

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

**PROGRESS REPORT – TWELVE RECOMMENDATIONS**

Inadequacies and failures in the delivery of the Senate recommendations to provide real and immediate support to sufferers.

**RECOMMENDATION 1**

<p><b>2.90 The committee recommends that the Australian Government Department of Health engage with stakeholders following the publication of the National Serology Reference Laboratory review to discuss the findings of the review and any bearing those may have on testing for Lyme disease in Australia.</b></p>	<p><b>D<sup>-</sup></b></p>
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**Chief Medical Officer (CMO), Mr Brendan Murphy Response Senate Estimates Ref No: SQ19-000595:**

Completed In November 2017, the final report from the NRL was published on the Department’s website <sup>3</sup>. Key stakeholders, including patient groups, were consulted on the outcomes of the report. A Questions and Answers document was also produced to support the release of the report

LDAA: The National Serology Reference Laboratory review does not take into consideration the existence of potential Australian pathogenic *Borrelia* species or complications in testing for borreliosis in its chronic or persistent form. The NRL report does not agree on criteria that determines a positive test. All labs have their own ideas and there is no standard. Also, some stakeholder questions were not answered during the consultation.

Key laboratories were excluded from the review. The review focuses on tests for limited species from the *Borrelia burgdorferi sensu lato* group but excludes Relapsing Fever and emerging international pathogens. The review focuses on limited IgG tests, not extending itself to fully explain the positive results held by many Australian patients from international laboratories.

*“It should be made clear that overseas laboratories—for example, IGeneX, in San Diego, in the United States, Infectolab and ArminLabs in Germany—have sought their own certification in their own countries. I have been told that they are compliant with the international standard on requirements for quality and competence. From a recognition of their accreditation, there is no argument there.”*

Dr Gary Lum

Since the formation of the Clinical Advisory Committee on Lyme Disease in 2013, knowledge has grown, including the discovery of new Australian pathogens. Patients have tested positive internationally and in Australia to a range of tick-borne co-infections. The review proceeded and was published in May 2017, adding nothing of relevance to the Australian circumstance or clinical situation for patients.

There has been no review of non-Borrelia tick-borne pathogen testing and whether NATA-accredited laboratories are using world-class tests. While the Inquiry recommendations were made in 2016, patient expectation is that they should have been long-fulfilled and the Government proactively taking next steps.

**RECOMMENDATION 2**

<p><b>2.91 The committee recommends that the Australian Government increase funding for research into tick-borne pathogens as a matter of urgency. This funding should include:</b></p> <ul style="list-style-type: none"> <li>• <b>funding for research on pathogens which may cause infection;</b></li> <li>• <b>funding for research on whether newly identified pathogens can cause illness in humans; and</b></li> <li>• <b>funding for the development of diagnostic tests which can detect infection by any newly identified pathogens endemic to Australia.</b></li> </ul>	<p><b>D<sup>-</sup></b></p>
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**Chief Medical Officer (CMO) Response Senate Estimates Ref No: SQ19-000595: Progressing. The Department has commenced exploring options to fund future research into tick-borne pathogens and the impact on human health. The NHMRC has made \$3 million in funding available through a Targeted Call for Research into Debilitating Symptom Complexes Attributed to Ticks (DSCATT)**

**LDAA:** Funding of research into tick-borne pathogens that may cause infection and illness in humans has been somewhat addressed by the allocation of \$2 million of the NHMRC Targeted Call for Research grant to Peter Irwin’s research team at Murdoch University. The expected end date of this 4.5-year long-term project is 31 October 2023. Compared to Billions thrown at Covid19 and livestock testing, for a zoonotic disease that causes similar high morbidity and mortality, particularly by suicide, this is mere token money.

Further, it is noted at the time of writing this review that the Lyme disease position statement was updated on 17 Aug to include the following projects:

“A tick survey to better understand which bacteria, viruses and other pathogens are carried by ticks in Australia and their impact on human health. The Commonwealth Scientific and Industrial Research Organisation has been engaged to progress this project. The project is due for completion in mid-2021”.

“A case study biobank to gather and analyse samples from DSCATT patients for possible biomarkers. The Commonwealth Scientific and Industrial Research Organisation has been engaged to progress this project. The project is due for completion in mid-2021”.

Past stakeholders, including doctor and patient groups and advocacies including LDAA were not notified or included in the terms of reference of and have very limited information about these research projects. The CSIRO biomarker project necessitates biological samples from “*DSCATT positive and DSCATT negative patients.*” As there is no test that identifies DSCATT, and guidelines specifically state “DSCATT is not a diagnosable disease or a clinical diagnosis”, how are patients designated as “DSCATT positive or negative?”

It is of concern that we do not know the CSIRO’s criteria of a DSCATT patient, whether a mix of chronic, very long-term chronic and acute patients will be included, and whether patients from many localities will be included.

Funding for the development of diagnostic tests, as a matter of urgency, has not been allocated, and it would seem will only be addressed subsequent to completion of in-progress research, if at all, depending on research results.

\$1 million of the NHMRC Targeted Call for Research grant was allocated to Richard Kanaan’s research team at the University of Melbourne for a project focusing on Cognitive Behavioural Therapy and Acceptance and Commitment Therapy. Why has no funding gone to human research apart from cognitive behaviour therapy and why did the Cognitive Behavioural Therapy researchers deliberately exclude the peak body, LDAA from patient engagement?

While the DoH has continually advised over the years that a case definition for Lyme-like illness cannot be created without a known pathogen, Kanaan’s abstract states, *“We would first develop a case definition.”* Granted, that case definition would exclude cause of disease (so pathogen not required) as the project has a psychological focus. Patients, however, have been begging for exactly such a case definition, while research is in-progress, for years.

This study has caused much distress to the patient cohort because the government spent a third of the available NHMRC funds on a project to help patients better live with their disease, rather than diagnose and treat their disease. Some patients originally enrolled in Kanaan’s research have since dropped out or been excluded due to unwillingness to proceed with a psychological therapy without any address of underlying disease. **Cognitive Behavioural Therapy in the absence of targeted medical treatment condemns sick Australians to continued suffering.**

**RECOMMENDATION 3**

<p><b>3.54 The committee recommends that government medical authorities, in consultation with stakeholders including the Australian Chronic Infectious and Inflammatory Diseases Society (ACIIDS) and the Karl McManus Foundation, establish a clinical trial of treatment guidelines developed by ACIIDS with the aim of determining a safe treatment protocol for patients with tick-borne illness.</b></p>	
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**Chief Medical Officer (CMO) Response Senate Estimates Ref No: SQ19-000595: Progressing.** The Department has engaged consultants to develop, in consultation with stakeholders, an evidence-based clinical pathway and multidisciplinary care model for patients suffering from DSCATT (Refer Recommendation 5). Expected completion of project in early 2020. Further understanding of the underlying cause of DSCATT is required before discussions on potential treatment trials can progress.

**LDAA: ( RECOMMENDATION 3 HAS BEEN SO FAR IGNORED )** – The establishment of a clinical trial of treatment guidelines developed by Australian researchers and the ACIIDS doctors who were successfully treating tick-borne illness has not been funded due to disagreement on the likely cause of Lyme and associated diseases. \$3 million has been repeatedly requested for a project that would incorporate this research, however this request is consistently ignored.

LDAA has been specifically excluded from this process. Both are registered charities and patient advocate groups. It is also unknown why this is not prioritised as urgent considering the disease burden.

The failure to implement this recommendation, and the Government’s choice to instead contract Allen & Clarke to develop a Clinical Pathway, is a major reason why we now have a not-fit-for-purpose Pathway published on the government website.

It would seem obvious that the medical practitioners already experienced in treating over 4000 of the patient cohort should have been the project leads.

**RECOMMENDATION 4**

<p><b>3.55 The committee recommends that the Australian Government allocate funding for research into medically-appropriate treatment of tick-borne disease, and that medical authorities measure the value of treatment in terms of patient recovery and return to health. The best treatment options must then be developed into clinical treatment guidelines.</b></p>	
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**Chief Medical Officer (CMO) Response Senate Estimates Ref No: SQ19-000595: Ongoing. The Department has engaged consultants to develop, in consultation with stakeholders, an evidence-based clinical pathway and multidisciplinary care model for patients suffering from DSCATT (Refer Recommendation 5). Expected completion of project in early 2020. The NHMRC has made \$3 million in funding available through a Targeted Call for Research into DSCATT. Further understanding of the causes of DSCATT is needed before ethical clinical trials can be designed.**

**LDAA: ( RECOMMENDATION 4 HAS BEEN SO FAR IGNORED )** – Funding for research into the appropriate treatment of tick-borne diseases has not been allocated due to disagreement on the likely pathogenic cause of Lyme and associated diseases. This recommendation and the CMO’s statement implies that ‘DSCATT’ may be treatable with crisis counselling services. Ironically the [funding application](#) for these counselling services was based on the term Lyme disease for diagnosed Lyme disease sufferers. Additionally, the targeted call for research has provided \$1 million for cognitive behaviour therapy through Austin Health and \$2 million for vector research that may never find anything. We feel this is hopelessly inadequate and human research needs to commence immediately. Unknown how this can proceed without proper stakeholder engagement, data transparency and public consultation.

It would seem that treatment for current and future sick Australians will not be addressed until the completion of in-progress research which is an abject failure of duty of care.

**RECOMMENDATIONS 5 & 6 – SEE RECOMMENDATIONS 10, 11, 12.**

**RECOMMENDATION 7**

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



**Chief Medical Officer (CMO) Response Senate Estimates Ref No: SQ19-000595: Progressing. The Department has commenced exploring future projects which will contribute to the epidemiological evidence and prevalence of suspected tick-borne illness and the impact on human health in Australia. The Department notes the great difficulty in doing epidemiological surveys for conditions without a clear case definition.**

**LDAA: ( RECOMMENDATION 7 HAS BEEN SO FAR IGNORED )** – An epidemiological assessment of the prevalence of suspected tick-borne illness in Australia has not been undertaken due to disagreement on the likely cause of Lyme and associated diseases. This is avoidance at best. An epidemiological study based on a case definition by consulting experienced treating doctors from ACIIDS that have so far treated over 4000 Australian patients could be rapidly expedited by a government or contract agency given the funding.

Further international experts with no less than 100 times the clinical experience of Australian doctors at diagnosing and treating tick-borne illness have been standing by and have offered their support to assist these research projects with their expertise. This expertise and advice has been uniquely ignored in the tick-borne disease group where collaboration like this would likely be embraced in another disease group such as cancer.

The government has the tools but appears to have no willingness. An epidemiological study would likely demonstrate a much higher quantity of positive testing than is currently being reported, then proper consultation can commence with the stakeholder community about how large the problem really is with funding allocated accordingly. We also believe practitioners and pathologists do not have a clear understanding of test interpretation and do not address the presenting clinical picture of the patient.

The CSIRO host biomarker project includes the formation of a DSCATT biobank and the answer to Question on Notice 264 from the 27 October 2020 Budget Estimates advises that this addresses recommendation 7.

The LDAA's expectation of an epidemiological assessment is that it would be based on known criteria in relation to diseases of interest; incidence, prevalence, burden of disease, cost of illness and a much wider assessment than it seems the CSIRO study will be able to provide.

At a minimum, the patient Senate Submissions should have been subject to careful analysis as they are the most extensive source of evidence on record.

**RECOMMENDATION 8**

<p><b>3.59</b> The committee recommends that the Australian Government Department of Health establish the prevalence and geographical distribution of overseas-acquired Lyme disease in Australia.</p>	
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**Chief Medical Officer (CMO) Response Senate Estimates Ref No: SQ19-000595: Progressing.** Collecting epidemiological data on overseas acquired Lyme disease would be best achieved if overseas-acquired Lyme disease was nationally notifiable. Lyme disease has previously been considered by national public health experts twice for inclusion in the Australian National Notifiable Diseases List, however, on both occasions, the criteria for inclusion were not met. As an alternative to collecting epidemiological data, the Australian Government, through the Department of Health, has published a guideline on overseas-acquired Lyme disease, which is publicly available. The Department recognises that many medical practitioners are not familiar with overseas-acquired Lyme disease and will undertake an education and awareness-raising endeavour to inform Australian medical practitioners of the importance of recognising overseas-acquired Lyme disease.

**LDAA: ( RECOMMENDATION 8 HAS BEEN SO FAR IGNORED )** – The recommendation to establish the prevalence and distribution of overseas-acquired Lyme disease in Australia has been ignored. We would like to see absolute data transparency on the table. The minimum for this would be transparency of positive overseas acquired test results by including overseas acquired and locally acquired Lyme disease as a notifiable illness. It is unknown how this can proceed without proper stakeholder engagement, data transparency and public consultation.

**RECOMMENDATION 9**

<p><b>3.60</b> The committee recommends that Australian medical authorities and practitioners addressing suspected tick-borne illness:</p> <ul style="list-style-type: none"> <li>consistently adopt a patient-centric approach that focusses on individual patient symptoms, rather than a disease label; and</li> <li>remove 'chronic Lyme disease', 'Lyme-like illness' and similar 'Lyme' phrases from diagnostic discussions.</li> </ul>	
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**Chief Medical Officer (CMO) Response Senate Estimates Ref No: SQ19-000595: Ongoing.** The Department has published two position statements, one on Lyme disease in Australia and one on DSCATT, to assist with differentiating between the two, and to acknowledge some of the difficulties being experienced by patients. The position statements are available on the Department’s website. The Department has engaged consultants to develop, in consultation with stakeholders, an evidence-based clinical pathway and multidisciplinary care model for patients suffering from DSCATT (Refer

**Recommendation 5). The Department continues to promote the term DSCATT which has also been adopted by the NHMRC and CSIRO.**

**LDAA:** The flawed Department of Health Position Statements are factually incorrect, therefore irrational, illogical misleading and contradictory. The term DSCATT is not acceptable by international standards as a disease label, health problem or diagnostic code <sup>12, 13</sup>. It further adds to stigma and is diversionary and insulting to those that have been diagnosed with Australian acquired Lyme disease or relapsing fever Borreliosis and should be abandoned. It is unknown how this can proceed without proper stakeholder engagement, data transparency and public consultation.

The LDAA has chosen to adopt the international definition of Lyme and associated diseases, meaning a constellation infection of multiple species of Borrelia and associated co-infections from ticks and other vectors.

Irrespective of the name the Government uses, it refuses to adopt a patient-centric approach that focuses on individual patient symptoms and/or test results, rather than a disease label. Patients are now even more irrelevant than several years ago.

In recent years, the discouragement of over-servicing patients with tests and diagnostics has resulted in chronically ill patients becoming even more likely to remain medically unexplored and medically unexplained.

This sector of patients suffers from a gross under-servicing in relation to tests as diagnostics and monitoring.

**RECOMMENDATIONS 5, 6 AND 10, 11, 12.**

<p><b>Recommendation 5</b></p> <p><b>3.56 The committee recommends that the Australian Government Department of Health facilitate, as a matter of urgency, a summit to develop a cooperative framework which can accommodate patient and medical needs with the objective of establishing a multidisciplinary approach to addressing tick-borne illness across all jurisdictions.</b></p>	
<p><b>Recommendation 6</b></p> <p><b>3.57 The committee recommends that federal, state and territory health agencies, through the Council of Australian Governments Health Council, develop a consistent, national approach to addressing tick-borne illness.</b></p>	
<p><b>Recommendation 10</b></p> <p><b>3.61 The committee recommends that, to help the referral of patients for guided and comprehensive pathology testing, medical practitioners work with pathologists, especially microbiologists, immunologists,</b></p>	

chemical pathologists and hæmatologists to optimise diagnostic testing for each patient.

**Recommendation 11**

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

**FAIL**

**Recommendation 12**

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

**FAIL**

**Chief Medical Officer (CMO) Response Senate Estimates Ref No: SQ19-000595: Ongoing/Progressing. The Department is supporting this recommendation through the development of an evidence-based clinical pathway and multidisciplinary care model for patients suffering from DSCATT (Refers to Recommendation 5 for each)**

**LDAA:** Instead of adhering to the recommendations, the Government commissioned consultants, Allen and Clarke, to liaise with stakeholders and develop a national Clinical Pathway, with a multidisciplinary approach to DSCATT patient care.

The value of this contract is \$526,091 and it was published in March 2021, completely failing sick Australians and rejected by international Lyme scientists, experienced clinicians and every advocacy group.

Funds were allocated to a small boutique consultancy to develop a DSCATT education program and additional funds to Allen and Clarke to complete and finalise the educational materials. The combined value of this project is \$310,833.

The educational materials are based on the rejected Clinical Pathway, so are inadequate.

These projects do not take seriously the significant clinical evidence that strongly implies DSCATT patients are suffering from a tick-borne illness.

There has been no diagnosis data transparency, public consultation or stakeholder engagement on these projects, with key expert consultant and patient stakeholder feedback categorically ignored. The time between the distribution of the draft Pathway and the close of the consultation period was not sufficient for patient stakeholders to attempt a complete re-write of the Pathway, especially without the literature review which remained unpublished.

## **APRIL 2020**

In April 2020, in response to correspondence, Minister Hunt advised:

*“These projects are intended to benefit multiple stakeholders and will provide much needed guidance for health professionals and the public. Overall feedback on these projects has been largely positive, particularly among health professional groups.”*

From the Minister’s response it is evident that non-DSCATT-treating health professionals were considered the most important stakeholder group, as only they (and government representatives) gave positive feedback.

DSCATT-treating health practitioners and patient groups gave negative feedback and rejected the Pathway.

The Minister seems insensitive to the fact that the Pathway does not benefit patient stakeholders and that our feedback is negative. The Minister has rejected the overarching Inquiry recommendation “... *people are unwell ... put the patients first.*”

## **FEBRUARY 2021**

In February 2020 the LDAA requested a moratorium on progressing the draft document due to obvious inadequacies, but this was denied by Minister Hunt.

Under the new Clinical Pathway, a Lyme disease diagnosis may only be considered if the patient has travelled overseas, yet thousands of Lyme-positive patients in Australia have not travelled. Many recall exactly where and when they were bitten by a tick/s. And a [2019 study](#) by Dr Jyostna Shah found 36 out of 100 Australian patient samples tested positive for 1 or 2 species of the Lyme bacteria.

## **AUGUST 2021**

In August 2021, with the support of over 60 international scientists, clinicians and stakeholders, the LDAA [wrote to Minister Hunt](#) outlining the gravity of the impact of the DSCATT Clinical Pathway on sick Australians.

The Pathway ignores the World Health Organisation’s documentation of the Lyme pathogen in every region of the world and creates unequal and discriminatory access to diagnosis and treatment for all tick-borne disease patients.

Under the new Clinical Pathway, the diagnosis and treatment of Australian Lyme and associated diseases, labelled Debilitating Symptom Complexes Attributed to Ticks (DSCATT) by the Department of Health, is limited to infectious disease specialists or microbiologists. These practitioners often have waiting periods of several months and their clinics are usually limited to highly populated areas.

According to the WHO and other international guidelines, Lyme disease must be diagnosed and treated early in order to avoid an unnecessarily long and debilitating illness.

**Minister Hunt’s response: “I am, at this point in time, satisfied the clinical pathway, and the educational materials currently being developed to support it, do not constitute a risk to patient health or safety.”**