LYME DISEASE
Association of Australia

Sarcoidosis & Lyme
Support Group Australia

MSIDS INC.
Multiple Systemic Infectious Disease Syndrome Inc.

23 January 2020

Minister Hunt,

We write to urge you to intervene in the DSCATT Clinical Pathway Project and its proposed approval process. We ask that you **call an immediate moratorium** on further progression of the draft Clinical Pathway through formal channels of endorsement until all patient community stakeholder feedback is provided and incorporated in revisions of the draft document.

We are concerned that the Department of Health appears to be satisfied with the content of the draft Clinical Pathway (Pathway) supplied by Allen & Clarke (consultants) and considered it fit for circulation to stakeholders, despite its failure to address the Department's Statement of Requirement. We also have serious concerns regarding the draft Tick Fact sheet supplied by Executive Impact Consulting.

The Pathway circulated for consultation is highly unsuitable as a fit-for-purpose pathway to address patient needs; and the proposed Tick Fact Sheet places the Department in a precarious legal position, as it contradicts the Department's own published recommendations and globally recommended practice. A high-level summary of the patient community concerns regarding these commissioned projects is at **Attachment A**. Given the extensive inadequacies of both documents, patient community stakeholders need to commit extensive additional time researching and writing responses to address the shortcomings and patent biases of the documents.

Furthermore, the Pathway is unlikely to be acceptable to the scientific community, with international medical experts advising the document is incomplete, misleading and will contribute to ongoing patient suffering in Australia.

It is unclear if the motivation for pushing such critical documents through is based upon contractual timelines, or a tick-box attitude; either way, it is abominable to ignore the harmful impact this Pathway would have on sick Australians and to obfuscate public health information on tick bites.

In respect to the Pathway, a four-month postponement of the project timeline negotiated by your Department and occurred without consulting stakeholders. Hence, the consultation period for stakeholders was compressed into a period where stakeholders faced numerous competing demands. Given the importance of these documents, stakeholder representatives raised serious concerns about the substandard performance of the consultants in every respect and sought time extensions to enable a thorough review of the documents before providing feedback. While some additional time has been granted, it incorporated the Christmas-New Year period. In response to these concerns, the Office of the Chief Medical Officer has either ignored correspondence from patient groups or responded with obfuscating waffle, which failed to address the detailed correspondence. Since then we have also encountered an unanticipated, unprecedented fire season during which many key volunteers in patient groups have been significantly impacted.

Fast-tracking endorsement of the Pathway via Committees after giving only cursory consideration to verbal stakeholder feedback and wilfully impeding the time provided for detailed critique is neither professional nor ethical. Patient groups - all volunteers and all affected by illness - have spent considerable unremunerated time liaising with the consultants and have repeatedly indicated they are unwilling to support or endorse the Pathway in its present form; yet the process has continued without redraft.

It would be prudent to conduct a formal risk review of the Pathway, incorporating a legal opinion of the rights of patients to unbiased, non-discriminatory health care and their human rights. Existing government policy fails to inform the public of the risk of tick bite and about the unreliability in pathology testing, or the risk of disability, and even death, from lack of appropriate diagnosis and timely treatment; the proposed documents compound the problem.

Patient community stakeholders are unified in their rejection of the Pathway and are appalled that their considerable body of work established over a decade is completely disregarded within this document. The ultimate purpose of the Pathway is to serve the interim health needs of people affected by debilitating illness, not for patients to be made unwell meeting timelines set for the convenience of your Department or its contracted consultants.

While the consultation process - intended to engage us in a patient centred, multidisciplinary care model - continues to dismiss our concerns and ignore our difficulty in meeting arbitrary timelines, we will not remain silent. The Pathway reinforces the stigma, formalises and consolidates the systemic denial and dismissal that motivated patients to lobby government prior to the Senate Inquiry. In fact, it worsens our situation.

In its latest response to Questions on Notice, the Department asserts that the Pathway fulfils seven of the recommendations of the Senate Inquiry, which called for a 'patients first' focus. Senators and other supporters will be very disappointed to discover that the LDAA's Patient Support Program is the *only* government-funded program that puts patients first.

There is considerable bi-partisan Senate support for real action for Australian patients who continue to suffer debilitating illness following a tick bite. We will be briefing those supporters, individual state and territory Health Ministers and all members of approving Committees on our concerns with the consultation process, the Pathway and the tick education materials should you choose to progress these projects without considerable redraft based on further stakeholder consultation.

Internationally, the era of Lyme denial is coming to an end, with increasing lawsuits against jurisdictions that fail to protect their citizens. It's time to be on the right side of history, to embrace all that is known without bias and to actively pursue answers. We implore you, Minister Hunt, to intervene in this process by calling a moratorium on further progression of the Pathway and tick education materials until the patient community is provided appropriate time to respond and ensure that their concerns are incorporated in revisions.

Yours sincerely

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ATTACHMENT A

Patient community concerns includes, but is not limited to, the following points:

The Clinical Pathway (Allen & Clarke):

- The consultation process with stakeholders is disorganised, tokenistic, biased and patronising, with patient community feedback being either disregarded or diluted to be meaningless. Requests for transparency within the consultation process are ignored. The process neglects the established principles of the Department's Stakeholder Engagement Framework intended to prioritise equitable participation by people with disability.
- The Pathway fails to meet the Statement of Requirement. The required cooperative, patient-centred, multidisciplinary framework is completely absent, despite your personal commitment that this work would focus on multidisciplinary person-centred care.
- There are multiple contradictions, flaws, inconsistencies and omissions in the Pathway, with evidentiary bias in the research articles referenced and the selective use of the referenced content. The bibliography provides secondary references that perpetuate scientific error, to the detriment of personal and public health. The poor state of referencing and bibliography error raises serious credibility questions.
- The Pathway assumes that laboratory testing means antibody testing serology, and this is the only method that should be used in the detection of the aetiological agent of this syndrome in Australia. The consultants have missed the critical fact that we don't yet have a serology test for an 'unknown' aetiological agent/s for this syndrome. In respect to Lyme disease, the reliability of serology testing as the basis for diagnosis is highly contested.
- The Pathway is anti-competitive in its stance on pathology testing and in prescribing and restricting the laboratories permitted to test for tick-borne pathogens. This is likely to be interpreted as collusion and necessitates legal review.
- The Pathway obstructs the clinical autonomy of medical practitioners by requiring specialist advice prior to ordering tests or prescribing treatment. This is in stark opposition to clinical advice provided in other countries with considerably more experience in tick-borne illness, where prophylactic use of antibiotics is routinely recommended. In fact, this requirement imposes on all Australian practitioners the same restrictive conditions as were applied to Lyme doctors disciplined by AHPRA.
- The Pathway aims to support decision-making only from a medical perspective and fails to recognise individual patient needs or choice. The immediate requirement for specialist advice establishes a dangerous precedent for patients, imposes delays that could have serious adverse health implications, and adds significantly to their burden of illness with a time delay and unnecessary cost. Delays in testing and treatment can cause totally avoidable harm; such delays place medical practitioners in a precarious situation in respect to non-maleficence. This issue should have been legally and ethically investigated before dissemination of such a document.
- The Pathway is predicated on biased and arbitrary views, arguably unscientific, that ignore multiple pieces of critical contemporary evidence regarding the persistence of Lyme and Borrelia and it completely ignores the role of complementary and comorbid infections; known to affect more than 60% of Australian patients.
- The notion and use of 'medically unexplained symptoms' (MUS) terminology in a Pathway designed to support patients is an embarrassment. Naming a disease DSCATT and allowing the commissioned Pathway to place DSCATT under the MUS banner is a demonstration of the tokenistic efforts by the Department of Health to 'tick boxes' in their handling of Australian Lyme-like illness and Multiple Systemic Infectious Disease Syndrome.

- If endorsed by the Department of Health, this Pathway provides an official document promoting a harmful bias to justify the denial of medical diagnosis and medical care for Australian patients. This is imprudent, given the rapidly increasing cases of discrimination on public record and the copious public reporting of medical misdiagnosis and mistreatment of Australian patients who have become seriously ill after a tick bite.

Tick Fact Sheet (Executive Impact Consulting):

- The consultants' communications with stakeholders have been casual and haphazard. After inviting stakeholders to work in close consultation in developing educational materials in early July, a nearly five-month silence was followed by presentation of an unsuitable draft document with a two-week period for stakeholder feedback. This poorly timed deadline competed with the, also postponed, stakeholder feedback period for the Clinical Pathway.
- Your Department has neither consulted with stakeholders when negotiating timelines with consultants, nor given due consideration to reasonable deadlines required for stakeholders affected by disabilities.
- Draft documents have not been presented in a format readily accessible to stakeholders; the quality of writing and punctuation is at secondary school English level; and the 'Fact Sheet' lacks scientific referencing to support its statements. Stakeholders have indicated they do not have time to review, research and re-write substandard documents, particularly with conflicting demands due multiple postponed consultations.
- Although promoted by your Department as an initiative to address 'DSCATT', the draft Tick Fact Sheet seriously downplays the risks inherent in Australian tick bites. Even more concerning, it devotes only a single paragraph to tickborne infections that can be acquired in Australia and mentions only one of the four infectious organisms known to be carried by Australian ticks and reflected in patients' clinical presentations; and references none of the newly discovered tick pathogens that may pose potential risks to humans[1].
- The Tick Fact Sheet promotes tick removal methods that are contrary to the current recommended global best practice and have not been scientifically proven to be safe regarding tickborne infections.
- Stakeholders have recommended legal review of this document as well.
- Patient community stakeholders have not been invited to provide feedback on documents being produced for health professionals by these consultants and would be seriously concerned if medical practitioners are being offered the same limited and potentially harmful advice as appears in the fact sheet aimed for the public audience.

[1] Chalada, M. J., Stenos, J., & Bradbury, R. S. (2016). Is there a Lyme-like disease in Australia? Summary of the findings to date. *One Health*, *2*, 42-54. https://doi.org/10.1016/j.onehlt.2016.03.003