On 29 May, the Department of Health (DoH) published information entitled ‘response’ that asserts some progression with Lyme disease, or Lyme-like illness, has occurred. It is unclear as to what or whom the ‘response’ is responding, although it might be assumed that it is triggered by the thousands of postcards sent to MPs from their constituents demanding action on an emerging epidemic called Lyme disease.

A review of the ‘response’ was conducted and is presented here in italics and interspersed with the Department of Health (DoH) statement.

Response:

The Department of Health, through the Chief Medical Officer, Professor Chris Baggoley, has taken an interest in Australian patients who are experiencing and sharing their stories of a chronic debilitating illness which some medical and health practitioners have ascribed to Lyme disease or a Lyme disease-like syndrome.

Throughout the month of May, approximately 22,000 postcards were sent to MPs by their constituents to let them know that they are concerned about Lyme disease or Lyme-like illness and want them to do something about it. Several letters returned by MPs to constituents indicate that they have, indeed, taken an interest and have sought the advice of the Minister for Health about the issue.

The Minister for Health and representatives on both sides of politics have replied with a standard letter that is illogical and largely dismissive of the very real epidemic affecting thousands of Australians. These letters provide no definitive timelines for the actions they propose and patients are left wondering how long they must wait for quality care; ‘to-do lists’ do not equate to action. Australian patients with a Lyme-like illness have been receiving the standard letter from both sides of politics for more than four years; patients are legitimately tired of the holding pattern response.

The Department is aware that some patients in Australia have developed symptoms that are similar to those of Lyme disease. This disease is a common tick-borne illness in the United States of America, Europe and parts of Asia which is caused by an infection with a bacterium carried by ticks.

The assertion that Lyme disease or a Lyme-like illness is limited to a ‘tick-borne infection’ ignores the growing body of evidence that Lyme is becoming a global epidemic, and research is consistently demonstrating that there are other mechanisms for transmission than through the bite of a tick.
It’s also relevant to note that more than 10 emerging tick-borne diseases have been reported in China\(^1\) in the past few years. Importantly, contemporary research indicates that tick-borne disease is prevalent in areas previously considered non-endemic and that research needs to address patients who are ill rather than ticks that might carry disease.

Research in China, focusing on patients who are ill, indicates a high prevalence of emerging tick-borne viruses related to relapsing fevers, rather than a spirochete-related infection. Similar research in Australia published in 2014\(^2\), also finds a zoonotic phlebovirus, genetically related to those found in China, exists in Albatross in Tasmania and identifies ticks as the vector. This research, conducted in part by the CSIRO, warns that heightened surveillance is needed to better understand the public health risks of these emerging tick-borne diseases, especially viruses. Yet, in Australia, we continue to search for the presence of spirochetes in ticks, or in human blood; those few research projects are not even considering a viral pathogen.

More than 15 months ago, in their response to the DoH’s Scoping Study, patients raised the importance of proper assessment of the signs and symptoms prevalent in a growing cohort of sick people. Put simply, research analysis of the hundreds of Australians holding internationally agreed positive results for Lyme disease – Borrelia burgdorferi, B. afzelii, or B. garinii – highlights statistically relevant results that warrant further scientific investigation.

If Australia’s modest research endeavours continue to focus on looking only for spirochetes in ticks, in companion animals or in human blood, we will be selectively ignoring a significant scientific phenomena causing increasing cohorts of Australians to be ill.

As yet, neither a causative agent nor a vector for Lyme disease has been identified conclusively in Australia, despite research on this topic.

There have been more than 11 independent studies\(^3\) since 1959 isolating Borrelia in Australian ticks, yet a 1994 government-funded study, with methodology that has been broadly criticised, remains the sole reference point of the ‘no Lyme here’ position. While this historical research has been discounted, there have been at least three recent research papers presented by Doctors\(^4\) and Laboratories in Australia who report the unequivocal presence of Borrelia burgdorferi, and that have sequenced the organism at the Australia Genomic Reference Laboratory. Yet this research is systematically ignored.

It is misleading to both patients and the scientific community to continue to state a ‘no evidence’ situation and claim ‘despite research on the topic’ while systematically ignoring any research with a

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1 See: Distribution of Tick-borne Diseases in China: [http://www.parasitesandvectors.com/content/pdf/1756-3305-6-119.pdf](http://www.parasitesandvectors.com/content/pdf/1756-3305-6-119.pdf)
positive finding as ‘not quite conclusive’. It’s unclear to both patients and researchers what the exact criteria are for ‘conclusive’ evidence, as the current system makes it unattainable.

There has been no formally-funded contemporary research on the topic until the Australian Research Council provided a linkage grant to fund a research partnership through Murdoch University in WA with Bayer Australia in 2013. Findings from that research were reported on the 25 June 2015. It highlights a number of significant findings that will irrefutably alter the landscape for patients in Australia, however this relies on an appropriate response from the Government.

The Murdoch Research report finds a number of known human pathogens in Australian ticks. It provides the first scientific evidence that a Borrelia relapsing fever, Bartonella henselae, a novel Candidatus, Clostridium histolyticum, Rickettsia and Leptospira were present in Australian ticks. The report concludes there are significant amounts of ‘endosymbionts’ (organisms that live within the body of another organism) which mask the less abundant bacteria, including pathogens. This may provide the long-awaited explanation for the effectiveness of microbiological testing and sequencing because the pathogens are hidden within other organisms. From a technology perspective the next generation sequencing used in the Murdoch study provides new evidence that medically important pathogens can be accurately detected; this raises an urgent issue about the use of this technology, and the newly developed blocking primer, to solve the complex problems associated with the Lyme-like illness suffered by many Australians.

Additionally there is research currently underway at the University of Sydney’s Tick-borne Disease Unit, which relies on inadequate private funding. Despite several years of research, this project has yet to present or report any of its findings.

The findings of the Murdoch research mean that the assertion that there is ‘no conclusive evidence’ is no longer acceptable.

In a country where the presence of Lyme disease has not been confirmed, such as Australia, it is not possible to reliably diagnose Lyme disease on clinical signs and symptoms alone as there are many other diseases (infectious and non-infectious) that can have similar clinical features.

This reasoning is inherently flawed. If a patient encounters a doctor educated enough to suspect Lyme disease and order the appropriate tests, (for the reasons we’ve raised in earlier submissions) testing in Australian public health laboratories will, in a majority of cases, produce a negative result. Australian physicians rely upon ineffective laboratory testing protocols which are widely acknowledged to be ‘discordant’, for example a patient might test in two different laboratories which return two completely opposite results.

Patients want to know, in the first instance, what the Australian Government has done to educate doctors to recognise Lyme disease. How can these doctors rely on tests that are ineffective and unreliable? If clinical diagnosis is considered invalid and laboratory testing purported to be the key to

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5 See: Murdoch University, Inhibition of the endosymbiont “Candidatus Midichloria mitochondrii” during 16S rRNA gene profiling reveals potential pathogens in Ixodes ticks from Australia
providing clarity about the cause of illness, then it seems evident we cannot rely upon Australian tests to make any definitive statements.

In all other countries Lyme disease is able to be diagnosed on clinical signs alone if a ‘bullseye’ (Erythema migrans, or EM) rash is present. The bullseye rash is known as a ‘pathognomonic’ sign that warrants an immediate diagnosis of Lyme disease as it is unique to Lyme disease; this is a CDC-agreed diagnostic position, negating the need for any diagnostic test. Australian doctors are not given the appropriate tick-borne disease education, and therefore are not equipped to recognise the EM presentation. The NSW Department of Health, which provides the pre-eminent advice to guide physicians, is not specific on the presence of the bullseye rash. Instead, they recommend that physicians pursue costly and unnecessary laboratory testing which, for many Australian patients, is highly unreliable.

Patients who present with a bullseye rash should immediately be treated with antibiotics. According to the LDAA’s statistics, a bullseye rash occurs in only 31% of cases. Yet even when patients do present to Australian physicians with this distinctive diagnostic marker, they are denied early intervention treatment under the prevailing ‘no Lyme here’ policy.

Tests to diagnose Lyme disease are technically complex and require specialist expertise. They should only be conducted in laboratories that are accredited in Australia with the National Association of Testing Authorities/Royal College of Pathologists of Australia (accredited laboratories are listed on the National Association of Testing Authorities website). Such accredited Australian diagnostic laboratories are able to diagnose Lyme disease by serology in patients who have returned from overseas areas where Lyme disease is endemic.

Diagnostic tests for Lyme Borreliosis are not overly complex; they are consistent with international best practice and the methods required for them should be within the technical competence of a qualified pathologist. What is complex is the inconsistent and scientifically disputed test kits used in Australian laboratories. Labs use test kits that are relevant to infections found in other areas of the world – for example, in Australia we only test for three strains of Borrelia, when we know there are many more.

An additional complexity, conveniently ignored in Australia because we don’t educate doctors about this peculiarity, is the patient’s immune response; not all patients mount an appropriate immune response to a Borrelia infection. In fact, Borrelia suppresses the immune system and prevents many people from reacting to the stealth infections that invades their body. Applying a limited ‘three strain’ antibody test approach to people whose immune system may be significantly impacted by a stealth infection (that could be any one of multiple strains or in fact a totally different infection), is illogical and potentially wasteful.

The Murdoch study findings on the abundance of bacterial endosymbionts in Australian ticks raises new issues and provides greater insight into why these pathogens are so hard to detect; because they are embodied within other organisms. It’s a further demonstration that our current testing processes are substantially inadequate and will continue to let patients down; it requires immediate attention.
Australian laboratories that are not using commercial test kits (which focus only on three strains) consistently isolate organisms via Polymerase Chain Reaction (PCR). This means that they locate the actual DNA of the organism and do not rely upon the immune system’s antibody response to an organism. When they are able to isolate the organism, they pass it to the Australian Genome Research Facility, a NATA accredited lab, that uses sequencing processes which consistently find organisms related to known Borrelia burgdorferi strains. This indicates that there is potentially an indigenous strain of Borrelia in Australia. However, because the isolating laboratory is not NATA-accredited, the entire chain of results is disregarded. As such, the scientific relevance of an indigenous strain of Lyme disease (Borrelia) continues to be ignored, however the Murdoch study throws new light on the presence of pathogens in Australian ticks.

The lack of research prioritisation means the discovery of new infectious organisms with significant public health risks goes undetected. The Murdoch study raises new questions about tick-borne pathogens in Australian ticks and validates the need for further research, particularly studies focussed on humans suffering from a Lyme-like disease.

The LDAA has previously highlighted the inconsistency and extreme bias in the Royal College of Pathology Australasia’s (RCPA) stance on Lyme disease. When the RCPA is the greatest agency to actively and widely promote the ‘no Lyme here’ position, the stance places them in a significant conflict of interest when called upon to exercise impartiality and scientific objectivity required in accrediting laboratories, particularly in relation to a laboratory which consistently isolates organisms that are able to be successfully sequenced as a ‘species’ of Borrelia. Australian Biologics has had NATA accreditation ‘pending’ for more than a year and the imposition of continual delays for NATA accreditation are professionally inexplicable.

Furthermore, RCPA continually denigrates the use of overseas testing laboratories and maintains the position that these tests are not to be relied upon. Australian patients want to know why, for example, Infectolab’s results aren’t accepted here if they’re a NATA accredited lab, which has reciprocal rights. Infectolab is accredited by the German accreditations office DAkkS in accordance with DIN EN ISO 15189:2007, an RCPA accepted standard.

In terms of access to treatment, GPs in Australia are able to refer their patients to specialist clinics at public hospitals. For example, in a case of suspected Lyme disease, an appropriate referral could be to the infectious diseases clinic at the local hospital. Outpatient appointments at public hospitals are free-of-charge to the individual. In Australia, infectious diseases physicians are the appropriate specialists to support patients with questions and concerns about Lyme disease. If Lyme disease is diagnosed, antibiotics to treat the disease are readily available.

The LDAA research indicates many Australians will have progressed to late-stage Lyme disease before they’re assessed by a doctor who is able to properly diagnose and treat. On average Australian Lyme patients take 6.5 years for a diagnosis and often see more than 4 doctors. Many of those doctors have been Infectious Disease Specialists.

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After reading the DoH’s ‘response’ statement, many Lyme patients contacted the LDAA to share their experiences with infectious disease specialists; the overwhelming assertion was that they were some of the most discriminatory physicians the patient had ever seen. Issues presented to the LDAA ranged from blatant criticism of overseas lab test results, to flat denial of treatment and the often-used diagnostic dumping ground of ‘it’s all in your head’. Several patients reported the infectious disease specialist preferred to prescribe anti-depressant medication or refer to psychiatrists for treatment rather than further investigate infectious or physiological causes for their illness. In a misguided show of compassion, one infectious disease specialist was quoted telling more than one patient that there was ‘something definitely wrong, but it wasn’t ‘Lyme’ and offered no further medical help.

Sadly, the stories were so blatantly discriminatory that the LDAA will now take up an advocacy role and work closely with these patients to facilitate formal complaints against those who practice this type of discrimination with patients who have a Lyme-like illness.

The Murdoch study also raises new issues about how equipped our GPs and infectious disease specialists are in dealing with endosymbiont infections, that appear to be stealth and according to the findings, present new novel strains never reported in Australia.

The Chief Medical Officer convened a Clinical Advisory Committee on Lyme Disease (the Committee) to provide advice on the evidence for Lyme disease in Australia, diagnostic testing, treatment and research requirements. The Committee met five times and outcomes of the meetings are available on the Department of Health’s Lyme disease webpage. The Committee has now ceased, with the last meeting held on 15 July 2014. A report that details the progress achieved against each of the Committee’s terms of reference is also available on the website.

Though the Committee has ceased, the department’s interest is being maintained. The Department continues to:

- consult with members of the Committee;
- monitor progress made in research;
- act as a point of contact within the Australian Government for the Lyme disease community, including medical practitioners and state and territory health authorities;
- work on the diagnostic pathway with relevant stakeholders (including laboratory collaboration) and will inform patient groups of progress;
- seek advice from international partners; and
- write to patient groups and medical practitioners to update them of any progress.

There was no consultation with patient groups representing the key stakeholders who are likely to be impacted by this reviewed official position.

The LDAA asserts there is limited monitoring of the situation relating to Lyme disease in Australia. The Government has adopted a ‘wait and see’ approach with regards to research. This does little to

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assist people who are in a dire situation and face continual barriers due to the lack of medical support available to them.

Furthermore, the LDAA, as the pre-eminent patient group in Australia, has had no communication regarding the progress, or lack of progress, in research. Through other sources, the LDAA is aware of a presentation, provided by the Australian National Reference Laboratory and outlining a proposed research project, which was delivered to a Lyme disease forum in the UK in March 2015. No consultation about this research or its proposed methodology has taken place, either with members of the CACLD or patient advocacy groups, yet it is expected to solve the discordant results in testing in Australia. Given the previously raised issues about inefficient testing and discordant results, this is an important development and should attract significant consultation. We note this research project is, as yet, unfunded. Given the findings from the Murdoch study, new questions are raised about the validity of such a study, especially in light of the complexities in searching for organisms within organisms. There may be better ways to direct that research and focus on the primers developed in the study and the use of next generation sequencing and bioinformatics methods to better equip labs and doctors in clinical diagnostic settings.

Not a single state or territory has updated or refined their Lyme disease advice for clinicians or researchers. Not a single state or territory has provided formal advice to their medical communities on maintaining an open mind in respect to Lyme disease or locally acquired illness. In fact, in two states it has been quite the opposite, with both Queensland and Western Australia imposing sanctions and conditions on doctors who were treating patients with Lyme or Lyme-like illness and banning them from prescribing antibiotics without the concurrence of an infectious disease specialist. As noted earlier, infectious disease specialists are heavily in the ‘no Lyme here’ mind-set, routinely ignore overseas testing results of Australian patients and subject patients to undeniable discrimination, with many being referred to psychiatrists and a range of other specialists who can’t effectively treat the symptoms as they haven’t correctly identified the disease.

From a public health perspective, it is irresponsible to ignore the growing epidemic of Lyme-like illness all over the world. At the very least, a taskforce should be established to anticipate the impact that an emerging stealth infection like Lyme disease could have on a largely seaboard population. It is not prudent to ignore the serious growth rates when even the CDC acknowledges more than 300,000 new cases per year are occurring in the USA. The government mounted a coordinated policy response to Ebola in the recent outbreak and conducts/funds ongoing research for other vector-borne diseases like Malaria, why not Lyme disease?

The Murdoch study presents significant new and novel species of organisms that cannot be ignored. The discovery of known Bartonella species and other medically important pathogens in Australian ticks may prove to be the agent, or combination of agents, causing Australian Lyme-like illness that could resolve the controversy for the scientific community and enable patients to receive the care they need to return to wellness.

The Department is also working with state and territory government health agencies on a diagnostic case definition which will assist Australian medical practitioners better recognise Lyme disease. In its first iteration the document is focused on infection acquired in endemic areas overseas. It is hoped that as the Department learns more about the chronic debilitating illness affecting Australians, it will be able to modify the document to accommodate their situation.

In reference to the assertions regarding the diagnostic pathway for Lyme disease, the LDAA was represented on the Diagnostic Pathway Working Group which last met in December 2014. The group
agreed a diagnostic definition of Lyme disease acquired by Australians who travelled to overseas endemic areas. The agreed diagnostic definition is intended to aid Australian medical practitioners in developing a greater familiarity with the disease and the diagnostic approaches, as many Australians legitimately acquire their disease in endemic regions during travel. It required the clearance of the Australian Health Protection Principal Committee (AHPPC) which would confer state, territory and Australian Government support for a document defining Lyme disease.

That was more than six months ago and there is still no definition for overseas-acquired Lyme disease in Australia, nor any communication or consultation about its delay. As such, a significant cohort of patients are unable to obtain adequate treatment for a disease that would be routinely treated overseas, but is treated with high suspicion and discrimination in Australia. This is unacceptable. What is the stumbling block that is delaying publishing a case definition that has clear consensus in several other countries?

The other project the Department is working on is an evaluation of diagnostic tests used here and overseas to try to determine the reason for discordance in pathology testing and provide solutions to this problem.

A significant issue in the diagnosis and subsequent treatment of Lyme or Lyme-like illness in Australia is the state of diagnostic testing. The Department of Health has already acknowledged the diagnostic uncertainty and the discordant results provided by laboratories that test for Lyme disease. The material effect is that many Australian patients return different results from different laboratories, both in Australia and overseas and so they are denied treatment, which means their disease progresses to a more chronic state. This delay in treatment impacts lives unnecessarily and causes considerable loss of function, debilitation and sometimes even death.

The Department recently sponsored a presentation by the National Serology Reference Laboratory, on their proposed strategy to address the discordant results in a UK forum on Lyme disease, titled “Review on Serology Tests for Lyme disease”, previously referenced. The presentation asserts that overseas laboratory testing providing positive results casts doubts of the quality of Australian tests, and sets about a process of verifying those laboratories against four Australian laboratories, as yet unnamed.

Interestingly, the research outline also proposes to test Australian Blood Donors who have not been tested for Lyme disease or those who have a low risk of Lyme disease. Given that the Australian Red Cross has specifically vetoed the donations of people who have been diagnosed with Lyme disease or Lyme-like illness, this is an interesting examination. It also proposed to follow manufacturer test kits instructions but conveniently misses the fact that in-vitro devices for Lyme disease testing are in the highest risk category for interpretive results.

Of interest to the LDAA is the information that the testing processes were recently changed in the reference lab at Westmead. We understand the lab recently introduced the use of commercial tests

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kits to replace the ‘in house’ testing methods they have relied upon for more than a decade. Unconfirmed advice indicates that the rate of positive test results has significantly increased since the change to a new commercial testing kit. However, since the lab does not report on its results and there is no surveillance of Lyme disease, these figures are not publicly available. The LDAA wishes to confirm these claims and understand how the new test results will be interpreted without a case definition.

Furthermore, the LDAA seeks the Department’s clarification as to whether the Westmead lab will continue to utilise the CDC surveillance criteria (requiring five positive antibody bands) or be guided by the diagnostic standard recommended by many commercial test kit manufacturers (three positive antibody bands) in their accompanying advice to physicians regarding the presence of infection.

The Department of Health will continue to monitor progress made in research. For example, the Department continues to seek updates on the work currently funded by:

- the Australian Research Council and being carried out by Murdoch University, which involves dogs as sentinels and is also looking at human specimens; and
- the University of Sydney’s Tick Borne Diseases Unit.

References to the current status of research were made earlier. The newly published Murdoch study raises significant issues that cannot be ignored and requires urgent response.

The Minister for Health remains concerned about Australians suffering a chronic debilitating illness with unexplained symptoms that some healthcare practitioners have ascribed to Lyme disease. The Department will continue to monitor the situation and encourage efforts made by Australian medical practitioners and medical scientists to undertake research to define the cause of this chronic debilitating illness.

Upon reading this ‘response’ from the Department on behalf of the Minister for Health, many patients felt insulted and rightfully angered by the suggestion that appropriate and timely action was being undertaken on their behalf. Far from experiencing ‘unexplained’ symptoms, these patients have suffered first-hand symptoms consistent with Lyme Borreliosis and associated co-infections, commonly referred to as ‘Lyme disease’. Many have endured these debilitating symptoms for years – and sometimes decades – while navigating an array of physicians and specialists who were unable to find a satisfactory and consistent explanation for their ‘mystery illness’. For most, finally discovering a doctor who was able to put aside any dogma about the possibility of Lyme disease or consider a Lyme-like illness, who was able clinically diagnose and prescribe a treatment that began to alleviate these symptoms, was life changing. Repeated use of the term ‘ascribed’ in reference to doctors diagnosing Lyme disease denigrates a doctor’s clinical expertise and infers a lackadaisical approach when those doctors have devoted considerable time and effort to research and investigate the constellation of symptoms typically suffered by Lyme patients and eliminated mimicking conditions before concluding a diagnosis. Doctors treating this disease in Australia must be willing to put their clinical judgement and the needs of their patients well above peer pressure and the risk of sanctions that might be imposed by a medical board. It is illogical that they are persecuted simply because they prescribe treatments that are readily available to overseas Lyme disease patients and clearly set out within international treatment guidelines.
Many doctors have indicated privately that they concur with a Lyme disease diagnosis for their patients but are unwilling, in the culture of fear that has been generated, to sacrifice their reputations or risk losing their registrations to provide treatment. This results in the few doctors willing to treat Lyme disease being overburdened with complex cases, leaving an increasing number of patients at risk due to insufficient medical oversight or pursuing alternative treatment modalities because the mainstream medical system dismisses their needs. Perhaps the Murdoch findings will help to legitimise the treatment of suffering patients with Lyme-like illness, however practitioners will need to have urgent and reliable support on how to deal with the six types of medically important infections found in Australian ticks.

Through the Murdoch study we have:

1. irrefutable evidence of medically important pathogens present in Australian ticks, which address key research questions highlighted in the DoH’s Scoping Study\(^\text{10}\) yet it also raises more questions about the multi-systemic infection processes occurring;
2. established the abundance of endosymbionts in Australian ticks, which throws new light on testing and diagnostic practices and raises significant issues for the treatment of such infections; and
3. proven that next generation sequencing and bioinformatics methods could be useful in clinical diagnostic setting.

More than 15 months ago Australian patients outlined their strategic action plan for the Australian Government to take a proactive and preventative approach to this serious health problem. To date little progress has been made, more tick bites have occurred and several thousand more Australians will be well on their way to developing a chronic and debilitating illness that is largely preventable.

Australians need authentic action now.