result of successful bacterial die off. Some patients consider themselves 'in remission' or even 'cured'.

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[28] Agency for Healthcare Research and Quality, *What is the National Guideline Clearinghouse?,* accessed Nov 2016, https://info.ahrq.gov/app/answers/detail/a_id/230/~/what-is-the-national-guideline-clearinghouse%E2%84%A2%3F
[29] Agency for Healthcare Research and Quality, National Clearinghouse Guidelines, https://www.guideline.gov/summaries/summary/9537
Lymedisease.org, *IDSA Lyme guidelines removed from NGC; ILADS guidelines still there*, accessed Nov 2016, https://www.lymedisease.org/idsa-guidelines-removed-ngc/4
[30] L Johnson, *IDSA say revision of Lyme disease guidelines expected to take 2-5 Years*, accessed Nov 2016, https://www.lymedisease.org/lymepolicywonk-idsa-says-revision-of-lyme-disease-guidelines-expected-to-take-2-5-years/
[31] ILADS, *ILADS Guidelines are now summarised on the National Guideline Clearinghouse Website*, accessed Nov 2016, http://www.ilads.org/ilads_news/2015/ilads-treatment-guidelines-are-now-summarized-on-the-national-guideline-clearinghouse-website/
[32] Centres for Disease Control and Prevention, *Lyme Disease Treatment*, accessed Nov 2016, https://www.cdc.gov/lyme/treatment/index.html
[33] Centres for Disease Control and Prevention, *Post-Treatment Lyme Disease Syndrome*, accessed Nov 2016, https://www.cdc.gov/lyme/postlds/index.html

The Committee has read the submissions of patients, and heard testimonies including those who offer objective evidence of improvement resulting from this treatment, such as SPECT scans.

In the Sydney hearing 2 November 2016, ACIIDS' Chairman, Dr Richard Schloeffel stated *"Seventy per cent of my practice's patients recover fully and get on with their lives. They work, they get married, they have children, they study and they come back and visit. They send me postcards. Some of them have been bedridden, housebound, wheelchair-bound, seizing and unwell. I have treated them appropriately with appropriate care and they have fully recovered."*[34]

While 70% is not an ideal figure, it brings hope to many despairing patients; that hope is realised for most of them. We note that treatment for Lyme disease overseas also has a less-than-perfect success rate. We attribute this to the severity of damage caused by delayed diagnosis, and a lack of research. We also note that the treatment of many serious illnesses does not have 100% success rate. Chemotherapy for cancer patients is the obvious example. Yet cancer patients aren't denied their right to treatment.

During the Perth hearing, Prof Collignon suggested improvements in patients' health may be resulting from "*a placebo effort, or the natural course of the disease*."[35] We dispute this. A placebo effect cannot cause clinically observed Herxheimer reactions, improved SPECT scan results and the regaining of normal life as outlined by Dr Schloeffel above.

Table 1 of the LDAA's initial Submission reveals that it takes an average of 10.75 years from the time of tick bite, for patients to receive diagnosis. Figure 19 shows that 33.51% of patients consult more than 10 doctors prior to diagnosis. We wholeheartedly agree with the submission of patient Naomi Hart, who points out *"And when people suggest it could be a placebo effect, I ask, what about the 50-100 treatments I tried before this? Why didn't they work as a placebo?"*

Prof Collignon's alternative explanation of "*the natural course of disease*" relies on a huge amount of coincidence; that after more than a decade of illness, the disease spontaneously resolves in the period following initiation of treatment by a Lyme-literate practitioner.

LDAA volunteers are very involved with the patient community, including online groups with over a thousand members. We currently collaborate with 14 patient groups representing all states and territories of Australia, and one group from New Zealand. We have never heard of a spontaneous resolution of illness occurring, either directly or via a third party.

The Professors expressed the opinion that studies prove that long term antibiotic treatment is ineffective for Lyme disease. We dispute that these findings are conclusive, based on not only our own experiences, but the fact the ILADS guidelines were accepted onto the evidence-based NGC, while those of the IDSA were withdrawn.

That said, we are aware, of course, that CLD and its treatment are the subject of controversy. The CDC and NIAID sites make particular reference to that.

There are two key research areas relating to CLD:

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[34] Dr Richard Schloeffel, *Committee Hansard Proof*, 2 Nov 2016, p.56
[35] Prof Peter Collignon, *Committee Hansard*, 14 Apr 2016 p. 31

- the existence of chronic Borrelia infection after 2-4 weeks antibiotic treatment; and
- the impact of long-term antibiotic treatment on chronic Borrelia infections

There are literally hundreds of peer-reviewed studies on these topics. For the purpose of addressing this question, we'll focus on the research that the CDC and NIAID refer to.

Chronic Borrelia infection after 2-4 weeks treatment

Although the CDC and NIAID express doubt about the existence of CLD, they do acknowledge recent studies regarding Borrelia infections persisting in animals after antibiotic treatment.[36]

A summary of the studies are as follows:

Persistence of Borrelia burgdorferi in Rhesus Macaques following Antibiotic Treatment of Disseminated Infection, 2012[37]

In this NIAID-supported study, Rhesus Macaques monkeys were infected with B. burgdorferi spirochetes. These monkeys were chosen "*as they can reproduce many of the key signs of human Lyme disease, including neuroborreliosis*." There is also a similarity in the way the relevant antibiotics move through their bodies, compared with human bodies.

Six months after infection, the monkeys were given ceftriaxone via IV for 30 days. They were then given doxycycline capsules for 60 days. Pathology testing was then carried out to identify signs of remaining Borrelia.

The study reported that "*B. burgdorferi antigen, DNA and RNA were detected in the tissues of treated animals". It goes on to state that "Our results indicate that disseminated spirochetes of two different B. burgdorferi strains can persist in the primate host following high dose, or long-lasting antibiotic therapy."*

***Spirochete antigens persist near cartilage after murine Lyme borreliosis therapy, 2012*38**

This study used laboratory mice infected with B burgdorferi. A month after infection, some mice were given a 30 day doxycycline regime. Others were given ceftriaxone for five days. Tests were then conducted to identify any sign of remaining Borrelia. Borrelia spirochete antigens were located in the connective tissues.

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[36] Centres for Disease Control and Prevention, *Post-Treatment Lyme Disease Syndrome,* accessed Nov 2016, https://www.cdc.gov/lyme/postlds/index.html
National Institute of Allergy and Infectious Diseases, *Chronic Lyme Disease*, accessed Nov 2016, https://www.niaid.nih.gov/diseases-conditions/chronic-lyme-disease

37 Embers et al, *Persistence of Borrelia burgdorferi in Rhesus Macaques following Antibiotic Treatment of Disseminated Infection*, 2012, http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0029914

[38] Bockenstedt et al, *Spirochete antigens persist near cartilage after murine Lyme borreliosis therapy,* 2012, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3386809/

The authors state "*This is the first direct demonstration that inflammatory B. burgdorferi components can persist near cartilaginous tissue after treatment for Lyme disease. We propose that* ***these deposits could contribute to the development of antibiotic-refractory Lyme arthritis."***

Remains of Infection, 2012[39]

This article provides an overview of the controversy surrounding CLD. It also summarises relevant studies, including (but not limited) to those above. It refers to these as "compelling evidence."

Resurgence of Persisting Non-Cultivable Borrelia burgdorferi following Antibiotic Treatment in Mice, 2014[40]

This study was also completed on mice infected with B. burgdorferi. A month after infection, the mice were treated with ceftriaxone for 30 days.

Pathology testing was conducted on different mice 2, 4, 8 and 12 months after treatment. Borrelia DNA was found on each occasion, with the frequency declining between 2-8 months. However, at the 12 month mark, increased levels of B. burgdorferi DNA were found. The study notes that these levels were similar to those in infected mice who had not been treated at all.

The authors state that "*Results of this study demonstrated not only persistence, but also resurgence of non-cultivable B. burgdorferi in tissues of mice at up to 12 months following antibiotic treatment."*

They also note that "*The current study builds upon similar evidence of non-cultivable B. burgdorferi persistence in studies involving dogs, mice and macaques…as in various animal studies, persisting B. burgdorferi-specific DNA has been documented following antibiotic treatment in human Lyme borreliosis."*

In light of these studies, NAIDA have expressed an interest in finding evidence of Borrelia in Lyme disease patients who have undergone treatment. They state "*In a first-of-its-kind study for Lyme disease, NIAID-supported researchers have used live, disease-free ticks to see if Lyme disease bacteria can be detected in people who continue to experience symptoms such as fatigue or arthritis after completing antibiotic therapy. Larger studies are needed and ongoing to determine significance of preliminary findings presented by Marques*"[41]

[39] Barbour, *Remains of Infection,* 2012, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3386833/

[40] Hodzic et al, *Resurgence of Persisting Non-Cultivable Borrelia burgdorferi following Antibiotic Treatment in Mice*, 2014, http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0086907

[41] National Institute of Allergy and Infectious Diseases, *Chronic Lyme Disease*, accessed Nov 2016, https://www.niaid.nih.gov/diseases-conditions/chronic-lyme-disease

Details of the Marques study are below:

Xenodiagnosis to detect Borrelia burgdorferi infection: a first-in-human study, 2014[42]

This study used ticks raised in a laboratory, to ensure they were disease-free. When the ticks were ready for their first meal of blood, they were placed on people. These included patients who had had Lyme disease for varying periods.

The ticks were then tested to see if they had contracted B. burgdorferi from the blood. B. burgdorferi DNA was found in ticks that fed on a patient 8 months apart. That patient had already been diagnosed with "post-treatment Lyme disease syndrome" prior to joining the study. The patient had also completed antibiotic treatment more than three months prior to the study.

The impact of long-term antibiotic treatment on chronic B burgdorferi infections

The CDC and NIAID [43] refer to the following studies when discrediting long-term antibiotic treatment.

***Two Controlled Trials of Antibiotic Treatment in Patients with Persistent Symptoms and a History of Lyme Disease,* 2001**[44]

This study was conducted 1997-2000 and funded by NIAID. It involved patients diagnosed with Lyme disease who had experienced chronic symptoms for between 6 months and 12 years. The patients had all been previously treated with antibiotics.

During the study, half of the patients were given 30 days of ceftriaxone via IV line, followed by 60 days of oral doxycycline. The other half were given placebos.

Patients completed surveys before commencing the study, and again at 30, 90 and 180 days. These surveys documented patients' quality of life as a result of their symptoms. Physical examinations, neuropsychological testing and pathology testing were also completed at regular intervals.

55% of patients using the antibiotics "had improved health status" as measured by the surveys, compared to 42% of the patients using placebos. While this result clearly indicates more improvements in patients using antibiotics, the study's authors did not consider the percentages to be statistically significant.

We agree that a 13% difference between the two patient groups may not be very significant. As a result, we believe the study could reasonably be considered inconclusive. Instead, the CDC and

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[42] Marques at al, *Xenodiagnosis to Detect Borrelia burgdorferi Infection: A First-in-Human Study*, 2014, http://cid.oxfordjournals.org/content/58/7/937.long

[43] Centres for Disease Control and Prevention, *Research into Prolonged Treatment for Lyme Disease*, accessed Oct 2016, https://www.cdc.gov/lyme/treatment/prolonged/index.html
National Institute of Allergy and Infectious Diseases, *Chronic Lyme Disease*, accessed Oct 2016, https://www.niaid.nih.gov/diseases-conditions/chronic-lyme-disease

[44] Klemper et al, *Two Controlled Trials of Antibiotic Treatment in Patients with Persistent Symptoms and a History of Lyme Disease*, 2001, http://www.nejm.org/doi/full/10.1056/NEJM200107123450202#t=article

NIAID are using it as evidence that long-term antibiotic use is ineffective. This contradicts the study's findings, however small the statistical significance might be.

We note also that the daily dosage of doxycycline was only 200mg. In their 2008 treatment guidelines, ILADS state that "…*doxycycline can be very effective but only if adequate blood levels are achieved either by high oral doses (300 to 600 mg daily)."*[45] We wonder if patients would have had even greater improvements, had the treatment been considered adequate by ILADS' standards.

The study reported that "*evidence of persistent infection"* was not found. This result is not unexpected. Current pathology for Borrelia is not sufficiently reliable. That's why the CDC advise that Lyme disease is diagnosed based on symptoms.[46]

***Study and treatment of post Lyme disease: a randomized double masked clinical trial,* 2003**[47]

This study was also funded by NIAID. It involved Lyme disease patients with "*persistent severe fatigue at least 6 or more months after antibiotic therapy.*" Half were given 28 days of ceftriaxone via IV. The other half were given placebos.

Fatigue levels were measured via surveys. Cognitive function was also measured, via a "reaction test".

Again, the study reported some positive results. *"Patients assigned to ceftriaxone showed improvement in disabling fatigue compared to the placebo group".* However, *"No beneficial treatment effect was observed for cognitive function."*

Unfortunately, we only have access to the summarised version of this study. Our request to the authors for the full text of the study was not granted. Because of this, we can't tell you whether there was in fact some improvement in cognitive function, that wasn't deemed statistically significant.

The study concluded that *"Ceftriaxone therapy in patients with Post Lyme Syndrome (PLS) with severe fatigue was associated with an improvement in fatigue but not with cognitive function or an experimental laboratory measure of infection in this study. Because fatigue (a nonspecific symptom) was the only outcome that improved and because treatment was associated with adverse events, this study does not support the use of additional antibiotic therapy with parenteral ceftriaxone in post-treatment, persistently fatigued patients with PLS."*

Again, we believe this conclusion to be unreasonable. We agree that fatigue is "nonspecific". We therefore wonder why scientists used it as their main criterion for selecting patients. We also wonder why fatigue levels made up 50% of the measurable indicators of patient improvement

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[45] Burrascano, *Advanced Topics in Lyme disease – diagnostic hints and treatment guidelines for Lyme and other tick-borne illnesses*, 2008, p14, http://www.ilads.org/lyme/B_guidelines_12_17_08.pdf
[46] Centres for Disease Control and Prevention, *Lyme disease*, https://www.cdc.gov/lyme/, accessed Nov 2016
[47] Krupp, *Study and treatment of post Lyme disease (STOP-LD): a randomised double masked clinical trial*, 2003, https://www.ncbi.nlm.nih.gov/pubmed/12821734

identified by the study. Cognitive function made up the remaining 50%. This is a very broad field that was measured purely by the reaction test.

We don't consider "*experimental laboratory measures of infection*" to be significant. As earlier mentioned, even approved laboratory testing can't always identify infection.

Regarding the "adverse events," the summarised version of the study states, "*Four patients, three of whom were on placebo, had adverse events associated with treatment, which required hospitalisation."* Three of the four impacted patients weren't even using antibiotics. The problem wasn't the antibiotics themselves, but rather the use of IV.

The treatment of CLD doesn't require antibiotics to be administered via IV. Obviously, it's preferred in some instances, such as for patients with damaged guts, who cannot tolerate oral antibiotics. But it's not necessary for all CLD patients.

Many treatments for serious illnesses are risky. That doesn't mean that patients aren't treated. Instead, doctors inform patients of the risks, and the patient decides whether to accept treatment. If treatment is accepted, the risks are monitored accordingly. The Institute of Medicine calls this "patient-centred care." They define this as "*Providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions."*[48]

Why should the treatment of CLD be approached any differently?

Furthermore, the study clearly states that it doesn't support the use of one particular antibiotic via IV to treat persistently fatigued patients. At no point does it state that any long-term antibiotic use via any method is ineffective in treating patients, which is what the CDC and NIAID are implying.

Finally, we note that ILADS state that "*Treatment of chronic Lyme usually requires combinations of antibiotics."*[49] This is due to a number of reasons:

i) no single antibiotic currently used to treat Lyme disease effectively kills bacteria in both fluid and tissues
ii) treatment needs to address intracellular and extracellular bacteria
iii) Borrelia can change form to avoid the effects of certain antibiotics. Currently, no single antibiotic kills all forms of Borrelia[50]

It is therefore unrealistic to expect broad results using a single antibiotic.

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[48] Agency for Healthcare Quality and Research, *The Six Domains of Healthcare Quality*, accessed Oct 2016, http://www.ahrq.gov/professionals/quality-patient-safety/talkingquality/create/sixdomains.html

[49] Burrascano, *Advanced Topics in Lyme disease – diagnostic hints and treatment guidelines for Lyme and other tick-borne illnesses*, 2008, p12, http://www.ilads.org/lyme/B_guidelines_12_17_08.pdf International Lyme and Associated Diseases Society, *Evidence assessments and guideline recommendations in Lyme disease: the clinical management of known tick bites, erythema migrans rashes and persistent dise*ase (summarized version), *Recommendation 3b*, 2014,

[50] Burrascano, *Advanced Topics in Lyme disease – diagnostic hints and treatment guidelines for Lyme and other tick-borne illnesses*, 2008, p12-13, http://www.ilads.org/lyme/B_guidelines_12_17_08.pdf

A randomized, placebo-controlled trial of repeated IV antibiotic therapy for Lyme encephalopathy, 2007[51]

This study involved Lyme patients with "*objective memory impairment...marked levels of fatigue, pain, and impaired physical functioning*." All patients had previously had at least three weeks IV antibiotic treatment.

For the purposes of the study, patients received 10 weeks of either IV ceftriaxone or a placebo.

The study then looked for evidence of improved memory at Week 12. Patients were reassessed again at Week 24, to see if any improvement had been sustained.

The group who received antibiotic treatment had generalised "*moderate"* improvements in cognitive function in Week 12. The patients with "*more severe*" fatigue, pain and impaired functioning also improved. At Week 24, only the improvements in pain and physical functioning were sustained.

The study concluded that "*IV ceftriaxone therapy results in short-term cognitive improvement for patients with posttreatment Lyme encephalopathy, but relapse in cognition occurs after the antibiotic is discontinued. Treatment strategies that result in sustained cognitive improvement are needed."*

We are disappointed that the conclusion doesn't mention the sustained improvements in pain and physical functioning. As for the cognitive issues, we believe more reasonable conclusions are that more than one antibiotic should have been used, and/or that length of treatment was inadequate.

We are aware of many patients in Lyme-endemic countries who have required more than a year of combined antibiotic therapy in order to sustain improvements.

We note that all three studies actually record improvements in patients using long-term antibiotics. This occurred even when ILADS guidelines were not followed (ie inadequate dosage or failure to use a combination of antibiotics.) It occurred despite the likelihood of patients also having co-infections,[52]which would result in more intense and varied symptoms. We believe that the fact the CDC and NIAID were unable to reference any studies with no improvements shows that their argument is far from conclusive.

We acknowledge that Prof Collignon also expressed concerns regarding health risks associated with long-term antibiotic treatment. We have partly addressed that above, but would also like to share the opinion of ILADS on this topic:

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[51] Fallon et al, *A random, placebo-controlled trial of repeated IV antibiotic therapy for Lyme encephalopathy,* 2007, http://www.neurology.org/content/70/13/992

[52] Moutailler et al, *Co-infection of Ticks: The Rule Rather Than the Exception,* 2016, http://journals.plos.org/plosntds/article?id=10.1371/journal.pntd.0004539
J Mackenzie, *Scoping Study to develop a research project(s) to investigate the presence or absence of Lyme disease in Australia*, 2013, p20, http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-lyme-disease.htm/$File/scoping-study-2013.pdf

> *"Over two decades of experience in treating thousands of patients with Lyme has proven that therapy… although intense, is generally well tolerated…Remember, years of experience with chronic antibiotic therapy in other conditions, including rheumatic fever, acne, gingivitis, recurrent otitis, recurrent cystitis, COPD, bronchiectasis, and others have not revealed any consistent dire consequences as a result of such medication use. Indeed, the very real consequences of untreated, chronic persistent infection by B. burgdorferi can be far worse than the potential consequences of this treatment."*[53]

Other "non-mainstream" treatments that were not mentioned by Assoc Prof Zaggarella and Prof Collignon include hyperthermia treatment and blood ozone therapy. As such treatments are relatively new, and only performed overseas, we cannot comment on them in detail. However, anecdotal evidence from patients (including one of our own volunteers) indicates that these can be successful.

Furthermore, we refer you back to the 'Lyme Tick' segment aired on the ABC's 7:30 report in 1992, as previously references in APPENDIX 2 where Dr Bernie Hudson, addressing his young patient, mentions the 5th day of IV antibiotics provided, and note that she will be treated for 30 days of IV antibiotics. We assert that we have regressed a long way since then with many of our patient cohort unable to even obtain a 10 day course of oral antibiotics, for fear of turning Lyme sick patients into super-bug resistant beings. This is discrimination of course; no other patient group is singled out as one that generates super-bugs.

[53] Burrascano, *Advanced Topics in Lyme disease – diagnostic hints and treatment guidelines for Lyme and other tick-borne illnesses*, 2008, p22, http://www.ilads.org/lyme/B_guidelines_12_17_08.pdf

Appendices

APPENDIX 1

Dr Michelle Wills – Qualifications, experience & publications

1988- 1989	Part time Research Assistant in Virology, Mater Hospital. Duties: To develop a Membrane Filtration ELISA for the study of *Mycoplasma sp.*
1988- 1989	Part time Hospital Scientist in Virology, Royal Newcastle Hospital. Duties: Isolation and identification of pathogenic organisms, handling infectious materials, supervision and training of staff, review and revision of laboratory manuals, training medical students during laboratory placements, involvement in NATA accreditations, attend and carry out presentations at research meetings and journal clubs, Compliance with Occupational Health and Safety Standards.
1987	Part time Tutor in Microbiology, University of Sydney. Duties: To supervise practical classes, mark and assess practical exercises and general Microbiology tutoring

Publications

Chapters:

Barry RD, Hudson BJ, Shafren DR, **Wills MC.** Lyme Borreliosis in Australia, in *" Lyme Borreliosis"* ed Axford JS and Rees DHE, Plenum, London 1994; 75-82.

Refereed Journal Articles:

Wills MC, Barry Rd. Detecting the cause of Lyme Disease in Australia. *Med. J. Aust.* 1991;155:275.

Hudson BJ, Barry RD, Shafren DR, **Wills MC.** Lyme Borreliosis in Australia. *J. Spirochaetal and Tick Borne Diseases.* 1994; 1:46-51.

Hudson BJ, Barry RD, Shafren DR, **Wills MC.** Lyme Disease- made in Australia? *Today's Life Science 6, No 9,* 1994; 48-52

Conference Papers:

Shafren DR, **Wills MC** and Barry RD.
Antigenic properties of *Borrelia Burgdorferi* isolated from *Ixodes Holocyclus* and other Ticks in eastern Australia.
Proceedings of the V International Conference on Lyme Borreliosis, Arlington, VA, 1992, A44, 256.

Wills MC, Shafren DR, Hudson BJ and Barry RD.
Lyme Borreliosis in Australia.
Australian Microbiologist, 1993, 14, A104 GL17

Barry RD, Hudson BJ, Shafren DR, and **Wills MC.**
Evidence for an indigenous form of Lyme borreliosis in Australia.
Australian Tropical Health and Nutrition Conference, 1993.

Barry RD, Hudson BJ, Shafren DR, Caves SF and **Wills MC.**
Immunoblotting for the detection of Lyme borreliosis in Australia.
In Conference Compendium: Lyme Diseases: State of the Art- Neurological Manifestations, Connecticut, 1994.

Hudson BJ, Barry RD, Shafren DR, **Wills MC** *et al.*
Multisystem involvement with Lyme borreliosis in Australia.
In Conference Compendium: Lyme Diseases: State of the Art- Neurological Manifestations, Connecticut, 1994.

Barry RD, Hudson BJ, Shafren DR, Caves SF and **Wills MC.**
Immunoblotting for the detection of Lyme borreliosis in Australia.
Proceedings of the VIth International Conference on Lyme borreliosis,
Bologna, Italy, 1994, P103T.

Barry RD, Hudson BJ, Shafren DR, Caves SF and **Wills MC.**
Multisystem involvement with Lyme borreliosis in Australia.
Proceedings of the VIth International Conference on Lyme borreliosis,
Bologna, Italy, 1994, TO33T.

Research Grants

PhD and related grants:

Incidence, severity and prevalence of Lyme disease in Australia
1993, $8000., Arthritis Foundation of Australia

How important and serious is Lyme disease?
1992/3, $30,000., Roche Pharmeceuticals

Epidemiology of Lyme diseases
1994, $28,000., Roche Pharmeceuticals

The natural history and prevalence of Lyme disease in Australia
1994, $14,000., Pfizer Ltd.

Post Doctoral Grants:

Research grant currently offered and under negotiation:
Approx. $100 000., VACS of Life Plc./ Oxford University, London

APPENDIX 2

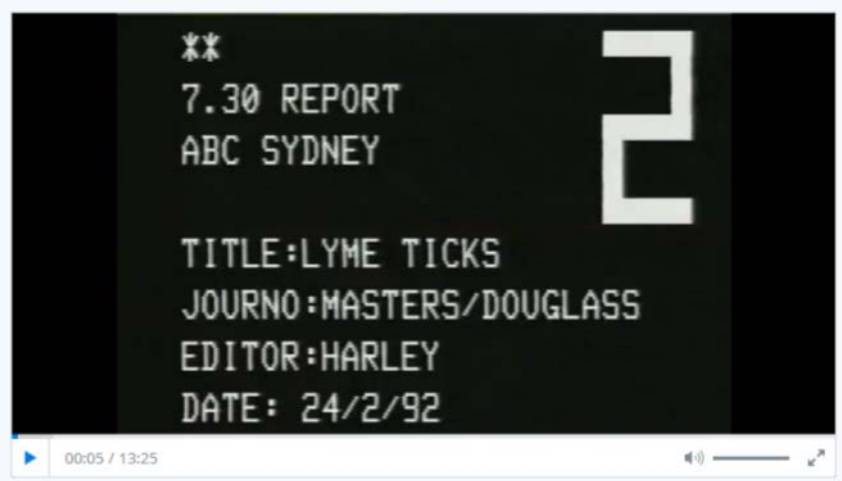
ABC 7:30 REPORT

TITLE: LYME TICKS

JOURNO: MASTERS / DOUGLASS

DATE: 24/2/1992

FILE: Access via YouTube link https://youtu.be/wnnFrC2x-zA



APPENDIX 3

Interview with Dr Michelle Wills 10 November 2016

FILE: AUDIO mp3 Access via SoundCloud Link -

[redacted]

Transcript – LDAA – Dr Michelle Wills PhD Interview

November 9th, 2016

AUTOMATED VOICE: The conference is now being recorded.

SHARON WHITEMAN: So, my name is Sharon Whiteman. I'm the President of the Lyme Disease Association of Australia. And Michelle Wills has put her hand up to offer some evidence for the final terms of the Senate inquiry into Lyme-like illness.

So, to start with, Michelle, thank you for being willing to put your hands up to help us out as a country and as Lyme patients. Thank you. I know you're on holidays, I appreciate you being here.

MICHELLE WILLS: No problem.

SHARON WHITEMAN: OK. Could you please state your name and address, please.

MICHELLE WILLS: My name is Michelle Wills and I live [address redacted].

SHARON WHITEMAN: Excellent. And as I just said, you're speaking with Sharon Whiteman, the President of the LDAA. Can you please provide your verbal consent for me to record this interview.

MICHELLE WILLS: Yes that's fine to record the interview.

SHARON WHITEMAN: Thank you. And do you also provide your consent for a copy of this interview to be made available as part of a supplementary submission to the LDAA that we will be sending to the Senate committee regarding, regarding the inquiry into 'Growing evidence of a Lyme-like illness in Australia.'

MICHELLE WILLS: Yeah, I give permission for that as well.

SHARON WHITEMAN: Thank you Michelle. So, to start with, can you please let us know and state your academic qualifications.

MICHELLE WILLS: Yes, I have a PhD in Medicine from University of Newcastle. I'm a Bachelor of Science in Agriculture, with first class honours in Microbiology from University of Sydney and a Postgraduate Diploma in Education with merits from University of Newcastle.

SHARON WHITEMAN: Thank you. And can you please confirm that you are the Michelle Wills which is the author of the thesis in regards to Borrelia in Australia. What exactly was it, Michelle?

MICHELLE WILLS: Yeah, I am the author of that thesis. That was "Lyme Borreliosis: The

Australian Perspective," and I am the author.

SHARON WHITEMAN: Excellent. So, tell us a little bit about your research findings back at that time.

MICHELLE WILLS: The research that we were looking at, there was really a couple of components. The first component was to see if Australian ticks carried spirochetes. That was the main focus initially in the process. And very quickly we did find that Australian ticks do carry spirochetes. There was no question about that.

From there, we found it very difficult to grow these spirochetes. And what we believe is that they were fastidious organisms, slightly different to what we've seen in the US. And for that reason, we felt a lot of work needed to go into appropriate growth conditions for the spirochetes. However, we could grow them [inaudible]. And on our limited molecular biology at that time, remembering that was 20 years ago, we were able...

SHARON WHITEMAN: Sorry, you're just breaking up a little**.** So I'm not sure if you knew. I know you're on your mobile.

MICHELLE WILLS: Yeah, I'll just move around a little bit, if that's better. So we were able to show that they were Borrelia species. But we couldn't do a lot of work on it, primarily because we didn't have the funding to really look at culture conditions. So from there we decided, and we linked up with Dr Bernie Hudson from Royal North Shore Hospital and we then decided to look at whether people in Australia that *clinically* presented with Lyme disease actually had antibodies in their blood that would suggest they had come into contact with Borrelia. And we were able to show that, I think quite conclusively, that Australian – people who'd not even been outside Australia - who did have Lyme disease symptoms, did have antibodies to Borrelia. So, in our minds, this was evidence that Lyme disease was the cause – well, at least they'd been, come into contact with the Lyme disease organism, even though they had not left Australia.

SHARON WHITEMAN: OK, and was there anything more about your particular discoveries in this research? You had a different kind of…excuse my lack of scientific knowledge, but didn't you have to use a particular…*adjust* you cultured them because it had a different medium?

MICHELLE WILLS: Yeah, OK. So, umm, the two key things I think which were interesting in the Australian case, so, as far as the tests we used to test for the antibody in the patient's blood, we used three different species of Borrelia.

And what we found is that Australian patients, or Australian people who clinically presented with Lyme disease, did not often show antibodies to Borrelia burgdorferi senso stricto, or the primary organism that isolated - not isolated, but, umm - described to cause Lyme disease in the US.

However we did find most patients had antibodies to afzelii and there was another strain we tested which, right this moment I've got a mental blank. But what this shows is that…

SHARON WHITEMAN: Was it afzelii?

MICHELLE WILLS: Sorry?

SHARON WHITEMAN: afzelii, was it?

MICHELLE WILLS: So that one and there was a garinii, garinii. So, there was two extra species; they were still considered Borrelia burgdorferi, but they were given, and I'm not so whether the names have changed over the last 20 years, but they were also known to cause Lyme disease.

So what we found was, Australian patients would not react, but you couldn't detect whether they had Lyme antibodies using traditional methods that were based upon using Borrelia burgdorferi senso stricto in the test. We set up a Western blot system which allows us to look for specific markers against Lyme disease and definitely, we were able to show that people with Lyme disease symptoms definitely had antibodies to specific markers that were known to cause Lyme disease in the Northern Hemisphere.

SHARON WHITEMAN: Excellent. And so, you, did you find those same spirochetes in ticks as you did in humans who presented with Lyme-like symptoms?

MICHELLE WILLS: OK, this is one of the weaknesses of the study, it's because the [inaudible] …spirochetes from the ticks. [inaudible] there was no question about [inaudible], they were Borrelia spirochete, and in fact we took some samples to the United States to Professor Bundoc's [factual correction Alan Barbour's] lab, who is actually, was um, who originally worked with Willy Burgdorferi, so we felt he was quite expert. And he, he agreed these were Borrelia species…

SHARON WHITEMAN: ...in Australian ticks.

MICHELLE WILLS: In, from Australian ticks. So he was, he was convinced that they were. However, the growth medium that was designed to grow these spirochetes did not sustain them. Now that's not unusual with bacteria or, or fastidious organisms. Sometimes they need extra nutritional supplements in the medium to ensure that they can multiply. Now, we knew that more work had to be done in that area, but we didn't have the resources to do so. So the only thing we could do is to look at the spirochetes we had, and see if they had, um, markers on them that would indicate that they were Borrelia and we were able to show that.

We also did some preliminary, preliminary molecular biology on them. But as I said that was 20 years ago; so it was a completely different world back then for molecular biology. And our results did indicate they were Borrelia.

SHARON WHITEMAN: OK, excellent. And you also had, um, was it your supervisor was Professor Barry? Can you tell us…[inaudible]

MICHELLE WILLS: Yeah, my - yeah. Yeah. So, Mr, um, Dr, Professor Barry was my supervisor. I'm quite lucky to come across him. Research in Australia if you're, if you want to do a PhD, usually

you have to do a project defined by your supervisor. But quite fortunately I approached Professor Barry about doing this project on Lyme disease, and he was extremely supportive. Um, we then had to tackle the problem of funding and that was the biggest problem that we faced. We had very little funding in the projects and basically I think our outcomes considering the small amount of funding we had, I think they were quite significant; we really worked hard. But you know, there is a lot of questions unanswered and we identified them in my thesis and we said you know these are areas that need to be investigated with some urgency and we did try to get funding after I submitted my thesis. But the politics at that time in Australia, there was no way you could continue with Lyme disease research. There was just.. no one was willing to fund it.

SHARON WHITEMAN: And you've um, shared with us a 7:30 Report segment where you were interviewed, and some patients. Can you tell us, is there anything you'd like to add to that video, or anything that was highlighted in that media segment?

MICHELLE WILLS: Um, we did that, um, 7:30 Report, and we wanted to highlight that Lyme disease did exist in Australia, and that we were doing research on it. Um, I know - and I was quite a young naïve scientist at that time - I know it did cause a lot of controversy and I do understand there were threats of legal action against 7:30 Report from other researchers, but I can't give you the details of that. Except I do know that it became a major political issue in the scientific circle, and there was a lot of….egos, um, *very hurt* by that report.

SHARON WHITEMAN: So it was pretty well simultaneous to your work, um, the Professor Russell and Stephen Doggett research group got a significant NHMRC grant to study ticks, almost around the same time; they overlap your research, is that true?

MICHELLE WILLS: Yeah, they were actually awarded the funding before we found the spirochetes. So…

SHARON WHITEMAN: OK

MICHELLE WILLS: …at the time they got the funding; well, at the time they applied for the funding, um, no one in Australia had found spirochetes in ticks. But then they got the funding, and I think, I think by the time they got their funding, we had reported there were spirochetes in ticks.

SHARON WHITEMAN: OK. And can you comment on the, on the situation…or did you have any other relationships with the Russell and Doggett group at Westmead?

MICHELLE WILLS: Um, no. We, from the beginning they just said Lyme disease didn't exist. And I can't recall, I think we did have some, we did go down to meet some people at Westmead, but they weren't interested in collaborating, which is not unusual; their research direction was slightly different to ours.

We were, we were approaching it from a microbiology point of view, because we were interested in the disease and the treatment and diagnosis, whereas they were approaching it

from the insect, entomology point of view. So we were coming at it from different angles. I think the biggest problem for our research was a paper that they published [inaudible]…but it was called, it was about spirochete-like organisms.

SHARON WHITEMAN:. Yeah, you just broke up a bit there.

MICHELLE WILLS: Oh sorry. Yeah, the paper that was published about spirochete [inaudible]… and that bought into question whether or not what we were isolating were actually spirochetes. Now we knew they were, we had, you know, had it confirmed from, you know, an expert in the United States; they were spirochetes. Um…[inaudible]…conclusively. we needed to do more research into how to grow the spirochetes. We had no funding so we couldn't do it. And one of the, the issues that... around that time was if people have Lyme disease in Australia, why can't we grow the spirochetes from their tissue samples?

And we kept saying the problem is, the growth medium that has been developed does not grow the spirochetes we have in Australia. It's not good enough; there's some nutrient missing in it, that stops that. Now we all we already knew that isolating, isolating Borrelia from a person infected with Lyme disease is not easy. It's all [inaudible] a physical thing. Then you add on to that the fact that we didn't have an ideal growth medium to grow the spirochetes. Now, we identified this as a problem. However, there's just no money, no research.

People had decided Lyme disease didn't exist, so they, so basically, their argument was we don't believe it exists. We're not going to fund it. So therefore, it'll go away. It didn't go away, obviously. So, that was a problem, you know, we just didn't have the resources to continue with the work.

SHARON WHITEMAN: OK, excellent, and so just to confirm, you found what you thought was three different strains or whatever the scientific term is, of spirochetes, in 1992; they were confirmed by the US lab which discovered the original US strain. Umm…

MICHELLE WILLS: OK, we'll go back. We'll go back a step. So in the Australian ticks, so we looked at Australian ticks; we were able to grow and isolate spirochetes that we could, which we confirmed by the techniques available at that time. So again I keep saying, 20 years ago it was a different world scientifically. So, at that time we were able to show that what we had isolated were Borrelia species. What we couldn't do was grow them very well, because they were [inaudible]…organism, that were not the same as what's observed in the Northern Hemisphere. And clearly, so, logically, they needed to grow [inaudible]…we didn't have the resources to investigate. So we knew the Australian ticks had spirochetes.

When we tested people for Lyme borreliosis, we were able to show that they had - so, people with clinical Lyme disease, as diagnosed by a specialist, clinically they fit the picture of Lyme disease although it was much more neurological Lyme disease than what we've seen in the US, it was much, many more neurological symptoms. What we could show is that these people even though they'd never left Australia, have antibodies in their blood that showed that sometime in their life had come in contact with Borrelia. So that meant that even though we couldn't say the Borrelia caused the disease, what we could say was these people with symptoms of Lyme, like

Lyme disease had markers in their blood which indicates they had, somehow in their life, come across Borrelia.

Now in the ones that we report on, they also say they do remember a tick bite. Some of the evidence that we presented was quite circumstantial, but we identified that in the research and we said more research needs to be done. And it wasn't done.

SHARON WHITEMAN: Excellent, and um, in your expert and professional opinion, is there Borrelia in Australian ticks that are known to bite humans.

MICHELLE WILLS: OK. In my opinion - I'm not an entomologist - in my opinion and from my research, there is no question in my mind that there's Borrelia in Australian ticks. Whether or not it is the same as exists in the Northern Hemisphere, that's yet to be proven. Whether or not it causes the Lyme disease symptoms we see in Australia, that's yet to be proven.

But I think the thing is here is that 20 years ago, and if you put that into perspective - well more than 20 years ago, 20 years ago - we knew Australian ticks had Borrelia; we knew that there were people with clinical symptoms of Lyme disease. We knew these people had a, had a history of tick bite. We knew these people had markers in their blood called antibodies that showed that they had been exposed to Borrelia.

And also very importantly, we know they responded to the treatment for Lyme disease; they got better. If they were treated early, they got better. Now we knew that 20 years ago. We knew we didn't have proof, we had no proof – conclusive, ultimate proof - Lyme disease exists in Australia. What I don't understand is, why the government didn't want more research into it, or whether they didn't accept the fact that people with this particular clinical picture responded to this treatment and they should be given the treatment if they present in that way. It was kind of, um, when I submitted my thesis, that suddenly Lyme disease became a black hole and nobody wanted to talk about it again.

SHARON WHITEMAN: I know as President of the Lyme Disease Association I can concur with you. Even in 2015, I spoke to a researcher from [redacted] and when he agreed to do be supervisor for a PhD student who wanted to study the ticks in their area, because acquaintances or friends of hers had got Lyme disease from ticks on a sporting field, he said as soon as I said yes as soon as we publicised it, I lost count of the emails from my colleagues saying "Oh, you're committing professional suicide to even put your name against it."

So outside of anything you said now is there anything in regards to what you think the controversy might be founded in, or from your perspective, and your own personal experience?

MICHELLE WILLS: In my personal experience, and I'm not, you know, I don't want to put a blanket over all research because it's just not true. Australia has poor funding on research; just not much money. It's very competitive, and, for an academic the only way to get promoted is to get the money and do the research.

Now, small scientific communities; everyone knows everyone else. It's true, everyone wants to support their mates. Umm…I have had personal experiences where I've been told if I don't keep my mouth shut about particular issues of academic misconduct, then I'll lose my job. So there is,

there is significant problems in the academic community perhaps all over the world but definitely my experience in Australia; where there is a lot of pressure, a lot of pressure to fit in with the status quo. So to speak, to speak out and say Lyme disease exists… You know, you have a lot of pressure from people to say, you know, a lot of people's egos are going to be hurt if you know we accept Lyme disease exists.

Twenty years of people are not getting treatment that's a big thing. So people are nervous. People are nervous that the truth may come out, and it's not just in Lyme disease. In my experience I have seen it on so many levels, and you know I did speak out about academic misconduct and I did lose my job over it, and, um, I'm not the only one.

And there's many many academics now who are saying, you know, that there's got to be a change in the way we address research funding. I don't know the answer but I do know that, you know, if academia is there to help people, then I don't think we're really helping people the way we should be doing.

SHARON WHITEMAN: Do you have any professional comments on why it's seemingly entomologists' opinions or research overrules, like, a biologist when this is a human disease issue?

MICHELLE WILLS: I really, I can only speak from my time back 20 years ago because I haven't kept up with some research in Australia in the last, let's say 10-15 years.

When I was going through, you have, um, strong packets of research groups, and once that research group is seen as the expert regardless of what it, what other evidence comes up, it's very hard to convince people that the experts could possibly be wrong.

Why entomologists given microbiology research, I think to be fair to the group that did that, the project that they submitted to the NHMRC was more based on the insects. It was more based on the ticks, whereas really, what needed to be done was a focus on the patients and the organism itself. And I think that was where, in my opinion, there was a hole in the research. Yes, I know the research was published by the entomologists, but they weren't looking at people, they weren't looking at blood tests and they…entomologists probably don't and I know, I might be speaking out of turn, but I mean, that perhaps an entomologist is not the best person to investigate a microbiological disease. Perhaps it should have been a microbiologist or a kind of microbiologist investigating it. I mean, and that's just my opinion.

SHARON WHITEMAN: That's fine. And two more questions, Michelle. As part of the ABC 7:30 Report interview, you mentioned that test kits for blood testing based on your findings could be developed in a matter of months.

MICHELLE WILLS: Yeah.

SHARON WHITEMAN Now my understanding that didn't happen. Do you know, what's in your opinion again, as an expert, why there's been no test kits progressed since that time?

MICHELLE WILLS: OK. So, um, we did develop a test. It was a, it was a laboratory based test, in that it wasn't set up for a commercial facility. It was very time consuming and labour intensive,

but we knew it worked.

To do the next step as a commercial project, we needed support from umm, well, we needed support, so people would say "Yeah there is Lyme disease." But unfortunately we had this test that showed people had Lyme disease, and then suddenly the Australian medical community said "No, there's no Lyme disease."

And so, there was no market for a test for Lyme disease, if the Australian medical community is saying "There is no Lyme disease." And at that time, I completed my PhD and I do know…um, Professor Barry tried to continue to get funding to develop it further but, you know, by this stage [inaudible]. If you have a community that says "Lyme disease doesn't exist", then a commercial body, looking at developing a commercial, you know [inaudible]…you kind of go "What's the point? There's no point"

SHARON WHITEMAN: You're breaking up there again.

MICHELLE WILLS: Oh, sorry.

SHARON WHITEMAN: So it's not commercially viable, you're saying?

MICHELLE WILLS: Sorry?

SHARON WHITEMAN: You're saying that it wouldn't…

MICHELLE WILLS: Yeah, that's right, that's right. It's not commercially viable if [inaudible] …these tests… and I think that's what we got in that ridiculous cycle where people go "It doesn't exist, we won't test for it." But if they tested for it, then maybe you'd find it did exist. So, you know it's just a ridiculous situation that developed.

SHARON WHITEMAN: And you know, I know from witnessing that ABC 7:30 video, you connected with some of these sick patients and tested many of them, as a - you know, with a PhD in Medicine, which obviously is help people - how do you feel about the last 20 years' delay in…or denial, or regression, or whatever, I don't know what you would call it?

MICHELLE WILLS: You know, I think it's really heartbreaking, because um, I did know, at that time I did know some of the people with Lyme disease and you know, many of them did get better. You know the ones who got treatment got better. There's some, some people I know have ongoing symptoms of Lyme disease. And then I, you know the other night I was watching a story, of, you know, the current Lyme disease victims and they're not getting treatment. And it breaks my heart because I don't know why they're denied treatment when we know the treatment works. It's - because regardless of what's causing the disease, if someone's sick, you treat them, you're treating the symptoms - you want them to get better.

And I don't understand as a scientist, why medical people aren't doing their job, treating people for a disease - regardless of whether they believe it exists or not - but treating those people with medication that could, you know, save their lives.

Um, I mean I've been quite shattered; as an academic I thought you're going to academia to help people and - not just the Lyme disease stuff, but my last 20 years experience on a number

of levels - I've realised that academia now is not that. It's …unfortunately it has become a lot of egos and powerful research groups, and it really breaks my heart. I mean there's some fantastic researchers out there who are doing *everything* they can to make this place, you know, a better world. But there's so little research money and so many egos, and in the end, it's the community who's suffering, that's what I think.

SHARON WHITEMAN: And, in completion, Michelle, is there anything else you'd like, if you think it's important for the Committee to know, in making their deliberations and towards the final report in this inquiry?

MICHELLE WILLS: I will add - and I'm assuming that I'm allowed to say this at an inquiry – but, you know, I have been told that there are people involved in Lyme disease research that have been um, threatened if they talk out publicly about Lyme disease. Threatened about losing their job [inaudible]..had probably not death threats and and, you know, it sounds unbelievable that in a country like Australia, that it would get that nasty. But my own experience if you do speak out against popular opinion you do lose your job in academia. And I'm sure it's the same in other you know other areas such as, you know, Department of Health or whatever.

So I think what's happened here is 20 years ago, perhaps, perhaps some egos, some powerful people; their egos were hurt. And we've had 20 years that people haven't got treatment and I think it's time to give these poor people the treatment they need, and stop trying to cover up a mistake and just help, you know, these people. It's a desperate situation. And anyone with any empathy or, um, you know, understanding of how sick these people are, need to stop trying to cover up mistakes of the past and just deal with the present and help these people as soon as they can.

SHARON WHITEMAN: It's hard to be an 'innovation nation' if innovation is perceived as a threat to the status quo, isn't it?

MICHELLE WILLS: Sorry, could you just repeat that question?

SHARON WHITEMAN: It's hard to be an 'innovation nation', as you know, as is spouted at the federal level, if innovation is threatening the status quo.

MICHELLE WILLS: And that's exactly right and I mean, honestly, if you look in the whole history of science nothing's really changed. Whenever you have a status quo or an opinion in science, trying to change that opinion's almost impossible. And it's because people don't like to find out they're wrong. And that's a sad thing, because that's what science is, isn't it, really? It's looking at a problem and finding the answer and it doesn't matter if you're wrong. It's about being honest about the truth.

But, um, you know I have…in just adding one more thing. I have, sort of, comments made by medical people saying "Well the scientists need to solve this problem. They need to solve it; they need to get out there and find the answers." And it's true. [inaudible]…but they can't do it without funding. It cannot…you know, you need funding, it's just the way it is.

And, in the meantime, while they're looking for the answers, we need to remember the real

people who are really sick and they shouldn't be denied treatment because the popular opinion is to deny the disease exists. The symptoms exist, so something is happening out there. So you know [inaudible] each other. We've got to stop looking in the past. We need to look at the future, but we need to treat the people who are sick today.

SHARON WHITEMAN: They're in a situation which could be now considered an emerging illness, since it's been emerging for 30 years.

MICHELLE WILLS: That's exactly right.

SHARON WHITEMAN: Patients are one third of the evidence, aren't, they, in any…in science and in medicine?

MICHELLE WILLS: Well in medicine, I think, you know, we have to look at patient completely because, you know, um, if we look traditionally at microbiology that's how you know, we, we learnt to treat people, we looked at how they were sick, and how they responded to treatment.

I mean…whether or not we can isolate a spirochete from Australian, from an Australian tick, is really [inaudible]...and they need a dose of Doxycycline to get them better. Why would we be waiting for that spirochete to be isolated? Why don't we just treat the person while we're still looking. Do we have to wait until science catches up with the clinical picture? I don't think we need to wait. Science can never catch up to the clinical picture if there's not money put into it.

SHARON WHITEMAN: Michelle, did you want to make any - you left your academic career, is it to do with any of this controversy or experience that you had?

MICHELLE WILLS: Um, I ended up leaving academia because I reported academic misconduct at a university. I was told if I kept my mouth shut, I would keep my job. I decided not to keep my mouth shut.

After that there were several other, oh, I would say in the hundreds of other people who have contacted me, who are academics who have been in the same situation. Unfortunately, universities seem to be a law unto themselves. And I'm shocked, but I'm glad I stood up and I'm glad I spoke about academic misconduct. The person I spoke about, the academic misconduct, was promoted. And even though it was proven in court without question that the academic misconduct occurred, yeah, I was still…ended up losing my job.

SHARON WHITEMAN: So sorry to hear that, Michelle. And I know it might have taken some emotional fortitude to speak with us and to talk about all this again, but thank you on behalf of Lyme patients of Australia.

MICHELLE WILLS: No, I hope it helps and I hope these people get the treatment that they need.

SHARON WHITEMAN: Thanks, Michelle thank you so much.

MICHELLE WILLS: OK then. Bye bye.

SHARON WHITEMAN: OK, bye bye.

------End------

APPENDIX 4

Letter from the University of Texas to Wills and Barry

The University of Texas
Health Science Center at San Antonio
7703 Floyd Curl Drive
San Antonio, Texas 78284-7758

Department of Microbiology

(512) 567-3950

14 January 1992

Dr. Richard Barry
Discipline of Pathology
University of Newcastle
Australia

Dear Dr. Barry,

Thanks for your reply of 24 December. It's exciting to know that at least 3 of your 9 isolates are positive for H5332. Were they all positive for H9724? This anti-flagellar antibody is specific for all Borrelia species.

We've just shipped today four tubes (numbered 1-4) for you. Note that they were declared as simply culture media. The Fed. Exp. Airway Bill # is 4405 7812. The corresponding B. b. strains are as follows:

1 - G1 (Germany)
2 - G25 (Sweden)
3 - IP21 (Leningrad, Russia)
4 - IP90 (Siberia, Russia)

As far as I know, Dr. Munro has had no contact with us. Best wishes and please keep us informed of developments.

Sincerely, Virginia A. Burmeister

APPENDIX 5

Sydney Morning Herald article, February 5, 1995

The Sydney Morning Herald

Lyme disease: the tick-born epic

By DEBRA JOPSON

A controversy is raging among NSW scientists over whether a debilitating disease transmitted by ticks, which has reached epidemic proportions in the United States and Europe, now exists in Australia.

Associate Professor of Microbiology at Newcastle University, Richard Barry, said he had documented 66 cases of Lyme disease.

"That is probably the tip of the iceberg. If we have found 66, there could be 6,000," he said.

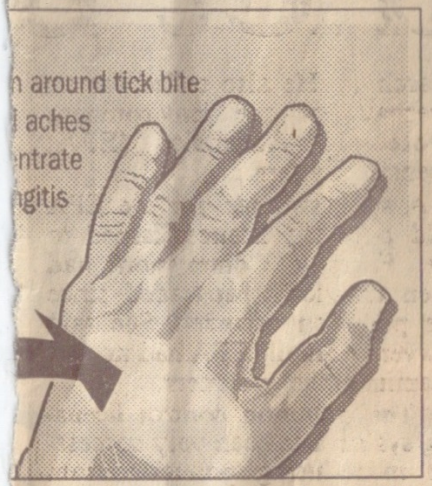
Professor Barry believes the disease, whose symptoms range from flu-like fever and arthritis to meningitis, exists along the entire Australian east coast and that the indigenous strain is slightly different from the overseas version. Native marsupials, particularly bandicoots, were once the main carriers of the disease but many dogs and cats now carry it, passing it on when a tick which has taken a "blood meal" from them bites a human, he said.

Despite Professor Barry's evidence, a 130-member Lyme disease sufferers' support group based in Sydney's northern beaches, Tick Alert Group Support (TAGS), has unsuccessfully lobbied for a Medicare rebate on a $50 Newcastle University diagnostic test they say is the most reliable in Australia.

Professor Barry has been unable to get his findings published in the *Medical Journal of Australia* and said that his team can only just "scrape by" in keeping its research into the disease going because it cannot get government funding.

A research team based at Westmead Hospital which searched for the organism in 13,000 ticks using a National Health and Medical Research Council grant two years ago

lemic the experts can't agree on



could find no evidence that the disease exists in Australia.

Westmead Hospital honorary clinical fellow Dr Richard Lawrence said: "What we have got is a disease that is a constellation of symptoms and if I called it anything, I would call it Lyme disease syndrome."

He said it was likely that Australians who believed they had it really had "a bunch of different diseases".

Miss Michelle Wills, a Newcastle University PhD student, claims to have isolated the spiral-shaped bug, or spirochaete, from ticks. Dr Lawrence said this was was "probably the tail of another organism".

Miss Wills yesterday rejected this, saying she had done further tests whose results had not been published proving that it was a separate organism.

A senior scientific officer in Westmead's microbiology department, Mr David Dickeson, said that in 5,000 tests on blood samples from those suspected of having Lyme disease, only those from people who had been overseas had been positive.

The co-ordinator of TAGS, Ms Terry Moore, said that it was unfair that the Westmead test was claimable on Medicare but the Newcastle test was not.

"There is a low level of awareness and it does not help to have a group in Westmead that clings to the idea that it is not here," she said.

"A lot of GPs simply do not know how to recognise the early signs of symptoms, so it gets missed early."

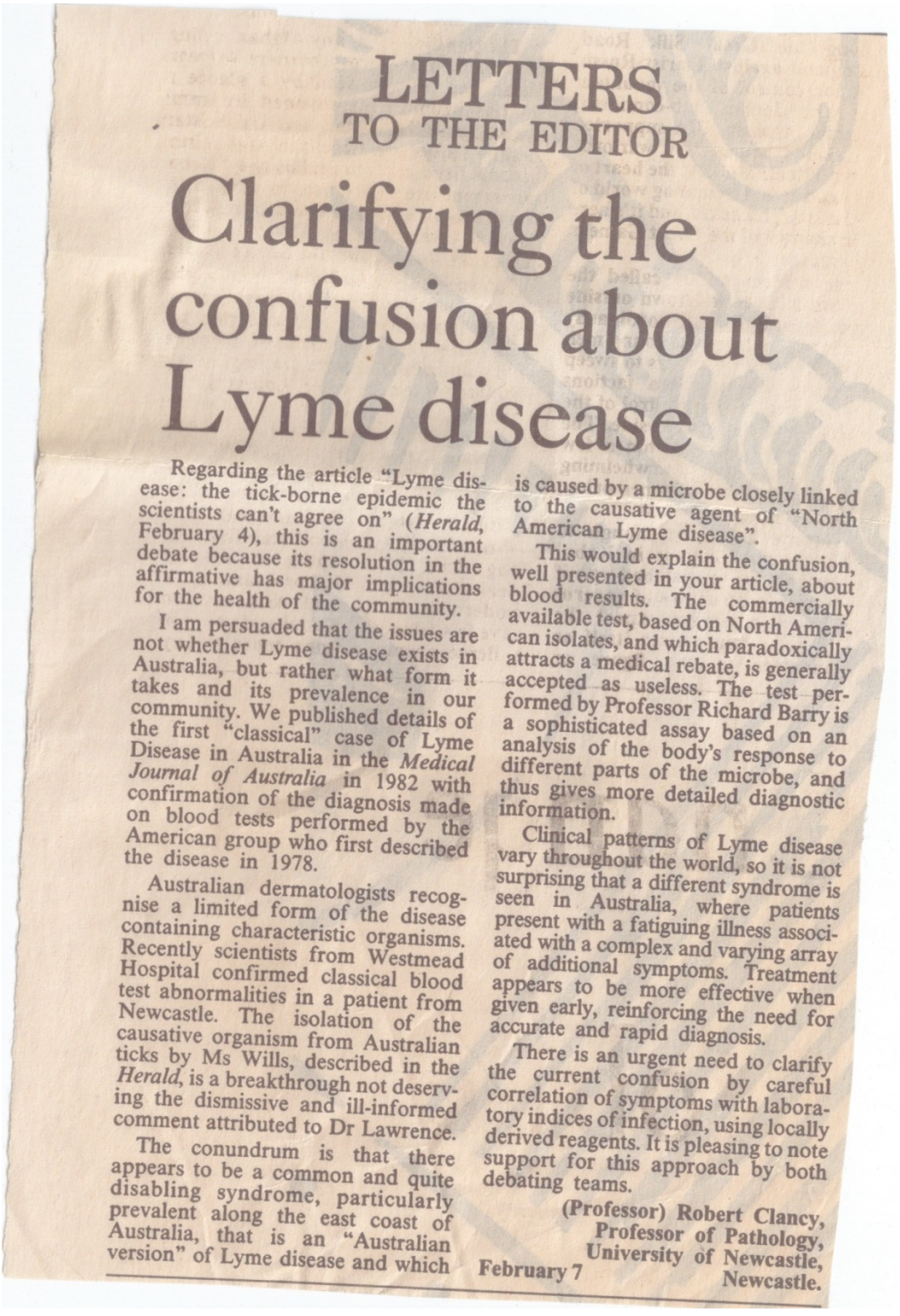
Caught early, Lyme disease could be treated with antibiotics, but once it became chronic, it could permanently disable people physically and mentally, she said.

Dr Bernie Hudson, a microbiologist who runs a clinic for Lyme disease sufferers at Royal North Shore Hospital, said it was better to treat those with symptoms of the disease as if they had it, rather than waiting years to have its existence in Australia accepted by other scientists, he said.

Westmead entomologist Dr Richard Russell said his group had been "painted as baddies" but he would like to see the Newcastle team "get some money to do a definitive study and find out if it does exist".

APPENDIX 6

Sydney Morning Herald Letter to the Editor, February 7, 1995



LETTERS
TO THE EDITOR

Clarifying the confusion about Lyme disease

Regarding the article "Lyme disease: the tick-borne epidemic the scientists can't agree on" (*Herald*, February 4), this is an important debate because its resolution in the affirmative has major implications for the health of the community.

I am persuaded that the issues are not whether Lyme disease exists in Australia, but rather what form it takes and its prevalence in our community. We published details of the first "classical" case of Lyme Disease in Australia in the *Medical Journal of Australia* in 1982 with confirmation of the diagnosis made on blood tests performed by the American group who first described the disease in 1978.

Australian dermatologists recognise a limited form of the disease containing characteristic organisms. Recently scientists from Westmead Hospital confirmed classical blood test abnormalities in a patient from Newcastle. The isolation of the causative organism from Australian ticks by Ms Wills, described in the *Herald*, is a breakthrough not deserving the dismissive and ill-informed comment attributed to Dr Lawrence.

The conundrum is that there appears to be a common and quite disabling syndrome, particularly prevalent along the east coast of Australia, that is an "Australian version" of Lyme disease and which is caused by a microbe closely linked to the causative agent of "North American Lyme disease".

This would explain the confusion, well presented in your article, about blood results. The commercially available test, based on North American isolates, and which paradoxically attracts a medical rebate, is generally accepted as useless. The test performed by Professor Richard Barry is a sophisticated assay based on an analysis of the body's response to different parts of the microbe, and thus gives more detailed diagnostic information.

Clinical patterns of Lyme disease vary throughout the world, so it is not surprising that a different syndrome is seen in Australia, where patients present with a fatiguing illness associated with a complex and varying array of additional symptoms. Treatment appears to be more effective when given early, reinforcing the need for accurate and rapid diagnosis.

There is an urgent need to clarify the current confusion by careful correlation of symptoms with laboratory indices of infection, using locally derived reagents. It is pleasing to note support for this approach by both debating teams.

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February 7

APPENDIX 7

Medical Journal of Australia – process of peer review and conflict of interest declarations

The Medical Journal of Australia (MJA) is owned by the Australian Medical Association. The MJA "follows the guidelines" of the International Committee of Medical Journal Editors (ICMJE) and the World Association of Medical Editors, in regards to peer review and conflict of interest. As far as we can determine, it appears to be a voluntary code of practice.

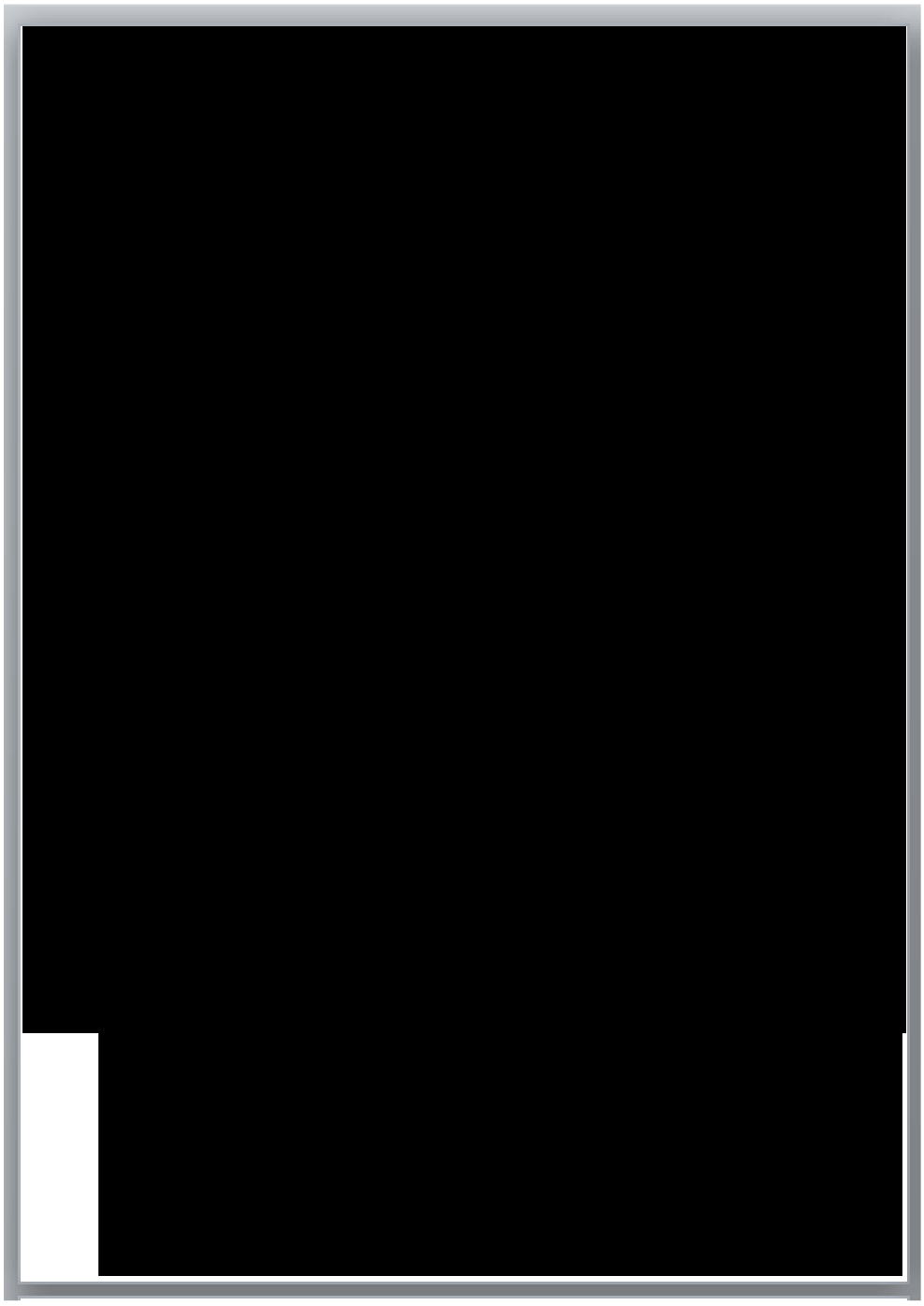
The ICMJE provides a set of guidelines[54] on author responsibilities in regards to declaring conflicts of interest. They also provide information on the peer review process standards[55]. Ironically, the most important statement notes that "reviewers should declare their conflicts of interest and recuse themselves from the peer-review process if a conflict exists."

We have not been able to establish how breaches to these rules are managed or how authors and reviewers are held accountable, outside of the funding process.

[54] ICMJE – Author responsibilities http://www.icmje.org/recommendations/browse/roles-and-responsibilities/author-responsibilities--conflicts-of-interest.html

[55] See: ICMJE – responsibilities in the Submission and Peer Review Process. http://www.icmje.org/recommendations/browse/roles-and-responsibilities/responsibilities-in-the-submission-and-peer-peview-process.html

APPENDIX 8



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