COMMONWEALTH OF AUSTRALIA

Proof Committee Hansard

SENATE

COMMUNITY AFFAIRS REFERENCES COMMITTEE

Emerging tick-borne disease

(Public)

FRIDAY, 15 APRIL 2016

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SENATE

COMMUNITY AFFAIRS REFERENCES COMMITTEE

Friday, 15 April 2016

Members in attendance: Senators Madigan, Moore, 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

WHITEMAN, Ms Sharon Lee, President, Lyme Disease Association of Australia

Committee met at 08:04

CHAIR (Senator Siewert): Welcome. Firstly, we have a packed program today as we are trying to get as much evidence as possible and give people every opportunity possible to make a statement. Please forgive me when I say we have to move on. So if everybody here today could bear that in mind. I am also flagging that at some stage media will turn up. That happened in Perth yesterday. I am required to check whether people giving evidence and those who are listening are happy with the media being present. If you are not happy, let me know and we will tell the media not to film you, or you could leave for a short time.

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 respects to elders past and present. This is the second public hearing for the committee's inquiry into the growing evidence of an emerging tick-borne disease that causes a Lyme like illness for many Australian patients. I thank everybody who has made a submission to this inquiry.

This is a public hearing and a *Hansard* of the proceedings is being made. The audio of this public hearing is also being broadcast via the internet. The committee has scheduled two sessions at 1 pm and 2.25 pm today for individuals who are not listed on the program to make a short two-minute statements. These statements will be broadcast and included in the *Hansard* of today's hearing together with the names of the speakers. The transcript will then be published. To participate in these sessions, please register with our secretariat. You need to get the information on parliamentary privilege and the protection of witnesses and evidence, and complete a Hansard witness form. The order will be first-in first-served.

Before the committee starts taking evidence, I remind all witnesses 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 contempt. It is also a contempt to give false or misleading evidence to the committee. We prefer all our evidence to be given in public, but under the Senate's resolutions witnesses have the right to request to be heard in private session. We call that in camera. It is important that witnesses give the committee notice if they intend to ask to give evidence in private because it takes a little time to clear the room, get organised and disconnect from the broadcast. If you do intend to ask to give evidence in private and you have not already informed us, could you please let us know as soon as you can.

Ms Whiteman, welcome. Have you been given information on parliamentary privilege and the protection of witnesses and evidence?

Ms Whiteman: Yes, I have.

CHAIR: We have your submission. Thank you very much. It is very extensive. I now invite you to make an opening statement and then we will ask you some questions.

Ms Whiteman: I have a statement that is about 10 minutes long.

CHAIR: Would you like to table that and make it shorter, as we tend to have a lot of questions and that is where we obtain a lot of the information.

Ms Whiteman: Certainly, and I will refer to it throughout because these are some things that are really important to highlight today that are outside our submission.

CHAIR: The information that is not in your submission would be helpful.

Ms Whiteman: Firstly, I would like to say that I am also a Lyme patient. In brief, in 2002 I was bitten by a tick on the Sunshine Coast. I had a bullseye rash and I thought: 'Oh, this is strange. I've never felt like this after a tick bite before.' We lived on a property where we often would get at least seven ticks off our pets in a day, so it was not unusual for us to get tick bites as well. I felt like I had a very severe flu, and I got up and looked on the internet. Unfortunately, I went to an entomology site with my Google search of this funny rash, and it said it is rarely fatal, so I carried on with my wellness commitment and just took lots of immune support.

Over the several months after, I developed fatigue and elevated liver enzymes. I went to the doctor. My symptoms were very non-specific, so it is understandable that they did not ask about a tick bite history. Over the next several years, by 2005, 2006 and 2007, I could not walk unaided, I could not drive, I had gained 25 kilos and I had seen 17 doctors. I had been kicked out of a couple of doctors' offices. My weight gain adds another level of stigma because they just accuse you of eating too much fat or having a fatty liver—none of which was substantiated on my blood tests. I had multiple diagnoses: chronic fatigue, sarcoidosis and lupus.

In 2006, I met someone who knew what a bullseye rash was. Then, I met a doctor from the US who said, 'You need to get your blood sent to America,' and it come back positive. I had a diagnosis but no treatment. I do not

have a doctor to this day. I have a doctor that is compassionate but frightened of the stigma herself. I went to her office and she showed me Dr Horowitz's book, and she said, 'I'm halfway through.' So, given that I had crawled my way back on my own to a level of quality of life, I was not willing to destabilise the progress I had made with someone who felt concerned about offering that help to me.

I would like to thank each of the senators who have spent such an enormous amount of time on behalf of Lyme patients and been willing to hear our stories. Thank you to the committee as well. I know we have overwhelmed you and I appreciate your time. For those that were at yesterday's hearing in Perth, again, thank you for making the way here for this pretty incredible couple of days of your time.

The patients shared such tragic stories yesterday. I wish that we could say that that was a rare occurrence, but it is what we hear and see every single day at the coalface of the Lyme Disease Association. We know there are many people who would like to be here today as well but are in bed and unable to make it, and we acknowledge those patients. I had some people text me this morning so distressed that they could not make it here today because they do want to support this, but for Lyme patients their health has to come first.

We would also like to acknowledge them for even writing the submissions. I understand there are over 800 now, and a considerable number of those are from patients. It was very distressing for many of the patients to write them. We would like to thank them and acknowledge that some of them had to revisit things they would rather not have to do. Yesterday in Perth, they also spoke about the incidence of Lyme-like illness in Australia. We note that, based on US figures, we expect there to be about 22,000 new cases of Lyme-like illness in Australia per year, and up to 450,000 cases from the past 22 years of stubborn and entrenched denial by our health officials.

Putting this into perspective—I think this is important—there are probably 16,000 new cases of breast cancer per year. HIV and MS have 1,000 new cases per year in Australia. Those combined are significantly fewer than the number of Lyme-like patients we expect to be discovered as this disease is recognised. There is also no official data that may help to quantify these numbers and we are the only organisation that is counting.

Unfortunately, the historical studies on Lyme disease are discounted by both the medical fraternity and the government. So the earlier studies, starting in the fifties, are all outlined in our submission and our website. We do know, and everybody is in agreement, even the people in the denial camp, that ticks are a cesspool of pathogens and that they carry many pathogens. On both sides of the camp, everybody agrees that ticks are dangerous and that there should be an awareness and prevention campaign in Australia, but again that has not progressed. We need to make sure that we put more effort into this. So, with grace, I ask you as a committee to recommend that this awareness and prevention campaign that has been promised now for over two years be actioned. How many more Lyme-like patients have got sick, even in the last two years?

Not only do ticks have *Borrelia*, but they have numerous other organisms that are known to cause illness in humans and they have been discovered in our Australian ticks. Medical authorities are able to competently mount public health warnings in response to other diseases. Hendra virus, bird flu and Zika virus have all received funding and emergency response, so we question why Lyme-like illness has not. In 2009, in the outbreak of the bird flu pandemic—which, at the time, was a novel virus spreading the world—the Australian government allocated funds totalling $7 million to conduct urgent research into this virus to mitigate the effects on the Australian population.

A further example is the Zika virus—attributed birth defects prior to the first solid evidence from two sets of research. In that case, they took action prior to any evidence. In January 2016, Latin American countries called for pregnancies to be delayed, the US announced warnings and the Department of Health here issued an interim recommendation for the assessment of pregnant women—in spite of also stating that further studies were required to prove that Zika was the cause. The argument seems to be entrenched that we do not have proof, but there is no argument that the patients are sick, so we do need to launch a response.

We put it to the committee that the reason for this lack of response is due to the stigma. The stigma arises from ignorance and is not helped by the derogatory words used to describe things. Those derogatory words do not just pop up in language; they are derived from the history, culture and world view of the people who use them, and they are particularly strong in situations of conflict between different opinions. Often, when people fail to use a logical argument to solve a conflict, they will turn, instead, to an ignorant, destructive yet powerful strategy using insults, generalisations and detrimental stereotypes as the form of persuasion for their point. There have been many submissions made in this inquiry that illustrate this perfectly. This is what we see in Australia in respect of Lyme disease. Not only did you hear it yesterday, but also, from listening, I know that you felt that stigma as well.

You heard yesterday from two professors with very strong opinions about diagnosis and treatment. One of those has even progressed a media statement headlined, 'Long-term antibiotics unethical for Lyme disease', yet

when those same professors were asked about their diagnostic and treatment experience, they could not quantify the number of patients they had treated. I put to the committee to consider those opinions with the weight that they deserve.

In contrast, the Australian Lyme-treating doctors report they have treated more than 4,000 cases and have vastly more experience than those two combined. You heard from Dr Nuttall and Dr Derham yesterday, who provided a much more detailed and substantiated record of what works on the patients that they have actually treated. You will hear today from Dr Schloeffel and Dr Dobie, who will no doubt share more experience from the front-line. The committee has also received a submission, yet to be published, from Dr Richard Horowitz. His bio tells us that, internationally, he has treated over 12,000 patients from the United States, Europe, Canada, New Zealand and Australia and he has consulted in many governments, including China, France, Belgium, the UK and the US on Lyme disease. He has significant experience at the coalface of clinical practice. These doctors, with considerably more experience, should be guiding the way forward for Australian patients.

We suggested two years ago, as part of our response to the scoping study, that the Australian government visit with the Brazilian government, who, in the face of the exact issue we face, have managed to mount an effective, scientific and public policy response with their Lyme-like issues. We ask that the committee prioritise engagement with international experts and those Australian doctors who are on the front-line here diagnosing and treating this disease every day.

How could any doctor actually call themselves a professional while they use tokenistic platitudes about caring for those of us—they all say, 'We know that they are sick,' but at the same time they do nothing to help us. This compassion box seems to be just ticked in all these submissions, however, they all still perpetuate the myth of denial. They maintain an entrenched position of, 'No Lyme here,' while there has been a research gap of more than 20 years. How could someone call themselves a professional in that position? In any other industry, you would be out of business operating in that way.

It is important that the committee also gain an understanding of the circle of bureaucracy here. In the past few years, the Australian government has done several things to try and support the Lyme community, however, it has largely been a bureaucratic process that has gone nowhere. It commenced with a clinical advisory committee, which abandoned after five meetings with no tangible progress. The advisory committee provided advice to the Chief Medical Officer, who sought advice from the Communicable Diseases Network, who needed more advice from the Joint Criteria Assessment Group, who provided even more advice. That advice resulted in more advice for the chief medical officers in each of the states and territories, who provided more advice to clinicians. Those are the frontline doctors who rely on contemporary and evidence based advice. That advice currently states that Lyme disease is not in Australia. At the core of all this advice stating that Lyme disease is not in Australia is: 'because it cannot be found in an Australian tick'. The facts are that, for the past 22 years, we have not actually looked for it. This defies both logic and scientific curiosity or integrity.

I want to use this quote that came from one of our briefings with one of the MPs. He says: 'Come on! Really! I lose my phone every other day and just because I cannot find it does not mean it is not here.' His honesty struck me, and has stayed with me ever since for its common sense and its simplicity. How can we, as a government or as a medical profession, deny it when we have not been looking and when there was no contemporary research until the last year?

I have a few more pages, but would you like me to stop now?

CHAIR: It is 20 past. I am sure some of the further points you have will come out in questions. Is that okay with you?

Ms Whiteman: Certainly.

CHAIR: Are there a couple of summation points that you want to make?

Ms Whiteman: Yes. In addition, almost two years ago the CMO advised that the current Australian NATA blood testing for Lyme disease was discordant. This means that a negative test does not mean that a patient does not have Lyme. But that information has not filtered down to the frontline with doctors. So just imagine how many thousands again have gone undiagnosed and therefore untreated in the past two years alone since that statement was declared by the Department of Health.

So, really, all this advice that I have just talked about has not changed a single thing for Lyme patients in the last year. We are in exactly the same place—or possibly, I think, an even worse one. There is more stigma, and more doctors are standing back, frightened, and refusing to treat, and more patients are showing up because, with this awareness, people go, 'Well, maybe this is what is wrong with me,' and they have a right, in Australia, to be evaluated, with Lyme disease included as part of their differential diagnosis.

It is absolutely incredible to us how so many professionals can acknowledge there is a problem but then quietly just simply do nothing about it. So what is left is for the patients to bear the burden of proof, and that just should not be happening in 21st century medicine in Australia.

The other thing is, as to stigma: we are denounced as the 'Lyme lobby'. I challenge any doctor to have a family member with Lyme disease or to spend an hour themselves in the body of one of our Lyme patients—they would be begging for mercy; they would be begging for help. So we are very grateful to have this voice today. Thank you.

CHAIR: Thank you. Senator Madigan.

Senator MADIGAN: Thank you, Ms Whiteman. In your evidence you said that both sides agree on this argument that ticks carry multiple pathogens. If it is the case that both sides agree on that, why does your organisation believe that the medical profession cannot work from that point, at the very least, and put the patients first, and then move on and try and work out what is going on?

Ms Whiteman: Thank you for the question, and it is a good question. We can only guess—we are not medical doctors—from anecdotal experience. They report to us regularly, and doctors report asking to be removed from our list of referring doctors. So we have a very short list of doctors who will accept referrals from us for patients who, again, are not saying, 'I have Lyme,' in the majority of cases; they are saying, 'I'd like to be checked out; I'm worried that I could have it,' or, 'I have a tick bite.'

My personal friend contacted me two days ago because she had seen on Facebook my connection to this. She said, 'My stepdaughter had tick bites and now she has flu and her arms are shaking.' I had to phone around and phone around and phone around to find a doctor to whom they could just say, 'Listen, I feel sick after a tick bite; can I have some antibiotics?' I said: 'Don't even mention the L word.' So, after three attempts, they found a doctor that they could go to and they did get them.

In addition, there is confusing advice from the Department of Health. The Department of Health, on the one hand, says, 'Patients are sick,' and that doctors should treat, but the advice is, 'Go to an infectious disease doctor.' For some reason, there is a major gap between that advice and the reality of the patients. Obviously, in the submissions I have read, the majority of patients are indicating that they do not get support in visiting infectious disease doctors.

It is also a very complex disease to treat. I am not a doctor but, as a patient, it affects every system in my body. The reason I had multiple diagnoses is that our medicine tends to look at fragment elements when it is affecting the whole body. And it is not any one specialty—a neurologist would treat one symptom and an infectious disease specialist would treat another. So it needs a very holistic treatment, and not many doctors want to work that intensively and they also would like more knowledge and support.

Member of the audience interjecting—

CHAIR: No, you may not ask questions from the audience, I am sorry.

Senator MADIGAN: Yesterday in Perth, we heard that there is research being carried out in relation to ticks. As I understood it, it was auspiced by an animal health company—I think that is right.

Ms Whiteman: Bayer.

Senator MADIGAN: Yes, Bayer. Is the LDAA aware of any research into ticks from the human perspective in Australia as opposed to the animal health perspective?

Ms Whiteman: That is not my area of specialty—I think Dr Schloeffel will be able to speak on that later—but I know there is a tick-borne disease unit at Sydney uni, and they will be speaking later today and be able to expand on that extensively. There is another unit at Sydney uni, in the entomology department, that is doing studies. I know some Lyme patients who went to a meeting in Sydney recently learnt more about their research as well. I believe they are also working in partnership with Dr Irwin, but, again, I think some of your witnesses later today are more qualified to speak on that.

Senator MADIGAN: You mentioned that for 20 years there has been no further research in Australia, until now. We heard yesterday from some medical professionals who, I suggest, were on the other side of the argument. They were telling us how we have to have empirical evidence and research. The question I ask is: if we have had nothing in 20 years and we are told that classical Lyme does not exist in Australia, and we are told science is continually improving and finding better ways, why do you think that we cannot seem to get over this speed hump to have another look?

Ms Whiteman: That is an excellent question and one that we would all like answered, but, from the Lyme Disease Association perspective, especially because of the delay in action in Australia, we really need a multi-

focused, immediate and urgent public health response—and that includes research. We want comprehensive research, but there is also stigma affecting doctors on the research side of things. One researcher I know, who asked not to be named, said, 'As soon as I put my name to supporting this tick project, I lost count of the number of emails I got from my peers saying I was committing professional suicide to be putting my name against tick-borne disease research.' I think the stigma is very broad and deep, and it affects all aspects of the patient community, the medical community and the science community.

We believe that we are insular here in Australia, and there is a silo effect where the doctors are doing one thing, the researchers are doing another thing and the patients are caught in the middle. Internationally, they have progressed beyond the myopic focus on a single bug infection for Lyme disease. I have seen papers this year where they are saying that we now know Lyme disease is caused by many *Borrelia* and I have even seen one paper that says it is up to 18. Again, this is outside of my area of expertise, and, to be honest, as patients we do not really care what it is called. That is not our area. We have progressed to 'Lyme-like' to try and embrace the Lyme deniers and the single-bug focus, because we are not trying to challenge what it is called; we would just like patients treated. We want it recognised that ticks have lots of pathogens. Karen Smith will give evidence next and she is more knowledgeable on this, but there are multiple pathogens known to be in our ticks and to make people sick, and patients cannot get treated for that either. We need patients treated and research progressed and prioritised. It needs to be made an urgent health priority by the government so that these researchers will stand up and put their hand up to do research, but we need to treat patients at the same time.

Senator MADIGAN: You mentioned in your submission the Chief Medical Officer. Could you clarify what you said about a negative finding not meaning that a patient does not have Lyme?

Ms Whiteman: The blood tests were discordant. As part of our response to the scoping study in 2013, our research showed that the two accredited labs in Australia that were testing for Lyme used different test kits and different criteria—a different number of bands—for declaring a positive. Again, it is outside my area of expertise but it is outlined in our submission. Therefore they realised that if you sent your blood to each lab you potentially would get a different response, and that it was lacking sensitivity. There is also evidence showing that the two-tier testing criteria that we have in Australia, which I know Dr Dobie will talk on later, is not globally recognised as international world's best practice. In other words, we have a problem with conflicting test kits; one requires a different level of bands to determine a positive. Patients, even if they have a negative response on those test kits, cannot trust the Australian tests until the test kit problem in Australia is cleared up. Again, I would like to refer to the doctors speaking later. Internationally they do not depend on blood testing positive to determine a diagnosis. It is a very complex issue.

Senator MADIGAN: Whilst this is being kicked around we have men, women and children suffering, as well as their partners and families. To clarify: are you saying that the Lyme 'community', for want of a better word, do not care what it is attributed to? They just want an answer, don't they? They are not interested in repercussions or attacking people; they just want to get well.

Ms Whiteman: Absolutely. I spoke to Dr Daniel Cameron about nine months ago. He is the immediate past president of the International Lyme and Associated Diseases Society in the US, an eminent, world-class Lyme treatment and teaching organisation. He said that in emerging disease situations evidence sometimes follows: you will see the patterns through patients and you treat the patients, doing your best, while prioritising research. That has not happened in Australia, and it is something that needs to change immediately. It is understandable. We either need to broaden the umbrella term 'Lyme disease' to include all tick-borne pathogens or call it something else. Like the ACIDS doctor or MSIDS in Perth, everybody has a different opinion, but from a patient's perspective we just want treatment and it does not matter what the name is.

Senator MOORE: Ms Whiteman, your very detailed submission goes through a lot of the arguments that we have heard. As I said yesterday in Perth, there seems to be very little common ground in the evidence we have. You could put one set of submissions on one side and other set of submissions on the other side and the only thing people would agree on is that people are sick. Everyone is falling over themselves to agree that people are sick and that they should be treated with respect. I want to talk about some of the major arguments that I have written down. You talked about the advice cycle, but the advice cycle from the government and the departments of health—every single one; there is no variation from the official group—is that it does not exist in Australia. The second thing was to do with testing. There seems to be absolute disagreement about what tests should and should not be used. We had clear statements yesterday that Australian testing is internationally the best and Australian testing says there is no Lyme in Australia. The last one is to do with the use of antibiotics. I would be interested to talk with some of the doctors later about their views and their vulnerability, because that is something that has come out.

They are the three main areas. With regard to the absolute disagreement around testing, we will ask someone else because you said there will be someone who is more expert here. With regard to antibiotic treatment, can you tell us, in your own experience, what has been the most effective treatment for you?

Ms Whiteman: I am probably not an average situation, on one level. I do not have medical treatment—

Senator MOORE: At all? So you are doing your own process. Can you put that on record for us?

Ms Whiteman: Certainly. My mother-in-law came to visit in 2007 and got frightened. I had an Alzheimer's like presentation—that was another one of my diagnoses. I did not know my right hand from my left hand anymore. If I went into the shower, I would look at the tap and I knew I was supposed to do something but I did not know what to do. I had to get help to turn the tap on. I could not drive. I did not know which foot or hand to use anymore. I would look at my family and it would take me a minute or two, three or four to remember their names. I knew I was supposed to know them. I had unrelenting pain.

Senator MOORE: Who gave you the Alzheimer's diagnosis? All those symptoms sound like Alzheimer's.

Ms Whiteman: Of the 17 doctors, there was one in Brisbane, Dr John Whiting. He said that my brain scan was not the worst he had ever seen but he could not understand how I was still even talking to him.

Senator MOORE: He is a neurologist?

Ms Whiteman: No, he is sort of an alternative GP.

Senator MOORE: You said you went to 17 doctors. He looked at some of your symptoms and said that.

Ms Whiteman: Yes. To cut a long story short, my mother-in-law went online and found a program called 'salt and C'. It is not going to fit anywhere in this, but you take table salt and high-dose vitamin C. It took me about a year and a half to recover 70 per cent.

Senator MOORE: And you have done that?

Ms Whiteman: For eight years now I have taken 15 grams of salt and 15 grams of C every single day, and it is torturous, to be honest. I cannot leave the house. I live a very disabled life. But it brought me from lying on the couch, praying to die, to where I am. I cannot really be a mum to my kids. I sit in a chair while they go in the water. They take a chair. Everywhere I go, I sit and watch them have a life. But I am alive and I do not pray to die anymore. My depression went. The reason why I put my hand up to volunteer for the Lyme Disease Association was that I was feeling depressed and I thought I had to focus on what I could still do rather than what I had lost. So they keep me very busy.

Senator MOORE: So the treatment that has worked to you—for some of your symptoms, anyway—was found through Google.

Ms Whiteman: Yes, absolutely. I have had two doctors who offered antibiotics to me, in a hands-off way. It is like being a hot potato. One said he felt okay using the South African rickettsial protocol, because I was rickettsial positive. I got handed six months to a year of scripts and a protocol and it was like, 'Don't come back too often.' That was the energy, not what was said. But they are scared to treat. They do not want to be too hands-on or involved in the process, but they could also have compassion and see that I was sick.

Then with another doctor it was the same thing. I had another tick bite in about 2012, I think. I did not want antibiotics again, just randomly and without a skilled practitioner. If I am going to do antibiotics, I want it to be with skilled knowledge, based on an evaluation. Again, it was just a set group of antibiotics given.

So in my experience as the President of the Lyme Disease Association—and I am also a critical care nurse with three certificates in critical care and 20 years in nursing—I see that an individualistic approach is needed for the most success for patients. It responds differently. The immediate past president's whole family is sick with Lyme and they have travelled to Dr Horowitz in the US. What they discovered is it is not a one-treatment-fits-all kind of scenario for patients. Some of them responded more to a herbal approach and did not tolerate antibiotics, and some of them really responded to antibiotics. So it requires quite an in-depth skill base to be treating this group of patients.

Senator MOORE: I only have one other question and it is to do with the doctors. We will have doctors coming to give us evidence, but we have had the evidence from your association and others about the fear, the pullback from doctors who fear they could be exposed. The AHPRA guidelines, which are the basis for investigations of medical practice in Australia, are based on complaints—people actually making complaints about a doctor. Through your Lyme disease network—and it is very large—are you aware of any of your members who have made a complaint about doctors?

Ms Whiteman: Thank you for that question. My perspective is that there is no one right doctor for every patient. We rarely get complaints, but, if we do, we have doctors who are just glorious. There are patients who could not go a day without them and are so grateful to them, and for somebody else it is not the right style. I do not have any knowledge of any of those patients who did not match with their doctor making a complaint, but I imagine it is possible. But probably not any more than any other medical specialty or any other illness.

With regard to the drawback, I know my children are showing early signs. One of the reasons why I pushed through so much illness and sacrificed a lot in my family and my life to do this is for them. My heart is affected, and I do not have treatment. I do not know how long I will be here, but my kids have the early signs. My doctor will not have anything to do with it. They should be vaccinated, but she will not sign, so we do not get help now. It is just wrong.

Senator WANG: Ms Whiteman, I gather that you are talking to a lot of Lyme patients and associations overseas. Could you share with us some stories from other countries and tell us whether they are comparable to what has been happening in Australia, whether they had stigma in the first place and, if so, how they broke the stigma?

Ms Whiteman: That is an interesting question. The US seems to be the birth place of stigma, even though it is an endemic country. You can be in one state and go to another state and be refused treatment because it is not in that state. That is beyond imaginable from a scientific perspective. They are progressing studies now about migrating birds. They have proven that in California somewhere in the vicinity of 49 per cent of the ticks from these migrating birds had *Borrelia* in them. That is significant. They go to Canada; they go everywhere. Even the Canadian government said: 'It doesn't cross the border here. It isn't in Canada.' They have the same problem in the UK. Germany is fairly progressive—they have Lyme treating clinics, which we need here in Australia—and there are some other European countries. China is recognising it, but New Zealand is not. We have, as you know, a very sick, young girl who got bit at one of our petting zoos here in Australia, and she is fighting for her life and fundraising to go to New York to stay alive, really.

I think the smartest thing for Australia is scientific and logical, that we embrace world's best practice and take on advice from people like Dr Horowitz, for example. He is not the only world-class treating doctor in the world, but, if he has treated 12,000 patients over 29 years, he is somebody whom we should be taking advice from. Why are we trying to reinvent the wheel in Australia? Why aren't we embracing international expertise and collaborating for the progress here? In Australia, we have the opportunity to be on the world stage for our response to tick-borne disease in Australia. That is our opportunity.

Senator WANG: I guess the problem, as we saw yesterday when we heard from the two professors, is people are quick to claim that they are the world leader in a certain field—believe me. I have only been a senator for two years, but I have met many, many people who like to claim they are the world best in something, which I would like to believe, but that is not often the case. That is harsh, but that is probably the harsh reality. If we were to follow any success stories from overseas in terms of breaking the stigma, which country would you recommend? Probably Germany, I gather from your comments.

Ms Whiteman: I think, again, the same as Lyme disease, it is different everywhere. We can take elements from different countries. Germany should definitely be embraced. There is some good collaboration happening with China and some of the work they are doing. Also, definitely, the ILADS group of doctors in the US is very progressive and has shown evidence based treatment plans in the US that are embraced by the National Guideline Clearinghouse, which is an important step forward.

Senator WANG: I am aware that in the US there are vaccines for dogs with Lyme. Have you heard of anyone doing any work on vaccines for humans?

Ms Whiteman: No, I have not, sorry.

Senator WANG: All right. That is it from me.

CHAIR: I just have one or two questions. One is the issue around the long-term use of antibiotics. To your knowledge, what is happening in the US? Several doctors told us yesterday that Lyme responds really well to short-term use of antibiotics—we resorted to going classic Lyme and then Lyme-like. The position that was being put to us was that with classic Lyme, or Lyme disease, we know if it is Lyme because it responds pretty quickly—within a couple weeks. So, for Lyme-like, you do not need to use long-term use of antibiotics because it is not Lyme—we need to be looking for something else. From your experience, looking around the world, the US and Europe, is that your experience with the research that you have done—that clear distinction being made by some doctors?

Ms Whiteman: Our research is anecdotal and is mostly through patients in Australia. I know that the doctors speaking today will touch on that, as well. From a very engaged process with Lyme patients in Australia, we get 100 emails a month from different people. We are coaching them as to where to get support. I personally believe that peer support is equally important as educated medical treatment. In Australia, you need so much help in getting around all of the information for Lyme.

In regards to treatment, it is, again, completely individualised—you cannot make a standard. I think, yes, there are dangers for long-term treatment of any drug. In any specialty, they have those areas where drugs have side-effects. They are a drug; they have to be watched and monitored by a skilled medical professional. With that in mind, you have to look at the patient's life. I can say with 100 per cent confidence that there are lots of patients in this room and around Australia who have recovered after long-term antibiotics. They are alive and have a quality of life—similar to my experience—where they are, maybe, not 100 per cent well, but the antibiotics is what has got them across the line. Then there will be a sub-group for which antibiotics is not the right thing. That is a medical decision for the patient and their doctor—hopefully, if they have one.

CHAIR: The other issue that came up was the interaction with genetics and people's genetic predisposition to a particular response. How much work, from what you are aware of, has been done in that particular area?

Ms Whiteman: I am not aware of any work that has been done in that area except by individual doctors that are treating Lyme patients, but I think it is a really important area.

CHAIR: So do I.

Ms Whiteman: Because it is the people that are far more except susceptible—like my partner, who is Lyme positive; the same titres, but symptom free. There is a difference in that—a different tick bite, and not sexually transmitted, but symptom free with the same *Borrelia* titres as I had. It flattened me.

CHAIR: Thank you. We have just gone a little bit over time, I think, but that is perfectly okay. We will make that up. Thank you very much for your time today and for your extensive submission.

Ms Whiteman: Thank you.

SMITH, Ms Karen Ann, Co-President, Global Lyme & Invisible Illness Organisation Inc; Founder, Lyme Australia: Recognition & Awareness

[8:49]

CHAIR: Welcome. Before we start, I would just like to check that you have been given information on parliamentary privilege and the protection of the witnesses and evidence.

Ms Smith: Yes, I have.

CHAIR: We have your submission—thank you very much. I would like to invite you to make an opening statement, and then we will ask you some questions.

Ms Smith: Thank you for the opportunity to be here this morning and put forward research and other information on behalf of all those living with Lyme and other vector-borne diseases. Your attention to the plight of all those suffering not only from illness but also from the fight necessary for medical treatment and understanding is very much needed.

As with most people involved with Lyme and co, I have Lyme myself, as do my three children. My youngest daughter, in fact, has the bullseye rash and positive PCR. I had brain scans which showed widespread hypoperfusion and encephalopathy, possibly due to Lyme, and I could not get treatment. For the first 2½ years of my illness, I was housebound. Twelve months of that was sleeping 21 to 22 hours a day, and for most of the 12 months I was unable to speak. I had to travel overseas to the UK for treatment.

It is hoped that the research that has been provided highlights the very real need for immediate investigations into the pathogens in Australian ticks and reservoir hosts. This need was noted by Whitby and Playford in 1996 and again by Richard Russell in 1998. Russell's paper 'Vectors vs humans in Australia' concluded:

> Despite the greater incidence of tick-related problems, there is also little to be optimistic about with prospective tick research. The groups working with tick-problems … have all been disbanded as funding has disappeared.

It is of urgent necessity that funding is made available for tick-borne research again. I hope that is obvious to you all, with all the submissions and information provided. Due to the sensitive nature of Matt's presentation I have asked that he closes. Therefore I would ask that we be given a heads-up five minutes before we finish so that Matt can present on behalf of all those who have lost loved ones and all those who are living with Lyme and co. The 'Time to Recognise Lyme' clock aims to show the human side of this disease, and the devastation its denial and the lack of treatment and medical care are creating.

CHAIR: Do you want to table your opening statement?

Ms Smith: No, that is fine.

Senator MADIGAN: I know that you have a Bachelor of Psychology. For the benefit of the committee, would you be able to elaborate on patients who have repeatedly gone to doctors to try to find out what is wrong with them, and what effect that is having on them directly and on their extended families?

Ms Smith: From that viewpoint, of seeing the Lyme support groups and the patients go through, over the last few years—with the media awareness that people were going to get better in 2012, to the commission in 2014, to this inquiry now—we have seen the hope of people go up and down. It is just incredible. You cannot imagine going to a doctor and being told that it is all in your head, or taking a daughter, who is nine years old and has seizures, and being told that it is all in her head and you should take her home. You cannot imagine the issues surrounding all of that. To be sick is one thing; to be sick and not be able to get treatment, and to have to fight for that treatment, is a totally different ballgame. It is one that is costing families, separating families. I cannot really give the statistics, but over half of the families and people living with Lyme and co get torn apart by this. People do not get support. They are not believed. The government says, 'Lyme is not in Australia, so you must be putting it on; you mustn't be that sick; it's not here.' We have a lot of relationships and families that get torn apart. There are the families that do stick together and band together for this, but unfortunately they tend to listen to doctors who say that it is not here.

Senator MADIGAN: Have you any figures on how prevalent it is for people who are attending doctors to be told that they are mentally unwell?

Ms Smith: I do not have any specific figures on that apart from what I see in the support groups, and that is more so the norm rather than something that does not happen a lot. I recently went to a neurologist who saw my two brain scans showing hypoperfusion throughout. The first one read 'encephalopathy possibly due to Lyme,' and he sat there and shook his head and said: 'How could they conclude that? Lyme is not in Australia.' According to him my first two brain scans, which were taken before I went to the UK for treatment, showed widespread hypoperfusion. After I returned home from treatment I had another brain scan that showed that that had returned

to within normal limits, so his conclusion was that the first two brain scans were incorrect, or that I must have been taking something to alter them because, of course, I do not have Lyme disease—I must have just been depressed or had decided to check out of life.

When he said to me, 'Are you sure you're not depressed?' I said: 'I'm not depressed. I know myself.' And he was like, 'What do you mean by that?' I said, 'I left home at 15; I raised three children; I did my first degree in four years, finishing at the top of my class; I got an APA scholarship to do my PhD.' He was like, 'So you're not depressed, you're just under too much pressure.' He was like, 'Most doctors will tell you that Lyme is not in Australia.' And I said, 'I will tell you that most doctors rely on research that is over 20 years old.' So we agreed to disagree.

Senator MOORE: Thank you, Ms Smith. Can you tell me what treatment you have had? You went to England, taking all the stuff in terms of your medical history. I forget how many people you said you had seen, but it was some phenomenal number.

Ms Smith: I have not put in a personal submission.

Senator MOORE: No, when you were talking about it. You said you went to the UK. What treatment did they give you, and did they think you were depressed as well?

Ms Smith: When I lost the ability to walk my 20-year-old daughter went to the bank and took out a loan, so I went overseas for treatment. The UK provided what I should have been able to get here. It provided oxygen terr—sorry, because it was a long-term hypoperfusion I do have damage to some areas—oxygen therapy, IV ceftriaxone and IV vitamins and minerals. I returned from there significantly better but still with a lot of damage. I have not listened to music for five years; I do not watch TV and do not drink alcohol; I do not interact, basically. A lot of my advocacy work is done at home because I cannot be around—I have taken a few anti-inflammatories and various drugs, but you will notice that my speech goes at times, and that is my—

Senator MOORE: It comes and goes?

Ms Smith: Yes, depending on how affected my brain is.

Senator MOORE: Over what period was that the antibiotic treatment you had in the UK?

Ms Smith: I was in the UK for 12 weeks, so it was a 12-week period. I also know that the clinic at the time was being investigated for treating longer than four weeks; even though they are private clinics they still get investigated for that treatment. I believe it was Dr Murakami in Canada who gave evidence at their hearing so that they could continue treating Lyme, but they were put on a lot of restrictions as well.

Senator MOORE: We have had the reason for this restriction about antibiotics and all those things explained to us. It all sounds very reasonable, but we had some evidence yesterday of—and I get the actual term wrong as well—the hypo treatment. You had some of that, which is not available here, in the UK.

Ms Smith: No, I did not have hypo.

Senator MOORE: In your role with the Lyme Disease Association have you been able to sit down as an association and have a face-to-face discussion with the people who you know are completely opposed to the statement that there is Lyme disease in Australia?

Ms Smith: No. Lyme Disease Association of Australia does most of those with my Lyme Australia: Recognition and Awareness. It is more the tick- and vector-borne research that my interest is in. The Lyme Disease Association of Australia is better enabled to do that. In the Global Lyme & Invisible Illness Organisation, rather than trying to get our point across that it is here, the angle we have taken is primarily about supporting the patients. Red Shoe Day is a day of remembrance. In holiday seasons we support patients that cannot get out; we have online events so that they are not alone over the Christmas period and stuff like that. So we have more of a supportive role in that aspect.

Senator MOORE: And all of that is done in a voluntary capacity?

Ms Smith: Yes.

Senator MOORE: In terms of your medical issues, and you are continuing to have treatment, have you had any interaction with Centrelink about your ability to get Centrelink support?

Ms Smith: For the first two years, even after my brain scans and not being able to really speak—I began to stutter and then I lost the ability to speak—I had to register every three months. I have only just, in the last three months, been able to drive any distance as well. I got a letter from Centrelink to say that, even though it has been acknowledged that I have been diagnosed with Lyme disease, I am not stable and it is not known whether it is going to affect my life for two years. Eventually, 2½ years down the track, I got disability support. When I had to

do the three-monthly assessment, with the normal, standard questions—what level of education have you received, what can we do to get you back into the workforce—and I was having a bad day that day, I said, 'Really—what level of education? Blah, blah, blah! What can you do? You can treat me for Lyme disease.' I have been on disability since 2011 or 2012, but it took a couple of years for that to happen.

Senator MOORE: You will probably be part of that ongoing review process as well, where they come back to you at different times. That is standard. But at least you were able to establish that you did have a medical condition, for the disability support pension. Some of the people we have been speaking to have not been able to get that acknowledgement.

Ms Smith: Yes. Even the lady I am staying with at the moment has been denied three times. The denial is more common than the acceptance. I believe mine was possibly even more so. The 'Lyme' word was not out there as much in 2011. The controversy was not so well known.

Senator MOORE: It was that combination of symptoms and diagnoses that you are using, as opposed to the 'Lyme' word.

Ms Smith: No, I was very stubborn and insisted that I had Lyme disease. Someone told me I should just say I had depression and get antidepressants, and then I would get disability. But I said, 'No, I have brain scans and I have a positive test.'

Senator MOORE: Thanks.

Senator WANG: So you had some tests in the UK, and, when you brought the tests back, the doctors here quickly discredited the test results. Is that correct?

Ms Smith: I had tests here in Australia originally. I have a positive PCR from Australian Biologics. I have the brain scans that show encephalitis. I have a positive IGeneX test for four bands. My test here at the Australian lab was negative. The only other test I did when I went to the UK was for co-infections; I also have *Chlamydia pneumoniae* and a few of the other community acquired infections which most of us carry—it is not until the immune system gets overcompromised that they come into play.

Senator WANG: Where or through which channel did you hear that the UK was the place to go? I have talked to a lot of patients who went to Germany or the US.

Ms Smith: It is different for me. I had Bell's palsy in 2009 and then I had a trainee doctor keep me on steroids for four months. That set off the 2½ years of being bedridden and housebound, which reduced my immune system. In 2010, when I worked out it was Lyme disease, there was only Peter Mayne's website up at that point in time. There were no support groups. There was a Yahoo! support group, but there were none on Facebook. Basically, it was from my own research. I looked at Germany's BCA, but by the time they got back to me I thought, 'I can't even speak English, let alone go to Germany and speak German.' I had read online about Breakspear, and I put it to the Yahoo! groups—had anyone heard about it—and one gentleman replied and said, 'I credit them with saving my life,' so I decided to go over there.

Senator WANG: Has your association had any success in talking to various government agencies about the illness?

Ms Smith: No. I presented to Dr Jeannette Young, back in 2012, the various research that needed to be done, the ticks that were in Australia and the reservoir hosts that were in Australia. The website at Westmead stated that we do not have any of the reservoir hosts here in Australia when in fact we do: mice, rats, hares, foxes. I gave her a list of four tick species that have been shown in the northern hemisphere to be vectors of *Borrelia*. I also said to her that the Queensland Health website shows that, if bitten by a cattle tick, illness could not occur. I told her that *Babesia* was a potential problem, as were other ticks, and they should look at changing that information. Basically, we did not get any satisfaction. In 2012 she deferred to the CDNA. We presented that and we presented to the scoping study response as well. We just keep putting the research out there.

Senator WANG: There was no response from the government on your presentation on the scoping study?

Ms Smith: No. I guess it was included in all of the responses that the Department of Health put out there. There are the ticks that I showed are in Australia, like the scrub and bush tick, which has been shown to be a vector in China, and the seabird tick, which I showed are on the Australian coastline. It was not really addressed in the scoping study reply. They said 'potentially.' It was kind of ignored.

Senator WANG: They did not give you any reason for not including your response?

Ms Smith: They did include my response as an overall response, that research needed to be done. But, as to their reason for not including that we do have ticks here, for some reason they keep thinking that the *Ixodes holocyclus*, or the paralysis tick, seems to be the only logical vector here and they keep pushing that, whereas

numerous tick species have been shown to be the vector. They just do not seem to want to do research on various tick species or reservoir hosts here in Australia.

Senator WANG: It is quite shocking that politicians are prepared to open their minds and the medical profession is still really narrow-minded, except the good Richard here today.

CHAIR: There are a couple of questions that I would like to ask. I would like to go back to the mental health issue. It seems to me that there are issues. Maybe this is not being recognised by some of the decision makers. Being told, 'It's all in your head,' which is what people yesterday said they were told, can have a separate impact on your mental wellness.

Ms Smith: Very much so.

CHAIR: I will ask other people this today. Have you found, in your contact with the community, that that is in fact what you are seeing—that there may be some impacts on people's mental health because of what they have been told by everybody, such as, 'It's all in your head' or 'You're not really sick' or 'It's not Lyme'?

Ms Smith: It definitely has an impact; it has a huge impact. At one time I had a squamous cell carcinoma removed from my chest. I said, 'Be aware that not everything is Lyme disease.' It was just something that I had thought was a skin problem with Lyme, and it took me 12 months to get it cut out. It turned out to be squamous cell carcinoma. Because I used the word 'cancer', people said, 'I hope you're going to be okay.' It got me a little upset because I thought, 'You know I've been fighting Lyme disease for years.' There is the association. No-one knows what Lyme is. We all look good on the outside. If you look good, you must be healthy. You are told it is all in your head and you have to prove you are sick. That is one of the worst things you can do to a person. You are not able to get out of bed, you are not able to do certain things and you are not able to interact. People need to understand. It is the lack of understanding that causes people to take their lives or become more depressed. You have to constantly fight for the medical. There are people in the group who constantly say, 'I'm not going to the doctor. I refuse to allow my family to take me to the hospital. I won't go there.' So people are putting their own lives at risk by not going to the hospital because of how they are treated when they get there.

CHAIR: We had some discussion yesterday and we just had some discussion previously in terms of the issues around the name. Ms Whiteman commented on that issue as well. Do you get the same response if you talk about tick-borne diseases? Is there the same level of stigma around tick-borne diseases?

Ms Smith: In my experience, a few times I have gone to my local doctor's surgery to have an IV or something like that and they will have trainee doctors. I have spoken to about 45 different trainee doctors. They will come in, they will be interested in why I am getting the IV and she will say, 'Talk to Karen about Lyme.' The medical profession is not taught about vector-borne diseases. They have no idea. If you say you have a tick-borne illness, they really have no clue what you are talking about. Lyme has a stigma in the medical community perhaps. People started to learn what Lyme borreliosis was. There are over half a million new cases per year worldwide. You have those and you have all the advocates who are already fighting in other countries for correct treatment.

I had to take my son to hospital a couple of years ago and I did everything I could to avoid the 'Lyme' word, because I just wanted treatment for him. I was too sick. It eventually came up because they asked for my history because he was quite sick and I said, 'Yes, I have been diagnosed with Lyme.' They let it go and I was like, 'Phew!' There is the expectation that you are going to be raked over coals. I spoke to a Western Australian mum, Elsa. You probably met her yesterday. She took her daughter to hospital and they knew she had adrenal insufficiency. They put the bung in her arm to give her saline. The doctor came out and read that since her last visit she had been diagnosed with Lyme disease. He ordered the bung to be removed and she had to carry her daughter out of the hospital, because we do not treat Lyme in Australia. There is a lot of stigma attached to it.

CHAIR: There is still a stigma attached when you talk about tick-borne illnesses or Lyme-like illnesses?

Ms Smith: I do not think we have been using the terminology enough. I have not spoken to enough people or seen the difference with using 'vector-borne' or 'Lyme-like', because it was only recently that we tried to accommodate for that.

CHAIR: I got the sense from yesterday that, at least with some people in the medical community, there is an acknowledgement that people are ill and that there could be co-infections. Is it the same case here?

Ms Smith: I believe so. Most of the research on ticks in other countries will show that the ticks carrying multiple pathogens is the norm. A number of people have *Borrelia*, *Babesia* or *Bartonella*. *Bartonella* is a common communicable infection. It could be from fleas, dog saliva or cat bites. So potentially, people have carried this or got this in childhood and their immune systems can take control of it. Because *Borrelia* is immunomodulatory, basically, until your immune system is lowered enough—it is similar to, say, HIV or AIDS. Four million or more of the population can carry HIV, but they are not actually designated as having AIDS until

their immune system is to a certain level. I believe it is similar to that in Lyme disease. There are a lot of people who can carry it. I actually contracted it in 2003. In 2002 my daughter had what we now know was a bullseye rash. They put it down to a rare fungal infection at the time. In 2009 a minor car accident set off Bell's palsy and the trainee doctor kept me on steroids—it was four months of steroids that crashed and burned. The multiple infections—usually that is where your different patient perspectives come from. If they have the multiple infections you see what their immune system is like and things like that.

CHAIR: In terms of your experience of classic Lyme disease and the bullseye rash—I will use that because it is one way of making it easier to talk about it—if there are people with Lyme-like or tick-borne illnesses that have not been diagnosed as *Borrelia* or the particular four that are known to cause Lyme disease, are there any cases where someone has had the bullseye rash from a tick-borne disease that has not been diagnosed as *Borrelia*? So somebody had it and they have not been diagnosed with *Borrelia*, but you know that there is some form or tick-borne or Lyme-like disease. Is there any association there of having that type of rash without being diagnosed with *Borrelia*, but where there may be some other form of bacteria that has been found?

Ms Smith: Generally, with bullseye rash in the United States it is pathogenic Lyme; it is a definite indication. My knowledge on the other co-infections is not as good as on *Borrelia* and *Babesia*, which was what I focused on, but *Rickettsia* can cause different rashes. Some of the different infections can. You say you have had a tick bite, but it does not really enamour them for medical treatment. I do not think there is knowledge of the fact of how many pathogens our ticks carry and what they can pass on and what they can do to humans. The bullseye rashes, I believe, are discarded by Russell and Doggett at Westmead as tick reactions. A lot of people also do not know. I did not know in 2002 what the rash on my daughter's face was. I just knew it was something that kept growing and covered half of her face. They gave her some medication—some antifungals—and kept an eye on her liver. When you do not know what to look out for—

CHAIR: It can have come and gone before you even know.

Ms Smith: Usually, your typical bullseye rash will expand and be around for around a month, anyway. That is the difference. I think information needs to be taught about each different disease and each difference.

CHAIR: A lot of the photos that we have had in evidence and a lot we were shown yesterday were the classic view. What I understand from what you are saying is that it is not necessarily the case.

Ms Smith: When I became sick I got my doctor's records and tracked it back to 2002 for my daughter with the bullseye rash. I had gone to the doctor in 2003 with a reoccurring rash on my thigh, but it was not a bullseye rash; it was just a rash. It was a little bit raised and it would come up once a month or so. I do not know the exact time. So I went to my doctor in 2013 and said to him, 'I have this rash', and my jeans were too tight, apparently. So it is not always going to be a bullseye.

CHAIR: There must be a lot of those rashes around at the moment, then, given the streamline style that is favoured! If there are no other questions, we will invite Mr Chant up.

CHANT, Mr Mathew William, Private capacity

[09:20]

CHAIR: Mr Chant, I need to do the official bit. Could I confirm that you have been given information on parliamentary privilege and protection of witnesses and evidence?

Mr Chant: I have. I am here to read out come stories that have been presented to Karen on behalf of the suffers. The time to recognise Lyme clock is a call to action to show that acknowledgement and treatment can help restore hope and health, that the denial of Lyme and other vector borne diseases in Australia is causing devastation and the loss of years of people's lives, and, in far too many instances, their death.

To start with, the call to action—acknowledgement and treatment can restore hope and health. This is Sarah Night's story. She still has a long way to go to fully restore her health but that opportunity is now there, made possible with her diagnosis and knowing what to treat. Sarah Night is from Victoria. She is aged 23 and has been sick since the age of 12. Since 2005, Sarah's health has been up and down. A severe downturn in 2014 saw her lose the use of her legs. Doctors had no idea what was wrong and she was told to get used to life in a wheelchair.

Sarah was diagnosed with Lyme and co early in 2015. She is slowly regaining the use of her legs. Some words from Sarah that echo the sentiments of those living with Lyme and co:

My life has been turned upside down. There isn't a single aspect that has remained untouched—my independence, finances, freedom, friendships and career just to name a few. Since the age of 12, everything has been dictated by illness despite best attempts to stop it.

I have been accused of putting it on or making it up. What no-one sees are the many tears that have been shed as I watched my life go by, sitting on the sidelines wishing for the day I can participate again and be a normal 23-year old.

So many who are sick are left searching for answers, for professionals who will help, while being subject to bullying that in other aspects of life would be deemed unacceptable. Many others with a similar health status yet a different diagnosis would receive the support and resources required to make their journey as easy as possible.

My family has all experienced the emotional and physical tolls, the sacrifices they have made just to give me the opportunity to fight. All this due to an illness that is a mystery to many. The psychological impact of which is now becoming just as debilitating as the illness itself.

My question is that if it is not Lyme like illness, then there is something that is making so many sick, what is it?

The next topic is: before more lives are devastated by illness. If Lyme and co were recognised, the infection could be treated early and people would not have to lose years of their life to illness, progressively getting more and more unwell.

Janine Riani is from New South Wales. She is aged 27 and has been sick since the age of 11. She says:

I was bitten by a tick on a primary school camp in 1998. I have been suffering from debilitating symptoms for the past 18 years. Before getting sick, I was an energetic, social and creative person and had a passion for dancing, singing and acting. The intermittent loss of feeling in my legs and seizures put that to an end.

Throughout the 16 years before a proper diagnosis in 2014, I saw over 100 doctors and specialists, had numerous misdiagnoses and presented to multiple hospital emergency departments—over 75 times. They did not have answers for me, ultimately blamed me and told me that my symptoms were psychiatric and that there was, 'nothing wrong with you'. I was told, 'Your subconscious is causing your seizures and you're making yourself sick.'

This treatment has left me mentally damaged. I have completely lost my sense of self and self-worth. I now finally have answers and I just want to be able to have access to proper care and treatment so I can live to my full potential again. I really just want my life back.

That was Janine's recount of her experience in reaching the diagnosis.

Dave Mane is from South Australia and is aged 39. Dave has been sick since a tick bite in 2008. It was at his honeymoon. He spent much of his time sick with his new bride, Paula, concerned and caring for him. Dave was eventually diagnosed with Lyme and co in May 2012 as were his wife and twins later that year. Either David passed the infection on or Paula contracted it unknowingly at the same time. Either way, the lack of acknowledgement of Lyme meant that, when Paula gave birth to twins, they were born prematurely and the embryonic sac was found to have an unknown infection. The lack of acknowledgement of Lyme means the warnings about Lyme being able to passed from mother to baby are also denied in Australia.

Amara Campbell, aged 38, from Queensland has been sick for 15 years. She was initially diagnosed with ME and CFS in 2001. By 2010, her health had deteriorated dramatically and she has been housebound ever since. Amara was diagnosed with Lyme and co in 2013. If awareness and early diagnosis were available, the odds are that Amara's health would not have had the chance to deteriorate so badly. She may even have achieved her dream of becoming a mum.

Ms Smith: Amara may have even become a mum and she would certainly not have lost so many years of her life due to illness. The clock then moves on to those lost forever. Those three represent that we need help before people are lost forever.

Karl McManus, aged 43, from New South Wales was bitten by a tick in July 2007 in the Northern Beaches. He was diagnosed with Lyme and co in 2008. Karl passed away suddenly on 14 July 2010 after catching the flu. Due to paralysis of his tongue, excessive mucous choked him. During the seven months prior to Karl's death, he had managed to reduce is deterioration. He had gained 15 kilos in weight and his muscles had stopped twitching. He was feeling positive as he could feel his body starting to repair and grow muscle. Karl's decline and death was due to his hospital admission and the medical system ignoring his condition and refusing to accept that he had borreliosis and treat them accordingly.

Theda Myint, aged 37, from Western Australia received multiple tick bites in Western Australia. She was sick for 14 years and most of those years were housebound. She was diagnosed with Lyme and co in 2011.On 25 July, just one day after her last medical appointment, at which a neurologist advised her that she had tried all options available for pain management, Theda euthanised herself. For Theda, a return to hospital was not an option as they did not believe she was really sick and, on her last admittance, the hospital staff had tied her down in the psych ward.

Mr Chant: In the words of her mother, Carol, Theda never lost her love of life, she simply became overwhelmed by the desire to escape her pain.

Bevan Jefferies, aged 44, from Western Australia was bitten by a tick near Quedjinup in WA. He had over six years of illness and was diagnosed with Lyme and co in 2014. Bevan was a very passionate person—a lover of classical music and an artist. After six years of illness, the constant battle with illness and the fear of perhaps never being able to overcome Lyme and return to a healthy life simply became too overwhelming for Bevan. He ended his health struggles on 25 February 2015.

Bryce Nettle, aged 25, from Western Australia collapsed in 2009 due to an unknown illness. He was diagnosed with Lyme and co in 2014. Bryce's mum, Michelle, said Bryce was a very active young man who had a wide circle of friends and participated in a variety of sports from a young age—soccer, cricket, football and the surf club. By 14, he had an intense passion for body boarding and surfed at every chance he had. Life changed in December 2009, when he collapsed. He was 19. He had countless visits to doctors and hospitals, numerous tests and re-examinations and a plethora of treatments, but none of these investigations proved satisfactory. Bryce's mental state began to deteriorate a few weeks before his 25th birthday. He gradually became really down, very discouraged and anxious. He had been sick for six long years—one fifth of his life—and he had started to doubt that he would ever get better. On 17 November 2015, after six long years of suffering, Bryce chose to end his suffering on his own terms.

My brother, Scott Chant, had a tick bite at a northern New South Wales property while doing some work there. He found out he had Lyme after seeing a Lyme-literate doctor. That was after probably 12 months of just not knowing. He gave up his fight on 8 February this year. I think every day about what led him to make that decision but, from reading these stories, it is obvious. Being so debilitated, he had to spend his days in bed or on his fold-out chair. It was not the life he envisaged or wanted to live.

I do blame the medical system in Australia. Yes, there were those who were doing their best to help, and I think of those people every day. Without them, he would not have lasted three years. But when the time came that we needed that next step of help, it was not there. Hospital admissions often ended with Scott being sent home and us, the family, being told it was all in his head and we should stop encouraging it. There were really rough nights. I do believe that, if those experiences had been different, Scott would be here right now speaking to you all and telling you his story.

CHAIR: Thank you very much for outlining those experiences. That gives us information and a sense of the impact this is having on the community. You are going to table the document?

Ms Smith: Yes.

CHAIR: Thank you.

SULLIVAN, Mrs Meaghan, Private capacity

[09:32]

CHAIR: Welcome. Information on parliamentary privilege and the protection of witnesses and evidence been provided to you. For the Hansard record, could you please tell us your full name and the capacity in which you appear.

Mrs Sullivan: My name is Meaghan Sullivan. I am here on behalf of my family and my brother, Scott Chant.

CHAIR: I now invite you to make an opening statement and then we will ask you some questions.

Mrs Sullivan: Ten weeks ago I lost my brother, Scott Chant, to Lyme disease. I am not scientifically minded, nor do I know everything there is to know about Lyme disease and its co-infections. What I do know firsthand is the toll that it took on my brother and my family. In August 2012, Scott was bitten by a tick whilst working in northern New South Wales. I remember not thinking much of it, just that he was very tired and not up to doing much because he had contracted Lyme disease—something I had never heard of before. He was prescribed a course of antibiotics—and then he would be fine. Or so I thought.

What happened over the next 3½ years was anything but fine. Scott did not share much about what he was going through after being diagnosed. It was not until February 2013 that we had our first wake-up call about just how serious his condition was. Scott had attempted to take his own life. He had suffered what he later described as suicidal terror—an immense onslaught of panic, anxiety and terror that came on all at once. The only way he felt he could get relief was to end his life. Fortunately for us, he was not successful with his first attempt. However, another attempt would follow just one month later. This time we were more prepared and we were able to get the police to him in time, which resulted in another trip to emergency—and a visit from a psychiatrist, who proceeded to tell Scott that he had OCD and this was all in his head.

After many doctors having told Scott the same thing, this came as no surprise to any of us and we simply smiled and nodded. We had sat in countless doctors' appointments prior to this and, on mentioning the word 'Lyme', we were quickly told that it does not exist in Australia and dismissed. There was no follow-up questions, no empathy—nothing. It was very black and white to these doctors: Lyme did not exist and, therefore, everything Scott experienced he had made up. Again, it would be up to Scott to do his own research to find the answers and treatment he needed to beat this disease.

It was going to be a long road to recovery for Scott, now with his injuries from the suicide attempt on top of his symptoms from Lyme and co-infections. We had a numbering system so that Scott could tell us where he was mentally. He generally sat around a two or three, which meant he was suffering anxiety, but it was manageable. If he ever got as high as a five or a six, we were to call the ambulance as this meant he was bordering on having another suicide or terror episode. I learnt to read Scott quite well over this time. You could see a complete shift in him when the anxiety and depression had set in. He lost all life in his eyes and would just stare at the wall or the ceiling, blinking constantly. It was heartbreaking to see, never knowing once the anxiety hit how far it was going to go—if it would simply pass after an hour or so, which was the best-case scenario, or if we would be calling an ambulance.

The next two years saw Scott stabilise somewhat. He had his good days and his bad days. However, most days were spent lying down on his iPad speaking to the other Lyme patients through the forums and researching constantly. This is what his life had become—a never-ending search for answers. After Scott had passed, I was looking through his phone. For the last year, he had been keeping a symptoms diary. There were pages and pages of the ailments this disease was causing him and, beside that, possible reasons for the symptoms, if he had changed a medication or if he had had something different to eat that day. He could not get the help he needed from the medical system, so he was forced to do that all by himself on top of trying to make it through each day.

On 8 February this year, Scott disappeared from the unit where my mother had been caring for him. We were on high alert as he had disappeared the week before, but we managed to convince him to come home. This came as a surprise to all of us as he had been doing so well over the holidays and in the new year. He was well enough to write his incredible submission for the Senate inquiry, submission No. 116—a piece that we as a family will be forever grateful for as it gives a very truthful and concise insight into his pain and suffering for the last 3½ years. It gives a great understanding as to why he had to do what he did on that Monday. The battle had gone on for too long and he had endured more than any one person should have to.

Scott lost his life to Lyme disease well before he passed. He loved surfing, hiking, nature, music and having a few beers with friends. However, he had to drastically change his diet, cut out all alcohol and could not stay outdoors because the medication he was on made him susceptible to burning from the sun. When I look at photos of him prior to his August 2012 tick bite, he is almost unrecognisable. The once carefree and happy brother that I

knew was no longer. The disease had taken his freedom, but it was the medical institution that took his will to live and his desire to fight. Scott would often tell me that knowing he could end his life was the only thing that made him feel better—knowing that he had that option. I could never understand this when he said it to me. Never could I imagine feeling so bad that I would want to end my life. No matter how much he explained it to me, I could never fully understand just how much he was suffering.

He held on for the last 3½ years because of his love for his family and friends. He knew how much it would devastate us if we ever lost him, so he continued to battle through. It was a very difficult time for all of us, never knowing if, when you rang him in the morning, he would answer or what you would be faced with when answering a call from him late at night, or any time of the day for that matter. We never knew how he would be. One day, he would be fine; the next day, we would be calling an ambulance. That is how quickly things could turn around. The impact and stress this had on our family pales in comparison to what Scott was going through. The joint pain, anxiety, insomnia and fatigue were just a few of the symptoms Scott dealt with on a daily basis.

What is devastating to me is not the fact that Scott took his own life. I am happy that he finally, for the first time in 3½ years, had control of the situation and was able to relieve himself from his pain and suffering. What devastates me is that, if diagnosed properly and quickly, this disease is treatable. I cannot understand why when Lyme is mentioned to doctors they immediately shut down. If it is not Lyme, then what is it? What else is causing these symptoms?

How is telling someone that this is all in his or her head a reasonable diagnosis? It is not good enough, and denial is not the answer.

My brother was an active, independent and happy person with ambitions and dreams. He had a powerful and curious mind and there was so much more that he had to offer this world. Now, he will never have the chance to. We will be forever broken without him here and continue to fight for a cause that meant so much to him and ultimately took him from us. Nothing will change the fact that he is gone, but what can change is the attitude this country has towards this disease. Please, for the sake of those still fighting, recognise Lyme-like illness in Australia before another life is lost. Thank you.

CHAIR: Thank you. Are you okay if we ask you a few questions?

Mrs Sullivan: Yes.

Senator MADIGAN: Thank you, Mrs Sullivan. When your brother Scott was bitten and started to show signs of illness, can you give us a rough idea of how many doctors he approached in his search for doctor specialists to try and get answers to what was wrong?

Mrs Sullivan: In the beginning, I think he went to about three or four doctors before he found an actual Lyme-literate doctor, who was able to give him the antibiotics, which he took. I believe it was a two-week course, and that saw his symptoms completely disappear. But, I believe because it took so long to get him diagnosed, taking the antibiotics only made the bacteria lay dormant until his body was in a position for them to thrive again, which is why he had the return of the symptoms about three or four months after that initial course of antibiotics.

Senator MADIGAN: After he had his initial course, did he have another course after that?

Mrs Sullivan: After the three or four months of the initial one, and when the symptoms showed themselves again, he did take antibiotics for another three months. But this time the symptoms, once he stopped the antibiotics, returned much more quickly, and he believed that the bacteria was becoming more resistant to the antibiotics and that he had to either change the antibiotics that he was on or take a higher dosage in order to eradicate the bacteria.

Senator MADIGAN: At that point, was he looking for other ways to combat his illness?

Mrs Sullivan: He was looking at more holistic approaches and changes to his diet and his lifestyle—yes, absolutely. He had to completely change everything that he had been doing previously.

Senator MADIGAN: Whilst he was suffering and was looking to try and get answers, at what point was he told that it was all in his head?

Mrs Sullivan: That was after the trip to emergency. There was one infectious disease—I cannot recall the name. A doctor we went to see basically told him it was all in this head as well. That was actually quite shattering for him because he had put all of his faith into thinking that this doctor was going to be able to fix him because he had heard so many great things about him. This was after the second suicide attempt, and he basically belittled him for doing that to his family. I was there at the appointment and you could just see it break him.

Senator MADIGAN: You said in your earlier evidence to us, 'If it's not Lyme, what is it?' Amongst the people who Scott communicated with—fellow sufferers—would you say that that is a common point that they have all got?

Mrs Sullivan: Absolutely. To me, it is criminal. These people are being turned away, and they are sick. They are fighting for their lives, and they are having to find treatment on their own as well as battling each day just trying to get through. I do not blame him at all for doing what he did. I would do the same if I was in his shoes. Something needs to change because it is just going to keep happening.

Senator MADIGAN: Would it be fair to say that the other sufferers, like your brother, and their families just want the government to move on in the medical profession and come together, rather than banging their heads against each other?

Mrs Sullivan: Yes, absolutely. What I cannot understand is why nothing is being done and why denial seems to be reasonable to these doctors.

Senator MADIGAN: Thank you, Mrs Sullivan.

CHAIR: Thank you very much. We are now going into an in camera session.

Proceedings suspended from 09:45 to 10:31

DOBIE, Dr Peter, Secretary, Australian Chronic Infectious and Inflammatory Disease Society

SCHLOEFFEL, Dr Richard John, Chairperson, Australian Chronic Infectious and Inflammatory Disease Society

Evidence from Dr Dobie was taken via teleconference—

CHAIR: I welcome our next witnesses. Have you both been given information on parliamentary privilege and the protection of witnesses and evidence?

Dr Schloeffel: Yes.

Dr Dobie: Yes, I have.

CHAIR: Would you like to add anything about the capacity in which you appear?

Dr Dobie: I am a general practitioner.

Dr Schloeffel: I am the medical director of Pymble Grove Health Centre. I am also an adviser to the tick-borne diseases unit at Sydney university and I have been treating Lyme-like illness for 20 years.

CHAIR: Thank you for appearing today. I invite you both to make short opening statements.

Dr Dobie: I have a five-minute opening statement, if that is acceptable.

CHAIR: Yes.

Dr Dobie: In addition to being secretary of ACIIDS, I am a member of the International Lyme and Associated Diseases Society, commonly referred to as ILADS. I have attended conferences on Lyme disease in the United States and Europe. I am currently treating 180 patients with Lyme disease or Lyme-like illness. Approximately 50 per cent of my patients have acquired the illness in Australia. The preponderance of the evidence suggests that *Borrelia* is the principal causative organism responsible for Lyme-like illness in Australia. *Borrelia* is the bacterium that causes Lyme disease in the United States and Europe. The species of *Borrelia* causing the Australian illness has not yet been formally identified.

I wish to comment on three important issues relating to pathology testing for Lyme disease and Lyme-like illness. The first issue is that most Australian pathology laboratories are doing the wrong blood test for Lyme disease. This is one reason why Lyme disease and Lyme-like illness are underdiagnosed in Australia. Most laboratories are using a test called the ELISA test. This test is not sensitive enough to detect most cases of this illness. There is a large body of scientific opinion that this test should be abandoned because of the high rate of false negatives. The laboratories are using this test because it is the first test in the so-called two-tiered testing protocol for Lyme disease proposed by the CDC in the United States. Under this protocol, the western blot test is not performed unless the ELISA test is positive. This two-tiered testing protocol was, however, established for disease surveillance, not diagnosis. The CDC state that surveillance criteria should not be used for diagnosis. Australian pathologists and infectious disease specialists are incorrectly using surveillance criteria for diagnosis.

Pathology laboratories should be doing western blot and PCR as the frontline tests for Lyme disease, not the ELISA test. If laboratories persist in using the ELISA test and they report a negative result, they should be required to add a note stating that a negative result does not exclude infection. Infectious disease specialists commonly speak of false positives in relation to testing for Lyme disease, but they rarely mention the high false negative rate of the ELISA test. It is the experience of ACIIDS and ILADS doctors that, with regard to laboratory testing for Lyme disease, false negatives are much more common than false positives.

The second issue I want to mention is that patients can have Lyme disease with negative blood tests. This is known as seronegativity, and it appears to be an issue that most Australian doctors, including most infectious disease specialists, are unaware of. Seronegativity means that some patients with Lyme disease do not develop antibodies and will have a negative western blot test as well as a negative ELISA test. There are a large number of scientific papers in the peer reviewed literature relating to seronegativity and Lyme disease. A paper published in *The New England Journal of Medicine* concluded that the presence of chronic Lyme disease cannot be excluded by the absence of antibodies against *Borrelia*. State legislation in Virginia in the United States mandates that all physicians who suspect and test patients for Lyme disease must disclose that a negative test result does not necessarily mean the patient does not have Lyme disease.

The third issue I want to mention relating to pathology regards overseas laboratories that some Australian doctors are using for testing. One of the reasons that doctors are using these overseas laboratories is that these laboratories will do the western blot on request. Doctors treating this illness are not interested in the result of the ELISA test. If Australian laboratories would do the western blot on request, there would be less need for us to use overseas laboratories.

Some doctors have claimed the overseas laboratories are not accredited. That is not true. These laboratories are fully accredited in their own countries. The two laboratories in Germany that are commonly used are fully accredited with DAkkS, the German accreditation authority. There is a reciprocal recognition agreement between NATA, which is the Australian accreditation authority, and DAkkS. Both organisations are signatories to the International Laboratory Accreditation Cooperation. There is thus no rational basis for Australian doctors to reject a result from the German laboratories that Australian doctors are using for Lyme disease testing.

That concludes my opening remarks. Thank you.

CHAIR: Thank you. Dr Schloeffel, do you have an opening statement as well?

Dr Schloeffel: I have a very short opening statement, because I realise that you probably have a lot of questions and, from my point of view, I would like to answer your questions. Basically, I have been treating Lyme-like illness and chronic fatiguing illnesses for 20 years. I have treated 3,500 people with chronic fatigue syndrome, borreliosis and autoimmune disease that I believe have been associated with infections. I have treated 600 patients with borreliosis, and I was sent my first patient with a diagnosis of Lyme disease some 19 or 20 years ago. I was told by the infectious diseases specialist who sent me the patient, 'I can only treat this patient for four weeks; can you take over this patient's management?' This patient had acquired Lyme disease in Norway. This man's blood tests are still used in Australia as a baseline for Westmead and PaLMS laboratory, because he had very strong ELISA tests and western blot. But the thing is I treated him for 2½ years with antibiotics before he became well.

In my experience of treating hundreds of patients and advising hundreds of doctors who refer to me and contact me, including specialists and other GPs, my advice is that a lot of the information given—not just about the diagnosis and treatment of this disease—is totally inadequate for the experience that we have in Australia with this developing and evolving illness. People need much more aggressive treatments, and it is not just about antibiotics. It is about total management of their total health, their mental health, their family situation, how to assist them getting pensions, how to help them rehabilitate once they have received treatment, and making sure that every patient has the right to have proper diagnosis and proper treatment that will lead to a positive outcome.

You may have noticed with the ACIIDS submission that there are 23 doctors in ACIIDS, and we are growing fairly rapidly. Even some infectious diseases specialists have joined ACIIDS. We have other specialist joining ACIIDS. We have treated 4,000 patients in five years. We are currently treating only 1,500 patients. Of the other 2,500 patients we have treated, most are better. They are getting better because they are having an appropriate diagnosis and appropriate treatment, sometimes with long-term antibiotics—oral in the main. But because we have so many sick patients we are doing a lot of intravenous therapies as well, including intravenous antibiotics for long periods of time, which is leading to a positive outcome, but under the same rigor that any intensive therapy would require, and we are doctors who are extremely qualified to do this work.

Unfortunately, there seems to be a thought that this is the realm of illness of the infectious diseases specialists. But I think they are not capable of dealing with the complexity of this illness. This is a much more difficult illness. I am sure they can be helpful, maybe with diagnosis and acute treatment in hospitals, but this is a specialist general practice treatment and diagnosis disease. What we need is more GPs diagnosing and treating this disorder, with the support of specialists, and not the other way around.

CHAIR: Regarding the comment you just made, I take it that you turn on its head what you would normally do in terms of going to an infectious diseases doctor?

Dr Schloeffel: Australia has a fantastic health system. We have extremely good and qualified and extremely expert infectious diseases specialists. But when I see a patient who comes in with a horrendous story like those we have been listening to this morning, obviously they are not getting it. They are not having an intellectual medical insight into what this patient is telling them, because they have this plethora of symptoms—from brain symptoms, to heart symptoms, to weakness, to tremors that do not like epilepsy, and they are told they have some conversion disorder because they are having a seizure. They might have gut problems. They have all these multi-system, multi-dysfunctions in their bodies and there is not a correlation from those symptoms by infectious diseases specialists to see that as an infection. Whereas, if you are an integrative doctor, a GP, you sit there for an hour and a half with every new patient, and you actually pick up that this person obviously has a multi-system disorder. Part of the differential diagnosis would be that they could have borreliosis or a co-infection. Many of the patients do not actually have a history of tick bites. They might have a history of bedbug bites or lice bites. They come from all over the world, because most patients who get Lyme disease that I have seen—say, 50 to 60 per cent—got it the overseas. They got it in America, China, Europe or Africa and came back to Australia. But they are still denied the diagnosis, even though they probably got it elsewhere. Some will remember a rash, but most of them do not.

This error theme and migraines theme that we are talking about is in America. We do not see that very often. But if you are a local patient who gets this Lyme-like illness, you are not likely to get the classic Lyme-like rash, fever, myalgia—a tick bite—and then have four weeks of antibiotics and get better. Most of these people, as you hear, have been sick for years. I take only referrals; I do not see new patients. All the patients I see probably have been diagnosis already with Lyme disease or co-infection and sent to me by other doctors. Some of these patients have had this for 20, 30 or 40 years before they have got to me, or they are the very sick ones who we are hearing a dying because the infection has gone straight to their brain. They have seen the infectious diseases specialist but they had been denied diagnosis and treatment. I am starting to wonder whether, really, they need to go where the doctors are properly trained to actually diagnose this. Does that answer your question?

CHAIR: It does. Infectious diseases doctors are perhaps used to looking at one—

Dr Schloeffel: One entity—one illness. I think it is the presentation. If you get someone with a tick bite and they have a rash and they have encephalitis, of course they go to hospital and see an infectious diseases specialist. They need intravenous antibiotics urgently, whether it is *Borrelia*, *Bartonella*, *Babesia*, or whatever they might have. That this probably relatively rare in the sort of patient groups we are seeing. I am sure it does happen. There are patients—that is what happened to Karl McManus. He was sick within six days of getting a tick bite. He had four weeks of antibiotics and was getting better, but because the criteria in America is four weeks of antibiotics, they stopped the antibiotics and then he progressively got worse and died. I imagine that if he had kept on with the antibiotics for six, 12 or 18 months he probably would have survived. But that is not the current guideline for infectious diseases specialists in Australia.

Senator MADIGAN: In your evidence before you mentioned the Western blot test. I do not want a verbal you, but did you say that the Australian laboratories did not do it, or it is difficult to get it done?

Dr Dobie: It is very difficult to get it done in Australia because Australian pathology laboratories follow what they call a two-tiered testing protocol, where they do the ELISA test first and then they will do the Western blot test only if the ELISA test is positive. The ELISA test has a very high rate of false negatives; it is almost always negative. So it is very hard to get the Western blot test done in Australia. Most laboratories refuse to do it unless the ELISA test is positive.

Senator MADIGAN: Why is there a reticence to do the Western blot test for patients. Is it because of cost or is it because that for them is the absolute? What do you believe it is?

Dr Dobie: It is because Australian pathologists are following what they call the two-tiered testing protocol laid down by the CDC in the United States, which says that the ELISA test should be done first and then the Western blot test should be done only if the ELISA test is positive. The Australian laboratories are following this protocol laid down by the CDC. It is very important here to note that that two-tiered testing protocol was set up for disease surveillance, not diagnosis. It should not be used for diagnosis. Laboratories should discard the ELISA test for Lyme disease, because it is so unreliable. They should just go straight ahead and do the Western blot test, if the doctor requests it.

Senator MADIGAN: Yesterday we heard testimony about how good Australian pathology is. You mentioned the CDC. Does Australian pathology abdicate their thought processes to the CDC? I thought that to question was to learn.

Dr Dobie: In regard to testing for Lyme disease, yes, they have abdicated their thought processes to the CDC, by following CDC guidelines. Australian laboratories do good quality testing. It is a matter of doing the appropriate test. We have difficulty getting the appropriate test in Australia and this is why we often send blood samples to overseas laboratories.

Senator MADIGAN: We heard a lot of evidence yesterday pertaining to tests obtained overseas from laboratories like Agenics and others. We heard evidence that the ISO accreditation that these overseas laboratories have relates only to quality assurance pertaining to, for instance, paperwork and the methodology by which they run their offices, but does not relate to individual tests. Every test that you perform in a laboratory has to have accreditation. Is that correct? Is that your understanding of how the accreditation process is for laboratories?

Dr Dobie: That is my understanding. It is also my understanding that both of the German laboratories we use are fully accredited with DAkkS with regard to ISO. I may be wrong there, but that is my understanding. Both laboratories have told me they are fully accredited with DAkkS, the German accreditation authority.

Senator MADIGAN: Does that mean that the tests that are performed by IGeneX, Infectolab and others are not recognised in Australia? NATA does not recognise their testing, so Australian laboratories do not acknowledge the way they conduct the tests. Is that what they are saying?

Dr Dobie: Australian doctors should recognise the results from these laboratories because of this reciprocal recognition agreement between NATA and DAkkS. That is a German laboratory, so I am not sure about IGeneX in that regard. I am not sure if there is a reciprocal recognition agreement between NATA and the United States.

CHAIR: We can find out from the Chief Scientist next week.

Senator MADIGAN: We have two distinct camps, as Senator Moore has alluded to on numerous occasions today. I go back to the point that we have children who are suffering and, as was said in evidence given previously, children do not have a voice. They cannot explain like an adult what they are suffering from and how they are feeling. Then we have people of all ages, all occupations, all geographic locations around the country who can explain how they are feeling. I note in ACIIDS's submission the fact that ACIIDS is not obsessed with it being tick bites. You are saying it is not just *Borrelia*. You speak about *Rickettsia*, *Babesia*, *Bartonella* and anaplasmosis.

Dr Schloeffel: Multiple infections.

Senator MADIGAN: So you are not absolute. Is it correct that there is one area of potential infection?

Dr Schloeffel: No. I think the trouble is you have two cohorts of patients. You have patients who acquire a vector borne illness from something overseas. Ticks are probably the main vectors that pass these illnesses on, but we know lice and fleas do. There is some evidence coming out now, which is quite disturbing, that mosquitoes can carry this as well as bedbugs. But when I start talking to patients, they will tell me, 'I got bitten by something, but it wasn't a tick.' My Chinese patients will often tell me they got bitten by lice when they were somewhere in China and have come back with a Lyme-like illness, or patients who go to Bali come back with a bedbug bite. They say, 'I got bitten by a bedbug—I saw the bedbug—and within two weeks I was sick and I'm now getting seizures.' They have pain and they get a positive test for *Borrelia* and co-infections. That makes me think that there are many vectors that carry these organisms.

The problem in Australia is that I do not think we have American Lyme disease. I think we have to give up on the term 'Lyme disease'. It is a bad term. Lyme is in America. What we have is multiple infections causing multiple disturbances of the whole body. I would not be surprised if the organism that we have here in Australia is a relapsing fever *Borrelia*, and there may be other forms of *Borrelia*. But relapsing fever *Borrelia* is not picked up on a standard test. If you talk about ELISA, Western blot or even PCR testing, it is difficult.

When you are looking at a tick or a human, you are trying to find an organism that is very small. If you are doing tick studies, you may have hundreds of organisms in that tick and you have to separate one out, looking for *Borrelia*, which is what Peter Irwin has been able to do, and then separate it from the pathogenic germs—viruses, parasites or bacteria—and the non-pathogenic germs that are all present in that vector. Then you have to give it a name. That is the process that has to happen with the ticks.

The trouble is we are still following the science for the ticks, but what we are not looking at is all the patients who are sick. If someone comes in to me and says, 'I had a tick bite two weeks ago and I'm sick,' and the illness evolved following that tick bite and I get evidence that they have so-called Lyme disease or a co-infection, I am obliged to make that diagnosis and treat those patients.

If it is a child, my first thought is: 'Have they had a bite or is it congenital?' I can tell you in my practice I sit there every day seeing babies and children born with Lyme disease and co-infections who are profoundly unwell. So I work with a paediatrician. We have a thousand children with autism. We are starting to find that quite a percentage of those children have positive Lyme tests. We are starting to treat those children with autism spectrum disorder.

On this business about having an area with juvenile arthritis that is seronegative, I would be doing a joint fluid aspiration on every one of those children and PCRing all their joints, looking for *Borrelia*, because I would say those children do not have juvenile rheumatoid arthritis. They most likely have a variation of a tick borne illness causing their arthritis, which is why it is seronegative. So the rheumatoid factor C-reactive protein and ESR are not raised, but their joints are hot and swollen. I see that in adults as well. I see motor neurone disease, Parkinson's disease and EMS. I see people with Alzheimer's disease who are 25, and we are talking about neurological SPECT scans. We can see reduced profusion and they are reported on as consistent with neuroborreliosis or Alzheimer's or their SPECT scans, and they are in their 20s. I find evidence they have tick borne illness.

I think the complication comes in the fact that the science has not caught up with the clinical picture. You look at these patients and you say, 'I have to help this person,' but it is not a matter of just giving them long-term antibiotics. I think we have to get away from that. That may be part of their treatment or they may not even be able to tolerate it. I listened to Sharon Whiteman this morning. She has not been taking long-term antibiotics. She

probably cannot. She is taking some other thing, but she still needs to be supported with all her symptoms and rehabilitated back to health, and antibiotics may have a part in that process. Sorry—that was a long-winded answer.

Senator MADIGAN: So we have babies, children, teenagers and adults suffering.

Dr Schloeffel: Yes, lots of them.

Senator MADIGAN: We have two distinct camps. We have had evidence given to us that says that Lyme disease does not exist in Australia—

Dr Schloeffel: They are wrong.

Senator MADIGAN: because they believe it does not fit the classic Lyme disease from overseas. They tell us the other side of the argument, that they have empathy with the people who are sick and that something is wrong. Very briefly, how can we get the two sides in the room to focus on the patients and to cure these people and restore their health?

Dr Schloeffel: I have spoken to a few people this week, including Peter Irwin and Chris Baggoley, who I speak to regularly, because there is a contention that we are poles apart. I am sure most doctors genuinely want to help patients. That is why we train to be doctors. We have to be compassionate first, but we have to be scientists as well. The trouble with borreliosis and co-infection is the science has not caught up, but the compassion needs to be there. I suggested to Chris that we bring in the researchers. We get Stephen Graves, Peter Irwin and Eddie Holmes from the University of Sydney, who has written a very good submission. We get Professor Collignon. We get doubting Thomases, but not too many—maybe eight of us. We sit down with a couple of ACIIDS doctors and we have a conversation.

In science, you do not always have the evidence if you have an evolving illness. The evidence will follow the evolution of the illness, because people will start researching it. Someone mentioned today it is the end of your career if you start researching tick borne illness. What a lot of nonsense that is.

This is the fastest growing vectorborne illness in the world and we want to put our heads in the sand. We need to sit together in a calm, collaborative environment and have a conversation. We are not quacks. We are extremely good at what we do. We are committed to getting these people better—70 to 80 per cent of my patients recover fully. They get their lives back. The kids are not autistic; they are infected. Kids with juvenile arthritis do not have juvenile arthritis; they have Lyme disease in their joints and they get treated appropriately. They get better.

Ultimately the duty of care of the doctor is to care for the patient. It is not about arguing about the science to deny the treatment. Denialism is not fact and unfortunately doctors are caught in this other paradigm. I do not know where they are coming from, but what I am seeing is that that is dangerous to these patients. You can hear that some of these patients are suffering and some of them die because they cannot make a leap into a new paradigm of illness, and that takes intelligence and discussion. We should sit down in a room with intelligent people with positions of power to make a change. We have to have that conversation. I wish they were all here. I wish I could go and sit down with Professor Colling and have a talk to him. Hopefully Stephen Graves will be here this afternoon so I can talk to him. I am not anti their thoughts. I just think that they are wrong. I just think that they have not shifted their mental processes to recognise that these patients are real. They have positive bugs. I can the measure them and I do what we call levels of evidence.

Lyme disease and co-infection, for want of a better name, is a clinical diagnosis. You develop levels of evidence as you go along treating them. Often the tests become positive the more you treat them, because these are stealth infections hiding within the body tissues. Some of them are hiding in what we call biofilms: parts of the body which are inert. As you treat one infection the other infections seem to come out, and you have this long-term process of chasing your tail until there are no infections left. The reason you do not get good pathology tests is because the body's immune system is actually not reacting against the organisms. It is a problem of the illness. The patient's illness is real but their response to it is difficult to measure. That does not mean they do not have the illness.

Senator WANG: Thank you for coming here today, Doctor. Dr Schloeffel, I understand that you worked on HIV cases in Africa—

Dr Schloeffel: No. It was not in Africa; it was in Australia.

Senator WANG: It was a battle like the battle we are having today, was it not?

Dr Schloeffel: In 1983 I was a GP in Bellingen; I was only very young. I had a few patients and they were gay men who were going to the bathhouses in San Francisco. They developed illnesses that I had never heard of

before—strange pneumonia, strange gut infections—and they became immunosuppressed and they died. So I took an interest in this. Then by the late 80s we were starting see a lot of these people, generally gay men, and we had the bowling ball and the Grim Reaper. We found a virus that caused an infection that lowered the immune response, and when the immune response was low enough people got opportunistic infections. We had a whole army of scientists working this out, finding the virus and developing medications to prevent the virus from replicating, so we actually stopped the epidemic. There was an intellectual process, but it did not happen until children and women who got blood transfusions, and kids who had haemophilia from the blood, started to get sick and die. They went, 'Oh my God! We have to do something'. Before it was only gay men, so it did not matter. There was the same sort of thought process among the medical profession, that some people are better than others and there was no emergency. Then it became very urgent and it was extremely urgent. I buried probably 100 of my male patients who had this disease before we had a treatment. Now, I was a GP treating their co-infections trying to work out how to help their immunity. I was an integrated doctor, even then. Then I went to Byron Bay and worked up there. They were all coming up there to die and I did palliative care. I saw all this, and it was all too late for them. There were a lot of patients that we were able to treat in the early 90s who went on to AZT and the associated medication. They are still alive and still well, just on medication to suppress the virus. Now that is one germ, one entity. The thing is that this illness is a multisystem infection with multiple organisms. Where people get it from is vague. It is sexually transmitted, it comes from blood transfusions, its congenital and it comes from vectors. The array of symptoms is enormous, which makes it different to AIDS, but the problem is the same. If you deny the illness is there but you have all these people sick, then what is wrong with them? If you say to them, 'Yes, you are sick. There's nothing you can do,' or, 'You're just putting it on,' that is not real medicine. That is denialism.

Senator WANG: Yesterday, we had two professors, one of whom said it was difficult to have a rational discussion with irrational people—referring to their patients, basically. When HIV broke out some medical professionals probably thought that because they were gay men they did not matter that much. Given that we have branded the patients irrational, I guess the mentality there is that they probably do not matter that much, either.

Dr Schloeffel: I cannot talk for other doctors and their thought processes, but I would like to say to every doctor in Australia, 'Wake up to yourselves. Start listening that we've got a real illness. Let's have a proper conversation. Let's do the proper science. Let's fund it.' How much money do we put into finding out whether wind turbines hurt you or into the Zika virus, which might affect 50 people? But we have tens of thousands of people with Lyme-like illness and co-infections, some of whom are dying, and they do not get a cent. Where is the research money for these infections? I can tell you the tickborne diseases unit at Sydney uni is funded through the public good of the Karl McManus Foundation. There is no government money; there are no research funds. I know Peter Irwin struggles to get funding for his tick project, even though he is praised for his work. I am 100 per cent sure that he will find the cause of these illnesses—he has already found lots of the bugs, and I am sure he will find a relapsing-fever bacteria. But we have to put money into it, we have to have a proper conversation and the denialism has to stop, because that is actually malpractice. It is actually negligence on the part of the medical profession.

CHAIR: Could I just stop you there. It is easy for us to interact with you but I am conscious, Dr Dobie, that we are talking here quite intensely and it might be hard to get a work in edgewise.

Dr Schloeffel: Sorry, Peter. I've stopped!

CHAIR: I am not having a go.

Dr Schloeffel: No, I get that.

CHAIR: This is a really important discussion and I want to make sure—

Dr Dobie: It is all right—I have been listening with great interest!

CHAIR: Just jump in and then I will know to come to you when we have a break.

Dr Schloeffel: A metaphysical kick, Peter.

Senator WANG: A lot of patients here have a really common story, that it usually takes them years to be able to finally have a positive diagnosis. I suspect that by that time they have already missed the window of opportunity to get the best effective treatment. From experience overseas, how effective is early intervention and probably even immediate treatment after the bite?

Dr Schloeffel: I will give you a quick story. I was on a plane flying to Canberra, a couple of weeks ago, and I was sitting next to an American. I told him I was going to give a talk on Lyme disease. He said, 'I've had Lyme disease. I had a rash on my arm—I got bitten by a tick—it had a bullseye. I went around to the GP and got six weeks of doxycycline and I got over it. I never got the illness.' That would be an ideal situation for anyone in

Australia or anywhere in the world. If you get a vectorborne illness that is atypical, that you have never seen before and it looks like that, it should be automatically four to six weeks of antibiotics, whether you are a child or an adult. The trouble is that people do not even know that they have been bitten by anything, and if you are a child who has this congenitally or someone who may have got it through a blood transfusion or even sexually you are not going to know that there was a beginning of the illness. This disease is a clinical illness, so when you present yourself as a patient to a doctor, every doctor needs to be trained to have in their differential diagnosis, as a matter of course: 'Could this be a tickborne illness or an illness related to a tickborne illness?' There should be a simple—

Senator WANG: It should be on their check list.

Dr Schloeffel: It should be on their differential diagnosis, and then the test that is appropriate should be done—and not an ELISA test. An ELISA test definitely will not pick up—

Dr Dobie: The issue of duration of treatments for Lyme disease is very controversial. In the United States, the Infectious Diseases Society of America says that no Lyme patients need more than four weeks of antibiotics. Four weeks of antibiotics might be enough if you treat someone soon after the tick bite. A lot of people do not get that initial treatment, and many of those people will therefore go on to develop chronic Lyme disease and get very sick and need much more intensive treatment further down the track. So the Infectious Diseases Society of America just does not address the issue of the patient who does not get the initial treatment. They are the people who end up getting very sick and need longer term treatment.

Dr Schloeffel: Yes. Even if you do get treatment, it does not always work, so they call it post-Lyme syndrome. But, really, the patient just has not been adequately treated, or they have other co-infections that were not treated with the antibiotics they were given. One antibiotic generally will not kill this; you need rotational antibiotics—usually oral. Vary rarely do patients need intravenous antibiotics, even though there is a lot of contention around that. It is just that the patients that we see are profoundly sick. Some of them are seizuring up to 23 hours a day. You cannot administer oral antibiotics. You have to do it intravenously. The thing is: when we do all of these treatments long term they get better. The majority of patients will recover if you treat them hard enough, long enough, safely enough in the proper clinical setting. But most patients do not have that opportunity.

Senator WANG: Doctors, very briefly, just tell me: are there any other alternative treatments in place for a Lyme-like illness?

Dr Schloeffel: Peter, do you want to answer that?

Dr Dobie: Alternative treatments? Certainly, the main treatment is antibiotics because it is a bacterial illness. If you look on the internet you will see hundreds of treatments that people have suggested for Lyme disease. Some of them might help in some cases. Many Australians patients have gone to Germany to have hyperthermia treatment, which involves heating the body up to quite a high temperature. This treatment does appear to kill off *Borrelia* bacteria. That treatment, the hyperthermia, could well be an alternative to antibiotics in most cases—or in some cases.

In my experience, a lot of patients use herbal medicines and other alternative treatments for Lyme disease. In my experience, herbal medicines do not actually kill off the bacteria and cure the illness. They might suppress the infection and lead to some symptomatic improvement. But, in my experience, herbal medicines on their own will not cure the illness. Most people do need antibiotics.

Dr Schloeffel: Can I just say something about hyperthermia. I have been to the Klinik St. Georg in Germany and I have been liaising with Dr. Fredrick Douwes. Ninety of my patients have gone there already for hyperthermia treatment at 41 degrees centigrade for eight to nine hours in an intensive care situation, feeding them the antibiotics. I went over to discuss whether we could increase and change the type of antibiotic for the Australian patient to treat the co-infections. So we have been doing a collaborative process. Recently, I have been doing it with Dr Radzi in Malaysia. A lot of our patients are choosing to go there. Many patients who go to these clinics do not have a doctor in Australia. My experience is that hyperthermia treats the *Borrelia*. I was rung on the weekend by a concerned patient who has access to a hyperthermia unit in Australia, but I said to him, 'We're not even at the stage of diagnosis let alone getting an intensive care unit with intensive care specialists'—which is what they do in Germany—'to treat people this way.' But it may be that, for the very sick patients, the neurologically affected patients, hyperthermia is a novel process. If anyone is interested, I can show you slides of the *Borrelia* coming out of cells with hyperthermia, because I have some of them here. But that would not be a mainstream treatment unless you had failed antibiotic treatment and other treatments before doing it.

There are a whole lot of other treatments sprouted like plasmapheresis and stem cell therapy, which some of my very sick patients are having when they have neurological damage. Surprisingly, they are getting better. So

kids who are wheelchair bound and paralysed are now getting up and walking with rehabilitation following stem cell therapy which is being done primarily in Switzerland and in what used to be Yugoslavia—in Zagreb.

Senator MOORE: Doctors, can you tell me that the Australian Chronic Infectious and Inflammatory Disease Society? How does it fit within the medical hierarchy and within colleges, and all of that sort of stuff?

Dr Schloeffel: Three years ago, I met with two of my colleagues—and I have been treating this disorder for 20 years; I have been liaising with an infections disease specialist, and we have been co-treating patients for 20 years. As the number of patients started to increase and there were a few more doctors interested in this, I was contacted to have a meeting. From that meeting—up in Byron Bay, because that was central to where we were—we sat around and wrote the original guidelines for ACIDS, Australian Chronic Infectious Disease Society. We decided to form an organisation of concerned doctors, an incorporated entity, and we asked people to join. We have got 23 members, and it is increasing slowly. We thought we would get 50 or 60 people who said they were going to join, but of the two doctors who were the initial people who set up ACIDS, one has been put on restriction and the other one has got physical ill-health and has medically retired. The other doctors became frightened to join our organisation, because just by association they felt that they would be victimised, persecuted and threatened to be deregistered by APRA.

We have resisted, because science has to progress over denialism. We are a collective of doctors, and we meet regularly. We have Skype meetings. I have clinical meetings at my surgery. I invite people over. We discuss papers and we share papers. We are a scientific organisation of doctors concerned about this illness, and that is all it is. It was created to look at Lyme disease and Lyme-like illness, and now we are doing a recruitment drive. We have several specialists who are joining us, including infectious diseases specialists, who do not wish to be named because of fear of persecution by their colleagues.

Senator MOORE: Do you get people from the colleges?

Dr Schloeffel: I am a senior fellow of the Royal Australian College of General Practitioners.

Senator MOORE: No, I did not mean you personally. Both you and Dr Dobie have listed your own qualifications.

Dr Schloeffel: No, we are an independent body. We are independent, but, by all means, we are happy to engage in education. I would be happy to go and lecture at all the colleges. I would even be happy to go to the infectious diseases conferences and talks to them about this, if that is what is required to have thought process and scientific thought change. At the moment, no, we are independent.

Senator MOORE: What status do the very detailed guidelines that you have given us a copy of have, medically or professionally?

Dr Schloeffel: Professionally, for our group of doctors and the hundreds of GPs that we contact regularly, I say they are just our personal guidelines. They are not approved by anyone other than ourselves, except we try to reference and evidence base everything we have done. We are aligned to ILADS, and also to the German guidelines.

Senator MOORE: We have had significant evidence about the fact that doctors are feeling frightened. That has been put on record yesterday and today, and in many of the submissions. The APRA process has been mentioned also, and it is something that we will follow-up with the department tomorrow, but, my understanding, looking at their guidelines, is that they get involved by complaint.

Dr Schloeffel: Yes, that is correct.

Senator MOORE: They do not do a review.

Dr Schloeffel: It is by complaint from other doctors.

Senator MOORE: They do not just come in off their own bat. Can you give me any information from the doctors that you know of about where those complaints come from?

Dr Schloeffel: The majority of complaints come from other doctors, usually specialists: neurologists, immunologists, infectious diseases specialists—particularly when a patient ends up in hospital. One of the most dangerous places for a patient with borreliosis and co-infections to turn up is in a hospital, because, automatically, the denialism starts and windows go up and the treatment gets stopped. Then who is treating you? And then a report is put in, because 'Lyme disease does not exist; we have to get that doctor.' That is a process that happens sometimes. Sometimes it is because the patient may have a PICC line—and a few patients do have PICC lines, because you cannot give them oral antibiotics or you can not access their veins anymore. Most patients receiving intravenous treatment have not got PICC lines, so we do not get into trouble. And most of those treatments are administered by other GPs other than the Lyme doctors—this group in ACIDS—but the GP does not want to be

named. They will just do the treatment and do not tell anybody, because they think that if they diagnose or treat Lyme disease, someone will dob them in and they will get deregistered just for saying the word.

Senator MOORE: Do you know how many have been?

Dr Schloeffel: Seven.

Senator MOORE: Seven have been deregistered?

Dr Schloeffel: Seven have been put on restrictions, and they are obviously complaints going in. Some have been successfully defended.

Senator MOORE: On notice, can you give us any details on that. Much of the evidence about this—

Dr Schloeffel: They are all different cases under different circumstances.

Senator MOORE: Are they all members of ACIDS?

Dr Schloeffel: No. There may be three that were.

Senator MOORE: We will be asking the department when we meet with them as well, but it just seems that this has been an ongoing issue across the submissions and the evidence.

Dr Schloeffel: The fear is—we are standing up for these patients. These patients deserve care. We have a duty of care to these people. If we deny that, that is a malpractice. So the doctors who are not diagnosing it and not treating it are really open to being reported to AHPRA for malpractice. Once the evidence follows this, I think the cascade will happen. We need to have a conversation with the doctors who do not believe this fairly soon, before they become the victims of complaints. So lack of diagnosis is actually because they have not given it due thought. I do not know where that is going to come from, but I imagine the patients may well get fed up with this. If their families are dying or are so sick, and then someone—I had a patient in hospital the other day, and—

CHAIR: We are way, way, way over time!

Dr Schloeffel: I know, if there is anything else anyone wants to ask—can I say one last thing?

CHAIR: As long as it is short.

Dr Schloeffel: It is very short: the future of Lyme disease in Australia. I was asked this week, by someone from the Senate: how do you see Lyme in the future? What I see is that we have centres of excellence in every capital city in Australia, public and private. Every major town in Australia will have a Lyme literate doctor, that ASIDs and other doctors competent to treat Lyme will train those doctors. We will change our pathology and there will be research arms associated with each one of those clinics. And we will start treating everybody in Australia. That is my wish list, and I wish that will happen sooner rather than later.

Senator MOORE: Like cancer centres.

Dr Schloeffel: Like cancer centres, yes.

CHAIR: I have some questions that I am going to put on notice, around some of the things that have just come up. But we will send them to you, if that is okay with you.

Dr Schloeffel: That is fine.

CHAIR: And the same with Dr Dobie: we will send you those questions on notice too. Some of them are around cost and antibiotics, and the use of antibiotics for something that is not necessarily *Borrelia*, but is still a tick-borne disease. Could you also think about, and I will not get your answer now, the issue around—we heard yesterday that some doctors were saying that using long-term antibiotics could do more harm than good. We would really appreciate a response on that. But we will send you those formally.

Dr Schloeffel: Yes, that is fine; we are happy to do that.

CHAIR: Thank you very much, both of you, for appearing today with the very comprehensive information that you have provided to us.

Dr Dobie: Thank you for giving me the opportunity to contribute.

CHAIR: Thank you.

CURNOW, Mr John Arthur, Veterinarian, Karl McManus Foundation, University of Sydney

McMANUS, Dr Mualla, Director, Karl McManus Foundation, University of Sydney

[11:23]

CHAIR: Welcome. You have been given information on parliamentary privilege and the protection of witnesses and evidence. Is there anything you would like to add to the capacity in which you appear today?

Dr McManus: I am also a researcher at the University of Sydney tick-borne disease unit.

CHAIR: I would like to invite you—one or both of you, depending on what you have organised—to make a short statement, or short statements, and then we will ask you some questions.

Dr McManus: My background is that I am an immunologist, a pharmacologist, a pharmacist, a neuroscientist, and a molecular biologist. My husband Karl passed away from complications from tick-borne diseases in 2010. In 2009, while he was still alive, I formed the Lyme Disease Association. When he passed away in 2010, I formed the Karl McManus foundation. I could not look after both organisations, so I gave it away. I am also an ILADS—International Lyme and Associated Diseases Society—board member as well as a member of the IDSA—Infectious Diseases Society of America. As you can see from my background, I have good capacity to be able to see the intent detail and the patient perspective. John and I have encountered the worst-case scenario of what you might call tick-borne diseases in the sense that both of our spouses have passed away from it. John is a vet and I have a medical background, so we understand the disease at a clinical level, we understand the disease at the scientific level. We also understand the disease at the patient level.

On that basis, I would like to say that as far as I can see—from the patients' clinical symptoms, from the scientific research and from the preliminary results from the tick-borne disease unit—we do not have *Borrelia burgdorferi*, or Lyme disease, in Australia. What we have is a unique *Borrelia* infection. The problem with this disease is the symptoms are non-specific, so not every single Lyme patient ends up with the same set of symptoms. It is very hard to diagnose clinically. You can check the literature: every single publication will say the same thing. In the US they ask for a history of tick bite, and in certain areas like Connecticut it is common to have an EM rash, or the 'bull's-eye' rash, so diagnosis is easier. But in Australia the symptomology is much more broad, and there are a lot more neurological symptoms. So you will end up with patients having seizures, patients having MS-like symptoms, patients having atypical Parkinson—atypical. Most of their symptoms are atypical, so a classical neurologist cannot put them in the perfect box of multiple sclerosis or whatever they are familiar with.

The biggest problem we have in Australia is lack of education. Over the last 20 years, there has not been any emphasis of Lyme disease in medical school curriculum; medical students have not been shown tick-borne diseases. It is considered a rare disease; therefore, it is ignored. The testing is problematic because the bacteria *Borrelia* has got very variable, hypervariable genomes. Basically, it can mutate inside you. If I had a rat injected in one leg with one genome species of *Borrelia* and I took blood from the other leg, I can get a different genospecies. That is not normal; you do not normally find that. If I inject a rat with a *staph. aureus*, or a golden staph, I get the golden staph, but a different strain—not a different genospecies. The reason for this is that this bacteria: (1) can mutate a lot; and (2) it has a lot of phages, or bacterial viruses. I can give you an example. Golden staph has only got one phage, and it is very difficult to eradicate from hospitals because of the way it develops a tolerance to all the treatment protocols. You have a *Borrelia*, the *burgdorferi* one in the US has 21 phages. That means it can dress itself in so many different ways that it can hide in your body—it can change from vector to vector; it can be in a tick; it can be in a deer; it can be in a human—because it has the capacity to change itself so enormously. I do not think that is really understood by the scientific community or by the clinicians.

The significance of this bacteria is that once you are infected with it, you have to be treated early so that it does not disseminate. Once disseminated, it becomes chronic. It is very hard to eradicate. At our conference, Dr Kenneth Liegner came out from the USA. He said that after 20 years of antibiotic treatment on a patient, they took the samples from the synovium, or the knee joint, and they could actually identify the *Borrelia*—after 20 years of treatment. So you are looking at something with a unique pathogen that is emerging, but the problem with this pathogen is that it does it very slowly.

Our society is very good at reacting to acute disease, like a swine flu or the Zika virus—they are acute; within 48 hours you get an effect. With this you do not. You might have got a tick bite five years ago when you went camping in Coffs Harbour, and the symptoms come on five years later because you got immunosuppressed in some way or you were stressed because you went through a divorce or you got pregnant, and the symptoms will flow on. All of a sudden, you have a whole of plethora of symptoms you cannot explain. And you doctor does not know how to interpret them because he is not educated about questioning the diagnosis. All he can do is treat your

irritable bowel syndrome, your tiredness, your depression—he cannot put them all together. And that is really the big thing.

The third thing is that there are lot of infections in there. A tick bite, mosquito bite, midges or flies deliver a lot of infections, and not just bacteria. You have bacteria, protozoa, viruses, worms—anything. It all depends on where the tick has been feeding previously. If the tick has been feeding on an animal that carries a lot of infections, like a bandicoot, which is very tolerant of tick bites—you can have 200 ticks on a bandicoot, which will be fine because they are asymptomatic—but the minute the bacteria or pathogens in a bandicoot come to you, you will be inundated with so many infections that your immune system becomes overwhelmed. That is where we need an extra stage—to test that the immune system is still competent after an acute tick bite. Most of the testing is done using direct techniques and antibodies—serology. In an acute state it is easy to diagnose. But once it becomes disseminated the immune system becomes dysregulated. You do not make the same amount of antibodies. You do not make the same isotypes of the antibodies. You might be stuck in making IgM antibodies. You cannot switch to IgG, which is more efficient in eradicating infection. Your T-cell system, which is your cellular immunity, might not be functioning well. You do not have enough interferon to produce the rest of the cascade of the immune response that actually kills off the infection. So you have a patient who is constantly ill, has depression and all sorts of problems, and there are so many problems that the average doctor, without the education, is not able to address these issues for the patient. The patient goes along, is suffering, and then they go on to the internet and realise, 'My god, my symptoms fit this. I've got Lyme disease.' But Lyme disease is something that is common on the east coast of the USA. It is not even common on the west coast of the USA, because on the west coast you are more likely to get relapsing fever borrelia, and the testing becomes problematic on that basis.

In Australia, we use a two-tier testing system, which Peter Dobie was talking about. The first tier is supposed to be of high sensitivity; it is supposed to detect everything. Your western blot is supposed to give you specificity. That is how the ELISA and western blot tests are designed. I suggested in one of our meetings with the clinical advisory committee that if a patient is prepared to pay $100 to get a western blot test without an ELISA test then that should be allowed, because it is not costing Medicare any money. But it was definitely ruled out by the consulting immunologists from Sullivan Nicolaides on the clinical advisory committee.

We need to change our view. The government only thinks of Lyme disease, and follows the CDC criteria. I have an explanation for borrelia, and I will just pass it on to all of the panel. We have *Borrelia burgdorferi*, and a subset of that is Lyme disease. We have relapsing fever, and it has over 20 genospecies already. We have reptilian borrelia, but the infection has not yet been found in humans. So if we concentrate on Lyme disease we are missing out on 80 per cent of other borrelia infections, and that is really dangerous. We are being short-sighted. Some of the relapsing fever genospecies can produce 80 per cent of their infections neurologically, but there is no research, because relapsing fever is a poor-country disease. It is endemic in Africa, Asia, India, Indonesia and Vietnam. All the focus is on Lyme disease; everyone makes such a fuss about it. Lyme disease, *Borrelia burgdorferi* sensu stricto, is much easier to treat than relapsing fever. This is something that has not been understood. I even suggested to Professor Baggoley and Dr Gary Lum on the clinical advisory committee that the case definition include the symptoms of relapsing fever because, for all we know, we cannot say that Australia only has *Borrelia burgdorferi*. We could have a unique class of borrelia. That is one problem.

The second problem is multiple infections. The scientific community is not in a state to understand the multiple infections. Over 100 years ago, Koch's postulates were formulated to say, 'You have one infection, one specific set of symptoms—we give you one antibiotic.' That was the treatment. But when you come to something with four or five infections—which one do you treat first? Which is the prominent one that produced the symptoms?

Doctors do not know. We do not know. There are no clinical trials. There are no investigations into it, because most of the research community thinks that it is too hard to handle. Most of the research on Lyme disease or any species of *Borrelia* looks at acute disease because it is easier to follow. You have got a tick bite, you have got history and you can detect it because the immune system is competent and you can follow it through and treat it. But when it comes to chronic—I have talked to IDSA members. They do not know what to do. ILADS tried to do something about it. They tried to give long-term antibiotics.

CHAIR: We are going to have to ask you to wind up very shortly, in case Mr Curnow wants to say something. As you can see, we have got senators who are really interested in asking questions.

Dr McManus: Basically, long-term antibiotics is the fact that we—for TB, if you treat for three months you only get 30 per cent recovery. If you treat for six months, you get 60 per cent. You have got to treat for nine months to get proper recovery. The idea that six weeks of antibiotics will treat the disease is not right, but neither is the idea that you treat it indefinitely with antibiotics. Somewhere in the middle is the right answer. That can

only happen by monitoring the patient's immune system. Once the patient's immune system gets back to normal and becomes competent, then the patient's immune system can eradicate the infection. Presently there are no studies about following patients from treatment, monitoring the immune parameters and looking to see when they are competent and then taking them off the antibiotics.

Mr Curnow: I am a veterinarian who, in the 1960s, was employed by the Commonwealth government to find out if *Babesia* was endemic in New South Wales. I used tests developed by the CSIRO in Brisbane. These tests were very effective as a diagnostic, not in picking up the immune response but just the diagnosis of the presence of the infection. This is what is needed with *Borrelia*. We did 170,000 tests and did not get one false positive. We did a lot of checking on the negatives and did not get any false negatives. I think that some of these older tests should at least be tried with *Borrelia*. One in particular, the indirect haemagglutination test, is so effective that you could use it on a blood sample you were going to use for a blood transfusion. That is something you cannot do now. I think this is very essential to preventing the spread of this, because all of these are potentially able to be spread by blood transfusions. In fact, I do not think I would like to have a blood transfusion in this country at the present time.

After this work, I moved on and did some work on how, why and when *Babesia argentina* relapsed. We could pick when it relapsed by taking daily blood smears from the calves and seeing the organisms. That happened about once a month for a couple of days. We could prove that each of the times that it relapsed they had changed their antigens, and it was a new antigenic make-up of the protozoa. When those variants were put through ticks, they all reverted to a single form. That was a 'serotype' or the strain.

Doing this work, I became sure that any test that worked on immune antibodies was doomed to fail, and that is what the ELISA test has done. We need to develop better tests that pick up just the presence of infection and are not affected by the immune process. This was borne out when they tested those 4,300 people between 1988 and 1994 and did not get any positives. It was pretty obvious that we were not dealing with *burgdorferi*; we were dealing with another. Unfortunately, instead of stopping the testing and going back and re-treating people like they had done previously—and also sought money for research and, particularly, started early treatment after a tick bite. I mean that every person that had a tick bite would be entitled to get the drugs through pharmacist.

Pharmacists are trained in the administration of drugs. Why can't you just turn up and get them? They did not do it. They continued with the ELISA test for 20 years. My wife was tested in 2011, and was negative, of course. She did not get to having the western blot. She died at the end of that year. Knowing how these tests work, and having been involved with them, and knowing how good they are, I am very upset about what has been done. These other doctors will tell you, these ELISA tests are useless, particularly on these organisms here. We might get an ELISA test for a specific organism we isolate, but it will still only be 50 per cent because it picks up these variants all the time. They get in the way. You cannot produce an antigen that covers all infections.

I found this with the work we did on *Babesia argentina* in 1970. I am not only blaming Australia; the Americans also charged ahead with the ELISA test and they have got into trouble. Over there, they do not say a negative ELISA test means you do not get treated; it does here, even if you are lucky enough to get an ELISA test. It took me 4½ years to get an ELISA test for my wife through public hospitals. That is why I think a lot of money should be spent going back and doing basic research and developing serological tests which work. You must have a test that can be done quickly, easily and accurately.

Senator WANG: I lack medical experience and knowledge, so if I can interpret this situation. When people are talking about classic Lyme, if I could use an analogy, they are probably talking about hepatitis B. What we are discovering in Australia, potentially, could be hepatitis A, C or D. Is it possible that classic Lyme is only a subgroup of a larger cohort of problems—a whole range of symptoms that is caused by a range of bugs?

Dr McManus: In Australia, classical Lyme would be any patient who travels in an area that is endemic with Lyme, *Borrelia burgdorferi* sensu stricto. In a sense, that would be classical Lyme. If you are talking about patients that have been bitten in Australia, that would not be classified as classical Lyme. It is probably, in an analogous way, hepatitis A, B, C, D, or E. That is where the genospecies separates into different bacteria in the family of *Borrelia*.

Senator WANG: If I may put it this way, if the doctors were denying Lyme exists in Australia, they were basically saying, 'Oh, it is not hepatitis B that was discovered in America', for example, 'therefore it is not hepatitis at all'.

Dr McManus: That is true, but then a similar problem exists in the United States, because if a patient gets tested for Lyme and they are negative, the diagnostic tree diagram does not say, 'Well, if the patient does not have *Borrelia burgdorferi,* can the patient have other *Borrelia* infections?' That has not gone into the thinking. The

patient is given six weeks of antibiotics, and then they say: 'You have post-Lyme syndrome. We just have to give you palliative care to support you through your life'. That is not the answer. The answer is that there is a bigger picture of *Borrelia* and, if I understand, relapsing fever *Borrelia* gives you a different immune response. If you have relapsing fever *Borrelia* infection, you will continually have IgM production because the bacteria changes its membrane proteins in a different way. The body is fooled into thinking there is a new infection all of the time, so you keep making IgM. You do not switch to IgG. You will see that most patients in Australia have IgM positive Western Blots from IGeneX. Under CDC criteria, you are meant to get IgM positivity within six weeks of a tick bite. Most of the patients in Australia have been sick for 10 to 20 years. So their IgM positivity under CDC criteria is not a true CDC positivity; it is actually an indication or suggestion that they may have relapsing fever infection, and that needs to be investigated. But there is not much research on it. Most of the research on relapsing fever is done by the WHO in Africa. Even within the relapsing fever group, we have *Borrelia duttonii* at the extreme end and then you have *Borrelia burgdorferi* sensu stricto at the other end. In between there is a stream of different genospecies which will give you different virulence, different specificities, different properties and different ways of dysregulating the patient. So for everyone to concentrate on Lyme is being very short-sighted. We really have to look at the big picture; that way, everyone can come to the table. In focusing on Lyme you are going to create silos, with everyone going, 'It's here; it's not here; it's not here,' but you could go: 'There is a *Borrelia* infection; let's sit down and talk about it; let's see how we can actually move forward and solve the problem.' It is not just in Australia—it is global.

Senator WANG: Yesterday we heard: 'Certain animals can be reservoirs for *Borrelia*; humans can't be a reservoir.' Is that your understanding as well? Not coming from the profession, I struggled to understand the concept.

Dr McManus: They are not the classical reservoir because usually a tick will bite an animal and each bite allows it to morph into different stages of the life cycle. They commonly bite animals that they encounter, whether deer, mice, rats, foxes or sheep. Humans are what we call 'accidental hosts'. What is an accidental host? If you are continually being exposed to ticks and continually getting tick bites, a human can potentially become another host in the development of the tick cycle. So, initially, yes, but, later on, no.

Mr Curnow: I think they were talking about *Ixodes holocyclus*, the commonest tick. At the larval stage, if they attach to a human and they mature, it has been found that most of them will die. CSL, years ago, tried to raise them for producing tick antivenene, and they found that, if you did not raise them on bandicoots—the larvae—there was such a high mortality that they gave up trying. So, even today, *Ixodes holocyclus* for producing antivenene are collected in the field.

Senator MOORE: Dr McManus, I want to find out about something from your very detailed submission—and thank you very much for it. One of the things you say in it is that you are the only charity that is operating to raise funds and get awareness of this in Australia at the moment. It also says that a lot of the money is used for research and for having conferences. Can you give us any idea about the nature of those conferences, the size of them and the kinds of people who go there?

Dr McManus: From 2013 to 2015, we hosted the tick-borne disease conference in Sydney. We had international plenary speakers invited. Dr Ken Liegner came the first year. We even got Professor Diego Cadavid, who is a relapsing fever specialist who works at Boston's general hospital; he talked to us via satellite.

The idea of the conferences was for them to be a platform where everyone could come and discuss and work out ways of moving forward, and that is why it was not a Lyme conference; it was a tick-borne disease conference. So if you were working in *Ehrlichia* you came along. We even had a professor who was the head of the CDC come out and talk to us about anaplasmosis. We had lots of GPs attending. We had interested parties from all over. I even sent an email to each of the colleges of medicine and also the body that actually advises the colleges of medicine and invited all the members of the colleges of medicine to come to the conference for free—but no-one attended, because, I think, there was some sort of peer-group pressure. They all sort of interpreted it as being a Lyme disease conference when it was not. It was a platform for everyone to come and talk. Professor Baggoley came for the first one. Gary Lum came for the next one. So we had very much an international flavour, and it was okay to have a 'yes' idea or a 'no' idea; it did not matter—it was an opinion. And yet most of the college of medicine members were reluctant to come. I have no idea why—I have tried. I even contacted the college of medicine's secretary and wanted to speak to the person who was involved, and they said, 'We can't force all the different members to attend.' After this Senate committee hearing I am hoping that, when we hold our next conference next year, they will be more likely to attend. We want to hear everyone's opinion, and the only way a problem can be resolved is if people talk to each other. If they do not talk you will just continue going on in the same silence, and nothing will be solved.

There is a common ground—everyone agrees that there is something in our ticks that is making people ill in Australia. We have Australians travelling overseas—9.2 million Australians have travelled overseas in 2014-2015—and a lot of them would have come back with some sort of a bite from overseas. Yet we do not have the knowledge in the medical fraternity to address these people and treat them. A lot of them get misdiagnosed, and that is not right. It is not a question of whether Lyme disease exists or not, because they come from an infected endemic area. It is only because the knowledge is not there. Most of the doctors do not understand it is a disease. I think there is a very urgent need for education for all of the medical fraternity, as well as the public, about the dangers of tick bites or any kind of bite that you might have. It is a stealth infection, and all we are doing is adding more and more people to the list of people who have become chronically ill, which we cannot really address. The best way is to prevent those patients from becoming chronically ill by getting them early.

Senator MOORE: We are talking a lot in this committee about the need for people to talk to each other instead of going into opposing camps and just throwing bombs, which seems to be happening. You said that the CMO and Dr Lum both attended. Do they just come in for their paper and then go, or are they active participants?

Dr McManus: No, they stay for the whole of the conferences.

Senator MOORE: That is really positive, and we have not had that kind of information before. Are you intending to have another one?

Dr McManus: In 2017.

Senator MOORE: Did the CMO or Dr Lum present a paper?

Dr McManus: At the first conference Professor Baggoley spoke about it. With the others I think Dr Lum sat there and took notes, because we had Professor Yoshinari from Brazil. We were looking at the similarity with Brazil because we are both Southern Hemisphere countries. They have some sort of Borrelia, but they did not call it Lyme disease—they called it Baggio–Yoshinari syndrome so that they did not have to comply with the CDC. The minute you put the Lyme name on it the CDC hunts you down and says, 'You've got to follow our criteria.' If you change the name you do not have to worry about that.

Senator MADIGAN: Thank you, Mr Curnow and Dr McManus. Yesterday we heard evidence about, as you say, the classical Lyme. I think we heard that four species of Borrelia are attached to the meaning box—that is, as you said, in the endemic areas, whether that be in the United States or Germany or wherever—and they have got different strains. Have I got that right?

Dr McManus: That is a genospecies.

Senator MADIGAN: Different genospecies? Okay. Would it not be plausible that we may have our own Borrelia that is indigenous to Australia? Let's park the classic Lyme overseas, but focus on the Borrelia: we may well have our own indigenous Borrelia in Australia that presents with similar symptoms to what people get from the European or the American Borrelia, or other symptoms—it attacks a person's immune system.

Dr McManus: That is quite possible, because already Peter Irwin has isolated relapsing fever Borrelia from a *Ixodes holocyclus* tick, and I think he found more of the same relaxing fever Borrelia in echidna ticks. Because echidna ticks do not bite humans he is making a presumption that it is not likely to be infectious but, on the other hand, there is a *Borrelia miyamotoi* which was found in 1995 that was only recently found to be infectious in humans. Relapsing fever *Borrelia* is supposed to only exist in soft ticks and *Borrelia burgdorferi* Lyme borreliosis is supposed to exist in hard ticks. But this *miyamotoi* is a relapsing *Borrelia* existing in hard ticks. It presents with symptoms. You can get an EM rash from *miyamotoi* and you can get all of the classical Lyme-like symptoms, but you can also get symptoms of relapsing fever. So we have a genospecies that has a combination of characteristics of both relapsing fever and your *Borrelia burgdorferi* class. In a sense, as I have said, because of the hypervariability of the genome of this bacteria, you were going to get species like that all along.

The other classical example is that there is a reptilian *Borrelia* which is a unique class on its own, but half of its DNA is *Borrelia burgdorferi* and half of its DNA is relapsing fever. It will produce a different set of symptoms, but it has not been found to be infectious in humans. It has not been isolated because it is most commonly found in the Middle East. Now it has been isolated from an amblyomma tick. Amblyomma ticks can bite humans, and a camel tick in the Middle East is an amblyomma tick. Australian veterans have been to the Middle East, Iraq and Afghanistan. In those places the actual hard tick would be hard to find because the idea of a perfect environment for a hard tick is 28 degrees. They come out in spring, lay 8,000 eggs and develop on. But in those areas where you have the desert there are no trees, so you are basically going to find ticks under rocks and in caves. If somebody fighting sits down in a cave to rest and gets bitten, they do not get an EM rash or any symptoms, and then they go back home and develop these seizures and things they would call Gulf War syndrome. Professor Garth Nicolson tested patients for Lyme *Borrelia* and they were not positive. They were positive for *Mycoplasma*

fermentans, but he did not test them for relapsing fever *Borrelia* because relapsing fever *Borrelia* testing is not common. In Australia, if you have relapsing fever *Borrelia* and if your doctor asks for relapsing fever *Borrelia* testing, no lab in Australia can do it; they do not have the capacity. We are missing out on information that could actually help in the diagnosis of the patient.

Senator MADIGAN: In layman's terms, it is a bit like cars. We have Holdens, Toyotas, Fords, Kias and god knows what else. They are all cars and they all transport us and get us to our destinations. They all have brakes and tyres, but they have different brakes and tyres that do the same job. Would that be right?

Dr McManus: That would be pretty analogous.

Senator MADIGAN: So what you are saying is that we have different brands of *Borrelia*. There are four brands of *Borrelia* that are attributed to the US and Germany.

Dr McManus: There are only four brands known to be infectious, but within that group to date there are 18. Every couple of months is a new one being discovered.

Senator MADIGAN: But there are four that are in that classic diagnosis. We know, as you have just said, that there are many others being identified but are not attributed to the classic thing. But it does not mean that they cannot—like a Kia or a Holden can get you to Sydney. So people are still getting sick. Going back to what I said earlier, we may well have our indigenous ones. People are still getting sick, but we have to not be obsessed about this diagnosis of it being one of those four.

Dr McManus: That is right. Indigenous Australia genospecies would have different characteristics and they may even have a different vector. It may be totally different because Australia is an old continent. I can give you an example. For a long time we thought that there was no leishmaniasis in Australia, until recently when they looked in some midges. Leishmaniasis usually lives in sandflies in Africa, so all along they were looking for it in sandflies and could not find it. Then a couple of years ago they looked in midges in the Northern Territory and they found it in midges. Our leishmaniasis was older than the African one, in genealogical terminology, so we probably have *Borrelia* and it is probably older than the American *Borrelia* or the Asian *Borrelia*.

Senator MADIGAN: Mr Curnow, you are a vet. From your evidence, you said that there has been research into how ticks affect animals going back decades in Australia.

Mr Curnow: *Borrelias* go back to 1905, when it was in chooks.

Senator MADIGAN: Yes. We heard yesterday that it was found in fowl.

Mr Curnow: Since then we have had it in kangaroos and in rodents, and also in bandicoots and cattle.

CHAIR: In Australia—

Mr Curnow: Yes, in cattle. We used to always see it in cattle that we were using.

Senator MADIGAN: There has been concern about how *Borrelia* affects animals going back decades in Australia.

Mr Curnow: Mainly poultry. The others are not so affected. The cattle did not seem to produce much in the way of symptoms. We were more worried about *Babesia*.

Senator MADIGAN: For decades, the veterinary sciences have been concerned about *Borrelia* in chooks. It is interesting, this concern, from the veterinary side as to the effects on animals and birds, but we have not had the same concern with *Borrelia* and how it may, or does, affect humans.

Mr Curnow: No. We have.

Dr McManus: The CSIRO actually had an anti-tick vaccine made to the Bm86 antigen, which is a protein in the tick's gut, back in the 1980s. The whole idea was that if a tick bit a cow it would drop off because it could not suck the blood, but then they never thought that there is a farmer next to the cattle so the tick can still bite the farmer.

CHAIR: Thank you very much. We have run out of time. I do not think we gave you any homework—we call that 'questions on notice'. Did you undertake to provide any more information on anything?

Dr McManus: Today? I was not contacted.

CHAIR: No, I meant during the discussion. Did you say you would provide more information? I do not think you did this time.

Dr McManus: I was going to give you handouts. I can give you these which will have more information.

CHAIR: Thank you very much for your evidence today. It is very much appreciated.

HARDY, Dr Margaret, Private capacity

[12:02]

CHAIR: Dr Hardy, can I double-check that information on parliamentary privilege and the protection of witnesses and evidence has been provided to you?

Dr Hardy: Yes, absolutely.

CHAIR: Thank you. Do you have any comments to make about the capacity in which you appear?

Dr Hardy: I work as a research fellow at the University of Queensland in the Institute for Molecular Bioscience.

CHAIR: Thank you and welcome. I invite you to make a short statement and then we will ask you some questions.

Dr Hardy: Thank you for having me. I want to first acknowledge that I think that the patients who have come forward are, in fact, suffering from a disease, and I want to acknowledge what they have gone through.

My own background is in entomology, which is the study of insects, and I have a PhD in chemistry. My research program is focused on the discovery of new insecticides and repellents, and acaricides, that attack ticks. I isolate those from the venom of native Australian spiders including funnel-web spiders and tarantulas.

The best way, obviously, to prevent having a tick-borne disease is to not get bitten by a tick in the first place. So I think that the emphasis on prevention is really valuable, and more research into looking at technologies that can help to stop people from getting bitten by ticks in the first place is really critical. Investment into that space from a research perspective would be really valuable.

Secondly, I obviously have an accent. I am originally from Boston, which is at the epicentre of Lyme disease proper in the United States. Something like 96 per cent of all cases of Lyme disease in the United States happen in 14 states, and they are all in New England and in the Upper Midwest. They are all adjacent states. When a place has Lyme disease, they have capital L Lyme—it is very common.

CHAIR: What we are calling 'classic' Lyme at the moment.

Dr Hardy: That is right. And the same thing happens in Europe; there are another group of species of *Borrelia*. So there is a genus of bacteria called *Borrelia*, and inside that genus there are different species. Just as we are *Homo sapiens*, within *Homo* there have been several other groups, including a great one that came out through some Australian researchers, *Homo naledi*, which you might have heard of. It is a way that scientists group organisms so that we can talk about them in a useful way. Under this *Borrelia* umbrella, we have probably 20 different species, and not all of them cause a Lyme-like illness, either classic Lyme or something similar.

Some really interesting work is happening in Scotland at the moment. The Scottish Highlands have an incredible prevalence of Lyme disease; something like 2,000 to 3,000 cases are diagnosed every year. It is not what I will call the American *Borrelia*. It is not the American Lyme disease. It is a different species. They realised that their testing was coming back positive for *Borrelia*, so it was showing that there was something there, but it was irregular. So they have gone back and done their own clinical development. They have their own laboratory assays as well as their own clinical diagnostics.

In Europe, when someone with Lyme disease presents to a physician, they do not have that classic bullseye rash. In America, something like 75 per cent of people that have Lyme disease have this big bullseye rash, and it is very distinctive. It is really obvious what it is. In Europe that does not tend to happen. They have a different set of manifestations of, again, the umbrella *Borrelia* but, inside that, a different species. That different group actually presents differently if they go to the GP.

The CDC say, 'You have a case of Lyme disease,' if you have a clinician's diagnosis—if you go to your GP and they say, 'Yes, these are the criteria for Lyme disease,' the bullseye rash and other things, and then they do a diagnostic test. They do some chemistries. There are two different tests that they use. One is a test based on PCR, which is polymerase chain reaction. It is very common for scientists. Essentially, you are looking for a fingerprint. It looks for a very specific signature in the DNA of an organism. That is what forensic scientists sometimes use when they are looking at someone's hair and whether it links them to a particular crime. So this is a very, very commonly used scientific technique. It is very accurate, and it can be used to match that fingerprint to parts of the *Borrelia* genome that are very specific to that umbrella group of *Borrelia*—not just the one species, like American Lyme, but *Borrelia* more broadly. It is very accurate in picking up who is who and what is going on.

If you do have an irregularity in the test, that is when those other clinical scientists come back and we can redevelop the assay for whatever particular species is more prevalent in those areas. You can test for more than one species at once and you can do the same kinds of tests over and over, and they are very reproducible. For a scientist, that is kind of the gold standard: 'If I do it once and it works, that's great, but I have to be able to do it reliably every time.'

Really interestingly, in Australia—this was just published in 2015—an Australian GP picked up Lyme disease in someone who had just returned from being overseas. That suggests to me that in fact our tests are working and that we can pick up cases of Lyme disease if people return to Australia with it. I think there is some really good news there.

There is another interesting paper that came out recently that described a number of pathogens, some of which are novel—they have not been described before—that are coming out of ticks. They are pathogens like *Rickettsia* that cause Q fever, tick typhus, Flinders Island spotted fever. All of those are part of a larger group. So we have the *Borrelia* umbrella and a whole separate group over here called *Rickettsia*, and other related ones. You can see *Borrelia* under a microscope, and in the 1990s a group of Australian scientists dissected ticks and looked for *Borrelia*. It looks like a corkscrew, a very, very distinctive shape under a microscope. They dissected a whole bunch of ticks from across the country and could not find it. Because it is something that takes a vector, the tick is necessary for transmission. So, if it is not in a tick, then it would be difficult for it to get into a human because the ticks kind of have to drive it from one to another.

In Australia we have a number of animals which are not found in other places—we have many marsupials; other places, not so much—and that may suggest that we have different kinds of bacteria or pathogens, which is pretty reasonable to expect. So I think the fact that we are now finding entirely new types of pathogens, as in they cause a disease, means that our tests are working.

The other thing that I would share is that, when we talk about the need for better diagnoses for Lyme, I think it is important that we at least acknowledge the fact that, in places where they do have Lyme disease—it is endemic—the same tests are used to diagnose it there. They are what we are using to diagnose it here. I think it is important that we maintain standards that are global, in terms of how we do our investigations here, and that we respond to best practices across the world.

As to that kind of *Rickettsia,* that new type of pathogen that has been found in Australian ticks: *Rickettsia* are what we call pleomorphic, which means that they have a very variable 'outer space', as it were. When you look at them under a microscope, you can see filaments and long strings; you might see rods; you might see short, fat, little cushions, but they are all the same kind of bacteria; they are all *Rickettsia*. *Borrelia*—which is what causes Lyme disease; under that umbrella—are a very distinctive corkscrew shape; they always look like a corkscrew. This other one is very difficult to see under a microscope. You could not look at someone's serum or cerebrospinal fluid and know, necessarily, what it was unless you were a real expert.

It is interesting to me that we have these two, kind of, very different things—that *Rickettsia* is not a notifiable disease in Australia. We probably have fewer than eight cases a year of it, so it is not very common. Again, in the United States, when they have it, something like 96 per cent of cases come from one geographic area, and it is the fifth most common notifiable disease in the United States. Again, where we have Lyme disease, we have capital L Lyme; we have a large concentration—all of our patients are in one place. That level of disease means that, across the country, it is the No. 5 most commonly notified disease in the United States. It is very similar in Europe as well. The places where they have Lyme disease, where they have *Borrelia*—so not the American Lyme, but *Borrelia* and that umbrella of species—they have very high concentrations, particularly in the Scottish Highlands. In some geographic locations, they have much higher concentrations of Lyme disease.

Senator MADIGAN: In your submission you say that tick typhus is found in Australia and that it is linked to *Rickettsia*. Is that right?

Dr Hardy: That is right.

Senator MADIGAN: So you say *Rickettsia* has been found and we have got our own, possibly indigenous, form of *Borrelia*, and then the other one is—is it *Babesia*?

Dr Hardy: Those are three different things. *Babesia* is a parasite, like malaria. That is a different group of pathogen. *Borrelia* is a bacterium and so is *Rickettsia*, but they are two different types of bacterium. The *Borrelia* that we have in Australia is avian, so it is the same kind of thing that is found in birds and poultry. It is a big problem for the livestock industry, so you can certainly be sure that our producers and our growers are very concerned about having it in Australia and that they keep those outbreaks very small where possible. We have really good treatments for that as well, but it is the same kind of thing where—do you remember when swine flu

and avian flu first came out? That is a virus, so that is different, again, from a parasite or bacteria. Influenza is a virus. The big problem there was that it actually jumped. It was originally found in poultry and it is a livestock issue—it is not great, but that is what it is—but then it jumped across to people and then we got really worried. The problem happens when the actual influenza strain mutates so that it goes into humans and it is a different thing.

What is happening with arthropod-vectored illness is that it just exists in the animals—it does not really hurt them. It gets into humans and then we have a problem. In the United States, deer and mice transmit it. It does not really do anything to them.

With the paralysis tick that we have here, which is unique to Australia, its native host is the bandicoot. Bandicoots can carry ticks and it does not hurt them, because there is a neurotoxin in the saliva—which is, again, different from a bacteria, a virus or a parasite. This is actually a toxin. It is not a venom, but it is something like a venom, where it causes neurological symptoms and paralysis.

Senator MADIGAN: Is that similar to Q fever?

Dr Hardy: *Rickettsia* causes Q fever, tick typhus and scrub typhus. They are all different types of—

Senator MADIGAN: Can people who are working in abattoirs or people working in saleyards contract Q fever from cattle?

Dr Hardy: We have a very effective vaccination program for those people that are in direct contact and might pick up Q fever. There is a really strong vaccination program to prevent those folks from getting it in the first place. Vaccination is a really good option when you can.

Senator MADIGAN: But there is some ignorance amongst people working in these places as to the fact that they can be exposed to that, isn't there?

Dr Hardy: No, I reckon they are pretty onto it now—once people start getting sick around you. The vaccination program has been very successful on a national level. In a lot of abattoirs we will have in-work vaccination programs. That *Rickettsia* issue is a bit little separate from some of what you are talking about here, for the Lyme-like illness. That being said, *Borrelia* and *Rickettsia*—those two umbrellas of different types of bacteria—do cause similar symptoms, but they are kind of nondescript. It is kind of like generally feeling unwell. You may have a fever. The bullseye rash is very common in the United States—60 to 70 per cent of cases have it there. It is not very common in Europe. It kind of depends. You are just generally feeling unwell. Then the clinician has to link it back to either a tick bite or you being in an area. Like I said, in the US there are those 14 states where, if you have been outside in the woods in one of those, there is a pretty good chance that you might have been bitten by a deer tick. In the United States, the ticks are the size of the head of a pin. I grew up there and I have never had Lyme disease. No matter how prevalent it was, even in places where you had a large outbreak of Lyme, it was still pretty hard to get it.

Senator MADIGAN: You spoke about how prevention is better than cure, so you would be supportive of a program to make people aware that, if you are in tick areas—like we have heard about in earlier evidence today—people are warned to keep an eye on their children, for instance, when they are out playing et cetera, or people working in the bush, or people working in a wool store for instance. I have heard evidence from people I have spoken to who have worked in wool stores that—this is about 20 years ago—they were told to keep their sleeves rolled down while they were grading wool in wool stores because tick bites were common.

Dr Hardy: Because of the paralysis tick I would say that is pretty good advice in the first place. Here it is something that is very bad for pets. That paralysis tick is also potentially lethal for young children. If you do not find it and it continues to inject that part of the saliva that causes that neurological reaction, you can definitely be in trouble. I think it is probably smart advice in general, if you have an area where there are ticks, to try to keep them off you.

Also I am being mindful of the fact that we only have a limited amount of money for research in Australia. Certainly, if there were a way we could ally ourselves with somewhere like the United States, where they have a massive amount of money for science research, I could almost guarantee that, if there were the potential to find Lyme here, we would have done it already so that we could access some of that funding from the United States. There is a very good chance if they find it in other places that they have collaborations in place. We would be very keen to work with any kind of evidence that there actually is *Borrelia* in humans in Australia—again, because we could leverage that on the global scale, collaborating with the United States and Europe to work on the problem together. But the evidence simply is not there, from what we have seen. That being said, clearly there is something happening here and it could be one of those things like Q fever or tick typhus—one of the *Rickettsia*.

Again, antibiotics have been shown to not necessarily be effective in curing either Lyme or Lyme-like disease or tick typhus. Certain antibiotics in particular do not work at all on tick typhus. I think we need to have a better understanding of what we are dealing with and what could potentially work against it. Again, certain classes of antibiotic that we have just do not work against *Rickettsia*.

Senator MADIGAN: Finally, while you were sitting here today you would have heard that there are two different camps. We are told that both camps acknowledge that people are sick. We heard earlier evidence from Dr Schloeffel and Dr McManus. Are you supportive of getting the two sides in the room to try to work out what the hell is going on for these people?

Dr Hardy: Absolutely. As a scientist who is working in an environment where our grant success rates are regularly sub par 10 per cent when we write grants and things like that, it is very important that we are intelligently spending the limited research dollars that we do have. We have a very good chance of having Zika virus come into Australia, which is the one that causes microcephaly; that has massive downstream effects for pregnancy and the community at large, because those babies that grow up after having Zika in utero will require long-term care from the government.

We have some real challenges ahead of us with what is happening on a global scale as part of this global economy. We have a lot of tourism coming in. We have cruise ships and we have cargo ships. So I think it is important that we are spending the limited budget that we have, for research and research scientists, prudently.

That being said, I think there clearly is something at work here. I am looking only at the peer-reviewed published literature and at labs that are verified with the CDC that they are used. That is government data, it is stuff from the CDC and the literature. That suggests that there is no *Borrelia* in Australia.

Senator MADIGAN: But we cannot have a closed mind, can we?

Dr Hardy: I agree. I think we should be evidence based. I think we should look at the peer reviewed evidence that is put in front of us, and I think we should rely on best practices that have been developed by a global consortium of scientists. Again, we have a limited research budget in Australia. I think it is important that we spend that wisely.

Senator WANG: Thank you, Dr Hardy. I just have a simple question—my famous lie again! Are you familiar with a vaccination that was once produced in the USA but stopped production in the year 2012, I believe?

Dr Hardy: A vaccination against Lyme disease?

Senator WANG: Yes. Have you ever heard of it?

Dr Hardy: I have not, but I would be surprised if it worked. If it worked, clearly it would be rolled out across the US, I would imagine, particularly near my home town, where it is essentially in epidemic proportions.

Senator WANG: Have you ever heard about vaccination for dogs against Lyme?

Dr Hardy: No. Again, prevention is the best option, particularly with your pets. We have really good technologies for flea and tick collars that actually repel the fleas and ticks from biting the dogs in the first place. It is the same thing with DEET insect repellent: that works against ticks really well. So in that column it was always DEET and the dogs always had flea and tick collars. Again, the best offence is a good defence. So we were always really conscientious, growing up, about making sure that we were protected properly and things like that going outside. I have three kids under three here, and I did the same thing here in Australia, because paralysis ticks can have really nasty long-term effects.

Senator WANG: So you have never heard of the vaccines. Are you aware of any pharmaceutical company that is looking to develop a vaccine for Lyme?

Dr Hardy: I would certainly help whoever is doing the one for Q fever. That is a distinctly Australian disease. There is money from the government to subsidise that. So I can imagine that, if whoever has been industrious enough to find and develop a vaccine for Q fever has the opportunity to do something for another tick-borne disease, someone has certainly been working on it. Again, in Australia it probably would not be as relevant, because there is no evidence to suggest that we have *Borrelia* here.

Senator WANG: Thank you.

CHAIR: I just want to check something. Am I to take it from what you have been saying that there is a potential that we have an as yet undiscovered unique species of *Borrelia*?

Dr Hardy: No, I absolutely would not suggest that. The recent data that has come out of a group in Western Australia shows that they found a new group of pathogens from ticks that are in that *Rickettsia* kind of clade.

CHAIR: Yes, we heard that yesterday.

Dr Hardy: Yes. So that is the newest evidence, I would suggest. The only *Borrelia* we have in Australia is found in poultry. It is a livestock issue and it does not jump to humans. It is not what we call a zoonosis.

CHAIR: So you think there are other pathogens such as *Rickettsia* or something like that that may be responsible for the symptoms that we are seeing here.

Dr Hardy: To me it is a much more parsimonious answer, isn't it? Rather than trying to make the jump that we have an entirely novel species of *Borrelia* which has never been found or described before, really it seems like we just have something else. In Australia we have a much smaller population than places like the US and Europe, and we would not have as many cases, full stop, of anything here, because we have fewer people. None of those few people that have had a Lyme-like illness have tested positive for *Borrelia* based on the protocols that are global best practice. Again, this is the same kind of testing protocol they have used in Europe, where again they have different species of *Borrelia*. The idea is that we have something that is completely novel and that no scientist has bothered to describe yet—because it would be a massive deal for us if a scientist could be a part of helping so many people. I imagine any one of us would dedicate our lives to that. So the fact that that has not happened so far, to me, suggests it is probably something else.

Rickettsia is very similar and it causes very similar symptoms, and it would not be picked up by a test for Lyme disease, because it is not Lyme disease. It is not under that umbrella of *Borrelia*; it is over here, under this umbrella of *Rickettsia*. Again, we have several native types of *Rickettsia* that are causing problems already: Q fever, tick typhus, Flinders Island spotted fever. Those are already here. They are endemic to Australia. They are only found here. So to me there is a much stronger case for the idea that we would potentially have more like that than over here, with this pile of negative data we have so far, which is peer reviewed, published in the literature and publicly available to anyone.

CHAIR: In your experience from the American evidence, classic Lyme disease in the States, as you have just articulated, is really clear. Is there a body of people in a similar situation to what we have here—they have symptoms but are then testing negative when they are testing for *Borrelia*, and they have similar sorts of co-infections or symptoms that we are seeing here?

Dr Hardy: Absolutely. The potential there is that you cannot always find the bacteria. If it goes down to a lower number of bacterial spores or units per mL of blood, for example, that means you need a very high level of sensitivity to detect—which is what that ELISA allows us to do in the PCR. They are very sensitive. Again, they are the ones looking for the specific fingerprint of *Borrelia*. They can detect very low loads. The CDC does have an allowance, however, for people that clinically present with symptoms but who have a negative diagnostic laboratory result for Lyme disease. They now call those probable cases of Lyme disease. You can see in one of the plots in my submission that they have a different bar on top of people who could be treated for Lyme disease—they likely have it—but who have returned a negative laboratory result, for whatever reason, because of what is going on.

Again, antibiotics are not necessarily always curing Lyme disease. There probably is no cure. In many cases, it can just reduce the load below where it is detectable. But there are a number of viruses and bacteria that we live with all the time that are existing in our bodies and do not really do much. So that is a kind of thing like staph aureus in hospitals; most of us carry it, but it is only really a problem if you have a compromised immune system or it gets internal when you have just had surgery, for example. Most of us have staph aureus already. We have golden staph in our nose and in our mucous membranes. It is common; it is just not something that is a big concern.

There is the potential that people have contracted Lyme disease—they have the bacteria. Antibiotics may not treat and fully eliminate the *Borrelia* from their system. There have only been seven cases of death related to Lyme disease since the 1980s. Those were because of something called Lyme carditis. That is when the bacteria actually gets into your heart and interferes with the mechanical rhythm of your heart. Lyme disease itself is generally not considered a fatal disease. People certainly live with chronic symptoms that are very problematic, very long term. It is something akin to chronic fatigue syndrome, as well. The two are often confused. That is another problem because, again, there are non-specific symptoms of having Lyme disease. If you do not have that bull's-eye rash, which is very indicative of American Lyme disease, then it is very difficult for doctors to say definitively, 'This is what you have.' Once it has gone on for a little while—so you have felt unwell, you have had a tick bite, you have let it go and then you have finally gone to the doctor—it may be difficult for them to diagnose that right away. That does not necessarily mean that you have it. Again, we cannot see it in the blood, the CSF, the serum. People have looked for it. They have not found it in ticks in Australia. If it is not in the vector and if it is not in the blood, the serum or the cerebrospinal fluid, then there is a very good chance that it is not there. But people have certainly looked. If you could find it, it would be an absolutely top-notch accomplishment

for Australian science. I would be delighted to make that kind of a contribution because, again, people are really in pain.

Senator WANG: You mentioned that our test procedure here is identical to what is being used in Europe. Am I correct?

Dr Hardy: I would say that it is similar—likely, yes.

Senator WANG: We definitely heard evidence yesterday that claimed that our procedure is superior to what they are using in Europe, in fact.

Dr Hardy: Outstanding. That would be great. The sensitivity of the assays is only as good as the amount of fingerprint that you have. They all operate on the same basis. It is little bit of comparing apples and apples with that one. In the Australian system, whatever the tests are, they did pick up the Lyme disease that came back in a returned traveller. That was just in the last two years. He came back in 2014 with Lyme disease. They picked it up, treated him and away he went. The tests in Australia certainly do work well enough to detect Lyme disease, if it is here.

Senator WANG: To detect the American Lyme?

Dr Hardy: Again, if it looks like a duck, walks like a duck and quacks like a duck, then it is probably a duck. That kind of *Borrelia* that we look for in those fingerprints are the very broad parts of the genome that are similar to any one *Borrelia.* So any member under that umbrella—that is what we look for. That is why they picked them up in Europe, as well. They are different species, but because they are in that species of Lyme-causing *Borrelia*, it picks up that fingerprint.

Senator WANG: Is it possible, given our geographic isolation over millions of years, that the umbrella itself is actually bigger than we thought it would be; that whatever bugs we have in Australia are probably the great-grandparents of your umbrella?

Dr Hardy: I would suggest that we probably just have a different umbrella. I think it is probably something more *Rickettsia*-like here, which is what we already have. We know we have a number of indigenous, endemic types of tick typhus that are under that *Rickettsia* umbrella. The only *Borrelia* we have was brought in on poultry livestock. There are no chickens that are native to Australia. Those are all imported; they are all invasive. We maintain them as livestock but they are not native. And they are certainly not native diseases. The ticks that we have here are endemic. The *Ixodes* ticks' native host is a bandicoot, so they certainly are endemic to Australia. Again, we have mosquitoes that are endemic to Australia that can transmit Zika and that does not mean we have Zika virus. The same goes for malaria and for dengue.

Again, America and Europe are much more geographically close as well, so it would make sense that if you had two co-evolving types of *Borrelia* you would see them across that close geographic range rather than coming all the way up from there, missing Africa and Asia entirely, and popping up over in Australia.

Senator WANG: Chair, can I suggest that some of the experts in this room today may have some response to what Dr Hardy just said. Are we going to allow them to make a written submission?

CHAIR: If people want to make a supplementary submission they are more than welcome to make a supplementary submission.

Senator WANG: Thank you.

CHAIR: We have run out of time. Thank you for your evidence today. It is much appreciated, as is everybody who gave evidence this morning. We will suspend until one o'clock, when we will start back with two-minute statements.

Proceedings suspended from 12:31 to 13:10

BAKER, Mrs Wanda, Private capacity

BALLARD, Ms Ailsa Victoria, Private capacity

BARSBY, Ms Leanne Bridget, Private capacity

BRADLEY, Mrs Rhonda Ruth, Private capacity

CHAPMAN, Mrs Wendy, Private capacity

ELLIS, Ms Dianne Elizabeth, Private capacity

EVANS, Ms Yvonne Denise, Private capacity

GRAY, Mr Barry, Private capacity

HANSEN, Ms Julieanne, Private capacity

SEEKAMP, Ms Vikki, Private capacity

SIMONSEN, Mr Jason Andrew, Private capacity

CHAIR: Welcome. Yesterday, what we found worked best was to ask each person to state their name and then make their two-minute statement. Megan will tap a glass at two minutes, and that is obviously the signal that we need to move on. I hope that is okay with everybody.

Mrs Bradley: I am here today representing my daughter Carolyn, who is 35 years of age. She is not well and not able to attend today. I thank the senators for having the inquiry. Senators, we have a dream that one day this nation will rise up and provide all of its citizens with access to affordable, unprejudiced and world-class health care for all illnesses, not just those with an acceptable name. We have a dream that our medical professionals will one day be able to provide their patients with holistic health care, without fear of recrimination. We have a dream that one day every citizen of this great nation of ours will be able to trust their healthcare professionals once more.

Ladies and gentlemen of the committee, in chasing this dream we will maintain the highest level of dignity, integrity, hope and resilience. So, senators, we note you have a choice. Will you enable our dream to become a reality or will you allow the proliferation of misery and suffering and the senseless discrimination of innocent Australians suffering from Lyme-like illnesses to continue on your watch? The choice is yours. Thank you.

Mr Gray: I live on the Gold Coast. I have Lyme disease. It was confirmed positive by blood tests. I represent the expected 30 to 60 per cent of Lyme sufferers in Australia who did not become infected in Australia. I have a European strain of *Borrelia*, which I contracted in Austria in 2002. I was not aware of the infection at the time. I returned to Australia soon after, and then of course the symptoms started. There are thousands of people living in Australia who, like me, are suffering the same indignity and barriers to medical diagnosis and treatment after having contracted a Lyme-like illness in Australia. Whichever group you belong to, there is a simple reality: you will not get diagnosed for Lyme disease in Australia by going via the medical system.

There is a process that I am sure every single person who made a submission to this committee would have gone through. First of all, they would have heard about Lyme disease from a friend or an associate or via the media, such as TV, as I did. Beforehand I had never heard of it. As I said, I contracted it in 2002. It is pretty well exactly one year ago that I was diagnosed. The second thing they will do is a Google search—Dr Google, which everybody says not to use. There you will find the Lyme Disease Association, which almost always comes up first, and from there you will find a Lyme doctor. Anyone not following this process will not get diagnosed with Lyme disease. Visiting the Lyme Disease Association website will take you to the doctors. You can make an appointment to see the Lyme disease specialist, and from there everything in your life is going to change. As far as treatment from the medical profession goes, I am disgusted at the way the medical profession is. If I may read from my submission: I have had such disgusting treatment from the medical paternity. My respect for the medical profession is all but destroyed. Business ahead of health care is the oath that doctors have taken.

Doctors are only saying to their patients what they are being told by the AMA, MBA or AHPRA—I do not know who heads it up. The government, AHPRA, the Medical Board of Australia, whoever, are the ones that are telling these doctors it does not exist, and they are the ones that are risking their licences. Of course, if your business is at risk, what are you going to do?

Mr Simonsen: In 2011, I was living in England but I came back to Australia for a short holiday. I was bitten by a tick. Basically, I had classic facial palsy. I went and saw a doctor near my parents' place. He said that I had had a stroke. I underwent a stroke test, and everything was okay. I returned to England, where I ended up in emergency care in hospital for a week. I was pretty close to dying. I was lucky enough to have treatment from a

doctor who understood Lyme-type disease, who took one look at me and said, 'That is what you have,' and ran all the tests. They all came back to say that that is what I had. I was extremely ill. Now, five years on, I still suffer. When I get run down or anything like that, I get an outbreak. I have been in hospital. I am getting better at managing the signs of when I need to pull up, but normally, I will go into hospital every two to three months, with either joint pain or cellulitis that has basically come from a joint exploding. I will get outbreaks where I got bitten, which is relatively painful. All I ask for is that we come up with at least an acknowledgement that there is a Lyme-type illness that is in Australia. Whether we have found the bacteria or not is irrelevant to me, because people are sick.

Ms Hansen: I am here because I am evidence, as well, that there is something here in Australia. My children and I have an infection that is compromising our ability to function. We have all tested positive for *Borrelia* by PCR. I saw a tick bite me. I had a bullseye rash. I had strange flu-like symptoms two weeks later. It happened in Australia. I believe that I passed it on to my children through pregnancy. Even though diagnosis is difficult, GPs need to have diagnostic tools available to them. They need to have the symptom checklist of Lyme-like illness to offer to patients. There is no good reason to deny patients who have chronic, debilitating, unexplained illness information that may help them to find answers. Doing this questionnaire allows a patient information, and based on their score, allows them the opportunity to choose to have pathology tests. Once you know that you have a specific infection, you can choose treatments that may help, instead of treatments that waste time and money and that possibly aggravate your condition.

With a positive diagnosis, a person has some way to explain the unexplainable to colleagues, friends, family and teachers. The Australian public needs to be informed through media sources that this inquiry has determined that these types of infections exist in Australia, and that doctors have received information to do the first level of diagnosis, so that anyone who has been misled in the past, or who is facing this in the future, will have the opportunity to seek help and not be turned away. The Australian public needs to be informed through media sources that this inquiry has determined that these types of infections exist in Australia and that doctors have received information to do the first level of diagnosis so that anyone who has been misled in the past or is facing this in the future will have the opportunity to seek help and not be turned away. If I had simply known that the bullseye rash I experienced many years ago was an important symptom that indicated I needed treatment, then so much pain and loss could have been avoided.

My father taught me to swim with the rip, and that is how my children and I have survived. I am treading water, holding up two children. The medical system is stuck on the rocks. Way before Lyme I learnt that the medical profession does the best it can, but they are swamped and they do not know everything. I see the responses from authorities added to the inquiry. They are debating if the rip exists, how they can test if it is a true rip and who has the accreditation required to tell if it is a rip. I am so relieved to see people on the beach now, but I need to know that you are not just going to write a report about what you see. I need decisions to be made that will save my children from sinking. I want my children and I to please receive the critical, effective and timely treatment that we need. Thank you.

Ms Ellis: As a child always in the bush, ticks were a common thing. In 1989 I was very sick and had every medication, vaccination and procedure the doctors gave me. For the next 20 years I pushed through symptoms of chronic fatigue. In April 2009 I was bitten by over 20 small ticks. I had a severe reaction, with fevers and sweats all night. The next day I was prescribed one course of antibiotics. One week later I went to hospital with heart troubles. I was told I had anxiety, given Valium and sent home. I refused the Valium and stated that I had been fine before the tick bites. I saw every medical and natural practitioner I could. By the end of 2009 I was barely able to walk, sleep or eat. I spent one week in hospital seriously unwell, in agony all day every day. I was told I had anxiety and I was sent home with Xanax. I saw a natural therapist who saved my life using gentle liver cleansing. I worked hard to gain strength, became active and looked well, but for the next four years I was in agony every single day.

In November 2013 I was given a clinical diagnosis of Lyme disease and began treatment with a holistic Lyme specialist in America via phone. My health improved quite a lot, but I still struggled. With intense natural treatment I now have very few Lyme symptoms. I am working to repair the damage to my body, which is successful but can be challenging. If I feel well enough I compete in longboard surfing. Last year I came third in the national titles for my age group and won a local sports award for my efforts, despite Lyme disease. Lyme disease, Lyme-like illness, tick-borne disease or whatever you want to call it has been an agonising and horrific experience. It has had a devastating effect on myself and my children. I had to sell my home to pay medical expenses. How many more people's lives need to be devastated before our government and medical establishment

will assist people to prevent this? I do not know what I have had, and I do not care. I just care that I am much better and living a productive life again.

Ms Barsby: However crazy this may sound, over eight years my quality of life had diminished to the point where I was struggling to survive. Being a patient symptomatic of Borrelia or Lyme disease with a positive test to co-infections and parasite infections is not enough to get treatment. As Lyme disease does not exist in Australia, I could only be treated for my co-infection, ehrlichiosis. Lucky for me it is the same treatment as for *Borrelia burgdorferi* or Lyme disease, Lyme-like, tick-borne—whatever you want to call it. Doctors are unfair in treating too many patients with large quantities of antibiotics as they appear to be oversubscribing their patients, risking their career—for example, Dr Andrew Ladhams, who I did try to go and see, but I could not get in. He was overwhelmed and has since been struck off.

My story is interesting because we lost our home, we lost our business, we lost the cars, five people lost their employment. My husband became my full-time carer. I am now 100 per cent well. I have a fantastic life. We have a new business. My husband saved my life. I did not even know his name—I was in bed and could not get out. He would bath me. He cooked, he cleaned, he washed, he ironed, he worked, he supported me, he did not leave me. He loves me. He said: 'If you die, I die. I'm going to fight for you.'

He found some help. We found a doctor who diagnosed me. Then I found a doctor who gave me the antibiotics under my co-infection. Two and a half years on, I am well. I have my high heels on. I run my business. I work from home. I go out. I walk. I run. I can get up the staircase and my knees do not hurt. My ears do not ring. I do not wear sunglasses. I can handle sound. I go to the movies. My seizures have stopped. I had seizures every day. I could not get out of bed. I know my husband's name, and he has his wife back, and he is a very happy man, and I am happy I have my life back. You can get better. Antibiotics, in the long term, do work. You pulse them, dissolve the biofilm, do all the natural things you can do and change your diet. I do everything; it is not just one thing. Antibiotics are not the one cure; it is everything. My arsenal—my weaponry that I use—is everything, and I beat it. I am here. I am well. I am here to say you can get better, because I am proof.

CHAIR: Thank you for sharing your experiences. You have probably heard me say this, but it is only through hearing people's lived experiences that we gain an understanding of the impact on people's lives—whether it is Lyme, Lyme-like illness or, as you said, tick-vector-borne illness. So thank you.

Ms Evans: I first got sick 43 years ago. I am female, and I do not really like to say how old I am, but I am 63 in a couple of weeks, and that means over two-thirds of my life has been lost to this hell. There has not been a day when I have not woken up in extreme pain and wondered how on earth I would get through that day. Forty-three years is 16,000 days of waking up and wondering how you are going to get through. Ms Whiteman said this morning that anybody who says that this disease does not exist or it is all in your head should spend an hour in our bodies. I have spent over 200,000 hours in this body, and I have begged for help.

For the first 12 years, there was no help—just pats on the back: 'There, there. It's hormonal. It's all this.' Then I met somebody who said to me, 'You have chronic fatigue syndrome,' but I was ridiculed by the rest of the medical profession, who did not believe in chronic fatigue syndrome. Funnily enough, 30 years later they believe in it. I was told, 'You've got food allergies; that's what's causing it.' I was ridiculed and laughed at, but 30 years later food allergies are accepted. I was told, 'You've got a meat allergy,' and doctors said, 'Oh, you couldn't possibly be allergic to meat,' but, funnily enough, last year researchers decided people are allergic to meat after tick bites. I was told, 'You've got chemical sensitivities and you need to go and live in a bubble.' I had kids. You cannot do that. But 30 years later the researchers have decided, 'Yes, people are allergic to chemicals.'

I watched my son deteriorate from the age of nine to the age of 19, and I took him to the emergency department, where they laughed at me for trying to tell them what was wrong with him. My son did not make it to his 21st birthday; he took his life, and I found him.

Please do not wait 30 years to say this exists. We are here. We are sick. There is something wrong, and I do not care what name it is given. I do not care whether it is this genome or that genome or whatever. Please just accept we are sick, we need help and it is up to this Senate inquiry. You can do something and actually bring Australia forward 25 years instead of waiting. Thank you.

Ms Ballard: I am here for my daughter. She is 39 now and she has had Lyme-like disease for eight years. I see her struggle every day. She has done the doctor safari and been everywhere. The story is just so familiar. She eventually found a doctor who was also an Ayurveda practitioner and she is getting some relief. It worries me how many drugs she is taking. I see her and there is this box of medicines, supplements and whatever, and that worries me. The other thing that worries me is the downward spiral. From the financial point of view, they are too sick and they cannot work. Then there is their mortgage, as you probably heard some other people say.

What I want to say to you is that I am very grateful and thankful that this inquiry has happened, and thankful to the researchers and the medicos because they have given us hope. You have all given us hope, and that is a big thing—hope that there will be money for research and education, and that from that will come some sort of a cure for these people.

My daughter was a very active girl. She used to bushwalk and do all those sorts of things. Her tick was in her head behind her ponytail. Her friend found it, so there was no chance of seeing a rash or anything like that. She just said to me, 'I just want my life back.' Hopefully, something will come of this. Thank you all.

Mrs Baker: As parents, all we ultimately want for our children is for them to be happy and healthy. My husband and I, who had healthy lifestyles, thought we were providing the best possible lives for our children. Our lives changed dramatically during my sixth pregnancy almost 20 years ago, when I experienced five threatened miscarriages. My health deteriorated further after our son's birth. After 16 years of misdiagnoses and mistreatment and approximately 40 years of less debilitating symptoms, I eventually tested positive for borrelia in 2013. It was also CDC positive, making it a very strong positive.

I believe that I contracted borrelia through in utero transmission from my mother, who was severely unwell, misdiagnosed and often severely mistreated through various Brisbane and South-East Queensland hospitals for over 40 years. My father, who died when I was 12 and already a foster child, also had many symptoms associated with borrelia and bartonella, a common co-infection of borrelia. Devastatingly, I have passed borrelia on to at least some of our six children, with three out of three also testing positive so far.

Our youngest son, now almost 19, has lost much of the past 10 years of his life to borrelia, which he tested positive for 18 months ago. Prior to that, he had seen dozens of doctors and specialists who failed to diagnose or treat him effectively, including a team of several specialists at a major Brisbane hospital when he was 13 and struggling to do homeschooling after already being very unwell with severe and constant nausea, headaches, migraines and very debilitating fatigue, et cetera. After approximately a year of various tests and no diagnosis, these specialists recommended putting our son into hospital for two weeks to do lumbar punctures and other invasive procedures. We instead chose to take him to an integrative doctor whose diagnosis and treatment improved his symptoms and allowed him to return to his mainstream school. Two years later, after contracting a virus that compromised his immune system, some of his previous symptoms returned and he again needed to be homeschooled during his important final year of school. He then tested positive for *Borrelia* and gained improvement from treatment.

During this experience, we became very aware of the need for our teachers and educators to gain a greater knowledge and understanding of this Lyme-like illness so that students are not incorrectly labelled as school avoiders or told they could not be that bad, and so that their parents are not accused of enabling their children to avoid attending school. It has been heartbreaking watching our children suffer so greatly and miss out on so many normal opportunities in life, including marriage and having children. This illness has had an enormous impact on our family, including financially. The hell we have endured as a family is not the life we had planned for our children and could have been avoided if *Borrelia* was recognised and treated by medical professionals in Australia.

Ms Seekamp: I am representing my daughter, Becky, who was too unwell to come today. Becky suffers chronic pain all day, every day, and this morning I just could not get her to the car.

Becky is a very intelligent girl. She was studying anthropology and psychology and worked for Tour Whitsunday up in the Airlie Beach area. They chose her to be a tour guide because of her bubbly personality and her gift with people. She had the tick bite at Airlie Beach. She got the tick bite and she did not know. She did not see a tick but she had the bullseye rash—she is one of them who did get the rash. She felt very unwell. She went to Proserpine Hospital, where they said: 'It's a spider bite. Go home. Just watch it. If you are concerned in a couple of weeks go and see your GP.' She went to her GP and they said: 'That's a spider bite. Don't worry about it. It will go away in time. There is nothing that you can really do about it. It's not severe. You'll be fine.' So she went home and she continued to deteriorate.

She presented with massive glands, swelling in her neck like big sausages, and could not get any help up there. They thought it might have been Hodgkin lymphoma or leukaemia. We did not want to muck around in a small area like that, so she came down to Brisbane and lived with me for six months, where we did the rounds of the hospitals and the doctors. In the end, they took them out. It was all negative. There was nothing. Every test came back negative. So, she had physical signs. This is not just a mental thing, this is not fatigue; this is something. All these things were presenting physically. She got no help anywhere she went.

Becky has now got a diagnosis, proven positive, from America and from Germany. She has a chronic case of this. She is 29 years of age and single. Her partner has had to give away work as a ship's captain from up there. They have now moved to the Gold Coast to try and get some treatment of some sort to save them, because at the moment her right arm shakes, her jaw shakes and her tongue shakes as well. These are not imaginary things. She has had an X-ray of her brain to say she has got early-stage dementia. She waited three months to see a neurologist and, when she got in to see him, within three minutes he said: 'Look, I'll see three more people like you today. You need to get a psychiatrist and sort out what is going on in your head because you are creating these symptoms through thinking about them too much.'

Becky cannot access any medical help. It has cost us $70,000 or $80,000 so far and she is no better at this stage. The future: does she get married? Does she pass it on to a partner? Does she have children and pass it on to her children? What is her future? We really need your help. Please, come to a conclusion with this.

Mrs Chapman: My name is Wendy Chapman. I have *Borrelia burgdorferi* confirmed by blood in Germany, in ArminLabs. I am not sure how long I have had Lyme disease but I have been very sick for the last few years. I was bedridden for months. I spent 80 per cent of my time in bed, horizontal, for many more months after that. If it was not for the support of my husband, who saw me in bed when he left for work, came home to see me in bed week after week, cooked for me and cared for me, I do not know how I would be. My limited knowledge of natural therapy, which is a passion for me, has kept me alive. I have no doubt that if I did not get the support that I have got to date I would be dead. I went from doctor to doctor—specialist—and nobody knew what was wrong with me. I had full body scans, X-rays, MRIs, SPECT scans. Everything has come through clear. It was not until I had the blood test confirmed and was able to get some treatment that things started to change. Up until that point I was using a walker to get around and I was heading for a wheelchair at the end of last year.

This has caused an enormous stress on my family—my children, who have watched me be so unwell for so long, and my husband, who has been relentless at supporting me—but nobody knows what it is like to be in the body of a Lymey, and I really do not wish it upon anyone, ever. I have endured so much pain in my life from various different things—operations and knee reconstructions—and nothing has prepared me for the sort of pain that I have endured day after day, week after week and month after month with this illness, Chronic Inflammatory Response Syndrome, trying to do small things like even readjust the washing machine when it is overloaded—to actually lift up the washing causes pain—to make it to the washing machine and not be able to make it back to the bedroom. Just basic daily things.

Something has to happen here. This is real. For doctors to say that Lyme does not exist in Australia is just rubbish. Lyme exists. It exists in me and it exists in us, so it exists in Australia. We need to do something about it. It is a holistic approach. Some people cannot go on just antibiotics. Some people need herbs and some people need both. We have to look at this on a much larger scale of what we need on so many different levels. Doctors say that it is in your head and not to think about it. You have to think about it. If you cannot make it from your bed to the kitchen you are thinking about it: how am I going to get from one place to another? I am worried about blood and organ donation. I would never donate blood or tissue. Sorry, I am getting a bit passionate and I could go on. We need help. We need support. Families need support. My children might have it, too, and how much is it going to cost them to get tested if it has cost me over $20,000 so far, and a mortgage on my home.

CHAIR: Thanks all of you for sharing your lived experience. You have heard me say before and it is true: hearing from you gives us an understanding of how it actually impacts on people's lives.

BATES, Mr John Robert, Chair, Public Health Laboratory Network

GRAVES, Professor Stephen Roger, Spokesman on Lyme Disease, Royal College of Pathologists of Australasia; and Australian Rickettsial Reference Laboratory

[13:42]

CHAIR: Welcome. Have you been given information on parliamentary privilege and the protection of witnesses and evidence?

Prof. Graves: Yes.

Mr Bates: Yes.

CHAIR: I invite both of you to make opening statements and then we will ask you some questions.

Mr Bates: I represent the Public Health Laboratory Network, which is the principal body promoting public health testing in Australia. As such, we promote best practice throughout Australia in pathology laboratories and we enforce the accreditation of laboratories, through NATA and the Royal College of Pathologists of Australasia, to ensure that the highest levels of testing are available throughout the country.

Laboratories cannot test for things that they do not know exist. Lyme disease is a well-characterised syndrome and as such we promote the testing for Lyme disease in Australia following the two-tiered system, using the immunoassay screening test and the immunoblot as a confirmatory test, or PCR, which is performed in a couple of specialist laboratories within Australia.

We are bolstered by the work of Professor Irwin. We think it is very interesting that some new agents have been identified. But, obviously, until those agents are fully characterised and we can see some evidence that those agents are occurring in patients, then it is very difficult to develop pathology tests to test for those things in afflicted people.

The other exciting area of work that we are seeing as a laboratory network whose role is to respond to emerging diseases is the new field of metagenomics, with whole genome sequencing, which shows great promise in pathogen discovery. When you are faced with someone who has a range of symptoms, you can take a sample from them and test for basically everything under the sun. We believe that Professor Irwin's work in this area will shed new light on this syndrome.

Prof. Graves: It is very hard to know where to start as it is such a big topic. I think I would like to start by saying that there is clearly something in Australian ticks, or some species of Australian ticks, that is making some Australians sick. I think that is a given. The question is, what is it, and why don't we always succeed in diagnosing it? That is the conundrum we are in. We have sick patients—you heard some of them today. There are lots of them. They often were very healthy and fit before they got bitten by a tick and then they got sick and their sickness has progressed for a long, long time. So there is something going on here, but we have not really got a proper handle on it yet.

What do we know, though? Can I just go back a step and say what we are reasonably confident about at this point in time. There is a big unknown but we can test quite effectively for Lyme disease as it occurs in returned travellers from North America and Europe. I say that categorically. There are several laboratories in Australia that can and do diagnose Lyme disease correctly in returned travellers from endemic areas. My laboratory is one of them. I have tested about a dozen patients now who have had no Lyme disease from North America, Europe or England, and they have come back and they have tested positive in my laboratory for all of the assays.

When we test people in Australia who think they have Lyme disease, or say they have Lyme-like illness, these assays, these tests, sometimes come up positive but mostly they do not. When they do come up positive they are not complete—full bottle, if you like. There might be one or two assays that come up positive but not all of them. I have not yet found—and I have tested almost 1,000 patients in my laboratory—one Australian patient, a non-travelling Australian patient, where all the assays have come up positive the same as they do in patients from Lyme disease endemic areas. What does this say to me? It says to me that what our poor patients in Australia are suffering from is not classic Lyme disease. So I think we can put that to one side now and say that it is not classic Lyme disease; it is something else.

So, what is it? It is something that they are getting from a tick bite that we are not able to diagnose properly. The reason we cannot diagnose it properly, as Mr Bates correctly says, is that we do not yet have assays for these unknown microorganisms. We need to have those assays, and that is where I am hoping that something will happen in the next little while. We do know that there are a lot of different microbes in Australian ticks. There are several ticks that bite and Australians regularly: *Ixodes holocyclus*, the paralysis tick, on the eastern side of Australia; *Amblyomma triguttatum*, the ornate kangaroo tick, on the western side of Australia; and a couple of

others as well, but that they do not bite so often. People do get bitten by these ticks and some people do get the Lyme-like syndrome.

Could it be of the *Borrelia*? We have heard some people argue that, yes, it is not the classic Lyme *Borrelia* but it is another *Borrelia*. Well, I am sorry, but I do not agree with that, because although we do have *Borrelia* in wildlife here in Australia—we have some introduced *Borrelia* such as the chicken *Borrelia*—there is no evidence that these cause infections in humans. In fact, we do not have the classic relapsing disease, relapsing borreliosis, here in Australia. In that situation the patients get a fever and they have a period when they are quite well and then they get another fever, a relapsing fever, and then they are well for a little while and then they get another fever, and the fevers gradually get less and less and then it fades away. You can diagnose this disease. It can be diagnosed in Australia. What you do is look at the patient's blood under a phase-contrast microscope during the height of their fever and you can see the spirochetes—you can see the *Borrelia* there as they are in very high concentrations in the blood. That is how it is diagnosed everywhere in the world, and that is how we diagnose it in Australia, although we do not see it in Australia very often, just in the occasional returned traveller.

This disease appears not to occur in Australia, because we do not have patients with that sort of relapsing fever syndrome. We are seeing patients with, as you have heard, long, drawn-out months or years of chronic symptoms of ill health, pain and various neurological symptoms. It is not the same.

So, if I may be so bold as to say, I actually do not think what we are talking about is the *Borrelia* infection. It is not classic Lyme disease. It is not a *Borrelia* infection, although I am keeping an open mind on that possibility—but I do not think it is. What is it?

This is where the work of Professor Irwin from Murdoch University has been so helpful. He is looking at bacteria in ticks and he has found a whole range of micro-organisms, some of which are known human pathogens, some of which may well be human pathogens but we do not know, and some of which are probably unlikely to be human pathogens and just part of the tick microbio. Mind you, he is only looking at bacteria, so he is not covering *Babesia*, which is a protozoa, and he is not covering the viruses. No-one is doing that work at the moment. There are huge gaps in our knowledge. There are huge gaps in our research capability at the moment. So he is looking at the bacteria.

Let us say it is bacteria, for argument's sake. Which one is it? Or is it more than one? We cannot tell because we do not have the assays to detect those bacteria or the antibodies produced in response to those bacteria in the patients, because those assays have not been developed. That research has not been done, and that is because the money has not been made available to do it. Sorry to come back to money, but that is really what it takes. We have the expertise to do it. I could develop an assay in my little laboratory for all of those bacteria that Irwin finds in his ticks, but I could not do it for less than half a million dollars probably, because we are probably looking at six, seven, eight or nine different potential pathogens.

There is one microbe in the tick that may well be a pathogen, called *Neoehrlichia*, which is a pathogen in ticks in other parts of the world. Irwin has found it in many Australian ticks, but we have no way of detecting it in the laboratory or in the patients. We do not have any assays to detect antibodies to *Neoehrlichia*. That is something that could be done as well.

So there is hope, there is the potential to do something, but you cannot just whistle in the wind and hope it will happen. Someone has to look at *Babesia* and other protozoa that might be responsible, and somebody has to look at viruses. In other parts of the world, there are many viruses that are tick transmitted and cause very nasty diseases. And we do not have one in Australia? Well, I cannot believe that. I cannot believe that, senators. There have to be some viral tick-transmitted infections in Australia; it is just that we do not know what they are.

So there is so much that needs to be done. It is so wide open. What the laboratories in Australia do, they do well. We are accredited. Our peers are looking over our shoulders all the time to see if we do things right. We put positive and negative controls on every assay. So, when we say we have found something or we have not found something, you can believe it. But if we do not have the assay to detect tests for something, such as the Lyme-like disease microbe or microbes, then we cannot find it; we cannot make the diagnosis. That is what is troubling so many of the patients: the medical profession does not have the ability to make the diagnosis and say, 'Yes, Mrs Brown, you've got this disease.' And then, of course, the next step is to try and find a treatment.

I am sorry that was rather a longwinded opening statement, but that is a summation of how I see the state of play at the moment.

CHAIR: Thank you.

Senator WANG: We have been hearing a lot about Professor Irwin. In fact, I had the real pleasure of having a couple of meetings with him. I guess the other side of the coin is that, when we talk about research into tick-borne

disease, Professor Irwin is the only name that comes up, really. All the people in this room agree that we need more research into this problem, but it seems to me we only have Peter Irwin doing the job and no-one else is doing it.

Prof. Graves: I feel about a bit embarrassed about saying this, but my laboratory is also doing research on ticks. We do not have a big research grant like Peter's, unfortunately—but we did not apply; that is probably why we do not have it! We have looked at about 350 ticks from around Australia, a dozen different species of ticks, including the ones that bite humans mostly, two of which I mentioned. We found about 14 per cent of them contained DNA from *Rickettsia*. So I think *Rickettsia* is a very likely cause of some of these Lyme-like syndromes. We found about four or five per cent of them contained *Coxiella. Coxiella* is another bacterium that can cause it. One *Coxiella*, *Coxiella burnetii*, causes Q fever, which can cause a chronic illness and a post-Q fever fatigue syndrome. So, we know the ticks contain those two. We looked at 300-and-something—and, okay, you might say it is a small sample but it was scattered from all around Australia and several different species—and what we did not find was any *Borrelia* DNA. That paper has not been submitted for publication yet; we are just putting the finishing touches on it. So, I am sorry; it is not in the literature.

We also looked at 14 people who live in the north-east corner of New South Wales who actually work with *Ixodes holocyclus* as part of their work. They have to go into the bush, collect the ticks and put them on dogs and things like that, so they are susceptible to tick infections. They are all perfectly well of course. We took blood from them and looked for antibodies. We found that 35 per cent had antibodies to *Coxiella burnetii*—so they had either inhaled Q fever or had been bitten by ticks—and I think it was five per cent who had antibodies to *Rickettsia*, or the spotted fever group. None of them—and there were only 14 patients—had any antibodies to *Borrelia*.

Take that as you may. It was a small sample. That is about to be published in the journal of the Society of Tropical Medicine and Hygiene. So, we are doing a little bit of work in that area but I do not put myself in the same league as Professor Irwin. He is using very sophisticated molecular techniques. His work is tremendous and I hope he continues to be able to keep going with it.

Senator WANG: His research grant is going to finish before the end of this year, and I believe he is in the process of applying for another grant.

Prof. Graves: I strongly recommend that he be refunded, if I may be so bold.

Mr Bates: I wonder where that funding is going to come from. The Public Health Laboratory Network is not a funding body. We promote best practice but we cannot go out there and give money to people to do research.

Senator WANG: Yes, I understand that. Does your network do any active research by itself?

Mr Bates: Not normally, no.

Senator WANG: What sort of expert advice or up-to-date information do you rely on when you give guidelines to the labs?

Mr Bates: It is based on experience as well as overseas experience. When you talk about research, all the Public Health Laboratory Network labs are in the business of capability enhancement and developing capabilities for emerging pathogens. Whilst we are not doing the sort of research that Professor Irwin is doing, were he to characterise a particular agent then the work-up to get a test for that agent would probably happen in a Public Health Laboratory Network laboratory.

Senator WANG: Again, I am not from the medical profession but I would assume that going out in the bush looking for random ticks and then hopefully finding some tick that carries the bug would be a problematical or troublesome process. We have sufferers of Lyme-like illness in this room. I would assume that if you took them into your labs and tested them straightaway you might find it much easier to find the cause of the problem, rather than going through the bush and finding ticks.

Prof. Graves: They are two arms of the same problem. Patients have been bitten by a tick, but mostly those patients do not keep the tick, so a laboratory hardly ever gets the tick that bit that patient. We have had a few cases, and we found *Rickettsia* and *Coxiella* in them, interestingly enough, but usually we do not get the tick that bit the patient. The people who are sending us ticks from all over Australia are medical doctors, who get them from their patients—so, they are ones that have been associated with people—and also veterinarians, who take them off various animals that they are associated with. It is not entirely random.

Senator WANG: Where I am coming from is: instead of looking at ticks, why can't we look at the patients?

Prof. Graves: That is what we would like to do and what we do with the assays we have available, such as the ones that John was talking about. But, as I mentioned before—and maybe I did not make myself clear—if we do

not have the organism that we think is causing the illness, we cannot develop an assay to detect the antibodies to it; there is no serological assay. In most cases you have to test the patient's blood, and the microbe is not usually in the blood at that stage; you are just looking for the antibodies. In the early stage of the illness the microbe might well be in the skin, where they got a reaction, and then you could find it. But nine times out of 10 you have to do what you want to do on the blood, and that is what we call serology, where you are looking for antibodies. If you do not have an assay that detects those antibodies, which means you know what the microbe is beforehand, you cannot do it. So that is the conundrum. It is like a loose end.

Senator WANG: So, in layman's terms, there are two options here. One is looking into the blood of those patients.

Prof. Graves: Yes.

Senator WANG: The other option is looking into the ticks.

Prof. Graves: Yes.

Senator WANG: So you are saying it is actually easier to look into the ticks to be able to find the problem, rather than into the patient.

Prof. Graves: Yes and no. I need to clarify that. If you are looking into the ticks—and assuming the pathogen is there—you will find the pathogen plus lots of other things as well, and that is the difficult part: working out which one of those microbes. Irwin has found seven or eight potential pathogens. We do not know which one is causing this problem—or whether any of them is, in fact. But, when the patient comes in, we know they have been sick. We know they have been infected with whatever this microbe is. Therefore, if we could assay for that, we would be able to make the diagnosis.

So what I am proposing—what I think we should do—is somehow make it possible for diagnostic laboratories—the sort of laboratory that is part of the Public Health Laboratory Network, like my laboratory, the Australian Rickettsia Reference Laboratory. If we get a serum specimen in from a patient who has query Lyme disease—endemic Australian Lyme disease—we can currently only test for Lyme disease. That is all I am allowed to do. If I do any other testing, it is basically called overservicing and, as a pathologist, I can get into big trouble over it. So I just have to do what is requested. So I do the Lyme disease testing. It is negative—end of story. But if I could also test for *Coxiella*, *Rickettsia*, *Anaplasma*, *Ehrlichia*, *Neoehrlichia*—although we do not have an assay for that yet—*Bartonella* or *Babesia*, that would make a big difference. We could possibly find out what is affecting these people. But not only cannot we do it; we are not allowed to do it. It is illegal.

Senator WANG: So potentially the cause of the problem of the patients in this room today is not even on the list of what you are allowed to test.

Prof. Graves: Yes, that is right. That is exactly right.

Mr Bates: That is one of the big ethical issues with pathogen discovery using whole-genome sequencing. We could get a sample from a patient and test to see whether there is a certain bacteria there making the patient ill. By the way, we might find that that patient is infected with HIV, and that creates an ethical dilemma, because the sample was not sent to us for an HIV diagnosis. So it is this conundrum that we find ourselves in.

CHAIR: If the patient has signed the release form to let you do that, would that not get over that ethical problem, or do I misunderstand?

Mr Bates: One would hope so, yes.

Prof. Graves: But there is also a financial problem with doing the additional test, because when I do a test for, say, Lyme disease and I bulk-bill it—because we bulk-bill all our testing so the patient is not out of pocket—I only get $60 or something for that. Therefore, if I were to do the other assays as well, that would all have to come out of the laboratory profit, which is very minimal anyway.

CHAIR: Just following up on where you are going, if there were a trial—if we say, 'Okay, we're going to have a trial with the people that we know have symptoms of Lyme-like disease; do an analysis for everything'—

Prof. Graves: Everything we can.

CHAIR: Everything you can.

Prof. Graves: That would be good.

Senator WANG: Everything you are allowed to do?

CHAIR: No, we are saying—

Prof. Graves: If we had funding to do it—and obviously we would have to get the patient's permission, but I do not suppose that would be a problem—

CHAIR: Yes, let's assume that everyone says yes.

Prof. Graves: Assuming you have the money and the assay—let's say there are seven, eight, nine or 10 assays you could theoretically do—then I could do all those assays on the patients' serum and try to find which ones are coming up all the time. Is it *Rickettsia*? Is it *Coxiella*? Is it something else? Is it *Babesia*?

CHAIR: Has this never been done?

Prof. Graves: But I cannot do it at the moment, you see.

CHAIR: But has this ever been done in a trial?

Prof. Graves: No.

CHAIR: Sorry, I got excited and took over. I apologise.

Senator WANG: That is all right.

Prof. Graves: It is your prerogative as chair.

Senator WANG: I would assume a patient does not care how much it costs. At this stage, after years of suffering, they do not really care how much it costs.

Prof. Graves: Yes, patients just want an answer.

Senator WANG: They just want an answer, and yet you are not allowed to give them an answer.

Prof. Graves: We cannot put our best effort into it, because of the way the Medicare system funds diagnostic laboratories.

Senator WANG: What if I come to you saying, 'I think I have a problem; I want you to test my blood, and I'll rebate whatever cost you incur'? Would you be able to do it?

Prof. Graves: Yes, of course, but you would have to pay for it from your pocket, because I would not be able to charge Medicare, because I would be accused of overservicing, you see.

Senator WANG: Okay.

Prof. Graves: If I could just follow on from that: if someone were to give me a research grant for a certain amount of money then I could do something like that.

Senator WANG: Which you haven't applied for.

Prof. Graves: Which I haven't got.

Senator MOORE: Professor Graves or Mr Bates, who is representing the college?

Prof. Graves: Me.

Senator MOORE: Thank you.

Prof. Graves: I am the college spokesman on Lyme disease.

Senator MOORE: Does the college do the NATA accreditation? In your submission it has 'NATA/college accreditation'.

Prof. Graves: They are a college of pathologists who are associated with NATA, but the accreditation is actually done by NATA itself. Because NATA is the accrediting pathology laboratory they have some expert pathologists there to help with technical type issues and things like that. It is not really the college accrediting; it is NATA, the National Association of Testing Authorities.

Senator MOORE: The testing process has been central to all the discussion we have had. Certainly, that has been part of the discussion with Senator Wang about the extra processing. We had evidence from Dr Dobie today, which went into great detail about what was wrong with the current process of testing in Australia and why there have been arguments in our evidence that we have the highest level of testing in the world. We actually had it put on record yesterday that our testing was at that level—and no questions asked. That was the process.

Prof. Graves: I would question that.

Senator MOORE: We did as well. The process that we have is along the lines of: is there the ability to be tested for this disease in Australia and is the process operating? I have written things down and then cannot read my own writing; it is a terrible thing.

Prof. Graves: Doctors have that problem too.

Senator MOORE: If someone's blood is tested in Australia and it is negative, that seems to be the end of the discussion as it currently works in Australia.

Prof. Graves: Yes, unfortunately, it is. If a doctor says to the laboratory, 'Doctor'—me—'please test this patient's serum for Lyme disease' I do that. I test it with the assays that we have. It comes up negative. I send the result back to the doctor.

Senator MOORE: End of story.

Prof. Graves: End of story; unless the doctor then sends another specimen to me and says, 'This time, Dr Graves, I want you to test for bartonella or babesia.' Then I can do that, you see.

Senator MOORE: But it has to be under specific direction from the doctor.

Prof. Graves: He has to do it again, and usually by that time the patient is fed up and goes elsewhere.

Senator WANG: Probably by that time the illness has already progressed into a chronic illness.

Prof. Graves: Most of the patients we see are at the chronic stage. I would love to see more patients at the acute stage, because we are more likely to get a diagnosis.

Senator MOORE: So, if people send the same blood to one of the other laboratories, particularly in Germany or America, they sometimes get a positive reading for the same blood?

Prof. Graves: My take on that is that the laboratories that we are referring to—the ones in America and Germany—are getting the wrong answer. I know this will not go down well with the audience. They are using the same assays as we are using, because we are using American and European assays

Senator MOORE: That is what I am wanting to get on record.

Prof. Graves: We are using the American and European assays because we have not got our own. We are getting the negative, where all our positive and negative controls are being done properly; they are getting the positive. Why? That is the question: why? And the answer is probably that the other labs are not doing them properly.

Mr Bates: The corollary to that is that these patients are being diagnosed with Borrelia burgdorferi, but all the evidence suggests that we do not have that organism in ticks in Australia—and there has been a lot of work already done to that effect. They have also done vector competence studies to see whether Australian ticks can carry Borrelia burgdorferi, and they do not appear to be able to do that. We are talking about one specific bacteria.

Senator MOORE: Yes. That is the core to this element of testing that we have had in evidence. Patients are getting a clinical diagnosis and they have not been to be able get positive testing in Australia—I do not think I am verballing anyone; I think that is fair. They have then sent their specimens elsewhere, including one particular lab in Australia—which will be giving evidence later, which has been able to have positive tests—and known laboratories overseas. As a result of the testing that then comes back, they can confirm the original clinical diagnosis that it is a Lyme condition. That then leads to people believing the process, and that they have Lyme. What I think I am trying to get on record—and which is similar evidence to what we had yesterday in many ways—is that, from your perspective, with the professional level of knowledge that you have in Australia, you believe that those other tests would not be accurate.

Prof. Graves: That is correct. They are what we call in the trade as false positives. We sometimes get false positive in all sorts of assays—there is nothing to do with Lyme disease. You will get the occasional false positive if you are testing someone of the leptospirosis, brucellosis or Epstein-Barr virus infection. It happens all the time, but they are usually very low levels—less than one per cent. So there is no laboratory assay that is 100 per cent sensitive and 100 per cent specific. It just does not happen. When people say that they have that sort of assay, they are lying; they are telling fibs. This happens so many times. We get a negative result for Lyme disease at a competent Australian laboratory—not just mine, but others. The patient is not happy with that result. The blood gets sent—at great expense, I might add—to another laboratory elsewhere. It may be another Australian laboratory not NATA accredited, or one overseas. Then they get a positive. What do you make of that? These people happen to pay large sums of money for these results, whereas our laboratory bulk-bills. They do not have to pay anything.

Senator MOORE: We have in some evidence from another provider a whole list of paperwork about how the tests operate. Professor, I do not understand it.

Prof. Graves: I could explain it to you if you want me to, but it would take a lot of time.

Senator MOORE: Yes—and we do not have that time. Basically, the bottom line remains. With this process, you have given lots of evidence about the fact that we can extend our tests, and we need to do that, but your bottom line remains: for the particular test that is now there for the particular *Borrelia* you stand by the situation that, unless it has been done in the NATA-approved processes in the labs here, that is the only genuine test that can be taken as evidence at the moment. Is that right?

Prof. Graves: In Australia, that is correct.

Senator WANG: What gives you such great confidence in our labs than European labs which are dealing with many, many more cases of Lyme than we are? I would assume that they are more experienced in those areas.

Prof. Graves: It is a good question, and I can understand why you are saying. It makes it look as through we are saying that we are better than the laboratories. The laboratories in Germany and the United States that you are talking about, and that we are talking about now, are a minority. They are an exception. The mainstream doctors in those countries do not use those laboratories. They do not use them because they give them the wrong result. They give them false positive results. So it is not just us. The doctors in those countries say, 'Don't send your stuff to such and such a laboratory; you can't trust the result.' People here who are not getting results from mainstream laboratories are sending them to very off-the-mainstream types of laboratories in other countries. They are not the mainstream laboratories that are doing the routine testing all the time.

Senator WANG: But I remind you that all today and yesterday we have heard evidence that the mainstream doctors do not even believe we have Lyme in Australia.

Prof. Graves: That is another issue. I am talking about the laboratories' assay.

Senator WANG: What I am pointing out is that sometimes the majority does not have the truth. Sometimes the truth is held by the minority.

Prof. Graves: As a general statement, that is true. One should always keep an open mind. I agree entirely with you. However, as more and more evidence comes, you have to be willing to finally nail your flag to the masthead. You have very good laboratories in Australia represented by a number of public laboratories and a number of private laboratories with highly skilled staff. We have the most regulated and controlled laboratories in the world. We have our colleagues looking over our shoulders all the time. That is what NATA assessment really is—our colleagues looking at each other. If I can find something wrong with his laboratory, I will. They are very picky. The assays that we do, we do properly, and we only occasionally get them wrong. The assays that these other laboratories are doing, I would be prepared to say that they get them wrong a lot of the time. I know that sounds funny to you, but that is the way it is.

Senator MOORE: On notice, would you mind having a look at the evidence from Dr Dobie—I will get you the right number for that submission—which goes through why he believes that the testing we do in Australia is not the most efficient testing and that there are better tests elsewhere. If you would not mind, could you have a look at that evidence and come back. There is also the evidence from submission 545, from Australian Biologics Testing Services, which is similarly about the testing process. If you would not mind having a look at that on notice and getting back to us, that would be good. Thank you.

Prof. Graves: Certainly.

Senator MADIGAN: Thank you, Mr Bates and Professor Graves. We heard yesterday, and we have heard again from you two gentlemen today, about NATA accreditation and the Royal College of Pathologists of Australasia. Could you just briefly explain to me how, for instance, if I were an Australian pathology provider, I would become accredited under NATA and the RCPA.

Prof. Graves: I am probably not the right person to ask, because I have never been a NATA accreditor, but I will just give you a rough outline of what you do. You have your laboratory and you are running this new assay—let's say for disease X.

Senator MADIGAN: Could I just clarify one thing there. Yesterday we also heard about laboratories being accredited under ISO—

Prof. Graves: 15189.

CHAIR: I knew there was a 9 involved.

Senator MADIGAN: For clarity for the committee, exactly what does that ISO accreditation pertain to? Is it just the way you do your paperwork and your procedures?

Mr Bates: It covers paperwork, procedures—

Senator MADIGAN: So it is more of a quality assurance thing around—

Mr Bates: Correct. It is very much quality driven, yes.

Senator MADIGAN: It is around book work and how you run the pathology.

Mr Bates: It is setting standards in terms of controls and all that sort of thing as well.

Senator MADIGAN: Okay. Continue, please, Professor.

Prof. Graves: So you have this new assay that you have set up for disease X or infection X—X for unknown

Senator MADIGAN: So a specific test.

Prof. Graves: Yes, a specific test. So you want to start offering it as a NATA accredited test, so when you have your regular NATA review you ask them to look at this assay and how you are doing it and see whether that is being done satisfactorily, basically. So you have your colleagues, who are other pathologists and medical microbiologists, like me, or other scientists—usually one of each, like John Bates. They come and they actually go into your laboratory and look over your shoulder while you are doing it. They see how you are doing it, how you are setting up your controls and what your results mean—having a look at all your results. At the end of the day, they have to make a judgement as to whether you are getting the correct results, really. If you are getting correct results, you will usually get NATA accreditation for that test. In my laboratory, for example, we have some assays which are currently NATA accredited and some assays which we are still developing and getting to work and which do not have NATA accreditation. We have to put that on the report: 'This assay is not yet NATA accredited.' That means there is a little bit of doubt about it, you see. If they do not think your assay is working properly—if they think there are mistakes and you are not setting up controls properly, your quality systems are not right, your staff are not adequately trained or you are misinterpreting the results—then you do not get NATA accreditation. You can still offer the test, of course—there is nothing stopping you offering the test—but you do not have that seal of approval from NATA or RCPA, so most people will not use your service, because they are not confident that your results are accurate.

Mr Bates: If I can just add to that, the whole process is one of peer review. It is unlikely that you would be setting up a test that was not already available somewhere in Australia, so the people who come in to do your NATA accreditation assessment will be people who are experienced in that test. What they are looking for is evidence that you have conducted that test a number of times and that you have a significant amount of validation data which shows that you can consistently and accurately get positive and negative results with that test.

Senator MADIGAN: Mr Bates, you just said that that is based on somebody else already doing the test. What about where you are doing groundbreaking work? You say there is peer review.

Mr Bates: Yes.

Senator MADIGAN: That would not follow in that case, would it?

Mr Bates: The classic example is the swine flu, and this is very much the sort of thing the Public Health Laboratory Network get involved in, because we are here to cope with emerging diseases. In the case of swine flu, there were sequences already published from the work that had been done overseas. Because we work in the whole area of DNA detection, once the sequences are published on the internet it is very easy to develop a test for that particular sequence of organism, whether it be a virus or a microorganism. After that, it is a case of saying: 'This test is like a number of other tests we do. This the sort of validation data that we did to establish those tests, so we will run the same sort of tests again on this new test to establish that this test is working reliably.'

Senator MADIGAN: We spoke about the quality assurance program before. How does NATA approve laboratories rate? Are they bad, fair or good on average? How do they rate?

Mr Bates: You probably should not think that NATA is the best that you can get. NATA sets a certain standard—

Senator MADIGAN: I have asked the question, Mr Bates, because yesterday we were told, emphatically by some people, that 'We're up here; we're beyond question.' That was the impression delivered to this committee. I am trying to get some clarity here from you, Mr Bates.

Mr Bates: I would say NATA sets a certain minimal standard, above which we—

Senator MADIGAN: Yesterday, we were led to believe it is the best in the world.

CHAIR: Aren't we talking about two different things here with respect to what we have heard? There is NATA, but my interpretation of what they were saying is, 'We're the best'—it is sort of related to NATA and it is sort of not. If you are saying that they are the minimum, you could then interpret what was said as, 'We're even better than that.'

Mr Bates: I think the standards that NATA sets as a minimum are higher than what occur in other parts of the world, which is how we can say we are among the best.

CHAIR: That is how we can—okay.

Senator MADIGAN: There has been a lot of conjecture around international tests with Infectolab or IGeneX in the US and Germany. As I understand it, Australia signed an agreement in January this year, which is called the *International Laboratory Accreditation Cooperation MRA*. Are you aware of that?

Prof. Graves: I am not, sorry.

Senator MADIGAN: You are not aware of that?

Prof. Graves: No.

Senator MADIGAN: Would you be able to take that on notice and get back to me?

Prof. Graves: What is called?

Senator MADIGAN: It was on 6 January this year and it is called the *International Laboratory Accreditation Cooperation MRA*.

Prof. Graves: What does MRA stand for?

Senator MADIGAN: I am not sure. As I have been led to believe, this agreement means that overseas laboratories meeting ISO standards for both their laboratory medical testing are able to be recognised and accredited by NATA.

Prof. Graves: Okay, that is interesting. That is not my understanding.

Mr Bates: I think there is a mutual agreement with NATA and these overseas laboratories. NATA recognises that those laboratories are operating under ISO 15189. I do not think that is the same as saying NATA approves, at a NATA level, the testing that is done in those laboratories.

CHAIR: That is what I understand they said yesterday.

Senator MADIGAN: What you are saying then is: you only recognise their quality assurance—that is all, not the tests that they perform. Is that what you are saying, that that is what that agreement means according to your understanding?

Mr Bates: That is correct.

CHAIR: We will actually follow that up. I think we need to follow that up. We can follow it up when we are with the Chief Scientist.

Senator MADIGAN: Were either of you aware of that agreement?

Mr Bates: I was not.

Prof. Graves: If what you say is correct, it is little bit concerning to me, because it means we might have to drop our laboratory standards a little bit to satisfy—

Senator WANG: Or maybe increase them.

Prof. Graves: It depends on whether you want the right answer or not.

CHAIR: MR is mutual recognition. Thank you, Dr Google.

Prof. Graves: You cannot go past Dr Google.

CHAIR: We are developing a list of questions to ask the Chief Scientist. We will ask him about that.

Senator MADIGAN: Finally, I believe the Chief Medical Officer in recent times said a negative finding does not mean a patient does not have Lyme. Are you aware of that statement?

Prof. Graves: That is true for any laboratory test. Any laboratory test can be negative when the patient has the condition. That is what we call a false negative. That is the opposite to a false positive. When a laboratory test gives you a positive result but the patient does not have that illness, it is called a false positive. When the laboratory test gives you a negative but they do have the illness, that is called a false negative.

That can sometimes happen very early in an illness—for example, they have not produced antibodies yet. It can sometimes happen if somebody has a particular genetic basis to their immune system and they cannot produce the immune response. We see that in five per cent of people who have hepatitis B vaccinations—they do not produce any antibodies to the vaccine. So there can be all sorts of reasons why laboratory assays can give false negatives. Certainly that is a correct statement. In some cases the patient can have an illness and the lab test can be negative. Everyone knows that.

CHAIR: I want to follow up on that. That is one of the points that Dr Dobie made this morning. He was saying that in the ELISA process, the tier 1 approach, you can get false negatives and then you never go on to tier 2. That was part of his criticism of the process.

Mr Bates: Again, the recommendation is that, if you get a negative test, you should wait four to six weeks and repeat the test to allow those antibodies to become more apparent.

CHAIR: Some of the information that we heard yesterday was that *Borrelia* can form something like a cyst, but instead of a thick walled cyst it is a thin walled cyst.

Mr Bates: Like a biofilm?

CHAIR: Yes, like a biofilm. So do I understand from what you have just said that, if you wait six weeks, you might be able to detect it?

Mr Bates: Your body is more likely to respond to the presence of a foreign body and mount an antibody response to it.

CHAIR: Even with a biofilm?

Mr Bates: Yes, because there would still be surface antigens there which the body would detect as foreign.

Senator MADIGAN: What happens if the body has not created antibodies?

Mr Bates: You will continue to get a negative test.

Senator MADIGAN: Then there is no way—

Mr Bates: The only option from there is if the person goes into a chronic condition. You may be able to take synovial fluid, do a PCR and look for DNA from the organism instead. That is a totally different sort of test to a serology test.

CHAIR: The next question is: how often do doctors go back after six weeks? Particularly if you are with a GP who is not what is colloquially being called Lyme literate, how often would they go back and check again in six weeks?

Mr Bates: I have no idea.

Prof. Graves: It varies. Some doctors are very meticulous and careful and others see the patient once and say, 'I can't help you—off you go.' So it is very variable, but in our laboratory we always like to see a second serum because it is very, very helpful. Not only can you go from negative to positive but you can also go from low levels of antibodies to high levels of antibodies, and that supports the diagnosis that that particular microbe is causing the infection. So a second serum or a second blood sample four to six weeks later is very useful, but we often do not get it. Either the patient has become fed up or the doctors do not do it, or maybe sometimes the patient gets better and they do not want to have another blood sample taken. There can be all sorts of reasons why you do not get it, but when we do get a second one it lifts our level of confidence in our diagnosis being correct.

CHAIR: That does not explain the difference between the labs here and the labs overseas, though.

Prof. Graves: No, not at all. Part of the difference between the labs overseas and here is how they interpret the results. The Western blot, for example, which is one of the serological assays, can be interpreted differently in different places. Some people want this number of bands and others want a different number of bands. It is a very technical thing, but there is a degree of interpretation involved, shall I say. It is not just positive or negative.

CHAIR: You have already taken a question on notice from Senator Moore about the evidence we received earlier. If you could also include some of that commentary, that would be really useful. Senator Madigan promises me this is his last question.

Senator MADIGAN: Professor Graves, you said it is open to interpretation, but how do we know your interpretation is correct and the overseas laboratories are incorrect?

Prof. Graves: That is a good point. Interpretations are always just that—interpretations. I have doubts about the overseas laboratories because my colleagues in America tell me that when they send patients' serum to these laboratories—they think they might have Lyme disease and it is early on in the illness—the test comes back positive, but then it turns out the patient actually had some other illness and it manifested itself a little bit later. Let's say they had tuberculosis, HIV or something else.

The way you determine a false positive result is knowing what the patient actually has wrong with them. If the assay gives you the wrong answer, that is a false positive. For example, if a person tested positive to Lyme disease and they did have Lyme disease, that is a good assay. That is not a false positive. But if they had a positive test for Lyme disease and they have something else altogether, that is a false positive. If that happens a lot of the time, it means the assay the laboratory is using is not a good assay. That is what is happening in some of these laboratories, particularly the one in America. I have a lot of colleagues in America and they simply tell me: 'Don't use that laboratory. They give you the wrong result.'

Senator MADIGAN: If the CDC puts out a circular, would you go by what the CDC says?

Prof. Graves: Mostly I would, but they have been known to get things wrong. Everybody can get things wrong, so you are right—you must always keep an open mind and be sceptical when people say they are certain they are right, because often they are wrong. But, generally speaking, with the passage of time—and I have been

in this game for a long time now—you get a feel after a while for which labs are doing a good job and which labs are not. It is not something that comes to you overnight; it is built up from experience over many, many years.

CHAIR: Thank you. These issues of tests are issues that we need to be getting our heads around, so thank you very much. We will need to continue to pursue this. Thank you for taking those questions on notice as well.

Proceedings suspended from 14:33 to 14:56

BURKE, Ms Jennie Maree, Director, Australian Biologics Testing Services Pty Ltd

CHAIR: Welcome. I understand that you have been given information on parliamentary privilege and the protection of witnesses and evidence. I invite you to make an opening statement, and then we will ask you some questions.

Ms Burke: I would like to talk initially about the accreditation with NATA, because we have found over the last few years that the fact that we do not have NATA at this stage has been used as an attack. What I want to say to start with is that accreditation with NATA is required for laboratories claiming Medicare. Laboratories not receiving Medicare payments have never had any legal or other requirement to gain NATA accreditation. There are quite a few small laboratories around Australia who do not have NATA accreditation and have no intent of doing so. Having NATA does not mean the laboratories' results are always correct, and not having NATA does not mean the laboratories' results are wrong. For example, in 2002, a Melbourne lab failed to test correctly for precancerous cervical cells. Approximately 34 Victorian women were urged to be retested. This was a Medicare/NATA-accredited lab. More recently, 100 patients in South Australia were given false positive tests for prostate cancer. This was only discovered when a urologist ordered some retesting. Again, this was a NATA-accredited Medicare lab.

We applied for NATA accreditation in early 2014. We submitted what we thought was ample validation for the test. This included five years of successful quality assurance programs. In June last year, our NATA representative suggested that we do a probit regression study. We did this, and this was submitted. We know of no other laboratory that has submitted a probit regression study. This type of study has been used, usually in research papers, to validate PCR testing in samples with low levels of bacteria. We employed the services of a mathematician from the University of Newcastle. We tested 850 samples and showed excellent results. The probit regression is in our submission.

We have also participated in a pilot study for Borrelia serology using our immunoblot test. We then did the quality assurance program. We scored 100 per cent in both tests. This quality assurance program came from the Royal College of Pathologists Australasia. While we were waiting for NATA to come back to us after we had lodged the probit regression, we received a letter from Mr Andy Griffin, who is the deputy sector manager of legal and clinical services at NATA. This was on 30 November. He stated that we had not provided details of how we undertake our assay—this is PCR—or the primers used, therefore, they could not confirm that we were detecting Borrelia. He advised that we should, 'Reconsider any decision to reapply for accreditation.' Our primers and probe for PCR are our intellectual property. They enable us to offer better and more sensitive PCR. We do not divulge our primers at all. NATA has received our laboratory manual, which carries our full testing methods.

In our paper, which was entitled 'Evidence of *Borrelia* in the *Ixodes holocyclus* tick', we found *Borrelia* DNA in the tissue of a patient at the site of the bite. The tick was still attached when the patient went to the doctor. The tick was removed. It was first sent to the University of Newcastle for identification. They were not sure. It then went to the University of the Sunshine Coast, and ended up going to Japan to be identified. This has been published. So it has been discovered in Australia.

We have spoken with many scientists in the molecular field, and I had a conversation with the head of one of the very large routine pathology laboratories. No-one has known of labs being asked to divulge their intellectual property, such as primers, nor has anyone known of a laboratory being asked to submit a probit regression study. Validation of PCR testing is through quality assurance programs and sequencing. Both areas have been submitted to NATA. PCR is considered the gold standard of testing for microbial infections.

We feel that there have been serious breaches of NATA's charter in their dealings with us. In their charter NATA has a guideline of the time they should take to respond to submissions. Over the two-year period of our application, we found that NATA had not responded within the times allowed by their guidelines. We calculated a loss of seven months. NATA is supposed to maintain confidentiality. We found that NATA had sent some of our documentation to the Society for Microbiology committee on critical microbiology, of which Dr Graves is the chair. This was without our permission. Dr Graves is our competitor, as he now offers PCR testing for *Borrelia,* and has been a vocal critic of our laboratory. This breached NATA rule R39(a). It should also be noted that the *Borrelia* PCR Dr Graves is offering is not NATA accredited.

RCPA maintains the stance that there is no *Borrelia* in Australia. This stance affects the NATA recognition of scientific fact. NATA has the monopoly on accreditation testing in Australia. We could go through accreditation with an American group called A2LA; however, TGA will not recognise any accreditation apart from NATA, even though the standards set by NATA and all other accreditation groups is an international standard. There is no organisation that acts as an overseer of NATA. If one has a problem with NATA, you complain to them and they

investigate themselves. I contacted the Commonwealth ombudsman to see whether they could do anything about it. They had no control over NATA. I contacted the Department of Health and I spoke to someone there. He seemed quite concerned, then realised we were not a Medicare-checked lab and that was outside his jurisdiction. He told me he would get someone to contact me, and I have now waited four months.

We have co-authored five papers on *Borrelia*, with the sixth almost finalised. We are part of a research group. Everyone else in the group is in America and Canada. When samples are sent to us for testing—and this is PCR testing—they are tested by us and by Professor Sapi of the University of New Haven in Connecticut. Our two labs form the basis of five papers. I would also like to be clear that we do not change our test results dependent on travel history.

We have also had conversations with scientists in European specialist laboratories and they have confirmed that PCR testing of borreliosis patients generally comes up positive with over 39 cycles in PCR. This is one of the problems that NATA appears to have with us—that we run our PCR to 45 cycles. In an acute infection, in most infections, there is a huge amount of DNA. You get a strong result when you do PCR on an acute infection. Borrelia is quite different. It just does not seem to be getting across that this does not act like most other infections.

Borrelia patients, particularly when chronic, have incredibly low levels of DNA present in their body—or it certainly may be in the tissue but not in the bloodstream. RCPA has a guideline that you should never test urine for Borrelia. We find urine is actually quite a good source of positives. We know, and there are research papers showing, that people shed Borrelia. A patient with Borrelia, as those organisms die, they will eventually be excreted through the urinary tract. There is work done, and we are doing some with an infectious disease specialists, where you can load a patient for three days or so with an antibiotic and then you collect the urine and we get quite strong positives.

In my submission, I have shown sequencing. I have brought another 10 sequences; I submitted four and we do have more at the laboratory. I would just like to say that all of the research that we have done, and I think, at the moment, we are up to 450 samples that we have done as part of our research, we fund. We have never had any help or any funding which does make it a little bit difficult for a very small laboratory. I am done.

Senator MADIGAN: Thank you, Ms Burke. Have you reapplied to NATA in recent times?

Ms Burke: Yes. After we found out about the breach of confidentiality and we had been told to not bother reapplying, we asked an appointment with the CEO. We had an appointment with Jennifer Evans, who is the CEO of NATA, Andy Griffin, who was the person who wrote the comment about 'rethink, reapply,' and John Styzinski, who is the general manager for NATA—myself, Moya and our quality manager attended. It was a very interesting meeting. I was saying, 'We have presented the quality assurance programs.' Of course we had to go outside of Australia for that; there are no quality assurance programs for PCR Borrelia in Australia. We go through Quality Control Molecular Diagnostics—QCMD. They are a very reputable group. They do quality assurance to 13 countries. They are based at the University of Glasgow. We pass; we always pass. We have got five years of that.

We have sequencing—this is a validation generally for PCR. We have also done a probit regression. Jennifer Evans looked at me and said, 'We do not believe that you are detecting Borrelia.' I really did not know how to respond because, to me, this is not science. They have been told, 'It is not here,' therefore, it does not seem to matter what we show.

We use three different technologies. We do PCR, which is considered gold standard for microbiology. We use a German immunoblot test and we use a German elispot test. These three are quite different: you have got a molecular biology, a serology and an immunology test. We get positives in all three tests. PCR is obviously the most sensitive. When we do our sequencing—we do not sequence in the laboratory; I cannot afford a sequencer. We send the product from our PCR to an external lab and they do the sequencing. That will tell us exactly what we have got from our PCR product. We use two different companies; we use a AGRF—Australian Genome Research Facility—they got NATA about three years ago. No-one cared before and I do not think anyone really cares now.

We also send to the Ramaciotti Centre. They are based at the University of New South Wales. Lots of people use them. They do not have NATA. No-one cares. I do not think anyone has ever worried about the fact that we do not have NATA for our mycoplasma test testing, which we have also done for 13 years or so. If it was not for the changes that were coming to the TGA, I really would not care if we had NATA.

Senator MADIGAN: Earlier, you mentioned the primers that you had developed. In my layman's interpretation, I would interpret that as being like if I did a quote for a job; I provide the quote to you as commercial in confidence. I would interpret that your primers are your intellectual property—is that correct?

Ms Burke: Yes, I pay a clinical scientist. He designed these particular primers. Mind you, I have a box of primers. Primers are what make your PCR work. You have these bits of DNA. We can get them out of research papers, and I have done that. I have read a good paper and had the primers made. I have tried them and they did not work on patients, so I have put them back in the freezer. We have had some designed. I know various scientists who are very good at designing primers. The set we have now are very good. We get excellent results. So, no, I do not want to tell. When the NATA assessor comes, they come from a different laboratory. It is like someone from your competitor coming to look at your work. No-one expects that one lab is going to show a different lab their intellectual property on how they might get really good results.

Senator MADIGAN: So the people that do the inspection of a laboratory for NATA do not actually work for NATA?

Ms Burke: And then they do not get paid. My clinical scientist is a NATA examiner himself. It is a voluntary thing. He will go to a lab and do an assessment there.

Senator MADIGAN: Doesn't this pose a potential conflict of interest?

Ms Burke: Yes, it gets better. We have now been told, because were supposed to have another assessment—normally, what happens is one technical assessor per section of whatever you are doing, whether is PCR, maybe immunology, and you would get one assessor coming to look at your PCR and one NATA rep. When we had the meeting at Christmas, Jennifer Evans told us that they would give us a choice of three assessors and we could choose one. Two weeks ago, my quality manager received a letter from NATA, in which she gave two assessors. One was a microbiologist/pathologist from Queensland. I do not want anyone connected to the RCPA doing our assessment. For me, that is conflict of interest. How are they going to assess a lab, when they have already been told, absolutely, by the college, 'It's not here'?

The second assessor was a senior scientist from Westmead Hospital. I do not particularly want anyone from Westmead, either. This is another conflict of interest. This is where they did the original papers that said, 'No, it's not here'. So I asked the quality manager to write back and say, 'Who is the third option?' We were given the name of another senior scientist from another lab in Sydney. Now, I probably would have a problem with him. Except in that letter, we were told that we were going to have all three assessors come to the laboratory. Instead of one NATA representative, we would have two NATA representatives, including Andy Griffin, who is the person who told us to rethink reapplying.

I have nine staff and they are not all full time. In my PCR section, I have one PhD who is full time, and I have one scientist who is part time. That is it. Apparently, I am going to have three people coming to assess 1½ staff. The quality manager wrote back and said, 'It's a really small lab; you won't fit'. I am at the point where I think is there any point in me wasting more money, because I do not think they have any intention of giving us accreditation no matter what we present.

Senator MADIGAN: When Australian Biologics applied to NATA for accreditation and submitted information was there a declaration, for want of a better word, that all of your particulars are confidential—a bit like a doctor patient relationship I suppose in laymen's terms?

Ms Burke: It is in their charter—

Senator MADIGAN: How does NATA explain the fact that the information in your application has been dispersed, for want of a better word, to other people. I am having difficulty because I have been into research facilities of manufacturers and I know these people very well—I have known then for 20-odd years. Even though I know them, when I visit and I go into their research facility, I have to sign a declaration that I will not divulge anything that I see in that research facility because they are receiving funding from the Australian government, foreign governments and Australian and multinational corporations. I cannot take a photo; I cannot take a camera in there. I have known these people most of my life. They trust me but they have to do that to me. I am having real difficulty understanding how your information of your company—your intellectual property—gets bandied around. I am having difficulty grasping this.

Ms Burke: What happened was they asked us to do clinical utility and clinical performance studies. We thought we were finished once we had done the progression. Apparently, the regulations had changed making a lab need to do these particular studies. Except they had changed a year earlier and they had not told us—so we got lodged with this. We produced these papers. One we presented was a paper Peter Mayne had written where he compared our results to IGeneX so that was the clinical performance. We also did a study where there was a survey done of doctors, who used the test, as to the usefulness of the test. We sent those to NATA.

Something else happened, and I wrote to them and I said, 'By the way, I don't want any of our information going to the Rickettsial lab because this is competition.' Their quality manager wrote back and said, 'It was a bit

of a whoops movement. We actually have sent your documents to the Australian Society for Microbiology, of which Dr Graves is the chair.' They said this approach sought the committee's opinion on the clinical utility of the assay in question. They said some submitted documentation was also supplied. I do not know what else was supplied; they would not tell me. It says, 'Whilst this was supplied in such a way that it did not identify Australian Biologics in anyway, NATA did not appear to either seek or receive your express permission to do so. This is contrary to NATA rule R39. NATA partially sustains your concern in this regard.' They apparently tried to redact the documents. It is the most bodgie job you have ever seen. There is a capital A at the beginning and you can see the ICS. It is obvious it is us. My name was mentioned.

Senator MADIGAN: This is a redacted document?

Ms Burke: Really badly redacted.

Senator MADIGAN: Last question: you mentioned the TGA before. That is the Therapeutic Goods Administration. If, for instance—correct me if I am wrong—a patient wants to claim a test, they have to have NATA approval for it to be able to claim it back on Medicare. The only way it can be acceptable to Medicare and the TGA is if it has NATA approval. NATA approval is like the gold tick. NATA is not accountable to any investigation or oversight from the Commonwealth.

Ms Burke: It would appear so.

CHAIR: I have also noted that down for checking with the Chief Scientist.

Senator MADIGAN: Thank you, Chair.

CHAIR: I have made note of the long list of things that we have got for the Chief Scientist.

Senator MOORE: Ms Burke, thank you for your submission. I did not understand anything from page 11 onwards, which was the laboratory manuals and all of those pieces of paper. I had no idea, but thank you for providing it.

Ms Burke: I think that was probit regression; it is not simple.

Senator MOORE: It is a scientific process. You have got those things, so I do not need to understand them. But I think we do need to have an idea, for the record, as to why you did attach that document. I have read the rest of the submission, which actually raises more questions about the process of your accreditation and which we have been through. In terms of the history of your laboratory, you have been in the business for a number of years.

Ms Burke: It has been 30 years.

Senator MOORE: You have been operating successfully that whole time within this field—no problems from the universities or any of the people?

Ms Burke: No, we provide the universities with samples for testing for mycoplasma.

Senator MOORE: You have the business model in place, but it seems to have been particularly around this series of testing that the problem—

Ms Burke: We started the molecular in 2002. When I first set it up I wanted to test bacteria that I was interested in. I am interested in bacteria that are involved in chronic disease. This is not tested in routine labs; they test acute infections. I used to be a colleague of Professor Lida Mattman, a professor in America, who did a lot of work on what are called 'stealth pathogens'. I worked with her at her university.

She did mycoplasma testing and *Borrelia* testing. I thought, 'Interesting bacteria, we will do these.' We set up a whole group of bacteria to test. At that stage, I actually did not know that *Borrelia* was not allowed in Australia. Of course, we got positives. It took me a while to realise that we were not supposed to be getting positives. The other tests came in much later, when we started bringing in the immunoblot kit and the elispot kit.

A lot of the argument that is thrown against us is: 'You are getting positives because your laboratory is contaminated.' We do proper contamination checks. I mean, this is ridiculous. You cannot contaminate a PCR lab and also have that contamination affect immunoblots and elispots. This is impossible. They ignore the quality assurance programs. I do not know how we could fake a quality assurance program. What happens is: Glasgow university sends us 10 samples. We do not know what is in them. We have to extract the DNA. We run the test and then we send a report back that might say, 'Sample A is negative, Sample B is positive,' et cetera. We wait about a month and then we get the result that tells us whether we are correct. We pass.

Senator MOORE: With the other element—and I think you have that on record, and we will follow up with NATA—certainly the changes in terms of process mean that, within the system, NATA accreditation is even more important than it has been, I think.

Ms Burke: What we were interested in were the potential changes to the TGA that would affect laboratories doing in-house tests. Our PCR is in-house; it is not a kit, it is our test.. This was really the point of applying for NATA.

Senator MOORE: I want to question, on the record, the statements you have in your submission about one of the other submissions, which has claimed to give information that was provided about your laboratory. I think it is important for that to be put on the record. Can you give a little bit of information on that. You have actually read another couple of submissions which are unnamed—which is not uncommon—in this process, but you believe that inaccurate information about what happened in your laboratory was put on the record?

Ms Burke: This was about our overnight incubation of the immunoblot?

Senator MOORE: Yes.

Ms Burke: Originally, when we first started doing a blot, we used a different kit. I was not very impressed with the results, because I assumed that if the patient has got *Borrelia* and I get a positive PCR we should be able to get a positive in another test as well—it certainly makes us feel better and probably the patient too. We used this other kit for six months to a year, and then I was reading various research papers where different immunoblot kits were being compared, and one of the ones that seemed to be quite good was the MIKROGEN kit. We made contact with the company. I have a permit to import the kits; we started using their kits. It was a little bit better than the original one, but it was not great. We were getting a lot more PCR positives and very few—some, but not a lot—of blot positives.

I was then reading a research paper from a European clinical microbiology presentation, and it was this poster. It was talking about the same MIKROGEN kit, and they were saying that when they were doing the tests, they did not find that the correlation between the other *Borrelia* tests and the MIKROGEN kit were all that great. What they did was increase the incubation of the test. Normally you do a one-hour incubation; they talked about doing an overnight intubation. I thought, 'That might be interesting.' I did not do anything for a while. The people who wrote the paper were doctors from the university hospital of Maastricht in Holland. What I did next was contact one of the doctors at MIKROGEN and say, 'I have read this poster. What do you think?' He said, 'No, no, no. You don't have to do that.' So I did not. I waited another few months. During that time I tried to find one of these doctors. I phoned Holland multiple times at different places and universities and I finally found Dr Van Loo and spoke to her. I said, 'I want to hear about how this worked.' We had a talk. She said that they had validated the tests. They found it much more effective and had a much better correlation with their other tests.

At that stage we ran two tests on a patient. If a patient was asked to do an immunoblot, we did one that was a one-hour incubation and one that was an overnight incubation. We did this for a couple of months. During that period, the result we gave the patient was from the one-hour incubation, because that was the kit method. After a few months of testing, where we had adequate data, and during this time we could also correlated to the results of PCR, it was obvious that we were getting much better results with an overnight incubation. I know this particular doctor talked about us incubating until we got a positive. We get more negatives than positives. We do not even get 50 per cent positives. This is a farce. What we found was that when you do this, you do not create new bands. When you are doing an immunoblot you are looking for specific bands. What happens with the overnight incubation is that the fainter bands become strong enough to match the cut-off and you can give it a positive.

I think one of the issues is, again, that *Borrelia* does not act like other infections. When you do, for example, an immunoblot or some kind of test for Epstein-Barr, you get really strong positives; they will have IgM positive for three to six months and then they are IgG and they stay that for years. *Borrelia* does not work like this; it affects the immune system so much that it just does not give you that standard effect. Until you come to realise this, it makes life really difficult.

CHAIR: I am going to have to get you to speed up a bit because we are going to run out of time. I apologise.

Ms Burke: While I was doing this process I also spoke to another colleague, who is a professor in Canada, Professor Vet Lee, and I told her about this. She started to do the same thing with her blot. She also had the same reaction—that it was much better, much more reliable—and we are looking at doing a research paper on this at some stage.

Senator MOORE: The point, Ms Burke, is that another practitioner has actually claimed that you are falsifying your tests. As someone from outside the industry, the way that I read that paragraph is that you are falsifying your tests.

Ms Burke: Yes. We have got used to this since we started testing Borrelia. I think as I wrote, one patient called and said, 'A doctor down here said that they sent you water and you gave us a positive.' and I said that if they had done that, they should have reported us. The stories are unbelievable. We have had had one scientist

from another lab tell a patient that we did all our PCR in one room and so everything was contaminated. Now, we have PCR in three separate rooms. This was how it was originally set up. The people who set up my PCR had been senior scientists at CSIRO. One of the scientists was a man who actually did the first crystal structure of DNA; he is famous in the PCR world. So our tests were set up properly; the work is done properly; we really try to do our best for the patients. I find it really distressing to think that people in senior positions, who are supposed to be in the caring profession, have no problem directly lying to a patient. They obviously believe the end justifies the means. It is very depressing.

Senator WANG: This may not be an accurate analogy, but NATA seems to be a group or association of Woolies and Coles, and even IGAs, and you are probably trying to open up a corner store and you have to apply to Woolies and Coles to have the permission to open up a corner store. This seems to be the case to me, which brings me to my question: it is probably more reasonable to have a government agency which is solely in charge of the testing procedures, rather than an association formed by the industry?

Ms Burke: Yes.

Senator WANG: That is all I need to know.

Ms Burke: That would be great.

CHAIR: Thank you very much. If you have further information, we are open to supplementary submissions as well.

Ms Burke: I was going to leave you with more sequencing.

CHAIR: That is fine.

Ms Burke: Would you like that?

CHAIR: Yes. That is fine. Thank you, but beyond that, if you have any further comments, the same offer is open to you as well. It is due as soon as possible. There are certain election things happening and so the sooner the better.

BRADSHAW, Associate Professor Stephen, Practitioner Member, Australian Health Practitioner Regulation Agency and Medical Board of Australia

FLETCHER, Mr Martin, Chief Executive Officer, Australian Health Practitioner Regulation Agency

Evidence was taken via teleconference—

[15:34]

CHAIR: Welcome. Could I invite you to make an opening statement, and then we will ask you some questions.

Prof. Bradshaw: Thank you for inviting Martin Fletcher and myself to talk today, and thank you for letting us do this by telephone. We really welcome this opportunity to speak to the committee and to clarify and add to our written submission, which I believe you have in front of you.

The Medical Board of Australia and AHPRA, represented by Mr Fletcher and I today, work in partnership to regulate medical practitioners in the public interest. Our core focus, at all times, is patient safety. We aim to protect the public and uphold quite high and rigorous standards of medical practice. We scrutinise doctors whose actions may be harming patients. Our functions and powers are defined in the health practitioner national law.

On this topic, we recognise that there is a perception by some patients that we have targeted medical practitioners who diagnose, treat or have a relationship with Lyme-like illness. I would like to put it quite clearly on the record that this is not true. In all the Lyme-related cases that we are or have been involved with, the board has always acted—not in isolation or on its own behalf—in response to a complaint. I would like to point out that in the majority of notifications that have been in some way related with Lyme disease or Lyme in some way, the board has decided not to act—not to act, to protect the public. The matters have simply been investigated and then closed. It is in the small number of cases where there is a greater risk, we perceive, to the public that the board has taken a regulatory action to protect the public. It is on the public record that we have received notifications about practitioners who have diagnosed and treated Lyme disease. I would like to point out that it is not because of the diagnosis that they are there before us, but because of their professional conduct in the management of these patients. It is for these patients that we have taken regulatory action.

The board does have a legal obligation to protect the public and take the regulatory action when this is needed to ensure public and patient safety. We are not actually legally able to comment on individual matters that are still under investigation, but we can refer you to the cases that have been considered by state tribunal. These decisions are on the public record and several of them are highlighted in our submission. These make clear that regulatory action is undertaken in relation to patient safety, and not whether Lyme disease exists in Australia or how it should be treated. The board holds all registered medical practitioners to account against the same professional standards, as articulated in our publication, called *Good Medical Practice*. This is regardless of which clinical condition they are treating, or their area of practice. The board expects all doctors to assess each patient carefully and be clear about the possible benefits and risks of harm of any treatment or care they may be suggesting. Doctors should also gain their patients' informed consent and provide treatment based on the best available information.

We have received a great deal of feedback from patients with Lyme or Lyme-like disease, on which the board has taken regulatory action to limit the practice of their treating practitioners. We recognise that these patients have significant health needs and that they have had great difficulty in accessing ongoing treatment. It is true to say it is quite heartbreaking at times to hear the level of stress and suffering from these patients and their families. We are concerned that they get the care they need and that is why we have raised these issues with the Commonwealth and the state departments of health, which are in a better position to help identify the possible referral options for these patients. As regulators, we cannot directly facilitate access to medical services for these patients. We simply ask doctors, who we do regulate, to practise good medicine. If a doctor knows the code of conduct and practises in line with it, the doctor has nothing to fear from the medical board or AHPRA.

Senator Siewert, I think that covers our opening statement. We are happy that you should have in front of you our written submission. I am not sure if Mr Fletcher is planning to add anything to what I have just said; I think we are both happy to receive any questions on what I have just said or on our submission.

CHAIR: Thank you. Mr Fletcher, are you okay for us to proceed to questioning or do you have additional comments?

Mr Fletcher: I am happy for you to proceed to questioning, thank you.

Senator MADIGAN: Thank you, Professor Bradshaw and Mr Fletcher. You said that you do get complaints referred to AHPRA and the medical board from patients. Do GPs or specialists also refer colleagues to the board and AHPRA?

Prof. Bradshaw: Without going to the specifics of specific cases, we certainly have had referrals from all the fields you mentioned.

Senator MADIGAN: I am not asking for specific cases, of course, but are you able to furnish the committee with some statistics? Is the ratio of referrals, complaints from patients to GPs or specialists, 80-20 or 60-40 or 50-50, for example?

Mr Fletcher: Do you mean across the board generally, in terms of all the complaints we have received?

Senator MADIGAN: No, I am speaking specifically in relation to Lyme-like illness and the ratio of general complaints from patients and/or doctors and specialists in reference to other doctors who are treating patients. I would like to see if there is a consistency in the number of complaints or if it is higher in this area that we are speaking about today. I am not asking for specifics. I am just asking for statistics.

Prof. Bradshaw: I think it is difficult to give you that breakdown today.

Senator MADIGAN: You can take it on notice.

Prof. Bradshaw: We are happy to try to furnish you with whatever information we can give you with respect to that. At the end of the day, we handle a notification that comes in by accessing it, in the first instance, and then investigating it to see if it is about a medical practitioner or other practitioner regarding the whole practice. I would like to emphasise the ones we have taken regulatory action on. We have been able to do some small amount of research in this area to find out the actual numbers. For the vast majority of people who are investigated, no further action is taken against those practitioners—and this is with regard to Lyme disease or Lyme-like disease. That is in keeping with the nature of the notifications generally. The vast majority end up with no further action, as they do with this disease.

As I point out quite carefully, we are not actually looking at patients or the doctors because of the disease; it is about their overall medical practice. We take the whole spectrum of what their professional conduct is like before coming to a decision, and only in a small number of cases have we taken regulatory action.

Senator MADIGAN: I realise that, but we are asking what the statistics are. Could you take that on notice.

Prof. Bradshaw: Yes.

Senator MADIGAN: You speak about the fact that doctors and specialists can refer complaints, but what about patients? Are patients able to lodge complaints with the medical board and AHPRA about the doctors who fail to treat them?

Mr Fletcher: Yes, that is correct. Basically, anyone can make a notification to AHPRA and the board. We get notifications direct from patients, carers of patients, other practitioners and also from employers. They are the main groups that are the source of notifications, which is what we call 'complaints' in our scheme.

Senator MADIGAN: Are you able to supply the committee with statistics on how many patients have lodged complaints with AHPRA and the Medical Board in relation to doctors who fail to treat them?

Mr Fletcher: If I can just set the context here: in 2014-15 we received 2½ thousand complaints or notifications about medical practitioners—that excludes New South Wales, which has a separate set of arrangements. If we include New South Wales, that is 4 ½ thousand complaints—

Senator MADIGAN: So you have had 2½ thousand from Australia, excluding New South Wales. Then there is another 2,000 for New South Wales alone.

Mr Fletcher: That is correct. That is because there is a separate set of arrangements in New South Wales for dealing with complaints about registered health practitioners. They are not managed directly by AHPRA or the Medical Board of Australia. That is for any issue; that is the total number that we have received. We publish and we can certainly provide data on the source of those notifications and complaints in general terms. That will indicate, as I say, whether it was a patient or a carer or an employer or another practitioner.

Senator MADIGAN: Could you divide that up once again—what is patient, what is practitioner, doctor, specialist?

Mr Fletcher: We can certainly break it down into patient and practitioner and employer and other. We can certainly break that down for that purpose, yes. In fact, we do publish that data in our annual reports so we can also make reference to that.

Senator MADIGAN: That would be appreciated. For the benefit of the committee, can you explain the complaint investigation process? Who investigates? What is their head of power, so to speak?

Mr Fletcher: Certainly, Senator. I welcome the opportunity to explain how the process works. Basically, as I say, anyone can make a complaint. We call that a 'notification' in our system. Those complaints can relate to three particular elements. It could be about the behaviour or conduct of the doctor; it could be about the health or impairment of the doctor; or could be about the performance of the doctor. As Dr Bradshaw said in his comments, our absolute focus is on establishing whether there is any risk to the patient or any risk to the public as a result of the conduct, health or performance of a doctor that might require regulatory action by the Medical Board of Australia.

When we receive a notification—first of all we have to establish that it relates to a registered medical practitioner. Once we have established that we would then do a preliminary assessment of that notification. These processes would be managed on behalf of the Medical Board of Australia by AHPRA. Once we have the information about the complaint and, usually, some response from the practitioner about whom the concern is being raised, it would go to the Medical Board of Australia, which has a board in each state and territory. They would make a decision about whether there are any grounds which might require further investigation. In some circumstances, if it is something that which raises significant concern about immediate risk to the public, they may, in fact, take what is called 'immediate action' under our legislation. They can, if needed, restrict or suspend the registration of a medical practitioner to address that immediate risk while the ongoing investigation occurs.

As Dr Bradshaw said, quite a lot of matters are closed in assessment where there is not a need for regulatory action—so the matter is closed after assessment. A proportion of matters would then go to investigation. Again, those investigations are administered by AHPRA on behalf of the Medical Board of Australia. In that investigation process we would collect and review evidence. We may, in some circumstances, get statements and reports from experts in relation to the clinical matters that may be involved in the notification. Once all of that evidence is gathered together, an investigation report is prepared. Again, that goes back to the board, and they would make a decision about what regulatory action, if any, was needed. In some cases, following that investigation, there may be a decision to take no further action. If it is a very serious matter of misconduct or it is a matter that might lead to possible cancellation of registration, then there would be a referral to the external independent tribunal that there is in each state and territory. A decision about cancellation or a decision about the most serious matters of misconduct is always referred to the tribunal.

The national law defines a range of actions that the board can take if it is required to take the regulatory action. For example, it could place restrictions on the registration of a medical practitioner, it could require that there be certain supervision requirements or certain additional educational requirements, or it could place certain limitations around the scope of what they can do within their registration. In some circumstances, if it is a question of concern about the health of the practitioner, they may be required to undergo a health assessment to make sure that they are safe to practice. If there are questions or concerns about the performance of that practitioner, there may be a requirement to undergo a performance assessment, which would involve things like observation, review of medical records and the like to establish whether there are any performance concerns that may need to be addressed by the board.

Senator MADIGAN: Finally, Mr Fletcher, on notice would you be able to furnish the committee with the guidelines governing the people that conduct investigations and the processes and rules that are in place to protect confidentiality and potential conflicts of interest? Would you be able to take that on notice and furnish to the committee the rules governing these people who conduct these investigations? Also, if the person that is being investigated is charged a fee for auditing or inspection, what are the rates of fees?

Mr Fletcher: Just to clarify, are you are talking about what our procedures are within AHPRA around these sorts of matters and with the boards, what the legislation says, or both?

Senator MADIGAN: Both.

Mr Fletcher: I am happy to take that on notice.

Senator MADIGAN: Thank you.

Prof. Bradshaw: Could I clarify one thing that Mr Fletcher said—and we can furnish you with this as well. Underpinning our investigations we have a set of regulatory principles now that we have established to follow this. It is a balance between patient safety, which is our primary focus, but we are appropriate and realise that there are practitioner rights as well. We have what we refer to as taking minimal appropriate regulatory force to come to an outcome. We are trying not to be overly punitive to doctors—knowing that they have rights as well—

but it is a matter of protecting the public at the same time. Most of our decisions are appealable by the practitioner to the relevant tribunal.

CHAIR: If you could put the rest of the information that Senator Madigan asked for on notice, that would be great.

Senator WANG: Your submission made it very clear that the MBA and AHPRA's role is to regulate practitioners to ensure the patient's wellbeing and public good. Am I correct?

Mr Fletcher: That is correct.

Senator WANG: Do you consider the failure of doctors to treat Lyme-like illness as is to be against the public good and the patient's wellbeing?

Prof. Bradshaw: We do not get down to the specifics of specific diseases. It is the overall management of cases. If doctors are not following good medical practice, not taking a proper history, not examining them, not investigating and not treating or disregarding something the patient is saying, we would take that as of concern.

Senator WANG: I would assume a good medical practice would mean the doctor would do anything within his or her power to get to the bottom of what is wrong with the patients. Just because the doctor could not find out what is wrong or even fear to tell the truth, not to simply tell the patients that there is something wrong with their head. Would you take any actions against doctors who do not want to tell their patients the real truth about what is wrong with them?

Prof. Bradshaw: It is difficult to talk in hypotheticals. The bottom line is that if a patient is concerned—we get notifications and complaints like this not infrequently, though not necessarily on this topic—and feels that their doctor has not listened to them, has not taken an adequate history and has been dismissive of them—not necessarily with this disease, but with lots of diseases—then they are right to make a notification. We then assess them and investigate them along the principles that Mr Fletcher just pointed out.

Senator WANG: I understand you are merely a regulator, but, given you are somewhat in the profession, what is AHPRA and NBA doing for Lyme-like illness patients?

Prof. Bradshaw: As I said earlier, we are not in the place of diagnosing or facilitating the treatment of individuals practitioners. We are aware that this is a large and unfortunate group of patients who are suffering from what has certainly been a difficult diagnosis to make. We are appreciative that some of our actions have not helped these patients by putting limitations on practitioners. We have spoken to the Commonwealth Department of Health and the state departments of health to try to facilitate a way forward for these patients. But, apart from that, it is difficult for us to get involved with individual cases.

Senator WANG: I am not asking you to get involved with individuals cases. What are the conversations you are having with the government and departments about Lyme-like illness?

Mr Fletcher: I have personally received a great deal of feedback from patients. Indeed, I have responded to over 55 letters from people who have written to me concerned about their access to health services. As Dr Bradshaw said, as regulators we do not provide health services, so we are not in a position to directly assist. We certainly have, and I have personally have, raised the concerns that have been expressed to me with representatives from the Commonwealth and our state Department of Health, particular here in Victoria, where a number of these patients are based, to try to make sure there is visibility about the concerns that are being raised and, if there is anything that either of those entities are able to do, in terms of facilitating access to services and referral options for these people so those options are fully explored.

Senator WANG: Have you been able to make any progress with the state or federal governments after you raised the concerns with them?

Mr Fletcher: The discussions are ongoing. Our role has been to raise the concerns and the issue. It is really then a matter for both of those governments and the relevant departments to determine what they might be able to do. I know that they were certainly looking at this very seriously.

Senator WANG: Would you be able to summarise the feedback you have got so far rather than looking at it seriously?

Mr Fletcher: Essentially, as Dr Bradshaw said, there is a recognition that there is a group of patients here who have significant health needs and, at times, have an experience of going to see a health service provider where they do not get those needs met. What is probably needed is a response both in terms of primary care services and access to specialist services. As I said, we are do not provide services. We are not in a position to solve that problem, but with the relevant departments of health we have certainly raised the sorts of concerns that have been expressed directly to us from these patients.

Prof. Bradshaw: We are, obviously, cognisant of some of the other evidence documented before you tonight. Certainly, the Commonwealth department where they are actively trying to facilitate research on this topic is being encouraged. We are gratified by that because that will help us as regulators and as practitioners to facilitate care for these patients if we can have some clearer research. We encourage the Commonwealth to continue that and to help facilitate that. On a more local level, for the actual patients we note that several of the hospitals have stepped up and are taking a number of the patients that have been disenfranchised recently into their clinics to try and facilitate some ongoing care for these patients. We have been gratified to hear about that.

Senator WANG: Are you able to give us the list of the hospitals who are willing to help Lyme-like patients?

Mr Fletcher: I think it is really a matter for you to take up with the relevant state health authorities. We do not really have an overview of that.

Senator WANG: There is a list somewhere.

Mr Fletcher: We do not have a list.

Senator WANG: How can you say there are several hospitals who are willing to help, if you do not have the names?

Mr Fletcher: As Dr Bradshaw said, we have anecdotal examples but we do not have anything like a list of those hospitals.

Senator WANG: I suppose as a regulator you should have power to collect such a list?

Mr Fletcher: It is not really within the scope of our work. As I say, our focus is very much on the question of individual practitioners and action that might need to be taken to manage risks around public and patient safety.

Senator MOORE: In your submission you made it clear that there was no particular focus on physicians who work on Lyme-like issues and you were very quick to make that clear in your evidence. As a result of the number of issues that have been raised, have you thought about having some kind of statement or gathering around people who work in this field to explain what has gone on and to reassure people that there is not any particular focus on physicians who operate in the Lyme's area?

Mr Fletcher: As I said, I have had more than 55 patients write to me to express concern about their treatment options and regulatory action has been taken in relation to practitioners that they have been seeing. I have written individually to every single one of those people to explain what we have done and why we have done it and to try and set out as clearly as I can the way that we work and what our focus is. I am hoping that has helped people understand what our role is and why we are taking the action that we have taken.

Senator MOORE: My question was more about talking to people in the medical profession. It has been clearly given to us in evidence that there is a concern amongst practitioners that they are being focused on and that they are feeling unsafe with some of the processes operating in the way they would like to do in this field. You made it clear in your evidence that there is no particular focus in this space—and you will give us the data that Senator Madigan asked for with the numbers—but you have identified that there has been some interest around Lyme's disease with the complaints and the number of practitioners you have had interaction with over the last year or so. Given that, my question is: has AHPRA, or the medical board, considered whether there should be some interaction with practitioners—some kind of statement from AHPRA or even a meeting—to let people discuss these issues? It has been quite a serious element of this inquiry. We have had an amount of evidence and information that some practitioners have not been prepared to give evidence, or have wanted to have their names kept confidential, because they do not want to go public about the actions they are taking on Lymes.

Prof. Bradshaw: To be honest with you, we have not considered what you have just suggested. We may consider that after. I re-emphasise to you that we are not a disease-focused organisation—be it Lyme disease, cancer or whatever. We are looking for good medical practice. It is disappointing that there is this perception out there that we are targeting particular groups; I re-emphasise and will keep re-emphasising that we certainly are not. At the end of the day, the number of practitioners that have regulatory action taken against them on this topic is extremely small. There are huge other areas of practice that have a lot more practitioners before us than practitioners looking after patients with Lyme disease.

Senator MOORE: All I can say is that there is very clearly a perception, felt very strongly from the evidence we have received in this inquiry, that practitioners are feeling vulnerable.

Prof. Bradshaw: Thank you for that feedback. We will certainly consider it.

CHAIR: Can a committee refer things to you?

Mr Fletcher: Do you mean about a registered health practitioner?

CHAIR: A complaint, yes.

Mr Fletcher: Anyone can make an application. The only thing I would add is just to remember that in New South Wales, they have a slightly different arrangement. A New South Wales based practitioner would need to go to the Health Care Complaints Commission.

CHAIR: Could you take on notice whether a committee has ever done that?

Mr Fletcher: Whether a committee has ever made a notification to us?

CHAIR: Yes.

Prof. Bradshaw: I will answer to a certain extent. I cannot remember whether a Senate committee ever has. We have had committees of hospitals and places like that that have referred practitioners to us on other issues. Committees, groups of practitioners or groups of concerned people can refer things to us.

CHAIR: Thank you very much for your time today and your submissions. That is the end of our hearing for today. Thank you to all our witnesses, particularly those that gave their personal evidence. I reiterate how important it is for us to hear that.

Committee adjourned at 16:07