COMMONWEALTH OF AUSTRALIA

Proof Committee Hansard

SENATE

COMMUNITY AFFAIRS REFERENCES COMMITTEE

Emerging tick-borne disease

(Public)

WEDNESDAY, 20 APRIL 2016

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SENATE

COMMUNITY AFFAIRS REFERENCES COMMITTEE

Wednesday, 20 April 2016

Members in attendance: Senators Bilyk, Dastyari, Ludlam, Madigan, Moore, Reynolds, Seselja, Siewert, Wang.

Terms of Reference for the Inquiry:

To inquire into and report on:

The growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients, with particular reference to:

a. the prevalence and geographic distribution of Lyme-like illness in Australia;

b. methods to reduce the stigma associated with Lyme-like illness for patients, doctors and researchers;

c. the process for diagnosis of patients with a Lyme-like illness, with a specific focus on the laboratory testing procedures and associated quality assurance processes, including recognition of accredited international laboratory testing;

d. evidence of investments in contemporary research into Australian pathogens specifically acquired through the bite of a tick and including other potential vectors;

e. potential investment into research to discover unique local causative agents causing a growing number of Australians debilitating illness;

f. the signs and symptoms Australians with Lyme-like illness are enduring, and the treatment they receive from medical professionals; and

g. any other related matters.

WITNESSES

APPLEYARD, Ms Sharon, First Assistant Secretary, Office of Health Protection

BARDEN, Mr Graeme, Assistant Secretary, Health Protection Policy Branch, Office of Health Protection

KELSO, Professor Anne, Chief Executive Officer, National Health and Medical Research Council

LUM, Dr Gary David, Principal Medical Adviser, Office of Health Protection, Department of Health

Committee met at 12:35.

CHAIR (Senator Siewert): I declare open this public hearing and welcome everyone here today. We acknowledge the traditional owners of the land on which we meet and pay our respect to elders past and present. This is the third public hearing for the committee's inquiry into the growing evidence of an emerging tickborne disease that causes a Lyme-like illness for many Australians.

I would like to clarify the purpose of today's hearing. It is to provide the committee with an opportunity to hear evidence from and ask questions of the three key agencies that are appearing. It was always the committee's intention that this hearing would focus solely on this. I regret that some people here today may have thought that they would be able to address the committee today. This is not possible and it was not the committee's intention. Having said that, I would like to assure everybody that the committee's inquiry will continue regardless of any speculation about the timing of the election. It is the committee's intention to hold further public hearings where possible and to provide further opportunities for members of the public to address the committee. We know, and I have said repeatedly, how important to this committee is people's lived experience—our hearing about it and understanding it.

While we cannot commit a future parliament, it is the intention of members of the committee here today that the committee inquiry continue into the future, and those of us who are around will do what we can to ensure that that occurs. I encourage everyone who wishes to make a contribution to this inquiry to make a written submission to the inquiry if you have not already done so. I thank everybody who has made a submission to date and remind everybody that the community affairs committee is notorious for its ability to take and accept late submissions. I would like to clarify and assure people that this is a public hearing and a Hansard transcript of the proceedings is being made. The audio of this public hearing is also being broadcast via the interwebz.

Before the committee starts taking evidence, I remind everyone here today that in giving evidence to the committee witnesses are protected by parliamentary privilege. It is unlawful for anyone to threaten or disadvantage a witness on account of evidence given to the committee, and such action may be treated by the Senate as a contempt. It is also a contempt to give false or misleading evidence to the committee.

The committee prefers to hear evidence in public but under the Senate's resolutions witnesses have the right to request to be heard in private session. It is important that witnesses give the committee notice if they do intend to ask to give evidence in private, because it takes us a little while to organise it. If you are a witness today and intend to make such a request could you please let the secretariat know as soon as possible.

I welcome officers of the Department of Health and of the National Health and Medical Research Council. I will double-check that information on parliamentary privilege and the protection of witnesses and evidence has been provided to you all.

Dr Lum: Yes.

CHAIR: I remind witnesses that the Senate has resolved that an officer of a department of the Commonwealth or of a state shall not be asked to give opinions on matters of policy and shall be given reasonable opportunity to refer questions asked of the officer to superior officers or to a minister. This resolution prohibits only asking questions on opinions on matters of policy and does not preclude questions asking for explanations of policies or factual questions about when or how policies were adopted. I invite each of you, or whoever wants to, to make an opening statement or comments. You have lots of interest here for questions.

Dr Lum: Thank you very much for asking the Australian government Department of Health to participate in today's hearing. At the end of this opening statement, I am happy to table this document for your consideration. The department began engaging with patients, advocacy groups and the medical profession in early 2013 to discuss the concerns about Lyme borreliosis, also known as Lyme disease. The Chief Medical Officer, Professor Chris Baggoley, established a short-term advisory committee to consider the evidence for a *Borrelia* species 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 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 in parts of the north-east United States of America, parts of Europe, including the United Kingdom, and parts of Asia as a tick-borne infection that is usually short lived but can last untreated from days to months, and that the majority of patients respond 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 non-specific 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. However, since early 2013 the department has become cognisant of the affected communities concerned 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 the 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 in defining and characterising the cause of the illness through to clinical research on patients and investigating common elements and potential causes for their disease processes. That scoping study was authored by Professor John Mackenzie, who you met last Thursday in Perth.

As part of the department's work on 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 define commonality in patient specimens. It may reveal a common pathogen or pathogens which can be further investigated. It will be essential to find the cause of tick-borne illness 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 that many antibacterial agents have anti-inflammatory effects independent of their anti-infective actions.

The department welcomes the research conducted at Murdoch University 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, No. 497, explains the approach Professor Peter Irwin's team has taken, and you heard from them last Thursday as well. 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 and to the contents of a tick gut, rather than sequencing separate microbial genomes one at a time. The submission from Professor Edward Holmes, No. 546, outlines new and potentially groundbreaking 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 Australian 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 important 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.

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. 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, other relevant specialists as well as the Australian Medical Association. In an effort to prevent tick-borne bites and raise awareness of tick bite first aid, we collaborated with the National Arbovirus and Malaria Advisory Committee as well as with 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 such 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 which involved 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 its 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 in 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 such multidisciplinary teams would form the basis for valuable, patient centred research. This type of approach may also be able to investigate those questions that exist around transmission between sexual partners and transmission from mother to fetus.

In conclusion, the department remains concerned for those Australians experiencing these chronic debilitating symptoms. The department remains willing to engage with patients, advocacy groups, medical practitioners and the medical research community to find answers. We will continue to work on resolving concerns about diagnosis in Australia. The department will continue to check for and, where appropriate, encourage research activities associated with Australians experiencing these chronic debilitating symptoms. The department will continue to recognise the role of states and territories in the delivery of health care.

CHAIR: Thank you. Professor, do you have an opening statement?

Prof. Kelso: Yes. Thank you for the opportunity for NHMRC to meet with you today. May I start by outlining the role of NHMRC before moving to support for Lyme-like illness related research. NHMRC is the lead Commonwealth government agency for funding of public sector medical research in Australia. It is responsible under the NHMRC Act for administering the Medical Research Endowment Account to support medical research and medical research training for the improvement of human health—so specifically to raise the standard of individual and public health throughout Australia. NHMRC is also responsible for producing or endorsing clinical public health and environmental health guidelines for the community, for clinicians and for government. We also play a leadership role for the country in developing and updating the Code for the Responsible Conduct of Research and ethical codes for human research and for animal related research.

In our role as a research funding agency, NHMRC distributes funding through a range of schemes to support research that will lead to advances in knowledge of human health and disease, development of new diagnostics, new clinical treatments and drugs, preventive measures such as vaccines and interventions to improve public health, and better health services. All of these have potential relevance to Lyme-like illness in Australia.

Most of the research funding administered by NHMRC is for grants to individuals or teams for specific research projects. Schemes range from small projects to large multidisciplinary team grants; scholarships and fellowships for outstanding researchers; targeted calls for research on specific problems, which I will return to; partnership projects with healthcare providers, policymakers and industry; and also partnerships with international funding agencies. Most NHMRC funding schemes support investigator-initiated research—that is, research which has been conceived and developed by the researchers themselves. But we also have some priority-driven schemes, notably the targeted calls for research on specific health issues where there is a clear gap in our knowledge and a significant unmet need or also a link to Commonwealth, state or territory priorities.

Applicants apply to NHMRC for funding for a defined program of work. All applications, regardless of whether they are investigator initiated or priority driven, go through a rigorous process of review by independent experts. They assess the application based on the significance of the research for human health and/or innovation, the scientific quality and feasibility of the research as well as the track record of the applicants in their previous research in this field. This process is highly competitive, and only research of the highest significance and scientific excellence can be funded.

In preparation for this inquiry, we have searched our electronic grants database to see whether we have received any applications or awarded any grants on Lyme disease or Lyme-like illness. We found that, between 1997 and 2015, NHMRC received 13 applications investigating diseases related to Lyme disease and one directly investigating Lyme disease. The one application directly investigating Lyme disease was submitted in 1999 and was not successful in winning funding. Of the 13 other applications, only one was successful. This was a postgraduate scholarship for the period 1999 to 2001 for work on a bacterium, *Bartonella henselae*, which is carried by ticks as well as some other insects and is often observed in patients with Lyme disease. But this project was not directly on Lyme disease.

Looking ahead, NHMRC would welcome high-quality research proposals on Lyme-like illness to our investigator-initiated research funding schemes. But I also want to draw the inquiry's attention to the new process we are putting in place for NHMRC's targeted calls for research. We recognise the need to consider the priorities not only of government but also of the wider community, so in addition to working with Australian governments we will shortly offer a web portal through which community and professional groups may submit topics for consideration for targeted funding. These will be evaluated and prioritised by a committee made up of consumers, health system and service experts, clinicians, Aboriginal and Torres Strait Islander health experts and experienced researchers. Recommendations of this committee will assist NHMRC in rolling out a series of targeted calls for research to address significant government and community health needs which are not already being supported through our other funding schemes.

In conclusion, NHMRC plays a critical role in funding research of the highest quality and significance for the improvement of human health in our country. NHMRC would welcome applications that address the many questions that currently surround Lyme-like illness in Australia, and shortly we will also offer a mechanism by which community and professional groups can assist NHMRC in identifying important underresearched areas of unmet need. Thank you.

Senator MADIGAN: Dr Lum, as you aware, the committee heard evidence last week in Perth and Brisbane. We have heard many heartbreaking stories of neglect from the medical system that your department administers. We have also heard many opinions of professionals, very few of whom, I believe, actually see patients themselves. They just offer opinion after opinion from their microscope without having to face a patient who is sick or potentially dying. Then we have heard from some doctors who are actually at the coalface, the doctors who treat these patients, who also tell us stories of bullying, dismissal and ridicule. I would seriously like to know what the Department of Health think about this and what is the department's plan to address the gulf of difference.

Dr Lum: I am aware of the hearings in Perth and Brisbane. I was at the hearing in Perth. When you comment that the department administers health, it does so in collaboration with states and territories, and I think it is important that the states' and territories' involvement is understood and acknowledged. You mentioned that some of the experts who are present do not see patients. I do not believe that is true. I know at least one of them personally and he does see patients very regularly. On the issue of how the department is working in this space and what we feel about this, I think that the statement I made explained just how concerned we are.

My personal experience with this, I think, is worth mentioning. I started my training in the early 1990s. I was fortunate enough in the two hospitals that I trained in, the Princess Alexandra Hospital and the Royal Brisbane and Women's Hospital, to have supervisors who were very open-minded about the teaching of clinical microbiology, and they encouraged me to explore all of the different possibilities. At around that time Dr Bernie Hudson, who was probably Australia's doyen when it comes to classical Lyme disease in Australia, came and spoke at a meeting. That was a really interesting meeting for me because normally when a visiting interstate or international speaker comes it is a meeting for medical people, but this was a patient-centred meeting. I went along to that and discovered for the first time, and understood for the first time, the depth of feeling amongst patients.

When I was in Darwin looking after the pathology services for the Northern Territory for 12 years, I came across quite a number of cases where patients who had travelled overseas, particularly to Germany or to the United States, had returned and they had signs and symptoms which were classical for classical Lyme disease. I was responsible for their laboratory diagnosis in the sense that I would organise referral, because I did not do the actual test in Darwin, but was intimately involved in the understanding and interpretation of certain results and explaining those results.

From the department's perspective, on 21 January 2013, I remember distinctly, at 4 pm, the Chief Medical Officer, Professor Chris Baggoley, coming to me, putting both hands on my shoulders and saying, 'Gary, I have a very important task for you.' And that was to do with this particular issue. Since that date we have taken a very strong interest in the issue of a chronic debilitating illness affecting many Australians. We are familiar with the

relevant science as it occurs at the moment. Through the scoping study with Professor Mackenzie and with many others we have explored what is happening around the world. I have attended tickborne illness meetings that the Karl McManus Foundation has put on. I presented at one of those meetings. I was fortunate enough to also be able to hear some of the work that is going on in Brazil, to try to get a flavour and understanding of what is happening there with their particular version of this chronic debilitating illness.

In addition to that, the Chief Medical Officer, as I said, set up his clinical advisory committee, which contained not only people from medical and scientific areas but also people from advocacy groups. While it is true that at first we did not have a patient representative on board, we did at the first meeting and at subsequent meetings. Since that time, the department has undertaken a variety of different work relating to this issue. We are hoping that we can now take that work back to the states and territories to try to work with them.

This started with Professor Baggoley when he was asked by one of the state and territory chief health officers to start looking at this seriously from a national coordination perspective. Professor Baggoley took that on acknowledging, as I think all senators will acknowledge, that under our Constitution the Australian government Department of Health does not have an active healthcare delivery role. We can do national coordination. It is the healthcare delivery role that belongs with state and territories. After we have spent I admit some time looking at this situation and trying to work with people, I think we are in a much better situation now to go back to states and territories, who are responsible for that activity, to work with them and to undertake that national coordination.

Senator MADIGAN: There has been considerable discussion, as you would be well aware, Dr Lum, about the name of the illness that is afflicting these people and there was discussion about how it may be advantageous to change it from Lyme disease. We heard last week in Perth and Brisbane from people who are seriously afflicted and suffering that they just want to get to the bottom of it. We have heard from doctors at the coalface and from patients. They are saying, whatever their differences are, they just want to sit down and work through the issues in an expedient manner so that we might get some answers. From your perspective, Dr Lum, how willing do you think the medical profession are to genuinely engage with these people, and the people who are looking after children who are suffering, to bring this about?

Dr Lum: I think that first point you raised about the name is an excellent suggestion. We are well aware from the patient community and from various members of the medical profession that moving right away from the notion of Lyme disease and Lyme-disease-like illness is probably a very good move.

The problem that we have in Australia in terms of how we work with patients, advocacy groups and the medical profession is that this is not unique to Australia. The issue of a chronic Lyme disease is very contentious and very controversial to the extent that we would like to steer away from that. That is why in the work that we have been dong we have tried to distinguish it by describing a chronic debilitating illness that manifests as a constellation of chronic debilitating symptoms. That is a mouthful and I would not propose that as a name. What I am trying to suggest though is that getting away from that name is probably a very good move.

While the medical profession by and large in Australia agree with counterparts overseas that chronic Lyme disease is contentious, then having anything linked to Lyme, or Lyme disease like, is probably not appropriate. I know that in the United Kingdom colleagues there—particularly Dr Matthew Dryden working in the Rare and Imported Pathogens Laboratory at Public Health England in Porton Down—have been advocating the term 'chronic arthropod-borne neuropathy'. That fits nicely for the UK situation. It may well fit nicely for us, given that most patients believe that their disease manifestation is more of a neuropathic manifestation than an arthritic or cardiac manifestation.

For that to happen, it is something that needs to happen not only with the medical profession but also with the patient community. I recall at the Perth hearing that one of the speakers did say that within the patient community it is a little bit divisive because so many people have invested in the brand. I think if we can get away from that it would be very helpful. I think that the way the WA society has moved away from the name is probably a good move.

Senator MADIGAN: Whilst I appreciate—and I am sure many on the committee appreciate—the work the department has done, the fact is that the adults and children who are suffering are not interested in having this ongoing debate about what we are going to call it. They are interested in getting results and they are interested in medical research being conducted. You were there in Perth last Thursday. To quote her, Senator Reynolds questioned the 'circular logic' that is employed. Would you like to comment on the circular logic that says positive tests for Lyme-like disease are false positives because it is not endemic, and that it is not endemic because tests are false positives?

Dr Lum: I am very happy to try to unravel what could be seen as circular logic. I think it is really important that when we are thinking about—sorry, Senator Reynolds?

Senator REYNOLDS: I just want to add to that. There was also the idea that it is not here because we do not have the diagnoses. It seemed to be that people were caught in this level of hell—I am not quite sure which—because they are sick. They get diagnosed and it is discounted because they have not travelled overseas, and then people say that it does not exist here because we have no research to show it. But the research that is there is discounted and not reviewed. People seem to get stuck on the name of—as you just said—Lyme disease. Clearly, people are ill and there seems to be this circle of hell of logic.

Dr Lum: I understand completely, Senator. I think that having this inquiry has been a fantastic event for the patients and also for the medical profession because it is opening things up and it is making more information available. When it comes to that conundrum of somebody coming up with a test result and you also hear from us as well as from other experts that classical Lyme disease does not exist in Australia, the explanation for that comes down to an understanding of diagnostic testing and in particular the classical diagnostic tests used for Lyme disease. For the most part classical Lyme disease is diagnosed in the laboratory, apart from a clinical diagnosis where a pathognomonic erythema migrans rash occurs in a person who presents with a history of a tick bite and who lives in an endemic area.

The laboratory diagnosis comes down to doing serology testing. Serology testing is in and of itself an indirect way of making a diagnosis. You are looking for the antibodies that are produced and the antigens that are on the surface of the micro-organism causing the infection. Serology, in some situations, can reflect a positive disease. When you hear experts in diagnostic pathology and laboratory medicine describe serology they do not use the terms 'positive' and 'negative'; they use the terms 'reactive' and 'non-reactive'. The reason we do that is because what we are looking at is reactions between antigens and antibodies. Those are reactions we can confidently say are occurring or not occurring. In that situation, we can provide a result. But almost all serology is very dependent on the clinical context in which we find the patient. That context is vital.

The particular tests in question—whether they be commercially available and commercially produced, or whether they be in-house tests—are designed for the diagnosis of classical Lyme disease. For that reason, you need to have the right clinical presentation. For most patients that we have in Australia who are presenting with chronic debilitating symptoms, that is not classical Lyme disease. When you get a reactive result that may or may not reflect a presence of disease, what it reflects is a reaction that is occurring in a reaction well, and that can be nonspecific.

We also know with bacteria like *Borrelia*, and particularly *Borrelia burgdorferi,* where there are so many genospecies and similarities with other bacteria, and also other proteins, that cross-reactions do occur. We see that very commonly in Australia with our rickettsial diseases. We see it commonly when we also have other important infections that you that you are probably aware of, like *Legionella*, because of the various types of *Legionella* bacteria. We see cross-reactions. It requires the expertise of experts in laboratory medicine to be able to do those interpretations. If you just receive a piece of paper as a report that says there is a reaction in an enzyme immunoassay for *Borrelia burgdorferi* IgM or IgG, but it is outside of the normal clinical context in which that test should be done, then you may interpret that as a positive result when in fact it is not. The other important thing that we know is that, when these tests are performed overseas, and also in some specialist laboratories in Australia, the interpretive criteria are different. What I mean by that is that they place less serological stringency on the test interpretation, so it makes it easier to diagnose a reactive result.

The other important phenomenon to understand—and, Senator Madigan, this is something that I raised in October 2015 at the Senate estimates hearing—is that when you do a test in a wrong patient population with a low prevalence, you will automatically get a higher number of false reactive results. If it helps the committee, I have a group of papers that I am happy to table. I understand from what I observed at the Perth hearing that you are very happy to take scientific papers for tabling, so at the end of the hearing today I am happy to provide those. They go into some of the details of an explanation as to why serological diagnosis can be fraught and very difficult to understand.

CHAIR: That would be extremely useful, thank you. I believe Senator Reynolds has one follow-up question.

Senator REYNOLDS: If Senator Madigan does not mind. I absolutely appreciate your answer, Dr Lum, and I think for those in the room you have just taken maybe five or six minutes to demonstrate perfectly the circular logic of this. I think that my understanding of what you are saying—not being a doctor—is that someone is very ill, they go for testing here in Australia and they might get picked up as having something or having some reaction, so they clearly have some illness. But, if it is not coming up to your standard to say is classical Lyme disease, then, 'You are sick, but we do not know what it is.'

Dr Lum: That is right.

Senator REYNOLDS: So that is it: 'You are sick; we do not know what it is.'

Dr Lum: That is why the department wants to encourage the research that is really needed. That is why it finds the work of Professor Irwin's team and Professor Holmes's team just so important, because what we really need to be able to do is to connect what is likely to be a tick-borne illness with the patients, working out the commonalities. We have already seen the announcement of some novel bacteria by Professor Irwin's team. I understand that he has new research, yet to be published, which Dr Charlotte Oskam described in Perth. That will probably reveal more important information that can be worked on. That also requires people to start making that link between what happens in a tick gut and what happens in a patient. That is why it is important that clinician researchers are involved.

We have been encouraging general practitioners who are working with patients to work with university medical schools to undertake the grant applications and to undertake the processes, but I think that, now that we have seen what has happened in the last 12 to 18 months, trying to get multidisciplinary teams involved, engaging with states and territories is probably going to be the direction that needs to be taken.

CHAIR: I just want to clarify, following a point that Senator Reynolds made. If I understand what you have just said and what we heard in Brisbane, it is that the test is testing for one bacterium. It is testing for the *Borrelia burgdorferi*—I can never say it, even after all this time—the classic line. But other illnesses have other bacteria and, because of the nature of the test, it is only testing for that particular bacterium.

Dr Lum: Yes.

CHAIR: That is why it is coming around saying, 'No, you haven't got it.' It does not say that you are not sick. But what we heard in Brisbane is—and I will put this on notice; you do not have to quite answer it yet, so maybe think about it—that all Medicare allows you to test for is that particular—

Dr Lum: No.

CHAIR: Okay, so all the doctor asked for. What we were told in Brisbane is that you can test for that and, unless you go back to the doctor and the doctor says you can test for these other things—

Dr Lum: I certainly can try to answer that for you. Before I do, I would like to mention that, as part of the department's response to the scoping study that Professor Mackenzie did, we did outline the importance of looking at other pathogens and looking at other vectors. So that is very important in that.

CHAIR: Yes, and that is what came out in Brisbane as well.

Dr Lum: That is right. I think that this whole issue of linking a name is just so problematic—linking a name and linking an organism. When it comes to pathology testing, when it comes to a patient presenting to a medical practitioner, they are not limited in requesting only one type of test. Having said that, a lot depends on how the request is made.

CHAIR: That point was being made, yes.

Dr Lum: If a general practitioner writes on a referral form, when he or she refers a patient to a pathologist, 'This is for Lyme disease serology,' that is all that will be done because 'Lyme disease serology' has a very specific meaning. If, however, that practitioner—and one of the things I would really like to encourage, if we can get this out to the broader medical community, is that general practitioners and other specialists are always welcome to contact specialist pathologists in pathology practices to get a better understanding of what tests are available and what tests should or should not be requested. In this situation, it is not unreasonable for a general practitioner or a specialist physician to make contact with the pathologist and just ask: 'I've got a patient who presents with these signs and symptoms. What should I be requesting?'

When it comes to the issues around the co-infections, the *Anaplasmas*, *Babesias* and *Bartonellas*, certainly in Australia *Bartonella* is best known in the context of HIV-AIDS medicine. *Babesia* is really only recently known out of one case study at the Canberra Hospital, where Professor Peter Irwin and Professor Peter Collignon teamed up under the leadership—on the paper, at least—of Sanjaya, who described a case of a patient with a *Babesia* infection.

When it comes to the other co-infections that are commonly described by patients who have tick-borne infections, if those pathogens are specifically asked for on a request form, then there may well be the possibility to do the testing. Some of those pathogens, though, are not readily identifiable in Australia, so some laboratories would then refer to other experts, either to reference laboratories in Australia or to overseas laboratories.

CHAIR: Thank you. The point I was trying to get to was that the GP has to specifically ask for the test.

Dr Lum: That is right.

CHAIR: The pathologist cannot then go, 'Well, it might be something else,' and look for anything else.

Dr Lum: That is right. Having said that, it is important to mention one other thing. The referral of patients for pathology testing follows a medical model, so the request form is a referral. As I said before, I would really encourage referring practitioners to speak with pathologists. Being a specialist pathologist means that, once you accept that referral, the patient is effectively under your care as well, which means that you have the ability then to advise and determine what is the right or wrong course of action. So there needs to be a discussion. I am confident that there will be some pathologists who would probably dismiss the need for certain testing. I think that, with the current Senate inquiry and with the advocacy that is going on and the publicity that this has gained, there may well be a stronger interest, and hopefully we can encourage pathologists in pathology practices to look at other potentials. But really it does come down to that expert medical interaction between a referring healthcare practitioner and the pathologist.

Senator WANG: I have a follow-up. I think there are probably another two layers of the problem here. The pathologist we spoke to in the Brisbane hearing mentioned that they are a little bit reluctant to test for other possible causes of the illness, because they can be accused of overservicing. That is one reason for the reluctance. The other reason for the reluctance—or probably not reluctance but inability—is the nonexistence or lack of assay available for other causes. Can you comment on that, please.

Dr Lum: I can try to elaborate on both of those questions. On the first one, it is very important, under the current way that pathology testing is remunerated, that there not be any sense of overservicing, but if there is a legitimate request then there will not be overservicing. The important thing to remember, though, is that the pathology profession is subject to various rules under the Medicare Benefits Schedule and, when referrals are made by general practitioners, there are rules in place which make it difficult compared to when, say, another specialist medical practitioner makes a referral, such that the ability to make a claim on those tests is different. That needs to be understood. For example, if a general practitioner requests more than three tests, there is a coning rule in place, and the pathology practice will only receive remuneration for the most expensive three tests, rather than all of the tests.

Senator WANG: Yes, I understand that.

CHAIR: Sorry, I just have to jump in there. I asked that question, and you just said, 'No, a pathologist can ask for what'—

Dr Lum: They can.

CHAIR: So now this is going around in a circle.

Dr Lum: No, they can ask.

CHAIR: But they cannot get remunerated, which was the start of my question about Medicare.

Dr Lum: I apologise. If a specialist requests then I understand, under the rules, that remuneration will occur. But the coning rules make it clear that if there are more than three tests requested then other tests are coned out, so it depends on the number of tests that are requested on the pathology request form.

CHAIR: Okay, so there is a limit. Just say they are trying to look for a number of potential pathogens here. There is a limit. You can look for three before you start getting coned.

Senator MOORE: Per visit.

Dr Lum: Yes, that is right.

CHAIR: Thank you.

Senator WANG: I have another follow-up. Given that the cause of the Lyme-like illness in Australia is a bit of an unknown, would it be prudent for the department, or whoever controls the guidelines, to loosen the rules a bit so that the pathologists who are working on the ground, dealing with the blood samples, can do a couple more tests if they feel that is required, and so that we have the ability to collect more data from the people who are working on the ground? Would that be possible?

Dr Lum: That is not an area within the department that I work in, but I do know that that particular area, the Medical Benefits Division, is currently undertaking a review of the Medicare Benefits Schedule, and that is probably an important question that should be put to it.

Senator MOORE: This question is linked to the testing. It is on the process. We had the roundtable, and many of the issues you have talked about—the multidisciplinary teams and so on—are there. I am not verballing you, but you said that the GP and the pathologist should have a relationship in looking more closely at the

process. Are you aware of the background to clinical guidelines? If there were a clinical guideline for doctors and pathologist in this area, it would then allow them under the system to work in this way. My understanding is there is none.

Dr Lum: At the moment, for this particular situation, there is not a specific guideline, nor is there—if I am understanding the terminology correctly—a care set for this sort of work. Certainly for overseas acquired Lyme disease, we have a guidance document in place. But I think, Senator Moore, part of the real difficulty is not having a case definition. This goes to the question that came up in the Perth hearing about whether this could be a notifiable disease and, therefore, what could be done in terms of information collection and statistical information. Without a clear case definition, it makes it very difficult.

The last time that the joint assessment group, under the Public Health Laboratory Network and Communicable Diseases Network Australia, looked at this particular request, as a result of a request from New South Wales Health, was in June 2013. Previously it had been looked at in 2008. The biggest issue with trying to get a notification process through is having a clear case definition.

Senator MOORE: I understand the notification point, but what I am trying to get to is the relationship under our system with Medicare for people to take the time to do the work to get to the actual result with the testing process. It was my understanding from the evidence that the patients were feeling that they were not being respected when they came to work with various practitioners. If there were clinical guidelines for GPs that gave them the freedom to take on board the opportunity to get more tests and to work more closely, it would give them a protection under our system which they just do not have now. Are you telling me medically that it would be difficult to have clinical guidelines for testing for GPs? It was about testing, was it not?

CHAIR: Yes.

Senator MOORE: I just wanted to double check. So are you saying that you cannot have clinical guidelines without having a clear diagnosis?

Dr Lum: Thanks for that question. In the current environment, if it were not such a controversial area, I think that that would be an entirely appropriate course of action. I think what we need to do first is sit down with the medical profession in Australia—and this is not just with general practitioners and pathologists—to get some agreement on what we can do as a way forward on this. In that way, if we can get to some sort of agreement, it may be possible that some sort of guidance document for testing could be done.

Senator MOORE: An agreed one across a range of professions?

Dr Lum: That is right. Having said that, as I said in my opening statement, where there remains controversy about a diagnosis and a cause, doing testing without any real medically scientific direction is very difficult. That is why I think that we need to look at the research on what is causing this problem. Also, we need to not limit ourselves to bacterial causes. As I said, we need to think about other micro-organisms and potentially environmental toxins, and there may be other medical explanations that need to be considered as well.

CHAIR: You were not able to answer the last question from Senator Wong. I am wondering whether you could take that on notice.

Dr Lum: We can go back to the department, yes.

CHAIR: Thank you very much. That would be appreciated.

Senator BILYK: I have a follow-on question.

CHAIR: On testing?

Senator BILYK: I am not quite sure, but it is from that answer.

CHAIR: Yes; let's see where we are going.

Senator BILYK: I was not able to make the other two inquiries because I had other committees to attend to. I am still confused as to why it is so controversial. You have used that term a few times, Dr Lum. Why is it so controversial if people have symptoms and illnesses? I do not think we are denying that there is actually some disease. Is the controversy just around the name? Otherwise, why is it so controversial? Why can't whoever is causing the controversy just sort it so that people's lives are not so disrupted and ruined?

Dr Lum: I would like that too, Senator. This stems back decades. The controversy originates in the United States and has spread globally. The issue was around the contentious diagnosis of chronic Lyme disease. There are many in the mainstream, conventional side of medicine that do not agree about chronic Lyme disease. What I meant by that—

Senator BILYK: It does not mean it does not exist though, does it, Dr Lum?

Dr Lum: If you could let me finish, Senator. The issue of chronic Lyme disease assumes that there is persistent, active infection. That is what is so contentious. The mainstream conventional position is that the sequelae that we see after an infection is post-infectious and not active infection. So we see commonly with the causes of glandular fever, like Epstein-Barr virus and cytomegalovirus, a chronic fatiguing syndrome. That is post-infectious. It is not due to active persistent infection. We also see that with things like Q fever, caused by *Coxiella burnetii*. We see a Q fever chronic fatigue syndrome. We also see it with other conditions and some other infections. What is very contentious is whether or not that is active infection.

So, in Australia, like in many other countries that we would be like-minded with in terms of medicine, the experts in microbiology and infectious disease will not readily accept that there is chronic Lyme disease or chronic persistent active infection. So, for that reason, and because of the association between what is happening in Australia with chronic Lyme disease, most of the medical profession expert in this field do not accept that it is Lyme disease.

The reality is—we heard evidence at the last two hearings; there have been a significant number of research pieces done as recently as the work from Professor Irwin—we do not have a *Borrelia burgdorferi* sensu lato genospecies indigenous to Australia. That does not mean that these patients are not sick. It does not mean that we do not have a problem. It does not mean that we should not investigate. But what it does mean is that those tests that are specifically designed for that particular bacterium do not have a role.

Senator BILYK: Okay. That does not quite solve the problem of how we stop ruining people's lives because the scientists can't—

Senator REYNOLDS: Agree on a definition.

Senator BILYK: agree on a definition.

Dr Lum: And, Senator, we agree wholeheartedly. As I have said, it took a while for us to work out what the lay of the land was on this. It was relatively new for the department to do something along these lines. It does not normally do this sort of thing. Given it was a request from one particular state chief health officer, the CMO took it on, and we believe now that what we need to do is go back to our colleagues in the states and territories and work with them. The nub of this is working with patients, and that is something where the Australian government Department of Health cannot lay on hands. It needs to be done with state and territory Health. I am very happy to try to answer as many questions as possible from our perspective here, but I cannot speak for the states and territories.

Senator LUDLAM: Professor Kelso, as a non-practitioner, can you talk us through the responsibility for administering Australian clinical practice guidelines. My understanding—pull me up if I have got any of this wrong—is that guidelines are meant to reflect the community's range of attitudes and concerns. They are informed by the evidence and by practitioners and they are meant to be updated every 10 years. Does this all sound reasonably familiar?

Prof. Kelso: NHMRC has a very particular role with guidelines—that is, where we have been specifically asked to develop guidelines, we will pull together an expert committee to do that, to review the full body of evidence that would provide guidelines for best clinical practice. We are also sometimes asked to endorse guidelines. We review what needs to be re-evaluated every five years and decide whether to undertake another exercise of examining whether there is new evidence that would alter the guidelines. So fundamentally it is a five-year turnaround based on the evidence.

Senator LUDLAM: I have missed a couple of hearings. I missed the Brisbane hearing. In the case of the broader categories around ME/CFS—and you can touch on Lyme and Lyme-like symptoms, if you like—when were the guidelines due to be updated? When did that five- or 10-year cycle lapse?

Prof. Kelso: I am not aware that we have a set of clinical guidelines specifically for Lyme disease or similar syndromes.

Senator LUDLAM: I might ask you to take that on notice. My understanding is that the CFS guidelines were due to be updated at the end of June 2014. Does that sound familiar?

Prof. Kelso: I am afraid I do not know, but I can find that out.

Senator LUDLAM: Put that one on notice as well. I am interested to know what the status is of those at the present time, because my understanding—I could be wrong; I am very happy for you to go back and take a look at what is going on behind the scenes—is that Emerge Australia, the Griffith University research team at NCNED, endorsed the international consensus criteria. I am trying to work out what the state of play is here in Australia at the moment.

Prof. Kelso: I am sorry. I do not know the answer to that question at this stage, but we will find out what we can.

Senator LUDLAM: I am bringing those international consensus criteria up because it does mean a faster diagnosis for patients—and less of a burden on the health system, but particularly for patients—but it will specifically preclude graduated exercise therapy and cognitive behavioural therapy as a helpful treatment for people with these symptoms. Does that sound familiar to you?

Prof. Kelso: I have not read the guidelines and I am not familiar with the clinical guidelines at all. I am sorry. I should be clear in saying that, as CEO of NHMRC, I am not personally involved in the development of guidelines, but I oversee the process of those guidelines which we have been charged with developing or with reviewing and updating. I am then in charge of that overall process, but an expert working group would be familiar with all the detail and be able to answer those sorts of questions.

Senator LUDLAM: Could you please provide us with some that detail. My information is that there has been a fairly significant breakdown in the way that people are being diagnosed at the moment.

Prof. Kelso: I see.

Senator LUDLAM: I will put a few questions on notice in written form, but, just briefly, Norwegian scientists have found an immune-modulating drug called rituximab, which is in a phase 3 trial in Norway with the results due at the end of 2017-18. Are you aware of that treatment? Does that ring any bells?

Prof. Kelso: No, I am not.

Senator LUDLAM: Could you look that one up for me.

CHAIR: Could we ask Dr Lum? You are not aware of it either?

Dr Lum: No.

Senator LUDLAM: The first two trials in Norway showed that it has moderately improved 67 per cent of patients versus 13 per cent in controls. It is approved for treatment of other diseases here in Australia. Specifically, could you take on notice how we get the drug trialled in Australia for ME/CFS patients?

Prof. Kelso: Again, I think this is moving into territory which is well beyond NHMRC. We are a research funding agency, but that does sound like a question for the Therapeutic Goods Administration.

Senator LUDLAM: The TGA? I will put those ones on notice. I will leave it there.

Senator MADIGAN: Ms Appleyard, from the evidence that we have heard in Perth and Brisbane and the submissions that we have received, the reality for people in the community who are suffering is that on the one hand they hear from government health departments and the like about *Borrelia burgdorferi*—there seems to be so much conflict over this term. But I have met numerous people who have been diagnosed with having contracted classical Lyme disease from overseas, and the fact is that, when they present to a practitioner and say they have Lyme disease—this is the reality in the real world for these people—they are treated like lepers. That is the reality for those people who have contracted Lyme overseas.

The reality for those people who are fortunate enough to have the means to get treatment overseas is that, as it is in the case of some people I have met who had been confined to a wheelchair, after having been to overseas clinics they are now re-engaged in society and are working. Having had some of the treatments such as antibiotics—I think, it is Dr Horowitz in the US—they have come home and are back in the community. But for those people who are not fortunate enough to have the means to be able to go to the likes of Dr Horowitz in the US, they are scorned in this country. We have heard evidence in this committee that you can get treatment in this country but the reality is that you cannot; you are a leper.

Senator MOORE: Lepers get treatment.

Senator MADIGAN: They get treatment, that is right.

Can the department tell the people who have classic *Borrelia burgdorferi* where they can get treatment tomorrow? Who is it that is going to treat them, not ridicule them, not vilify them, not denigrate them, but treat their illness so they do not have to go to the US to get treatment? I know for one lady, $90,000 is what she spent.

Dr Lum: I will take that question. In terms of classical Lyme disease caused by *Borrelia burgdorferi* sensu lato, if it is an acute infection, those patients can see a general practitioner who can refer the patient to an infectious diseases physician and be treated for classical Lyme disease. This goes to the nub of what Senator Bilyk asked in terms of the controversy.

The controversy is around these patients who have got a diagnosis, but they do not have classical Lyme disease. What they are presenting with are symptoms that are not in keeping with classical Lyme disease and are

more in keeping with the diagnosis that, there are some people who would believe, is chronic Lyme disease. As I said, that is contentious. The department itself does not have a position on that, but your question specifically around classical Lyme disease is that they can be treated by an infection diseases physician in either public or private.

Senator MADIGAN: I am sorry, Dr Lum, whilst I respect the fact you can all baffle us with bullshit here, the fact of the matter is I know people in the Australian community, across the length and breadth of Australia, who have lived and worked overseas, who were diagnosed overseas as having it. They have had the tests and had treatment overseas. But they had debilitating illness that they could not get treatment for when they came to Australia. You and I are fortunate. We do not have it. These people have it and they cannot get treatment in Australia. That is a fact. They cannot get it.

Dr Lum: Senator Madigan—

Senator MADIGAN: They are ridiculed, they are denigrated, they are told they are mental cases, they have kangaroos loose in the top paddock. That does not answer these people's concerns, especially when it is their children. It is bad enough if you are a parent and you have it, but when it is your children or your baby who has not got a voice, that answer is not in the real world.

Dr Lum: I acknowledge that. Your question was around classical Lyme disease and—

Senator MADIGAN: I just told you they contracted it overseas.

Dr Lum: Senator, you need to let me answer the question properly.

Senator MADIGAN: To answer the same thing, we are on this bloody merry-go-round.

CHAIR: Let Dr Lum answer and then we will keep going from there.

Dr Lum: As I tried to explain, we acknowledge that there are many patients, not just here in Australia. This is not a unique situation for Australia; this is a problem that occurs particularly in the United States and also in Europe because of the difference in opinion. So, when somebody says that they have classical Lyme disease, that has a very specific meaning. If somebody says that they have a diagnosis of Lyme disease and then they describe symptoms that are not classical, unfortunately the response in Australia will be very different. That is not to say that the treatment that they receive is wrong, but they will not get the sort of treatment that these patients who are well off in Australia are embarking on by going overseas. They will get treated; they just will not get the same type of treatment.

CHAIR: There are a number of different cases that we have come across. You have the people who have been diagnosed overseas as classical.

Dr Lum: That is right.

CHAIR: But what Senator Madigan is saying is that, for a start, even when they are already diagnosed as classical, they are not getting—

Dr Lum: I have been involved with a lot of patients, and as a pathologist I do not necessarily go and see all of them, but I have certainly seen patients in my clinical practice where they have classical Lyme disease and they get treated. The issue here is the type of treatment, and the issue here is also the interpretation and the definition of what classical Lyme disease is.

CHAIR: I think you are missing the point, and that is that some doctors probably do the right thing, but what we have heard is that some do not. That is the point the senator is making.

Dr Lum: Certainly the Chief Medical Officer has recognised that to the extent that that is why we have done an annual communication to medical practitioners across Australia trying to alert them to the fact that there is Lyme disease endemically in areas overseas. That is why we have the Australian guideline for overseas acquired Lyme disease. We have made that a public document. We have also made that a formal publication so that it can be recognised as part of the scientific literature.

Senator REYNOLDS: It is a real shame that you were looking at us and not at the back during your last answer, because the reaction that you got was that people who have been diagnosed according to your diagnostic levels were in tears, shaking their heads and are still incredulous. I am just sorry that you could not see the reaction of those behind you because, for me, that says more than anything else.

Dr Lum: That is why I went to Perth—so that I could be part of that, so that I could appreciate the stories that the patients were sharing. Certainly from our perspective in the department, we get a significant amount of correspondence. We get asked to review videos on YouTube of patients and their stories.

Senator REYNOLDS: Dr Lum, you have some of the people behind you and they are absolutely in tears. Just turn around and have a look at them. These are the people you have not yet talked to in person. I appreciate that you came to Perth, but I tell you what: their faces, their tears, their words and their head shakes tell us what you are saying is simply not the case. I am sure you believe it, but—

Dr Lum: I believe that Nikki Coleman particularly, who I know, and others sitting in the audience today are suffering. I know, and I understand the concerns that they have. I have heard them, but we have to go with where the evidence is.

Senator REYNOLDS: I am not quite sure whether you wilfully misunderstood what my colleagues have said, and I think clearly that the audience thinks that you have. The clear evidence is that the majority of those who have been diagnosed according to your diagnostic techniques—and it is certainly the evidence we have—are still treated with great stigma by doctors who do not believe it. They are treated with contempt and they are medicated for mental illness. So your belief here in Canberra is clearly not the case for many of these people with Lyme disease.

Dr Lum: No, Senator. I acknowledge full well that I have many colleagues who are in a situation where, when patients present to them, like Nikki and like others, they will not necessarily believe their stories. They will listen to what they say and they will provide an alternative opinion. I am aware of that. As I said, my personal journey on this goes back to the nineties, particularly when I went to that patient meeting, so I am very familiar with that. What the department has been trying to do is communicate with the medical profession. If, as part of the Senate inquiry and as part of the recommendation, we could possibly do more to communicate with the medical profession on this, we certainly would.

Senator REYNOLDS: Just on that point, can you either brief us now or tell us on notice exactly what communications you have had with the AMA federally and what their response has been on this issue?

If they have come back and said that what you have said is not correct, can you please provide that AMA advice to the committee?

Dr Lum: In 2013, 2014 and 2015, the Chief Medical Officer of Australia sent an update to the presidents of medical colleges of the relevant specialties plus the president of the AMA. We received no correspondence back from the AMA associated with that correspondence.

Senator REYNOLDS: So your correspondence was actually an update—

Dr Lum: We also made it publicly available on our web page.

Senator REYNOLDS: You never got on the phone to them and you have not talked to the president of the AMA or to any of their senior medical staff? You have sent an update and that is the limit of what the department has done.

Dr Lum: That is part of our regular communication framework.

Senator REYNOLDS: But you have never got on the phone, consulted or had a meeting.

Dr Lum: I did not personally get on the telephone with the president of the AMA, no.

Senator REYNOLDS: If you could take that on notice. It surprises me that you have never personally engaged with the AMA. If you check to make sure that the department has not had some form of advocacy or some more vigorous communication than an update.

CHAIR: If you could also take on notice whether you responded to the president of AMA's comments in Western Australia who said that we were an 'unholy waste of taxpayers' money', which seems to conflict with your evidence.

Dr Lum: The department has not responded to comments made by the president of the WA AMA branch.

CHAIR: Would you, given what you have just said about the value of this inquiry?

Dr Lum: We have not discussed it.

Senator WANG: In evidence at the Brisbane hearing, I was delighted to hear that there are a number of specialist clinics who deal with Lyme disease. But when I asked if we could have a list of the clinics, the answer was no. You have mentioned that GPs can refer their patients to specialist clinics at public hospitals. Are you able to give me a list of the clinics that the people in this room could go to tomorrow?

Dr Lum: In the context of the question that was asked about classical Lyme disease, any infectious diseases outpatients clinic in a public hospital and any infectious diseases physician working in private practice in Australia can have patients referred to them. Because of the contentious nature and the contested diagnosis around chronic Lyme disease, it is very difficult. I do not know, and I am not familiar with, all the clinics of general

practitioners and some specialists who are sympathetic to patients with this problem. Again, we would like to be able to steer away from that name Lyme disease. I know that there are more than two infectious diseases physicians in Australia who are interested in this particular situation. One of them has decided not to see patients, but I believe that the other two do.

Regarding general practitioners, I think that you have met with the chair of the Australian Chronic Infectious Diseases Society. Because of the stigma attached to this, I am also aware that many general practitioners do not want their names made public because there is stigma and there is controversy in the medical profession. We understand that and the last thing that we want to do is to worsen that stigma.

Senator REYNOLDS: But all you did was send out some circulars. If you are so concerned about it, you could have sent out an annual update but no phone calls, no meetings, nothing.

CHAIR: Hang on, we are going to run out of time. Dr Lum has taken that on notice and we can follow-up his answer on notice as well. You are going to give us a full list of all the communication approaches that you have taken.

Dr Lum: The list is basically in the submission.

CHAIR: So you have nothing that is beyond the submission?

Dr Lum: No.

CHAIR: Senator Wang, are you finished with that area of inquiry?

Senator WANG: Yes.

Senator SESELJA: In relation to your answer to Senator Madigan, you were talking about people who have a diagnosis of classic Lyme disease and he was asking about treatment options. Many of the people we have been hearing from do not have that diagnosis. Perhaps you could explain what the treatment options are for those people. Are there none in Australia? If there are treatment options, what are they?

Dr Lum: I cannot explain to you what is or is not necessarily available apart from what patients who have the wherewithal to travel overseas might access. What I can say is that those sorts of treatments are not necessarily wholly regarded and accepted by the conventional and mainstream members of the medical profession, because they are regarded in many ways as alternative. I am speaking specifically her about hypothermia treatment; I am speaking specifically about oxygen therapy. When it comes to the use of long-term multiple antimicrobials, that is certainly something that is not necessarily regarded as alternative, but it is certainly regarded as being inappropriate for a disease that, according to the mainstream conventional position, does not have active infection.

Senator SESELJA: So the options, then, for those who are suffering these symptoms but do not have a classic Lyme diagnosis include going overseas for treatment, if they have the funds. Here in Australia, they are looking at some form of alternative medicine or—what was the last one you suggested? You said it was not necessarily alternative.

Dr Lum: Long-term antimicrobial.

Senator SESELJA: Some doctors would prescribe that?

Dr Lum: Certainly.

Senator SESELJA: That is the extent of the options for people in this circumstance in Australia?

Dr Lum: That is right. When patients in this situation, say, go to an infectious diseases physician who does not agree with the diagnosis of chronic Lyme disease, that infectious diseases physician will try to find an alternative diagnosis and refer the patient for alternative testing. It could be that it is a rickettsial infection, it could be a viral infection or it could be an endocrine issue or a hormonal issue. Those particular practitioners will refer to the appropriate specialty areas. I also understand—and I heard this in the Perth hearing—that part of the problem with the way medicine works in Australia is that, because of the referral process, patients, unfortunately, will be moved between specialists and their GP and back again and to another specialist. That is really unfortunate, but that is the way the system currently works here in Australia.

Senator MOORE: Professor Kelso, I want to follow up on the information you gave us about the form of funding that you have for the committee separate to the grants that go out generally and for which people apply. You said that you had a separate form of funding that was looking at public demand around particular issues. I am not aware of that. Would you give us some information on that.

Prof. Kelso: For some years, we have had a scheme called Targeted Calls for Research—and, of course, 'targeted' means that it is around a particular target. We have had just a small number of them over the years on very specific questions where we, at NHMRC and with the advice of our council, thought that there was a specific

issue that deserved some extra funding because the work was not being supported. People were not applying, for example, to do that research. Examples of that over the years have been things like interventions to reduce Aboriginal youth suicide and interventions to reduce fetal alcohol syndrome. There have been a number of these over the years, but we have been talking a lot about it recently at NHMRC and thinking we need a broader approach to finding the major priorities that we should put this targeted funding towards. So we are setting up a scheme where we have two different pathways. One allows governments, through the Australian Health Ministers' Advisory Council, working with us to tell us what, from governments' point of view, are significant health priority areas where there is inefficient research; and the other arm would allow community groups or professional groups to bring to our attention areas that deserve special consideration for research.

That is a process that is being developed at the moment, but the web portal will be open very shortly—I hope next week—to allow community or professional groups to put forward a submission. That will not be simply, for example, 'We need more research on diabetes.' It will need to be an argued case, and so would there are a number of questions that we ask groups to answer that would help to give us some background to why this should be an issue to have particular focus. We have no idea at the moment what the demand will be. It could be enormous or it could be a very small number of groups coming to us and saying, 'Here's an area that deserves and needs specific funding.'

We are establishing a committee which, as I mentioned before, will be made up of a broad range of people to advise us on what will be the priority ranking of that list. That will then come to be considered along with the government priorities through our internal processes and with the advice of our research committee and council.

One way that a priority area could be moved up that list is if there is co-funding from another source. There will be various ways we can try to bring in and leverage in extra funding, of course, we have a tight budget, so that those areas which are not currently being adequately researched—and clearly Lyme disease in Australia is one of those. As I pointed out before, we have had very few applications over a long time. Few researchers are coming to our funding agency for support to do this research. From that point of view, Lyme disease fits that type of field of something where it is underresearched—there is clearly a gap, an unmet need—and it might be a suitable priority area.

Senator MOORE: The department gave a response to the government about the concerns that came out of the roundtable and recommendations, including a number of recommendations about research. One of the questions that has been asked in the inquiry is: what has happened with that? We had this process, got people together, they came up with a list of recommendations and seemingly nothing happened. It would seem to me that that is the kind of space that, if through a process the department and government agreed this is an area that needed some research, could be a way of entering that portal into this space. That would need to be refined, of course. When you described that kind of process, it seemed to me that this could be a way to take some of those recommendations forward. The previous time people got together they identified many of the same things that this inquiry is finding. We as a committee will have a look at that. In terms of quantum, what kind of money is available under this particular site?

Prof. Kelso: A typical targeted call for research is to have, for one topic or one defined area, a few million dollars over up to five years. It might support two or three substantial projects. But because of the range of research we need to cover across Australia we are imagining that there might be perhaps something like three or four of those per year.

Senator MOORE: We also spoke with people at Murdoch in Perth who talked about a research project that they were doing in this area about—I will not even try to go into the detail but we had a lot of information from them and their funding is running out—

Senator WANG: They have funding through ARC not NHMRC.

Senator MOORE: That is right. I am thinking in terms of linking this ongoing discussion we are having as a community about Lyme disease. It could be something we could work on. I wanted to get that on record.

Senator MADIGAN: Ms Appleyard, I see that you are the first assistant secretary of the Office of Health Protection. Tens of thousands of Australians go overseas every year. I am not interested in the debate about endemic Lyme disease in the US. But we know that tens of thousands of Australians go there. We as the government, and as representatives of people, have a duty of care. What do you reckon the chances are of the department putting in place a program to warn Australians travelling overseas to endemic areas to take care? You are going to areas where there is supposedly endemic Lyme disease. There are ticks. How about having a checklist of things that Australians should do when visiting these areas rather than coming home and spelling out the risks to them if they do not do the appropriate things to protect themselves?

Ms Appleyard: I think that would be completely consistent with the role of the department in health prevention and promotion activity. Obviously, it would be a decision that would be a consideration for government as to whether it was something they would like the department to do. In the same way as we often provide advice on communicable diseases—most recently Zika virus infection—which can be acquired in our region, we really are proactive in terms of providing advice to consumers and travellers.

Senator MADIGAN: So you are saying you are proactive, so was the department proactive of its own volition in the case of Zika virus or did you have to be specifically instructed by government to issue a warning to Australians as to what they could contract and where they could contract it?

Ms Appleyard: We have international obligations under the World Health Organization's international health regulations to take action in relation to communicable disease and prevention and promotion activities, so the department would very much see that as part of our role. We would not have to be instructed per se, but it is certainly advice that we would provide to government about what we would believe would be a good idea or an intention in relation to this area. We work for the government at the end of the day and, as part of the due consideration of working for government, we would consult with government and they would be very aware of what we think would be a good idea to do. We would provide advice and then we would get support.

Senator MADIGAN: In light of the fact that the evidence we have heard and the fact that we know that tens of thousands of Australians are travelling to these areas in the US and Europe, is the department going to put out a warning to Australian citizens that: when travelling overseas, you may be exposed to potential tick bites; you should go and see a doctor in whatever country, when you are there; and what the appropriate form of treatment in those countries is? Are you going to do it and when are you going to do it?

Ms Appleyard: The tick bite prevention fact sheet as you are aware, Senator Madigan, does exist. I imagine that you would be aware of that and that it is on the department's website, so we have already put out guidance or a fact sheet. In terms of broader promotion, that is most certainly something we could consider in conjunction with government. It is not actively under consideration at the moment but that does not mean that it is something that we could not take on board, particularly, given the outcomes and recommendations of this inquiry.

Senator MOORE: It could be linked to safe travel; it is not at the moment.

Ms Appleyard: Yes, indeed. There are two forms of advice for travellers, as you know: there is advice on the Department of Health's website as well as Smartraveller through the Department of Foreign Affairs and Trade.

Senator SIEWERT: How does it get on your list of things that you put on that list? How does it get on your list of things to do, because people are not aware they have got the tick bite notice, fact sheet, but people really are not aware of the possibility of contracting Lyme disease?

Ms Appleyard: Generally, I imagine a policy decision would have to be made in relation to prioritising this as an issue into which we would wish to draw to the attention of Australians travelling overseas. That is something that would be well within the wit of the Chief Medical Officer to consider and provide advice on.

Senator SIEWERT: It is a straight handball to you, Dr Lum: has the Chief Medical Officer considered asking the department to put this on that list?

Dr Lum: I am not aware specifically around Lyme disease. I would also augment that answer from Ms Appleyard, Senator, that Australia has a very good system of travel medicine practitioners. A lot of Australians who travel overseas and visitors to Australia who come here will see travel doctors, mainly GPs with a special interest in travel medicine—sometimes it is also specialists with a special interest. I know, having done some training in this when I was training in Brisbane, that when I knew that patients were going to endemic countries that we would explain the problems, not just with Lyme disease but tick-borne diseases. Tick-borne diseases around the world are a problem, so trying to educate people to prevent tick bite infection is really the most important thing.

Senator SIEWERT: So people go to travel doctors when they are told they have to get yellow fever injection—I know from personal experience, but—

Dr Lum: As well as a range of other good health advice.

Senator SIEWERT: where they are advised to go and see a travel doctor to get a vaccination or something, I would hazard a guess that people do not go when they do not think they have to get vaccinations.

Dr Lum: I agree: there would be a good proportion of Australians who travel without seeing their GP. I am aware that a lot of general practitioners, who may not believe that they have expertise in travel medicine, will suggest to their patients that they do see a colleague, expert in travel medicine. I do know that that occurs. I

cannot give you numbers and I do not know what proportion of Australian travellers do that, but certainly that does happen.

Senator SIEWERT: It would be interesting to see a survey of that, because I can tell you from personal and family experience: not one of my rellies goes to a doctor unless they have to get a vaccination. Then they go only once, because they have had the vaccination and do not need to get it again for however long, so then they do not go. That is a personal experience, and I would bet you that other people are the same.

Dr Lum: As I said, I am sure that is the case, but I do know that there is a good proportion. When you look at the way general practitioners are educated not only through their college processes but also in the medical media, you will see there are regular articles—I am thinking particularly now of *Australian Doctor*, which has a regular recurring article around travel medicine and the importance of seeing a travel doctor.

Senator MOORE: Can I clarify, Dr Lum: did you say that the travel doctors are aware and do talk about Lyme disease?

Dr Lum: I cannot say that every travel medicine practitioner in Australia would, but they would be aware of the possibility of tick bites in other countries as well as Australia, and that tick bite prevention is important—the same as bites from mosquitoes, infections and other diseases caused by bites from ticks and mosquitoes and other arthropods are very important, and part of the practice of travel medicine. It is not solely around immunisations and education around diarrhoea and vomiting.

Senator MOORE: Taking the point that Senator Madigan made about the importance of giving people information and the way that we can make that happen—and there will be more discussion about that through the committee back to the department, I am sure—I am interested in that issue about travel doctors, because I had not thought about it. Has the department looked at giving any information specifically to travel doctors to remind them of this issue of the tick process? I am one of the people who do go to travel doctors, but no-one has ever asked me about where I am going for ticks.

Dr Lum: In relation to Senator Reynolds's question, I have not picked up a telephone and spoken directly, but in our communication with general practitioners and other specialty groups that would encompass most of the travel medicine practitioners in Australia. By and large, they are general practitioners. There are also some who fall into some of the physician craft groups.

CHAIR: We have run over time. There will be a number of questions on notice. I would like to thank you very much for coming today, and to let you know that I suspect pretty strongly that we will need to ask you to come back again when we have completed all our various hearings.

Dr Lum: Happy to, Senator.

CHAIR: Thank you very much indeed.

GRIFFIN, Mr Andrew James, Deputy Sector Manager, Legal and Clinical Services, National Association of Testing Authorities, Australia

MITCHELL, Mr John Cameron, Manager, Government Relations, National Association of Testing Authorities, Australia

STYZINSKI, Mr John, General Manager, Operations and Technical, National Association of Testing Authorities, Australia

[14:12]

Evidence was taken via teleconference—

CHAIR: Welcome and thank you. Can I check that you have had information on parliamentary privilege and the protection of witnesses and evidence?

Mr Griffin: Yes, we have.

CHAIR: I would now like to invite whoever you have designated to make an opening statement or statements to do so, then we will ask you some questions.

Mr Mitchell: We thank the committee for the opportunity to explain NATA's role, our accreditation processes and how we fit with international practice. NATA is a 1946 Commonwealth and state construct that was cooperatively established to serve the national interest. We are, however, a private not-for-profit company limited by guarantee and, as such, have no statutory powers. We do not compel laboratories to seek accreditation, nor do we prescribe what they must be accredited for.

NATA is recognised by the Commonwealth through an MOU—a memorandum of understanding. That is administered through the Department of Industry, Innovation and Science. The relevant recognition for the purposes of this inquiry is as the national authority for laboratory accreditation. NATA accreditation involves processes to determine the collective competence and capability of services that produce test and measurement data that will be used as the basis for decision making. It is not a generic recognition of everything that a laboratory might do—rather, it is for specific technical competencies as defined in a scope of accreditation. The key element of the accreditation process is our on-site peer assessment—that is, the use of assessment teams made up of individuals having scientific and technical expertise that we match to the range of specific activities to be covered by the accreditation. Assessments cover all aspects of laboratory practice that are important in delivering confidence to the end user—the user of those testing services. Reassessments confirm continuing compliance with accreditation criteria, so it is not a set-and-forget process—there is an ongoing surveillance cycle.

The Mater-Royal College of Pathologists Australasia accreditation of medical-testing laboratories commenced around the mid-eighties—before I joined—and became a prerequisite for all pathology services wishing to have their testing eligible for Medicare rebates. It is not, though, just for MBS listed tests, and includes activities such as workplace drug testing and point-of-care testing—that is the sort of testing that might be conducted, perhaps, in a hospital environment but not in a laboratory.

To the best of our knowledge, the Mater-RCPA program is the oldest comprehensive medical testing accreditation system in the world. Indeed, Mater's expertise and experience is key to the development of the international standard for medical testing laboratories, ISO 15189. The current accreditation criteria is a combination of ISO 15189, together with the series of standards that are produced by the Department of Health's National Pathology Accreditation Advisory Council—known as NPAAC. The accreditation criteria are applied to MBS and non-MBS tests, so we have one standard across the board. Accreditation for medical testing laboratories is available to all facilities that can meet the accreditation criteria, whether they be public or private or large or small, or whether they offer a very broad range of capabilities or are even those that might only undertake a single test.

We note from the transcripts that there has been some discussion around international recognition. Mater was actually instrumental in the formation of the International Laboratory Accreditation Cooperation, which is a global cooperation of similar accreditation bodies, and it was a leading player in the development of the ILAC Mutual Recognition Arrangement. Mater itself was amongst the first signatories to this Mutual Recognition Arrangement. The ILAC MRA—and there are also associated regional MRAs—is designed to facilitate international recognition of test data and to reduce technical barriers to trade. MRAs are not just based on a handshake, but built on a system of periodic mutual peer evaluations to determine compliance with the international standard for accreditation bodies—we have one ourselves—which is ISO/IEC 17011.

The MRA evaluation process focuses on the equivalence of outcomes, not the detail of how the outcome was achieved nor, for that matter, that all is done identically. The fact is that we do not; it is really a performance-based outcome.

While one of the first signatories to the ILAC MRA—something driven by trade imperatives—we did not actually seek mutual recognition for our 15189 medical program. Primarily because it was so highly focused on domestic needs and having been driven around Medicare rebates, we were perhaps a little bit short-sighted. We did not really see that medical testing was a trade-sensitive activity. But the increasing internationalisation of medical diagnostic services finally meant that we needed to seek inclusion of the NATA-RCPA program under the ILAC mutual recognition arrangement. By 'internationalisation', I am referring to practices such as real-time telepathology and teleradiology, where there is online transfer of data to a diagnostician who may indeed reside across international borders. Then of course there is the growing practice—as we have seen in this inquiry—of sending patient samples offshore to foreign laboratories. MRA recognition for our medical program was achieved in January this year.

If I may, I will say a word on what mutual recognition actually means, particularly in this context. It is the testing performed to the same set of requirements and using the same methods can be regarded as being equivalent. I do stress the point 'same set of requirements and methods'. There is no implication that the MRA requires or expects recognition of another country's requirement and their context. So we need to compare apples with apples here. I also point out that the MRA is there to serve the end user. Our role under the MRA is to promote recognition of equivalence. It is the end user, however, who is actually the individual making the final decision on the recognition.

I will not take too much of your time, but I do want to finish with some brief points to address some specific matters that we are aware of through the last couple of hearings. The simple fact is that NATA, RCPA and MRA are partner-accredited facilities and are not perfect. They will make mistakes. There is no system that we know of that can render them all perfect, and we would happily adopt it if we did identify one. The point is that they have demonstrated competence and they also have systems in place to facilitate the protection of errors that they might make and, more important, initiate appropriate follow-up measures.

With regard to non-accredited laboratories, NATA makes absolutely no judgement whatsoever about their competence, for the simple reason we cannot know. So, if NATA states that the particular laboratory is not accredited, it is not a judgement but a simple statement of fact. Our longstanding commitment to the international accreditation community is not consistent with some suggestions we have heard that we fear international testing systems. With any type of testing, NATA bases its decisions on the soundness of the science and technology. For well-established, standard methods where there is an abundance of peer reviewed evidence, including validation data, the decision is relatively easy provided the laboratory is using that particular method without modification. In other cases, methods might be more of a proprietary nature but, in Australia, they would typically have been through the TGA's conformity assessment processes and are listed on the ARTG. That gives us confidence that the validation is in order.

For new and innovative methods for which the availability of appropriate validation is limited or where standard methods have been modified or, indeed, used outside their design parameters, the threshold of evidence for acceptance naturally becomes higher. The soundness of evidence provided is judged by relevant experts and professional bodies, not by employees of NATA. NATA must seek the best advice from expert sources, peers of the laboratory, before it commits to a precedent that will impact on the health and safety of the Australian population.

Finally, the scientific answers to the question that is the subject of this very inquiry will obviously dictate how testing services and methodologies develop in the future, but NATA's role is to respond appropriately to evidence based and robust science, not to pre-empt the outcome. NATA needs to get its accreditation decisions right.

We are happy to answer any questions from the committee. We do, however, want to point out that NATA has confidentiality requirements, as part of its rules, that preclude us from divulging information about applicant laboratories. If any of you have questions that relate to specific laboratories, we are happy to provide general answers for the record, but, if you wish to ask very laboratory-specific questions, we would prefer that these were dealt with in camera if at all possible.

CHAIR: Thank you very much for that. I will go to Senator Madigan and we will start the process. If we get to specific questions, you can request to go to in camera and we will go through that process.

Mr Mitchell: Okay. Thank you very much.

CHAIR: Let us start, and we will see how far we get.

Senator MADIGAN: Thank you, gentlemen. Say I wanted to get NATA accreditation for my laboratory and I wanted to run tests for classical Lyme *Borrelia burgdorferi*. I believe there are the ELISA test, the western blot test and the PCR test. What is the process for me to achieve this accreditation from NATA?

Mr Griffin: The process would be as follows. The laboratory would apply for accreditation. First you ring us and say, 'We're a laboratory. We want accreditation for X test.' The initial process would be an advisory visit. We would go out to the laboratory and just discuss, if you like, their readiness for accreditation, discuss the accreditation process and look at their quality system. Many laboratories may not have had anything to do with accreditation previously, so it is a good idea for us to give them some advice on the process. Depending on where they are within that process, at a point of time we might say, 'Our normal process is to go and take a peer team along to the NATA/RCPA program for a microbiology test.' That would normally include a micropathologist and a microscientist. That is the general process. During that process, we would assess the laboratory. It normally takes a day, depending on the size or the scope. The peer assessors ask questions of laboratory staff. They look at records. They look at validation, verification, quality control, training records, competence—all the things that are listed in the relevant standards. They really look at the whole competence of the lab. During that time then, at the end of the day, we provide a report. Oh yes, and, with the assessment team, we take a lead assessor, so a NATA employee goes along with the assessment team, and they act as the liaison between the lab and the assessment team and ensure that each assessment we do is consistent. The technical assessors may only go out once a year—maybe once every two years, sometimes more often—but the lead assessor will go out an awful lot more. So they know the accreditation process better than the technical assessor, if you like.

Senator MADIGAN: Is there a requirement for both the laboratory and specific tests to be accredited?

Mr Griffin: No. The laboratory puts forward the test they want accredited. We have no say in what they put forward. They could have 100 tests and put forward one, or they could put forward all 100 for accreditation. It is completely the laboratory's decision.

Senator MADIGAN: So you accredit the laboratory but then you individually accredit each test for that laboratory. Is that correct?

Mr Griffin: The laboratories are assessed for technical competence in the testing they put forward.

Senator MADIGAN: Okay.

CHAIR: Can I just clarify that. With each test, it is the test that you are accredited for?

Mr Griffin: The test list they put forward falls under a scope of accreditation. So it is about their technical competence to perform that test. We are not a product certification organisation; we do not certify that products meet a certain standard. We assess whether the lab is able to competently perform that test and produce a result.

Senator MADIGAN: Are you aware of a company called Australian Biologics, which has applied for accreditation to NATA?

Mr Styzinski: Yes.

Mr Griffin: According to my colleague, yes, I am!

Senator MADIGAN: Right. You mentioned confidentiality requirements earlier. No names, no pack drill—but do you have strict confidentiality requirements around applications for NATA accreditation?

Mr Styzinski: We do indeed have confidentiality around applicants. The expectation is that anybody who is involved in the accreditation process—obviously, NATA staff but also any technical assessors, the committees and other specialist experts who would have some role in reviewing material from the laboratory—will have signed a confidentiality agreement with NATA and a conflict-of-interest statement.

Senator MADIGAN: In my first question, I mentioned PCR. Is it common practice to ask a laboratory for their primers, their individual intellectual property?

Mr Griffin: It depends on the nature of the assay. If it is a commercial assay, it has been approved, if you like, by the TGA, so we do not need to ask for that; it has already been validated. If the test is a standard method and it has been published and peer reviewed—those primers and probes are normally published anyway—again, we would not need to ask for those; we would just confirm that they are using a standard method without modification. If it is a new method, then we certainly do an assessment, and the assessment team would look at the primers and probes that the laboratory is using.

Senator MADIGAN: How do you ensure that the intellectual property of a laboratory that is applying for NATA accreditation is not disclosed to their competitors?

Mr Griffin: As we have described, the technical assessors sign a confidentiality agreement and a conflict-of-interest statement. They are obliged not to take anything out with them. They do not take things away in their pockets. We do not take things away with us.

The assessor on the day is working for us. They are not working for the organisation that they come from. They are not representing a professional body. They are working as a technical expert on our behalf on that day. So they are actually considered a NATA employee on that day and have signed confidentiality and conflict-of-interest statements.

CHAIR: Can I just jump in there. So they will look at primers that are novel, but if they are standard ones they do not. Is that what you are saying?

Mr Griffin: Yes.

CHAIR: Australian Biologics said that you had asked them about their primers.

Mr Griffin: That is correct, yes.

CHAIR: Is that because they were considered novel?

Mr Griffin: It is an in-house assay and our understanding is that the assay is a modification of the general PCR assay being used. It is claimed to have more sensitivity than the standard PCR assay. Therefore, the assessment team would want to see those primers and probes when they do the assessment.

Senator MADIGAN: If a laboratory applying for accreditation alleges that their intellectual property has been divulged to their competitors, how does NATA assure that laboratory that their primers, for instance, have not been disclosed to their competitors?

Mr Griffin: At the end of the day, we are reliant on the integrity of the people in the NATA system. We do not just select assessors and committee members and experts on the basis of their technical knowledge. We also need to have confidence that they are individuals of integrity. That might not be bullet proof, but the other side of the coin is that this is a process of peer assessment. That is the way of getting the best outcome, the best evaluation, so we have to work within those parameters.

Senator MADIGAN: What disciplinary action, investigation, is undertaken by NATA in the event of a claim that your intellectual property has been stolen by a competitor?

Mr Styzinski: The number of complaints we have had of that nature have been very limited, so we would—

Senator MADIGAN: How many complaints has NATA received, in relation to disclosure of intellectual property at individual laboratories? Are you able to take that on notice and furnish that to the committee.

Mr Styzinski: We could do that but, off the top of my head, I can say that in the last number of years we have, probably, had one or two complaints only.

Senator MADIGAN: Was one of those complaints to NATA from Australian Biologics?

Mr Styzinski: There was a complaint received, and that was independently investigated by our quality manager.

Senator MADIGAN: So it is independently investigated by NATA's quality manager.

Mr Styzinski: Investigated by individuals who are independent of the assessment process, regarding—

Senator MADIGAN: The point I am making is that the person who investigated the complaint was an employee of NATA. Is that correct?

Mr Styzinski: That is correct, because any organisation that is required to operate a management system, whether it be to an ISO standard—you would be familiar with ISO 9000—requires a complaint handling process, which is normally an internal process.

Senator MADIGAN: What external oversight is available to a person who lodges a complaint with NATA?

Mr Styzinski: If NATA does not provide a satisfactory response to a complaint it receives, the complainant has the right of appeal to follow up with the Asia Pacific Laboratory Accreditation Cooperation. That is the regional body forming part of the ILAC arrangements that oversee our performance. So they have the line or channel for further complaint up the tree.

CHAIR: In terms of complaints, you said you think you have had only one or two on breaching the confidentiality process.

Mr Styzinski: No, it is specifically with regard to IP.

CHAIR: Sorry, with IP. How many complaints, overall, have you had?

Mr Styzinski: We probably receive about 30 or 40 a year.

CHAIR: Could you perhaps take on notice how many you have had and how many have been either not found to be—

Mr Styzinski: Substantiated or otherwise?

CHAIR: Substantiated or otherwise, yes, please.

Mr Styzinski: Yes.

Senator MADIGAN: For a pathology lab to be able to receive payments from Medicare, they must first have NATA accreditation—is that correct?

Mr Styzinski: Yes.

Senator MADIGAN: So—for crystal clarity—a laboratory cannot be paid for its tests unless it has NATA approval?

Mr Styzinski: Yes. There is another step in the process, which actually is a ministerial approval of the laboratory, but that is based on a report from NATA which goes to the Department of Human Services.

Senator WANG: From what I can gather, you guys are in a really wonderful position. It seems like you guys have a really good monopoly. We have heard comments from both sides that, when a patient was tested positive for Lyme, let us say, in pathology in Australia, the other side will quickly dismiss such a test result, and the argument they would always use is: 'That lab was not NATA accredited.' We have also heard comments—it seemed to me, some people are really confident about NATA accreditation. What makes you so special?

Mr Griffin: I think it is fair to say, firstly, that, as John said, we make no judgement on a lab that is not accredited. So that is not our opinion—that the result does get meaningless if they are not accredited. If we have not seen a lab, we make no judgement about their competence. I think that is important to note.

Mr Styzinski: In terms of NATA, you are inviting us, Senator, to blow our own trumpet, which we do not actually like doing, but NATA does have a long history. Our first accreditation, which was not [inaudible] but it was granted in 1950. We have some 3,300 accredited facilities nationally. We run the oldest medical program in the world. Many accreditation bodies around the world have been actually modelled on the NATA system. The simple fact is: if we were not doing a reasonable job of providing reliable tests and measurement infrastructure in Australia, things would have changed long ago.

In terms of your suggestion that the monopoly status is wonderful, it is swings and roundabouts. Obviously, we are not actually exposed to competitive pressures that, in this instance, for example, might mean that we cut corners. I do not know that competition and accreditation would resolve the science any faster.

In terms of the rest of the world, models around the world vary. The United States is probably the major example of where there is open competition. The European Union, on the other hand—through the European Parliament's decision 765—actually went the other way and mandated that there be only one accreditation body per member state. Competition was actually in conflict with the objectives of accreditation. That is a discussion that perhaps we can have some other time, but I think competition in the accreditation space is not going to resolve the committee's overarching question, which is the existence of Lyme disease and Lyme-like complaints in Australia.

Senator WANG: No, but a really common argument we hear is, 'That lab is not accredited, therefore the results cannot be trustworthy.' How would you describe the dilemma we are in at the moment, where mainstream doctors seem to deny that there is Lyme-like illness in Australia? We have had a number of minority doctors who are acknowledging the fact and also treating patients accordingly, and their patients are recovering. It seems to me that NATA is in a way representing the majority of the pathologists, who are denying Lyme-like illness as well. How can we make sure there is healthy competition—you probably do not really like competition in this area—between the minority and the majority, where both sides are really trying to advance their argument rather than resulting in the simple comment, 'That lab is not accredited, therefore they are rubbish'?

Mr Mitchell: The discussion about NATA being nonaccredited is unfortunate, to say the least. Unfortunately, I also do not think it is stating the problem. There is a sense in which NATA accreditation or accreditation by anyone in this context is a second-order consideration. The question is: is the science robust and valid? If the answer to that is yes, then accreditation follows. If the answer to the question is, 'We're not sure,' that makes it exceedingly difficult for us to make sure that we ourselves are taking decisions that are the best for the Australian public.

Senator MADIGAN: Gentlemen, is there any quality assurance program for Lyme disease tests in Australia such as the ELISA, Western Blot and PCR and, if so, who administers those quality assurance programs?

Mr Griffin: I understand that the Royal College of Pathologists quality assurance program administer a serology and maybe the immunoblot—I am not quite sure about that. I am not aware of an Australian based PCR QAP.

Senator MADIGAN: Finally, what does NATA plan to do about the recently signed a memorandum of understanding with respect to the mutual recognition of international laboratories who test for Lyme disease? How do these overseas international laboratories go about getting the NATA stamp of approval?

Mr Mitchell: They do not have to get our approval. The fact that we are all signatories to the ILAC Mutual Recognition Arrangement means that we are recognising the equivalence of our systems. Our obligation and the obligation of, for example, the German accreditation body, DAkkS, is to promote within our own countries the equivalence of ILAC MRA accreditation bodies and the accredited facilities under those accreditation bodies. As I mentioned in our opening remarks, it is not actually up to us to accept anyone's report. What we say to anyone who inquires is, 'If you use a NATA laboratory or a DAkkS accredited laboratory or maybe an IANZ laboratory in New Zealand or a UKAS laboratory in the United Kingdom, provided they are performing the same tests to the Australian requirements, you can have confidence that they are equivalent.'

One of the things I also mentioned in our opening statement is the issue of common requirements. If our laboratories test for Germany, they have to test to the German requirements. If a German lab tests for Australia, it has to test to the Australian requirements. I mentioned the NPAAC standards. The NPAAC standards are unique to Australia—they are not part of the MRA—but that does not preclude a foreign accreditation body being asked by a laboratory wherever to, as well as assessing them for ISO 15189, also include the NPAAC standards that are applicable to these tests.

Senator MADIGAN: Last week, we had a number of people who gave evidence to the committee who were quite adamant, for want of a better word, that these overseas international laboratories were not a patch on Australian laboratories.

Senator MOORE: Some of them.

Senator MADIGAN: They said that the Australian standards were so much higher—the best in the world. So some doctors and some specialists do not accept the results that come from these overseas international laboratories, yet we are told that there is this MOU, mutual recognition of international laboratories. We are trying to seek clarification here around this whole business of this international recognition and what part you play in it.

Mr Mitchell: I must admit that I am glad that we have people that spruik the national system, but quite frankly we are not in a position to comment on what they are saying, in a way. We stand by the mutual recognition arrangements, provided that we are comparing apples with apples.

CHAIR: Is the point that you are making here the bit that you have said about Australian requirements and standards?

Mr Mitchell: Yes. We have to make sure that in fact we are comparing laboratories that are accredited to the same suite of standards. Yes, while we use 15189, particularly for very specialised testing, some of the NPAAC requirements provide additional guidance and detail on the expectations that we see. We would have confidence that DAkkS or any of our MRA partners are quite capable of assessing laboratories to the NPAAC standards if they are requested to do so. Since they are publicly available documents on the Department of Health's website, access is not an issue, so they are non-discriminatory in that sense. So if a laboratory is accredited to the same suite of standards then you are comparing apples with apples. In the absence of that additional oversight, you may not get exactly what you are expecting.

CHAIR: Thank you. I have one last request that you may need to take on notice. We had evidence last week from Australian Biologics. It will be available on *Hansard* soon—it is only just going up. They made a number of comments—would you have a look at them, please, and respond to them? We would very much appreciate your response to a number of the points that were made during that evidence. Is that possible?

Mr Mitchell: Yes, most certainly. May I ask if this is for the public record, or would this be provided—

CHAIR: You can do either, or both. You can ask for it to be in confidence and the committee will consider that—

Mr Mitchell: Okay.

Senator MOORE: But Australian Biologic's evidence was in public.

CHAIR: Yes. Their evidence was clearly in public.

Mr Mitchell: Okay.

CHAIR: That would be appreciated. Thank you very much for your time today and for taking on notice the question that I have just asked and the other questions that I asked. The committee will be in contact with you about those questions.

Mr Mitchell: Okay, thank you. And should you actually think of any additional questions, we are happy to provide a written response. They can be sent to me.

CHAIR: Okay, thank you very much. We have run slightly over time, as we have been wont to do. I apologise for that, but it was very useful evidence that we got today. That is the end of the hearing for today. Obviously, we will release publicly when we will hold our next series of inquiries, bearing in mind that there will be an election in the not-too-distant future.

Senator WANG: Can we have a hearing on 2 July?

CHAIR: I think some people may be occupied on 2 July! The committee is now adjourned.

Committee adjourned at 14:56