Thank you asking the Australian Government Department of Health to participate in today's hearing. I will table this statement for your consideration.

The department began engaging with patients, advocacy groups and the medical profession in early 2013 to discuss concerns about Lyme borreliosis also known as Lyme disease. The Chief Medical Officer, Prof. Chris Baggoley, established a short term advisory committee to consider the evidence for a *Borrelia* sp. causing illness in Australians, diagnostic algorithms for borreliosis in Australians, treatments for borreliosis in Australians, and awareness raising and education plus research into borreliosis.

Through regular communication and correspondence the department has gained a deeper appreciation and concern for those Australians experiencing a chronic (probably) tick borne illness manifesting as a constellation of chronic nonspecific debilitating symptoms. We wish to remain engaged with the patient and medical community to continue to find, share and understand the Australian research evidence associated with this medical conundrum. We hope our engagement with patients and their healthcare practitioners along with the diagnostic pathology and biomedical research communities will result in answers and relief for patients and their families.

The department recognises that classical Lyme disease exists endemically (i.e., a disease regularly found among particular people or in a certain area) in parts of the northeast United States of America, parts of Europe including the UK and parts of Asia, as a tick borne infection that is usually short lived but can last untreated from days to months and that in the majority of patients responds to a few weeks of oral antibacterial therapy. We recognise that people infected overseas who return to Australia have a risk that their classical Lyme disease will not be recognised or appropriately treated, in spite of our regular advice to

Australia's doctors to pay attention to this situation. In some patients a post treatment late Lyme disease syndrome occurs with patients experiencing nonspecific symptoms such as headache, fatigue, muscle and joint pain and cognitive impairment. These symptoms are generally not regarded as persistence of active infection but rather post-infectious phenomena. The department is aware of the controversy in endemic areas overseas over the diagnosis of 'chronic' Lyme disease.

Since early 2013 the department has become cognisant of the affected community's concern that the constellation of symptoms experienced may have more than one cause. In the context of evolving Australian research data we need to consider that the cause may not be limited to a single bacterial species. Parasitic and viral causes as well as environmental toxins should also be considered for investigation as well as other potential medical explanations.

The department has embarked on multiple projects to assist Australians experiencing chronic debilitating symptoms associated with a tick bite.

In 2013 the department commissioned a scoping study to generate research priorities for the Australian medical research community to consider. The priorities spanned research into finding and characterising the cause of the illness through to clinical research on the patients and investigating common elements and potential causes for their disease processes. That scoping study was authored by Prof. John Mackenzie who you heard from on Thursday 14 April in Perth.

As part of the department's work in communicable diseases with states and territories we are developing an awareness of newer genomic technology that has the potential to use specimens from patients and to look for microbial nucleic acid in an attempt to find commonality in patient specimens. It may

reveal a common pathogen or pathogens which can be further investigated. It will be essential to find the causes of tick borne illnesses so that appropriate treatment can be instituted. Long term antibacterial therapy carries significant risks and is ineffective if the cause is a viral infection. That may sound like a contradiction, but we know many antibacterial agents have antiinflammatory effects independent of antiinfective actions.

The department welcomes the research conducted at Murdoch University (Prof. Peter Irwin) as well as the research funded by the Karl McManus Foundation at the University of Sydney's Tick borne diseases unit. The Murdoch University submission (number 497) explains the approach Prof. Irwin's team has taken. The department is also aware that the Marie Bashir Institute is embarking on metagenomic studies in an attempt to identify and characterise a common microbial agent or agents in ticks and patients. These metagenomic studies apply techniques like next generation sequencing to patient specimens or the contents of a tick gut rather than sequencing separate microbial genomes one at a time. The submission from Prof. Edward 'Eddie' Holmes (number 546) outlines new and potentially ground breaking work his team is doing in patient specimens.

The department has recently contracted the National Serology Reference Laboratory to undertake an evaluation of diagnostic assays used in Australia and overseas laboratories including specialist Lyme disease laboratories in Australia, Germany and the United States of America. It is hoped this evaluation will assist in better understanding the reasons for discordant results between the specialist 'chronic Lyme disease and associated diseases' laboratories and the Australian medical testing laboratories including the variables associated with differences in prevalence and result interpretation.

Because of the questions raised by advocacy groups about the accuracy of laboratory-based diagnosis in Australia, the department would welcome a review by the Medicare Services Advisory Committee. Likewise, given the desire by patients and advocates for subsidised pharmaceutical agents, the department would welcome a submission by the advocacy groups to the Pharmaceutical Benefits Advisory Committee for a review of the evidence. Both committees are in the best position to review the current data for the available diagnosis and treatment. Should the committees advise that supportive evidence of effectiveness and cost-effectiveness does exist, steps can be taken to update the Medicare Benefits Schedule and the Pharmaceutical Benefits Schedule.

To raise awareness and assist with diagnosis of overseas acquired classical Lyme disease, the Australian Government with state and territory health authorities have recently released the *Australian guidelines on the diagnosis of overseas acquired Lyme disease/borreliosis*. This guide was developed with the assistance of patient advocates as well as experts in immunology, microbiology and infectious diseases. The guideline was shared with Australian general practitioners, emergency physicians and other relevant specialists as well as the Australian Medical Association.

In an effort to prevent tick bites and raise awareness of tick bite first aid, we collaborated with the National Arbovirus and Malaria Advisory Committee as well as states and territories on a tick bite prevention document for public distribution. It is hoped in future we will incorporate emerging research into tick bite associated mammalian meat allergy and newer techniques for tick removal. The department is committed to education and awareness raising.

Care and treatment for patients is usually provided by general practitioners who are drawn to helping patients with chronic and complicated illnesses. The department has met with some of these general practitioners and has separately conducted a roundtable discussion with general practitioners, and medical experts in microbiology, infectious diseases, neurology and psychiatry. Long term treatment with multiple antimicrobial agents is favoured by some practitioners and argued against by others. It is difficult to draw conclusions on treatment while controversy remains on causation and correct diagnosis. The department remains interested in ongoing discussion in this area given our interest in antimicrobial stewardship and antimicrobial resistance. In addition, the department would encourage within states and territories, a multidisciplinary approach to patient care similar to what already occurs with patients with complicated diagnoses or uncertain diagnoses. A multidisciplinary team involving general practitioners, infectious diseases physicians, consultant rheumatologists, consultant neurologists, specialist microbiologists as well as other relevant medical specialties could undertake a thorough investigation and treatment approach for each patient. This could be coupled with metagenomic analyses of patient specimens and multidisciplinary teams would form the basis for valuable patient-centred research. This type of approach may also be able to investigate the questions around transmission between sexual partners and transmission from mother to fetus.

In conclusion, the department

- remains concerned for the Australians experiencing these chronic debilitating symptoms,
- remains willing to engage with patients, advocacy groups, medical practitioners and the medical research community to find answers,

- will continue to work on resolving the concerns about diagnosis in Australia,
- will continue to check for and where appropriate encourage research activities associated with Australians experiencing these chronic debilitating symptoms, and
- will continue to recognise the role of states and territories in the delivery of healthcare.

Dr Gary Lum, AM
Office of Health Protection
Wednesday, 20 April 2016

Committee: Community Affairs

Tabled Document

Inquiry: Lyme-like illness

Date: 20/4/16

Witness: Dr Gary Lum

Organisation: D.o.H