29th March 2016

The Secretary
Senate Community Affairs References Committee
Enquiry: "*The growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients*"

Dear Sir/Madam,

This submission is on behalf of the Infectious Diseases Department at Austin Health, Melbourne, Australia. I am Director of Infectious Diseases & Microbiology at Austin Health, and Professor of Medicine (Infectious Diseases) at the University of Melbourne, Australia. Fifteen Infectious Diseases Specialists from our department have contributed to this submission.

Qualifications for making this Senate Submission:
In addition to being specialists in infectious diseases, we believe we have expertise in Lyme Disease (and "Lyme-like Illness" [LLI]) since a number of specialists in our Department have worked in both Europe and the USA where we have managed patients with proven Lyme Disease. Furthermore, because of our perceived expertise and possibly as a result of recent actions taken by AHPRA in relation to a number of medical practices in our region, we have been referred a large number (n=31) of "Lyme-like Disease" patients for assessment over the past 6 months.

Our submission addresses 3 issues:

1. Summary of critical issues associated with patients suffering from "Lyme-like Illness" (Terms of reference a, b, c, f and g)

For patient confidentiality reasons, we cannot describe exact patient details. However, we have now undertaken very extensive assessment of our patient cohort and provide the following summary of our experience:

1. All patients are suffering and have had their lives affected by their illness, many for a very prolonged period.
2. All patients have become frustrated by both their illness and its treatment (or perceived lack thereof). In many cases (and perhaps not surprisingly) many have become depressed, and in some cases, preoccupied with their illness.
3. Based on results from NATA accredited reference laboratories and our medical experience of the known clinical manifestations of borreliosis, none of our cohort have proven Lyme Disease, or as best can be currently assessed, any form of borreliosis (Lyme disease or any of the other Lyme-like diseases caused by the species *Borrelia*). Furthermore, none of our cohort who believe they have babesiosis or rickettsiosis have had that diagnosis confirmed by our group, based on either laboratory evidence or response to medical therapy that is known to be effective against these two diseases.
4. However, among our cohort, after extensive investigation, we have identified that:

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

2. The impact of results from unaccredited laboratories on patients with "Lyme-like Illness" (Terms of reference: a, c and d)

All patients in our cohort believe they have LLI based on the results produced by one or more laboratories that have not been accredited by NATA. In most cases, these results have derived from one such laboratory in Sydney – one which we understand has already been the subject of an ACCC investigation and directive. Other similar labs are found in California, Belgium, Austria and Germany – none have been approved by their relevant Government accreditation authority.

Because these laboratories are unaccredited, the cost of testing is not covered by Medicare or private insurance (quite appropriately) – resulting in large personal costs to the patient. In some cases these laboratories are linked to treatment facilities for patients with LLI – a practice that carries obvious ethical and conflict-of-interest concerns since the treatment of LLI is frequently expensive and therefore lucrative to treatment providers.

In our experience, many of our patients have suffered serious financial hardship paying for unregulated (and often inaccurate) investigations and unproven (and in some cases potentially unethical) medical therapy. The human and social impact on these patients of the current situation is large and often exacerbates any psychological issues they may have managing their illness.

3. Suggested future approaches (Terms of reference: a, b, c, d, e, and f)

We believe the following issues warrant consideration if we are to assist patients who have, or believe they have, LLI:

1. Review and better regulate unaccredited Australian pathology services, including investigation into whether they (or the business owners) are linked to medical service providers.
2. There should be an improved system of warning Australians regarding the problems associated with using unaccredited pathology providers and the harm that can ensue from inaccurate results.
3. Many current LLI patients have known medical conditions that have either gone undiagnosed, or have been inadequately treated – this needs to be addressed.
4. Emerging antibiotic resistance ("Superbugs") is a major issue worldwide and has been the subject of recent Australian Government control initiatives. The inappropriate use of

antibiotics is a key driver of emerging resistance. In this context, inappropriate antibiotic therapy related to LLI is an important consideration that requires better management.

5. Tick-borne illnesses are an important concern in Australia, as elsewhere. It is almost certain that not all tick-borne infections have yet been identified. Nevertheless, currently available testing methods in accredited reference laboratories have the capability to make accurate diagnoses – these methods should be made more widely available and appropriate pathology funding provided.
6. Research into tick-borne infectious agents should be increased, including an improved system of medical assessment of patients to assist with the development of a clinical case definition of LLI. This assessment should include both medical and psychological components.
7. The current management of LLI requires a multi-disciplinary approach that includes long-term medical support structures. Current referral and funding models need to be reassessed to adequately facilitate such a multidisciplinary management model.

Thank you for consideration of this Senate submission.

Yours faithfully,

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