SUBMISSION TO THE SENATE INQURY

"The growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients"

SUBMISSION BY: **Name:** [redacted]
Age: [redacted]
Home & Postal Address: [redacted]
Contact: [redacted]

THIS SUBMISSION IS TO BE NAME WITHHELD
I want my submission to be able to be read and downloaded from the Senate website. Do not publish my name, the names of my family, doctor's names or anybody's contact details including address or email details in the submission body as well as in the attachments.

Please contact me if any further supporting evidence or information in relation to my submission is required.

SUBMISSION CONTENTS:

Terms of Reference 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.

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

Terms of Reference g - any other related matters.

SECTION 1 – TECHNICAL SUBMISSION

1.1 Known Borrelia Species and Ability to Diagnose in Australia

Figure 1 provides graphical representation of the types of borrelia known to exist worldwide as of March 20th, 2016. The red and orange sections list all 39/40 species known to infect humans, the yellow section lists 4 species where human pathogenicity has not been established.

Of the 39/40 known human infective species, the Australian laboratories conducting the Medicare covered “Lyme” testing (ELISA followed by Western Blot) can detect a maximum of 3 species – B. burgdorferi sensu stricto, B. afzelii and B. garinii. This testing is only able to detect an immune response to these infections, which is problematic due to the immune dysregulating capabilities of borrelia and variability of individual immune response.

The private Australian laboratory, Australian Biologics, can detect 5 species of borrelia using DNA Sequencing - B. burgdorferi sensu stricto, B. garinii, B. afzelii, B. bavariensis and B. miyamotoi (reference Page 20 of senate submission 545). This testing is able to confirm the presence of active infection.

Given the limitations in the ability of local testing to identify most of the species causing human infection, it is not plausible to dismiss a borrelia infection on the sole basis of a negative pathology result from any laboratory in Australia. Despite this, borrelia infections are dismissed in Australia on the basis of both negative and positive pathology. Section 1.4 of this Submission presents written advice from both State (Queensland) and Federal Health Ministers as such.

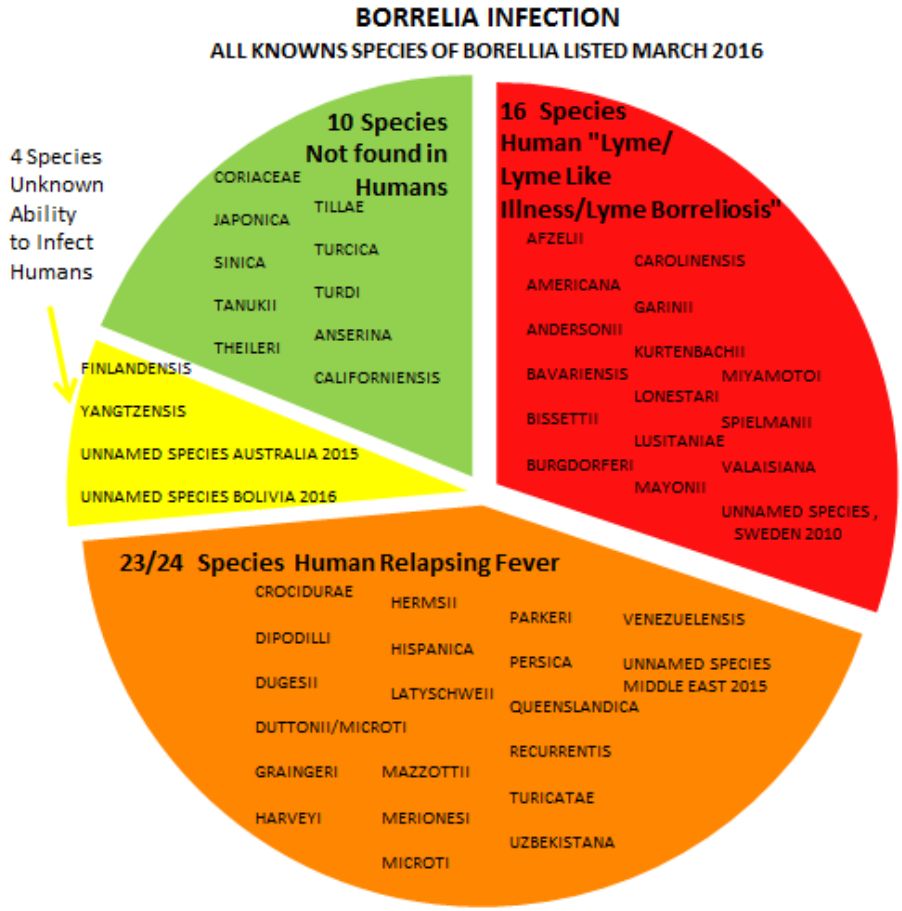


FIGURE 1 - LISTING OF KNOWN SPECIES OF BORRELIA

The detailed listing of all borrelia species, including countries of origin with references to scientific studies is presented in Attachment A.

1.2 Transparency of Testing in Australia

Previous enquiry by the Lyme Disease Association of Australia late last year advised that Australian laboratories conducting the Western Blot tests (as part of the testing available under Medicare), had changed over to European commercial test kits. The strains detectable using European commercial kits are - B. burgdorferi, B. afzelii and B. garinii.

Institute of Clinical Pathology and Medical Research's Microbiology (ICPMR) laboratory at Westmead, the main testing laboratory for Medicare 'Lyme" tests in Australia was only testing for two strains and using an in-house developed test kit in January 2014 when the LDAA survey for the scoping study response was prepared. Figure 2 illustrates testing available under Medicare as presented in the LDAA scoping study response.

	Laboratory	Pathology Service (100+)	Westmead[14] Primary reference lab	PaLMS
Tier 1	Method - kit - strain(s)	ELISA / IFAT - MarDX (Sonic)/ Vidas (BioMerieux) Varies	ELISA - MarDx (Trinity Biotech) - *B. burgdorferi*	ELISA - NovaLisa (NovaTec) - *B. burgdorferi* - *B. afzelii* - *B. garinii*
Tier 2	Method - Kit - Strain	Referred to specialist lab	Western Blot - In-house whole cell lysate - *B. burgdorferi* - *B. afzelii*	Western Blot - EU Lyme + VIsE IgG(Trinity BioTech) - *B. burgdorferi* - *B. afzelii* - *B. garinii*
	Criteria		CDC Surveillance criteria **5 bands**	European guidelines **3 bands**

Figure 2: Comparison of test processes

Figure 2 Testing under Medicare for "Lyme", comparison of test processes.
Excerpt from the 'Patient submission to the Australian Government Department of Health's 'Scoping Study to develop a research project(s) to investigate the presence or absence of Lyme disease in Australia' as prepared by the Lyme Disease Association of Australian Jan 2014

Western Blot pathology results from received from ICPMR Westmead in July / August 2015 lists only B. burgdorferi and B. afzelii bands. ICPMR Westmead has not responded to written or telephone requests regarding which borrelia species can be detected. A copy of the most recent written request is contained in Attachment B. In the absence of a response, it has been assumed ICPMR Westmead laboratory has not changed over to the European commercial test kits and at best can detect B. burgorferi and B. afzelii. The ability of the Western Blot to detect these two species is firstly dependant on the patient passing the ELISA which requires an immune response to B. burgdorferi to be detected. My family had Medicare testing from ICPMR Westmead.

Since Borrelia diagnosis, my family has consulted with 6 GP's, and 5 specialists seeking assistance. Not one of these medical professionals could answer the question as to which borrelia species the Medicare "Lyme" testing was able to detect. One of these GP's did make direct enquires to a public system infectious disease specialist and to ICPMR Westmead Laboratory.

There is a lack of transparency regarding publicly funded pathology tests for borrelia. It is unacceptable that a publicly funded laboratory will not provide advice to members of the public or practitioners. In order to resolve the issues surrounding diagnosis of borreliosis in Australia, the Senate Inquiry should establish which strains of borrelia each Medicare funded laboratory can detect in Australia and ensure this information is available to practitioners and the public alike. This publicly available information should also clearly communicate how many species of borrelia are human infective and the associated test limitations. This is a simple and vital first step in the accurate diagnosis of borrelia.

1.3 Case Study – ICPMR Westmead Detection Inadequacy

My family has undertaken extensive pathology to identify borrelia, all of which is presented in Table 1. Positive test results are shaded green, equivocal are orange with negative results not shaded.

Table 1 – Family Diagnosis of Borrelia

Person	Date	Laboratory	Test	Result	Test Type (Indirect or Direct)	Comment Refer to Attachment D for test explanation
Adult 1	Jun-15	InfectoLAB	Borrelia Immunoblot	IgM Borderline IgG Positive	Indirect	Diagnosis Borrelia Infection.
Adult 1	Jun-15	InfectoLAB	Borrelia Elispot-Lymphocyte-Transformation Test	Positive	Direct	Diagnosis Borrelia. Cellular activity against borrelia.
Adult 1	May-15	Australian Biologics	Borrelia Mikrogen recomLine Immunoblot	IgM Positive IgG Borderline	Indirect	Diagnosis Borrelia. Values exactly on lower limit of the detection range for IgG.
Adult 1	Aug-15	Australian Biologics	Borrelia Serum Culture PCR	Equivocal	Direct	DNA of bacteria present in 2 samples, not present in 2 samples. Retest recommended.
Adult 1	Sep-15	ICPMR Westmead	Borrelia ELISA	Negative	Indirect	No antibodies detected. Negative result is not proof of no infection, rather than of no detectable immune response to those markers the test can detect.
Adult 1	Jun-15	InfectoLAB	Immune System CD-57 Flow Cytometry	Positive	Indirect	The CD57-cell-count indicate a chronic immune-suppressive situation which may be caused by Borrelia burgdorferi.
Adult 2	May-15	Australian Biologics	Borrelia Blood Culture PCR	Positive	Direct	Borrelia bacteria in the blood. Active Infection.
Adult 2	Jul-15	Australian Biologics	Borrelia Serum Culture PCR	Positive	Direct	Borrelia bacteria in the serum. Active Infection.
Adult 2	Jun-15	InfectoLAB	Borrelia Elispot-Lymphocyte-Transformation Test	Positive	Direct	Diagnosis Borrelia. Cellular activity against borrelia.
Adult 2	Jun-15	InfectoLAB	Borrelia Immunoblot	IgM Negative IgG Negative	Indirect	Borrelia IgG and IgM not detected. Negative result is not proof of no infection, rather than of no detectable immune response.
Adult 2	Apr-15	Australian Biologics	Borrelia Mikrogen recomLine Immunoblot	IgM Negative IgG Positive	Indirect	Diagnosis Borrelia.
Adult 2	Sep-15	ICPMR Westmead	Borrelia ELISA	Negative	Indirect	Antibodies Detected. Not proof of active infection, just of immune response to those markers test can detect.
Adult 2	Jun-15	InfectoLAB	Immune System CD-57 Flow Cytometry	Positive	Indirect	The CD57-cell-count indicate a chronic immune-suppressive situation which may be caused by Borrelia.
Child 1	Aug-15	Australian Biologics	Borrelia Serum Culture PCR	Not Detected	Direct	DNA of bacteria not detected. Note this is not proof of absence of infection, just proof that the sample did not contain borrelia.
Child1	May-15	Australian Biologics	Borrelia Mikrogen recomLine Immunoblot	IgM Borderline IgG Positive	Indirect	Diagnosis Borrelia. Values well within detection range for IgG and at the lower limit of the detection range for IgM.
Child1	Jul-15	InfectoLAB	Borrelia Elispot-Lymphocyte-Transformation Test	Positive	Direct	Diagnosis Borrelia. The Elispot indicates a cellular activity against Borrelia.
Child 1	Jul-15	InfectoLAB	Borrelia Immunoblot	IgM Negative IgG Negative	Indirect	Borrelia IgG and IgM not detected. Negative result is not proof of no infection, rather than of no detectable immune response.
Child1	Sep-15	ICPMR Westmead	Borrelia ELISA	Positive	Indirect	Antibodies Detected. Not proof of active infection, just of immune response to those markers test can detect.
Child 1	Sep-15	ICPMR Westmead	Borrelia Western Blot	Negative	Indirect	No antibodies detected. Negative result is not proof of no infection, rather than of no detectable immune response with testing assay used (only sensitive to B. burgdoferi and B. afzelii)
Child 1	Jun-15	InfectoLAB	Immune System CD-57 Flow Cytometry	Negative	Indirect	Immune system on lowest end of normal range. The CD57-cell-count indicate the presence of a chronic immune-suppressive situation
Child 2	May-15	Australian Biologics	Borrelia Mikrogen recomLine Immunoblot	IgM Negative IgG Borderline	Indirect	Diagnosis Borrelia. Values were exactly on the lower limit of the detection range for IgG. Negative IgM result is not proof of no infection, rather than of no detectable IgM.
Child 2	Jul-15	Australian Biologics	Borrelia Serum Culture PCR	Equivocal	Direct	DNA of bacteria present in 2 samples, not present in 2 samples. Retest recommended.
Child 2	Jul-15	InfectoLAB	Borrelia Immunoblot	IgM Negative IgG Negative	Indirect	Borrelia IgG and IgM not detected. Negative result is not proof of no infection, rather than of no detectable immune response.
Child 2	Jul-15	InfectoLAB	Borrelia Elispot-Lymphocyte-Transformation Test	Borderline	Direct	Diagnosis Borrelia. Borderline means that values were at the lower limit of the detection range.
Child 2	Sep-15	ICPMR Westmead	Borrelia ELISA	Negative	Indirect	No antibodies detected. Negative result is not proof of no infection, rather than of no detectable immune response to those markers the test can detect.
Child 2	Oct - 15	IGeneX	Borrelia IgG and IgM Western Blot	Negative	Indirect	No antibodies detected. Negative result is not proof of no infection, rather than of no detectable immune response with testing assay used
Child 2	Oct - 15	IGeneX	Multiplex Whole Blood & Serum	Negative	Direct	Detects specific DNA sequences for B. burgdorferi, B. afzelii, B andersonii and B garinii.
Child 2	Jun-15	InfectoLAB	Immune System CD-57 Flow Cytometry	Positive	Indirect	The CD57-cell-count indicate a chronic immune-suppressive situation which may be caused by Borrelia.

In Australia, my family is not considered to have borrelia as our infections were not detected by ICPMR Westmead. This is concerning considering of the 28 tests results my family have, 15 are positive, 2 are equivocal and 11 are negative. Indirect tests represent the majority of all negative tests (9 negative indirect tests). Indirect tests measure immune response which is problematic in borrelia because borrelia dysregulates the immune system, so this outcome could be anticipated in a late stage borrelia infection. Direct testing shows an active infection. Only 2 of the 10 direct tests ordered were negative. Family test results indicate immune dysregulation and active infection. As ICPMR Westmead only undertakes indirect testing, 4 of the 11 negative indirect test results were from ICPMR Westmead.

Statistics presented by Test Type:

Direct Tests

Number of positive Direct Tests:	6
Number of equivocal Direct tests:	2
Number of negative Direct Tests:	2
TOTAL	**10**

Indirect Tests

Number of positive Indirect Tests:	9
Number of negative Indirect Tests:	9
TOTAL	**18**

Statistics presented by Test Result Type:

Positive Results

Direct tests	6	
Indirect tests demonstrating immune system exposure to borrelia	6	
Indirect tests demonstrating chronic immune system suppression	3	
TOTAL	**15**	

Equivocal Results

Direct tests	**TOTAL**	**2**

Negative Tests

Direct tests	2	
Indirect tests demonstrating immune system exposure to borrelia	8	(4 from ICPMR)
Indirect tests demonstrating chronic immune system suppression	1	
TOTAL	**11**	

1.4 Examples of Misdirection – Key Issues

1.4.1 Ministerial Correspondence

In my family's quest for medical treatment, we have approached both our Qld State MP and Federal MP. Our concerns were presented to the State and Federal Health Minister's offices. Attachment C contains correspondence as follows:

- **(Attachment C-1)** Letter dated 03/09/2015 sent by my family to the Office of the State Member for Mundingburra, Minister for Disability Services, Minister for Seniors and Minister Assisting the Premier of North Queensland, the Hon. Coralee O'Rourke MP.
  The Hon. Coralee O'Rourke advised in writing on 14/09/15 that response to our concerns was being sought from the Office of the Qld Health Minister, the Honourable Cameron Dick MP.

- **(Attachment C-2)** Letter dated 16/10/15 received from the Hon. Coralee O'Rourke MP conveying the response received from the Office of the Qld Health Minister, the Hon. Cameron Dick MP.

- **(Attachment C-3)** Letter dated 29/09/2015 from the offices of the Federal Minister for Health and the Federal Minister for Sport, the Hon. Sussan Ley MP, as sent to our local Federal Member for Herbert, Mr Ewen Jones MP.
  The letter from the Hon. Sussan Ley MP was in response to a letter sent by my family to Ewen Jones MP who then forwarded the correspondence under covering letter to the Hon. Sussan Ley MP. The letter sent by my family to Mr Ewen Jones's office is of very similar content to that contained in Attachment C-1.

The reply from the State MP made no attempt to address or acknowledge the situation the family was experiencing including the numerous positive diagnoses provided. This document presents an incomplete response which solely focused on justifying the refusal of the local Infectious Disease Specialist to treat my wife.

This correspondence is important as it provides concrete examples of the key areas where misdirection is hampering the diagnosis and treatment of borreliosis in Australia. Furthermore, this correspondence illustrates how misdirection dismisses and discourages the attainment of appropriate medical recognition and care. Particular examples are provided in sections 1.4.2 to 1.4.8 of this submission.

1.4.2 Pathology Testing

Blood testing for borrelia, falls into three broad categories:

1. Indirect Tests eg serum antibody tests: ELISA; Western Blot; IFA; Borreliacidal Antibody Assay (Gunderson test);T-cell Activation Test. A positive test indicates exposure to bacteria, a negative test does not necessarily rule out exposure.
2. Direct detection tests eg PCR (DNA amplification); Lyme Urine Antigen Test (LUAT); Antigen Capture Test; culturing of skin, blood, CSF, urine, or tissue; immune complex / antigen-antibody test. Positive tests are proof of active infection, a negative test does not necessarily rule out infection.
3. Tissue Biopsy and Staining eg Silver Stain; Gold Stain; Fluorescent Tagged Monoclonal Antibody Stains; Acrodine Orange; Gram Stain; Muramidase; etc. A positive test is proof of active infection, a negative test does not necessarily rule out infection.

The Government policy of using indirect tests only in Medicare testing for borrelia is a practice that permits a higher degree of uncertainty in diagnosis of active infection than a policy that employed direct testing methods would.

Response from the letter dated 16/10/15 received from the Hon. Coralee O'Rourke MP conveying the reply received from the Office of the Qld Health Minister, the Hon. Cameron Dick MP (Excerpt 1) illustrates the confusion between direct and indirect tests even at the level of the Infectious Disease Specialist. The letter sent to the Hon. Coralee O'Rourke was clear in stating that a positive blood culture (direct test) was provided to the [redacted]. The reply from the Qld Health Minister incorrectly stated that this positive blood culture could possibly indicate past or resolved infection (Excerpt 2). A positive blood culture is direct DNA evidence of active infection and does definitely not indicate a past or resolved infection.

Each testing method has limitations; however these limitations should be understood by those making decisions that result in denial of service to Australians and potential spread of disease.

Excerpt 1

> We are a young family with two children; all four of us have positive diagnoses to Borrelia bacteria. We have eleven positive diagnoses to this devastating infection from laboratories in Australia and Germany (appended). Borrelia is epidemic around the world including America, Asia and Europe

and

> [redacted] (mother) has four positive tests including positive blood and serum cultures. She has been symptomatic of neurological borreliosis since approximately 2003 and has suffered significant illness involving diagnosis of limb girdle muscular dystrophy, pancreas, neuromuscular and autoimmune conditions affecting thyroid and heart. In May this year after receiving the first two positive pathology results for Borrelia bacterial infection she presented to the infectious disease specialist (IDS) Dr [redacted] at the [redacted] hospital and was denied service. One of the pathology tests was a positive blood culture. Despite accompanying medical paperwork demonstrating a high degree of correlation with the medically known symptoms of borreliosis it was not the "belief" of Dr [redacted] that [redacted] had a "Lyme" infection. Despite repeated requests, explanation as to the basis of Dr [redacted] "belief" was not provided.

Excerpt 2

> I am informed that there are several laboratories that test for Lyme Disease in Australia including Westmead. I understand that Dr [redacted] clinical judgement was that you were not displaying symptoms consistent with a diagnosis of Lyme Disease, in accordance to international guidelines. Additionally, a positive test could indicate a past, resolved infection. Dr [redacted] clinical judgement was that current symptoms were not consistent with active infection.

Every single member of my family has positive direct tests, which demonstrate active infection. These direct tests are listed in Table 1 of this submission along with numerous positive indirect tests. These positive tests were presented to the Federal and State Health Minister's offices. The State Health Minister simply did not acknowledge the family situation, let alone the positive test results.

The remaining way to deny treatment of the active infection in my family is to discredit the testing laboratories, which both the offices of the State and Federal Health Minister have done. It is the right of the patient to be provided a robust technical justification for the government refusal of pathology results and it is expected that this would be provided. As discussed in the following section, no robust justification has been provided.

1.4.3 Refusal to Accept Results from non NATA/RCPA Laboratories

It is the position of the Government not to accept test results which are not from RCPA/NATA Accredited laboratories. This position is made clear in the refusal to clinically accept my family test results as stated in the letter issued by the Hon. Coralee O'Rourke MP conveying the response received from the Office of the Health Minister (Queensland), the Hon. Cameron Dick MP (Excerpt 3).

Excerpt 3

The test results you provided were not clinically acceptable to Dr [redacted] as they were not from laboratories accredited by the Royal College of Pathologists of Australasia (RCPA). An RCPA position statement approved in February 2014 Diagnostic Laboratory testing for Borreliosis ('Lyme Disease' or similar syndromes in Australia and New Zealand) specifically cautions against the validity of results from non-National Association of Testing Authorities/RCPA-accredited laboratories in Australia and overseas (mainly the USA and Germany) testing for Lyme Disease.

The issues surrounding the refusal to accept Australian Biologics Laboratory Test Results are responded to in submission no. 545 to this inquiry and will not be addressed in this submission.

NATA (National Association of Testing Authorities) is an Australian organisation and primarily relates to accreditation of testing facilities in Australia. The international standards for laboratory testing are provided in ISO15189:2012 and many laboratories identifying borrelia in Australian patients comply with this standard. It has been argued that no endemic borrelia has been identified as causative in Australia's lyme-like-illness. If this were true, one could assume that the borrelia infections being identified comprise of borrelia species originally endemic to other countries. If this is the case, it would make sense to rely on the ISO 15189 certification as the requirement for testing laboratories.

With respect to my family's InfectoLAB test results, InfectoLAB are accredited in accordance with ISO 15189:2012. Australia can now legitimately recognise the results from Infectolab, as on the 6th January 2016 after seeking membership, NATA was granted membership to the International Laboratory Accreditation Cooperation (ILAC). This means that ISO/IEC 15189:2012 and ISO/IEC 17043:2010 accreditation granted by NATA to Medical Testing laboratories and Proficiency Testing Providers respectively is internationally recognised and ensures the results of activities (pathology tests) conducted by these facilities can be accepted worldwide. Likewise, the test results from other members of the ILAC are now able to be recognised by NATA labs. This acceptance would include InfectoLAB.

I hope the Senate committee ensures Australia accepts InfectoLAB results including those results issued prior to 6th January 2016.

The testing qualifications of InfectoLAB have not altered in the 8 months between my family's diagnosis and Australia gaining ILAC membership. As such, the Senate could investigate why the position of not accepting ILAC accredited overseas results on the basis of lack of NATA accreditation, was in place to start with. It would be very difficult to argue that this Government policy was in place for technical reasons; given Australia was the country without the ILAC membership.

The response from the Hon. Coralee O'Rourke MP conveying the response received from the Office of the Health Minister (Queensland), the Hon. Cameron Dick MP, goes onto state (Excerpt 4).:

Excerpt 4.

In Australia, diagnostic criteria are very stringent requiring highly specific confirmatory tests at accredited reference laboratories; using laboratory tests from endemic countries would result in a high percentage of erroneous (false positive) results.

This position is unhelpful in the event treatment is sought in Australia for an overseas acquired and diagnosed infection. In relation to the statement that overseas testing would result in a high percentage of erroneous results, many of the overseas test laboratories have the ability to identify species, including novel species and endemic species that our local testing cannot identify. I am not aware of any novel borrelia species anywhere worldwide that has been identified through a NATA accredited laboratory. Additionally, it could be argued that pathology clinics local to the region are best equipped to detect the species endemic to the region. I request that the Senate Inquiry obtain technical explanation of this Government position, which is of critical importance in establishing infection (including overseas acquired) in patients. There must have been significant evidence / testing completed in order to arrive at this position.

1.4.4 Circular Pathology-Dependant Diagnosis Policy

Borrelia is a difficult infection for pathology to identify and as such, the accepted medical position is clinical diagnosis. However, in Australia this position is discouraged, even when patients present with likely overseas acquired infection with travel history, tick bite and positive pathology tests. Undue emphasis is placed on the attainment of a pathology diagnosis from an accepted (NATA/RCPA laboratory) as the only acceptable evidence of infection.

Excerpt 5 contains an explanation from the government justifying the requirement for positive pathology to obtain a diagnosis. This excerpt is from the letter dated 29/09/2015 from the offices of the Federal Minister for Health and the Federal Minister for Sport, the Hon. Sussan Ley MP. This is the answer received to justify the dismissal of the numerous positive pathology tests and overseas patient travel history provided by my family.

Excerpt 5

> In a country where the presence of Lyme disease has not been confirmed, such as Australia, it is not possible to reliably diagnose Lyme disease on clinical signs and symptoms alone as there are many other diseases (infectious and non-infectious) that can have similar clinical features.
>
> Tests to diagnose Lyme disease are technically complex and require specialist expertise. They should only be conducted in laboratories that are accredited in Australia and compliant with AS ISO 15189 (accredited laboratories are listed at www.nata.asn.au). Such accredited Australian diagnostic laboratories are able to diagnose Lyme disease by serology in patients who have returned from overseas areas where Lyme disease is endemic.
>
> The medical testing accreditation scheme is run jointly by the National Association of Testing Authorities (NATA), Australia with the Royal College of Pathologists of Australasia based on policy guidance provided by the National Pathology Accreditation Advisory Council. The policy guidance takes the form of standards and guidelines which pathology laboratories must adopt in order to be accredited.
>
> Individual laboratories apply to NATA for accreditation in medical testing and then undergo an assessment by NATA selected assessors. Once accredited, laboratories become members of NATA.
>
> The Institute of Clinical Pathology and Medical Research's microbiology laboratory has medical testing accreditation and is generally regarded as the reference laboratory in Australia for Lyme disease serology.

Patients presenting with overseas or locally acquired borrelia should not have to wait on the confirmation of endemic 'Lyme" disease in Australia first. "Lyme" disease will continue not to 'exist' in Australia as diagnosis will continually be denied to all presenting with locally or overseas acquired infections and positive pathology because the pathology will not be accepted and the laboratories that meet the government's requirements (NATA/RCPA) do not provide testing for the appropriate species and do not use direct testing. It is kindergarten school logic. This is the situation my family faces.

Furthermore, in the event a positive pathology test is obtained through the accepted NATA/RCPA laboratories, the patient may be denied treatment as the result can be / will be deemed a false positive or indicative of a past resolved infection. As the NATA/RCPA laboratories only use indirect tests (measure of immune response) as opposed to direct (measure of active infection), this argument is used.

1.4.5 Use of Unclear Medical Terminology

The letter from the Federal Health Minister presented in Attachment C-3 did not define what was meant by "Lyme". It is unclear if the correspondence is referring to human infective borreliosis generally; or to some or all of those borrelia in the Borrelia burgdorferi sensu lato complex or to the one species of borrelia burgdorferi ("Classic Lyme Disease"/ "True Lyme Disease"). All these possible interpretations have very different meanings. Without definition of "Lyme", the letter is vague and cannot address the issues.

An example is contained within excerpt 5 *" Such accredited Australian diagnostic laboratories are able to diagnose Lyme disease by serology in patients who have returned from overseas areas where Lyme disease is endemic"*

It is highly contentious that Australian Medicare NATA/RCPA laboratories are able to identify 'Lyme" disease serology in patients who have returned from overseas areas where "Lyme" is endemic. This statement would only be prudent if the interpretation of the word "Lyme" referred only to infections of B. burgdorferi,, B. afzelii or b. garinii and the two step ELISA Western Blot test system was revised, as the ELISA detects burgdorferi only and results in more false negatives than positives. The government is well aware of considerations related to use of the ELISA. Issues with the use of ELISA were presented in the LDAA response to the scoping study 2014.

The Government has omitted to state their position with respect to those patients presenting with borreliosis of species other than those few species able to be diagnosed in Australian NATA/RCPA accepted laboratories.

1.4.6 Discouragement of National Notification

Borreliosis is a disease that spans all continents of the globe and is in epidemic proportions in many other countries where Australians travel. Surveillance issues are not restricted to known vectors, but would also relate to migratory birds, imports including animals, congenital transmission, blood supply and organ donation contamination. Sexual transmission is subject to further studies, with sufficient evidence existing to warrant concern. Government notification via the Communicable Diseases Network Australia is an issue worthy of further address by the Senate.

Excerpt 6 contains a section of the letter received *from the Offices of the Federal Minister for Health and the Federal Minister for Sport, the Hon. Sussan Ley MP, dated 29/09/2015 (Attachment C-3)*

> CDNA considered that that national notification of Lyme disease is not currently warranted given there is currently no definitive evidence of Lyme disease being acquired in Australia and also the difficulties associated with developing an acceptable case definition. Rather they concluded that other methods for monitoring the disease would be more appropriate. One possible way would be for states and territories to work with public health laboratories to improve data on the number of cases and to ensure the appropriateness of laboratory protocols and practices.
>
> CDNA did note that the need for national notification would be reassessed if any new evidence of locally acquired disease and the presence of a competent vector became available.

The position of only considering local infection of borrelia as the requirement for establishment of a national notification network is not what is occurring for dengue or zika (both these infections are not endemic to Australia and both are notifiable). This is of great interest as the mosquito known to carry both zika and dengue (Aedes aegypti) is being release into backyards in North Queensland under the Defeat Dengue Now program. The Aedes Aegypti has been established as a borrelia vector. The wolbachia bacteria these mosquitos are infected with impacts on RNA virus, not borrelia bacteria; leaving my neighbours who have these boxes in proximity to my home exposed to my family infection.

1.4.7 Denial of Borrelia and Autism Connection

The letter from the Federal Health Minister dismissed Autism Borrelia, a position that is contradictory with recent published medical science. My wife's senate submission presents information on autism and maternal infection.

Figure 7 - Extract from letter received from the Offices of the Federal Minister for Health and the Federal Minister for Sport, the Hon. Sussan Ley MP, dated 29/09/2015 (Attachment C-3)

> For example, the children of the [redacted] family have been diagnosed with disorders on the autism spectrum. This is not caused by an infectious disease and specialist paediatric care is required. My Department is not aware of any verifiable evidence that classical Lyme disease is associated with autism in children. Additionally, there remains no verifiable repeatable evidence for Lyme disease transmission sexually or vertically from mother to child.

Maternal infection has been established as one of the causative factors in the development of Autism and indeed, this subject is discussed in the 2008 medical text "Autism Current Theories and Evidence, edited by A. Zimmerman", Part IV (Immunology, Maternal – Fetal Interaction, and Neuroinflammation). There is a great deal of information regarding borrelia infection and it's mechanisms of immune system disruption, including its role in the development of autoimmunity as found in Autistic individuals and their mothers. Simply put, regressive Autism (also known as autoimmune autistic disorder) is a condition caused by interplay between genetics, environment and infection.

The issue of Autism borrelia was raised on the 18th of September 2015 at a round table meeting in the House of Representatives regarding Lyme (Borrelia) infection in Australia. During this meeting, Dr Richard Schloeffel, a prominent Australian doctor spoke, an extract from the Hansard follows:

> *"This is never about the money; it is about treating people who are chronically ill and, if you do not treat them adequately, some will be disabled for their whole life at enormous cost to the community and some will die. Some of these people are kids.*
>
> *We have 1,000 children in my practice with autism spectrum disorder. I am doing tests with my colleague who is a paediatrician and some of the research coming out of the states shows that 40 per cent of children with autism have borreliosis or co-infections. That may be the case if translated here.*
>
> *Autism used to be an uncommon disease; now it is one in 100 in Australia. In America it is one in 50; it used to be three in 1,000. So, what is happening to our children?*
>
> *I asked the paediatrician to do IGeneX tests and, low and behold, what did we find? These kids come up positive for Borrelia. We treat them, and I guide him in treating under five-year-olds and they get better and they stop being autistic."*

The official autism rates for junior school children in Australia is approximately 1 in 40, skewed to a higher incidence in the younger grades. If Australian infection rates of borrelia in the autistic primary school children approach 40% as they do in the United States of America, this equates to 1 in 100 Australian children with borrelia autism. This is certainly the case for my children. This issue is worthy of government attention, but cannot be addressed without accurate pathology and good policy surrounding borrelia.

1.4.8 Debate Tactics

The issue the Australian community is grappling with is twofold, firstly concerning the existence of an endemic Lyme-like-illness and secondly concerning the lack of scientifically reliable diagnostic testing in Australia for all human infective borrelia species.

Only infection with Borrelia Burgdorferi (one of the 39/40 species known to infect humans) is termed "True Lyme Disease"/"Classic Lyme Disease". At no point have I observed any patient or patient advocate body arguing that borrelia burgdorferi ie – "Classic Lyme Disease" is endemic to Australia. The argument about the presence of borrelia burgdorferi in Australia is frequently used by the medical community during debate and is frequently successful in confusing, obscuring or redirecting discussion.

What complicates discussion is that many of the other species of borrelia known to cause lyme-like-illness are regularly and interchangeably referred to in published medical literature as "Lyme Disease" or "Lyme borreliosis" or "Lyme-like-Illness". To simplify, the public refer to these infections as "Lyme". Borrelia able to infect humans roughly falls into two groups, that causing "Lyme Disease/Lyme Borreliosis /Lyme-Like-Illness" and that belonging to the relapsing fever group which causes symptoms ranging from life threatening to mild infection. There is no testing for the relapsing fever group that I am aware of in Australia.

The remaining aspect of the debate centres squarely on the existence of an endemic lyme-like-illness which is thought to be likely a borrelia spirochete, given the symptoms Australian patients suffer are very similar to those of "Lyme borreliosis" and the same types of treatment are successful. This is a very similar situation to what is occurring in Brazil where the medical authorities (very much advanced on their Australian counterparts) have named the Brazil endemic lyme-like-illness "Baggio-Yoshinari Syndrome" and are treating their sick citizens as you would for borrelia infection and parallel to that, they are working on identifying the causative organism. It would be prudent for Australia to do the same.

I cannot find another example of any other disease anywhere else in the first world where such a dangerous and backward medical approach to an emerging epidemic has been taken. Pathology is a fairly recent invention and healing people is not. The excuse of holding off until there is 'evidence' and using 'evidence based medicine' is ludicrous considering never before has there been so much evidence or information readily on hand regarding diagnosis and treatment. Many other countries are doing a much better job of diagnosing and treating this illness.

1.5 Willingness/Ability of Australian Doctors to Treat

My family has attended hundreds of medical appointments with upwards of 50 doctors and specialists. Not one of these medical professionals considered tick borne infections of borrelia, bartonella, babesia, rickettsia or mycoplasma or for that matter, any vector borne disease with the exception of Dengue, Barmah Forest and Ross River (mosquito borne). Identification of my family's illnesses was a product of personal research.

My youngest child who has never left Australia presented with symptoms of Babesia (a common tick borne illness) and was diagnosed after positive overseas pathology showed active Babesia duncani infection. In Australia there is simply no testing available for this species of frequently fatal infection. The stance of our medical authorities is that this congenitally transmissible disease is not here. Details are contained in my wife's submission.

My family have faced outright denial of the presence of borrelia (overseas acquired, locally acquired, congenitally acquired) in Australia and a refusal of treatment. After presentation of positive borrelia pathology, of the doctors / specialists my family have consulted:

- **3 have expressed fear to treat borrelia** (note some compassionate doctors will provide partial treatment despite this fear);
- **4 have denied the presence of the disease** even when presented with multiple positive pathology results, travel history and medical history, one resorting to outright hostility. Appendix C contains a witness statement of a meeting between my wife and an Infectious disease specialist who denied treatment on the basis of 'belief'. Another doctor after agreeing previously that my wife did not have MS, continued to push her to obtain an MS diagnosis even after borrelia diagnosis were provided. After questioning the infliction of misdiagnosis, expense and ineffective treatment she was instructed to leave and not return. Another GP, on presentation of positive pathology stated "You can't have this because you are in Australia" to discourage service.
- **3 have advised that they could not/would not assist** given the disease complexity and their current knowledge and;
- **4 have advised it was not their position description** (job) to treat the infection.

Note some doctors have used multiple excuses.

1.6 Call for Review of the Medical Profession

1.6.1 Cost and Benefit

My family has paid large sums to doctors who have provided no discernible positive outcome in diagnosing, treating or healing Borreliosis; even though this occurs in other countries. Taken amass, the collective expense and experiences of borreliosis suffers strongly infers either gross ineptitude exists in Australian medicine as concerns infectious diseases and/or that there is a vested interest or political agenda working against the diagnoses and treatment of Borrelia in Australia. These are issues worthy of a Royal Commission.

1.6.2 Professional Standards

The ongoing professional registration requirements for professions such as pilots are far more rigorous than those for medical practitioners. They are pass / fail. If you fail you don't have a job. Given the powers of life and death that doctors wield on a daily basis and the vast amount of taxpayer money they consume, an annual pass/fail competency test should be mandatory for this profession.

SECTION 2 – PERSONAL STORY

2.1 Diagnosis

I have 4 positive blood tests and two borderline blood tests one equivocal blood test to borrelia as follows:

Positive Elispot to Borrelia Burgdorferi and CD57 Tests from InfectoLAB in Germany (below)

Analysis	Result	Unit	Reference Range	Chart
Please consider the results of the Borrelia-Elispot and CD57+cell-count. Please take into account further clinical symptoms, coinfections and differentials.				
Borrelia burgdoferi Elispot				
Borrelia burgd. fully antigen	**+ 10**	SI	< 2	
Borrelia peptide mix	**+ 14**	SI	< 2	
Borrelia LFA-1	**+ 3**	SI	< 2	
Diagnosis Borrelia				
The Elispot indicate a cellular activity against Borrelia burgdorferi.				
CD 57 Flow Cytometry				
Natural Killer Cells Heparin	7	%	6 - 29	
Natural Killer Cells absolute Heparin	135	/µl	60 - 700	
CD-57 positive NK-Cells Heparin	3	%	2 - 77	
CD-57 positive NK-Cells absolute Heparin	**- 48**	/µl	130 - 360	
Review CD 57				
The CD57-cell-count indicate a chronic immune-suppressive situation which may be caused by Borrelia burgdorferi.				

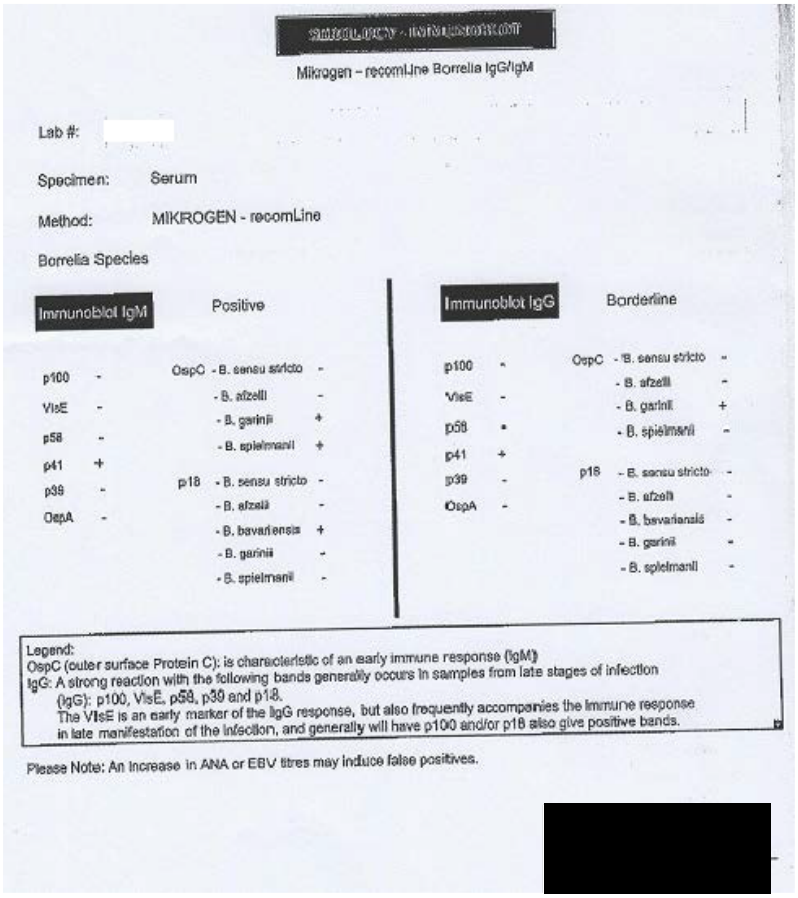
Positive IgG Blot and Borderline IgM Blot from InfectoLAB in Germany (below)

Material: CPDA-Blut, Serum, CPDA-Blut, EDTA-Blut, Heparin Blut, CPDA-Blut, Serum, Serum, Serum,

FINAL REPORT

Analysis	Result	Units	Reference Range	Chart
Borrelia burgdoferi Blot				
Borrelien Blot IgG	positive			
-- Blot IgG p18	negative			
-- Blot IgG p19	negative			
-- Blot IgG p20	negative			
-- Blot IgG p21	negative			
-- Blot IgG p58	negative			
-- Blot IgG OspC	negative			
-- Blot IgG p39	negative			
-- Blot IgG p41	positive			
-- Blot IgG p83	negative			
-- Blot IgG LBb	negative			
-- Blot IgG LBa	negative			
-- Blot IgG VlsE-Bg	positive			
-- Blot IgG VlsE-Bb	negative			
-- Blot IgG VlsE-Ba	negative			
Borrelien Blot IgM	borderline			
-- Blot IgM OspC Bg	borderline			
-- Blot IgM OspC Bb	negative			
-- Blot IgM OspC Ba	negative			
-- Blot IgM p39	negative			
-- Blot IgM p41	positive			
-- Blot IgM VlsE-Bb	negative			
Borrelia-Blot-antibodies				
Specific IgG-antibodies and borderlien IgM antibodies detected by immunoblot method against Borrelia burgdorfei suggest an infection. IgM-antibodies are borderline by immunoblot method against Borrelia burgdorferi.				

Positive Immunoblot IgM and Borderline Immunoblot IgG from Australian Biologics Testing Service in Sydney (below)



SEROLOGY - IMMUNOBLOT

Mikrogen – recomLine Borrelia IgG/IgM

Lab #:

Specimen: Serum

Method: MIKROGEN - recomLine

Borrelia Species

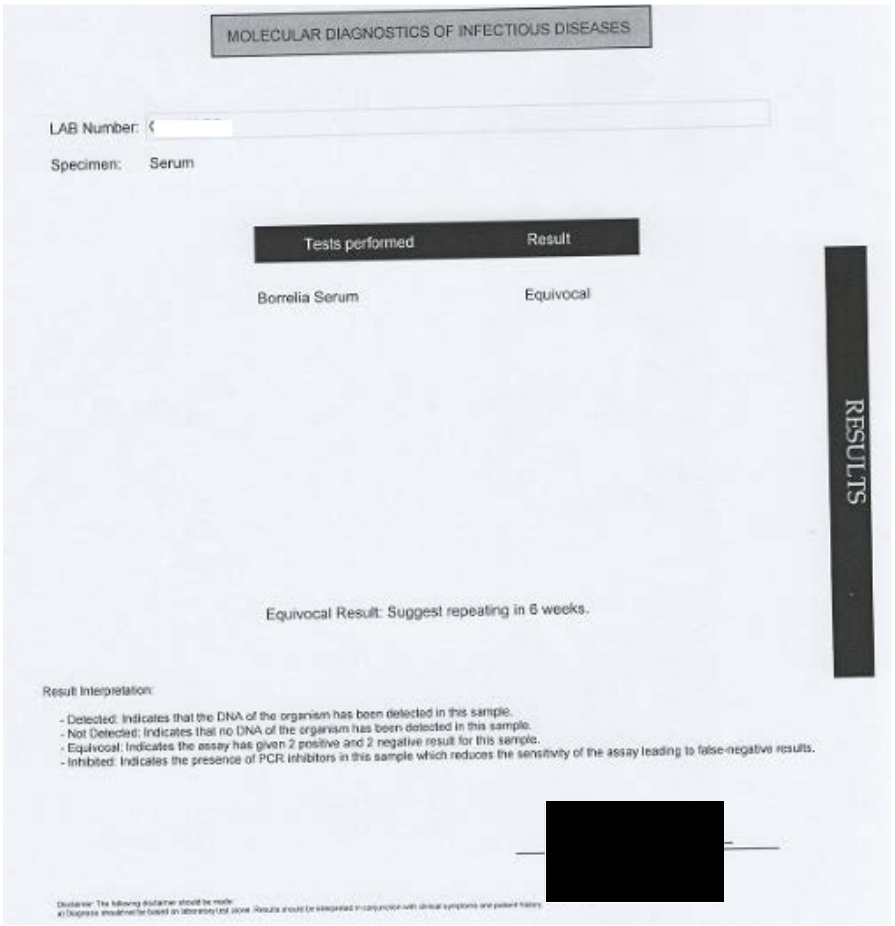
Immunoblot IgM	Positive		Immunoblot IgG	Borderline	
p100	-	OspC - B. sensu stricto	p100	-	OspC - B. sensu stricto
VlsE	-	- B. afzelii	VlsE	-	- B. afzelii
p58	-	- B. garinii	p58	+	- B. garinii
p41	+	- B. spielmanii	p41	+	- B. spielmanii
p39	-	p18 - B. sensu stricto	p39	-	p18 - B. sensu stricto
OspA	-	- B. afzelii	OspA	-	- B. afzelii
		- B. bavariensis			- B. bavariensis
		- B. garinii			- B. garinii
		- B. spielmanii			- B. spielmanii

Legend:
OspC (outer surface Protein C): is characteristic of an early immune response (IgM)
IgG: A strong reaction with the following bands generally occurs in samples from late stages of infection
(IgG): p100, VlsE, p58, p39 and p18.
The VlsE is an early marker of the IgG response, but also frequently accompanies the immune response in late manifestation of the infection, and generally will have p100 and/or p18 also give positive bands.

Please Note: An increase in ANA or EBV titres may induce false positives.

[redacted]

Equivocal Serum Culture Test from Australian Biologics Testing Service in Sydney (below)



MOLECULAR DIAGNOSTICS OF INFECTIOUS DISEASES

LAB Number:

Specimen: Serum

Tests performed	Result
Borrelia Serum	Equivocal

RESULTS

Equivocal Result: Suggest repeating in 6 weeks.

Result Interpretation:

- Detected: Indicates that the DNA of the organism has been detected in this sample.
- Not Detected: Indicates that no DNA of the organism has been detected in this sample.
- Equivocal: Indicates the assay has given 2 positive and 2 negative result for this sample.
- Inhibited: Indicates the presence of PCR inhibitors in this sample which reduces the sensitivity of the assay leading to false-negative results.

[redacted]

2.2 Infection History

- Prior to my illness I was a pilot and flew internationally. I was a very fit and athletic and enjoyed cross country running. Frequently whilst in the USA for work, I went running wearing shorts in the bushland of lyme endemic areas in the north east of America. I was unaware of borrelia and tick borne disease considerations.

- I am unsure of where I contracted Borrelia infection. I have travelled to the following countries: USA (10 times), Canada, Papua New Guinea (6 times), Malaysia (3 times), Singapore (4 times), Indonesia (3 times), Vietnam, Thailand, Myanmar, Kuwait, United Arab Emirates, United Kingdom, Italy, France, Netherlands, Belgium (2 trips), New Zealand (6 times), Japan, Solomon Islands (3 times), Peru and Argentina. I regularly travel to remote areas of Australia (Torres Strait, Cape York).

- I rarely wore insect repellent. I have been bitten numerous times by insects including ticks, bedbugs, lice, mosquitos, sand flies. Bites that have been noticeable that I can recall have occurred in Australia, Thailand, Papua New Guinea, USA, South America and the United Kingdom. I have had several rashes over my body following insect bite and also many eschar and rashes at location of bite.

- During overseas trips to America, Thailand and UK, I had acute febrile illness. I had periods of illness following work in the remote coastal north Queensland bush.

- During a trip to Papua New Guinea in 2012 I had fevers, fatigue, diarrhoea, joint pain and other flu like symptoms with an enlarged liver (12 months) and distended abdomen. I visited multiple doctors that only ran the standard ova cysts and parasite tests. At no stage was I ever investigated for any tropical disease or vector borne illness other than malaria. Shortly after this trip is when I started to experience fatigue, joint swelling and pain in my hands, knees, hips and elbows. Doctors had no explanation for these symptoms.

- In 2013 to present I have many ligament, tendon and joint issues, swelling and pain including ligament and tendon injuries with no obvious cause. This has affected my hands, fingers, wrist, feet, elbows, knees and hips joints. In 2013 for the full year it was very painful to walk due to pain inside my feet.

- Following my wife's borrelia diagnosis, at my last medical check up in 2015 after having arthritis and fatigue symptoms for years, and knowing my wife had tested positive for borrelia, I asked my doctor if I could have borrelia but was told "No you can't it does not exist in Australia". At this stage, I had not been tested for borrelia and sought testing through my wife's doctor.

- In 2015, my children and myself were diagnosed with borrelia infection. I do not doubt I have other co-infections however cannot afford further overseas testing which seems to be the only way to identify co-infections associated with borrelia acquired overseas. The testing simply is not available in Australia for many co-infections like babesia. I have exhausted the testing available in Australia under Medicare.

2.3 Health and Employment Impact of Borrelia

- In 2013 the pains in my hands and elbows were so great I had to stop flying as it was often too painful to hold the control column of the aircraft. My feet gave me constant pain which I suspect originated from my tendons. As I walked it felt like my the bones in my feet were broken.

- I commenced a Masters degree in 2013 with the intent of completing it in two years but have been unable to do so due to a marked decrease in my cognitive ability. My reading and comprehension has deteriorated remarkably and what I know to be simple concepts I am finding exceptionally difficult. I know this should be straightforward work but my visual processing and comprehension and ability to synthesise new information is almost non-existent. I have to read a page 5 – 10 times to understand it. My ability to manage noise has also deteriorated, I am now unable to understand speech in background noise, which I understand to be auditory processing but am yet to have this diagnosed formally.

- Fasciculation's in face, forearms, biceps. The fasciculation can involve entire muscle groups and persist for up to 10 hours and is frequently visible under my clothing.

- I am constantly tired.

- I have frequent burning sensations through my body and have muscular exhaustion without exercise. I often have to rest my limbs during the day.

- My ability to recover from infections is poor.

2.4 Family Impact of Borrelia

My wife ([redacted]) has submitted to the senate inquiry, separate submission to my own and containing the submissions of my children ([redacted]).

I met my wife in 2002. In 2003 she started having neurological problems related to motor control of her limbs. I married in 2005. In 2012 my wife became increasingly disabled and was diagnosed with limb girdle muscular dystrophy, the diagnosis was revoked following a negative muscle biopsy. Her variable condition has changed and she is now suffering seizures (some life threatening), up to three a day. She is unable to work.

This has placed our family under enormous stress, particularly considering the poor health and behavioural conditions suffered by both my children who have autism, ADHD, borrelia and many coinfections and associated diagnoses.

In 2006 my first child [redacted] was born extremely sick. [redacted] suffered numerous GI tract, ear and tonsil infections requiring 7 operations before the age of 3. Current diagnosis include: Allergies, spina bifida, reactive arthritis, Gastroesophageal Reflux Disorder, Partial Bowel Obstructions. Formal diagnosis under the DSM-V includes: Autism Spectrum Disorder, Attention Deficit Hyperactivity Disorder, Dysgraphia, Dyscalculia (disorder of Mathematics), Anxiety Disorder. Other diagnoses includes Sensory Processing Disorder, Central Auditory Processing Disorder, Visual Processing Disorder. Tick Borne diseases diagnosed are Borrelia (InfectoLAB, Australian Biologics, ELISA test medicare), Bartonella Henlesae (Medicare) and Mycoplasma pneumonaie (Medicare).

In 2009 my second child [redacted] arrived after a complicated pregnancy during which my wife haemorrhaged from 14 weeks to term. [redacted] was born very unwell with Allergies, GI tract problems, Gastroesophageal Reflux Disorder and stopped breathing daily multiple times during sleep, going on to suffer numerous ear and tonsil infections, eating disorders and requiring surgery at the age of 7 months which triggered an obvious regression into Autism. Current diagnoses are ADHD and Autism with further expected. Pathology has revealed infections of Borrelia (InfectoLAB, Australian Biologics), Bartonella henlesae (Medicare) and active Babesia duncani (IGeneX).

I cannot begin to describe the grief and loss associated with the disability diagnosis of my children which I believe to be a direct result of maternal infection with tick borne illnesses. There is emerging evidence of sexual transmission of borrelia.

2.5 Financial Impact of Borrelia

The cost of Borrelia Autism has devastated our family's finances.

We ceased counting expenses on early intervention for Autism five years ago, when costs exceeded $400k. They have greatly exceeded this figure now. Given my wife's position as a civil engineer, she suffered direct loss of employment with associated income of at least $100k/annum. In the last year alone since our family diagnosis we have spent approximately $30k. $20kof which was spent on pathology and seeking medical assistance including travel and accommodation, and $10k on supplementation to date:

Loss of wife's income to date	$ 700,000 (minimum)
Treatment of Autism:	$ 400,000 (exceeds this figure)
Borrelia diagnosis, doctors and treatment:	$ 30,000
Total:	**$> 1,130,000 WITH COSTS ONGOING**

I should not have to point out the additional burden to Australia in loss of taxable income, cost of disability and public medical treatment. We are unable to claim expenses on private health cover as borrelia infection is not a recognised condition in Australia.

This is not a self-inflicted condition like most diabetes, obesity and smoking related illness. It is grossly unfair that the government pays for conditions arising from poor lifestyle choices and provides nothing to support those families with borreliosis.

My wife, children and myself have not found appropriate medical support. We are in a position where we cannot afford the doctors' bills and the travel associated with treating this disease as well as finance the ongoing costs associated with Autism early intervention.

I am unable to finance the medical care required to treat four people with borrelia including two children with autism. It is my fear that further deterioration of my wife will leave the family in a position where I become the carer for three disabled persons, and at this stage work would not be possible. Given my wife does not have a condition to qualify her for support or access to her superannuation, this makes it incredibly difficult. I am also unwell.

Without borrelia we would be in a financially strong position with dual income and good learning and career development potential. It is very likely we would have had very healthy children. Now we face the real prospect of becoming dependant on social support.

Unless the Australian government remedies the deficiencies surrounding the acceptance of borrelia diagnosis and permits access to affordable treatment, our family has a very bleak future.

2.6 Social Impact of Borrelia on Family

Borrelia undiagnosed and untreated has caused a huge loss of quality of life for my family. It has disabled my children, left my family financially stressed, reduced career and education opportunities, taken my wife's ability to work, restricted her physical ability and reduced her ability to care for our children. The already stressed family has had to manage the social isolation associated with disability of children and illness of parents and now we have had to petition to remedy the mess our appalling medical governance has created and counteract a medical culture of bullying, fear, denial and ignorance.

In Australia there is only very limited, geographically inconvenient and expensive medical treatment available for what is a rather common diagnosis overseas.

Due to the complications associated with autoimmune presentation of chronic borreliosis, my wife and children are not responding well to treatment attempts and their borrelia and coinfections are unresolved, leaving them infective and by default, able to spread the infection further. I have not resolved my infection. Those that subsequently contract borreliosis from untreated members of my family will hold the political system accountable for its failure to remedy the situation. Failure to treat is to the detriment of all Australians, not just those infected as the incidence and transmission of this disease is largely unknown and the costs in loss of productivity and social services potentially enormous in the years to come.

Borrelia has been politicised and publicised unnecessarily. Australian medical authorities and the government continue to deny the diagnosis and existence of overseas acquired borrelia infections, as well as infections acquired in Australia. The associated image surrounding borrelia in Australia is one of a psychiatric condition not a medical condition. This has been highly detrimental to our family. Such is the extent of the problem that my wife has been the subject to the ridicule of medics attending to her mid seizure (life threatening) in her own home. Hospital trips are avoided as the explanation and justification of the diagnosis to medical professionals is frightening and service ultimately unable/unwilling to be provided that will remedy the situation.

ATTACHMENT A – Table of known worldwide borrelia March 2016

No.	Group LD - Lyme Disease Group RF - Relapsing Fever Group	Borrelia Name and year of discovery	Geographical Region/s. List not complete.	Known Association with Human Disease	References
1	LD	B. afzelii (1994)	Sweden, China, North America, Europe, Asia	Yes. Lyme borreliosis	1a, 1b, 18a, 51a, 51b
2	LD	B. americana (2010)	North America	Yes. Lyme borreliosis	2a
3	LD	B. andersonii (1995)	North America	Yes. Lyme borreliosis	3a, 3b
4	RF	B. anserina (1891)	Worldwide	No. Avian borreliosis	4a, 4b,12a
5	RF	B. baltazardii (1979)	Middle East	Yes. Relapsing Fever	17a, 17b
6	LD	B. bavariensis (2009)	North America, Europe	Yes. Lyme borreliosis	18a, 1a
7	LD	B. bissettii (1998)	North America, Canada, Europe	Yes. Lyme borreliosis	25a
8	RF	B. braziliensis (1952)	South America	Yes. Relapsing Fever	8a
9	LD	B. burgdorferi (1984)	Worldwide. Sweden, China, Eastern United States, Western United States, Europe, Asia, Japan, North America, Canada, Europe, Australia	Yes. Lyme borreliosis. “Classic Lyme”	9a, 9b, 12a, 51a, 51a, 51b, 18a, 1a
10	LD	B. californiensis (2007)	North America	No.	10a
11	LD	B. carolinensis (2009)	North America	Yes. Lyme borreliosis	11a
12	RF	B caucasia (1945)	Caucasus (northwestern Russia,Georgia, Armenia and Azerbaijan) to Iraq Iran and Central Asia	Yes. Relapsing Fever	12a
13	RF	B coriaceae (1987)	Northeastern Aftrica, Middle East, Southern Europe, Western United States	No. Epizootic bovine abortion	12a, 13a, 4b, 46a
14	RF	B crocidurae(1917)	West Africa, North Africa, Morocco, Libya, Egypt, Iran, Rturkey, Senegal, Kenya	Yes. Relapsing Fever	4b, 12a
15	RF	B. dipodilli	Morocco, Libya, Egypt, Iran, Rturkey, Senegal, Kenya	Yes. Relapsing Fever	12a
16	RF	B. dugesii (1949)	North America	Yes. Relapsing Fever	4c

17	RF	B. duttonii (1906) Ref 17b. This paper concluded that B. microti and B. duntonii might be same species.	Central, Eastern and Southern Africa, Sub-Saharan Africa, Middle East	Yes. Relapsing Fever	4b, 4c, 12a, 17a, 17b
18	LD	B. finlandensis (2011)	Finland, Europe,	Unknown Novel species isolated from a tick.	18a
19	LD	B. garinii (1992)	Sweden, China, North America, Europe, Australia, Asia, Japan	Yes. Lyme borreliosis	51a, 51b, 18a, 1a, 1c
20	RF	B. graingeri (1953)	Mombasa	Yes. Relapsing Fever	20a
21	Unknown.	B. harveyi (1947)	Kenya	Yes. 'produces a mild infection in man'.	21a
22	RF	B. hermsii (1942)	Canada, North America, Western United States	Yes. Relapsing Fever	22a, 12a, 4b, 4c
23	RF	B. hispanica (1926)	Spain, Portugal, Morocco, Algeria, Tunisia, North Africa, South Europe, Iberian peninsula and Northwestern Africa	Yes. Relapsing Fever	4b,12a, 23a, 46a
24	LD	B. japonica (1994)	Japan	No	24a
25	LD	B. kurtenbachii (2010)	North America	Yes. Lyme borreliosis	25a, 25b
26	RF	B. latyschweii (1941)	Iran, Central Asia, Middle East	Yes. Relapsing Fever	12a, 17a
27	RF	B. lonestari (1996)	North America, Southern United States.	Yes. Lyme borreliosis	4b
28	LD	B. lusitaniae (1997)	Sweden, Europe, Asia	Yes. Lyme borreliosis	28a, 28b, 51a
29	LD	B. mayonii (2016)	United States America	Yes. Lyme borreliosis	29a, 29b
30	RF	B. mazzottii (1956)	Southern United States, Mexico, Central and South America	Yes. Relapsing Fever	12a
31	RF	B. merionesi (1974)	Morocco, Libya, Egypt, Iran, Rturkey, Senegal, Kenya	Yes. Relapsing Fever	12a
32	RF	B. microti Ref 17b. This paper concluded that B. microti and B. duntonii might be same species.	Middle East, Morocco, Libya, Egypt, Iran, Rturkey, Senegal, Kenya	Yes. Relapsing Fever	12a, 17a, 17b.
33	RF / LD	B. miyamotoi (1995) Refer to Note 1	Japan, Netherlands, Russia, USA, Europe, North America, Eurasia, Asia, Sweden	Yes. Relapsing Fever / Lyme Disease. Refer Note 1.	33a to 33k, 51a
34	RF	B. parkeri (1942)	South America, Western United States	Yes. Relapsing Fever	8a, 12a
35	RF	B. persica (1913)	Central Asia, From west China and Kashmir to Iraq and Egypt, USSR, India, Middle East, Greece	Yes. Relapsing Fever	4b, 12a, 17b, 46a
36	RF	B. queenslandica (1962)	Australia	Yes. Relapsing Fever	36a
37	RF	B. recurrentis (1874) (syn. B. obermeyeri, B. novyi)	World wide. Africa, South America, Middle East, Europe and Asia	Yes. Relapsing Fever	4c, 17a, 12a, 46a
38	LD	B. sinica (2001)	China, Nepal, Asia	No	1c, 38a
39	LD	B. spielmanii (2006)	Europe	Yes. Lyme borreliosis	39a
40	LD	B. tanukii (1997)	Japan	No	40a

41	RF	B. theileri (1903)	Worldwide. West Africa	Bovine Borreliosis	12a, 41a
42	RF	B. tillae (1961)	Cape Provience South Africa	No	42a
43	RF	B. turcica (2004)	Turkey, Jordan, Romania	No	43a
44	LD	B. turdi (1997) (formerly B. turdae)	Japan, Korea, Portugal	No	44a, 44b, 44c, 44d
45	RF	B. turicatae (1933)	North America, Southwestern United States, Mexico, Central and South America	Yes. Relapsing Fever	4b, 4c, 8a, 12a, 46a
46	RF	B. uzbekistana	Central Asia	Yes. Relapsing Fever	46a
47	LD	B. valaisiana (1997)	Sweden, China, Europe, Asia, Japan	Yes. Lyme borreliosis	47a, 51a, 51b
48	RF	B. venezuelensis (1921)	Central America and norther South America	Yes. Relapsing Fever	12a
49	LD	B. yangtzensis (2015) (formerly proposed as B yangtze)	Asia, China, Japan	Unknown. Has not been examined in humans.	51b
50	RF	B. (Unnamed Species, 2015)	Australia	Unknown. Has not been examined in humans.	50a
51	LD	Unnamed (2010) Refer to Note 2	Sweden	Yes. Research required to identify new species in LD group. Studies in Sweden found strains of unknown borrelia in human subjects.	51a 51b
52	RF	Unnamed (2015)	Middle East	Yes. Novel borrelia relapsing fever bacteria sequenced from 2 patients.	17a
53	RF	Unnamed (2016)	Bolivia	Unknown. Novel tick borne relaspsing fever borrelia identified. Unable to determine if this borreia was the incompletey described Borreia mazzottii.	8a

NOTES

1 Borrelia Miyomatoi disease does not fit into categories of Relapsing Fever or Lyme Disease, but shares characteristics of both.

2 A 2010 study undertaken of borrelia in ticks found in Sweden (Reference 51) identifed borrelia of unknown type in 9 ticks. Primer solution was designed to detect burgdorferi, garinii, afzelii, valaisiana, lusitaniae, spielmanii, andersonii, hispanica, miyomoti, turdi, parkeri, crocidurae, tanukii, duttonii, hermsii, theileri, perscia, anserina, turicatae, turcica,japonica, coriaceae, recurrentis, lonestari.

3 Can be identified using Western Blot test which is completed only if the ELISA test is positive. ELISA relies on immune system function and borrelia is immundysregulatory so the test is unreliable.

REFERENCES

1	a	Piesman, J., and L. Gern. 2004. *"Lyme borreliosis in Europe and North America."* Parasitology 129(Suppl.):S191-S220.
	b	Masuzawa T. (2004) *"Terrestrial distribution of the Lyme borreliosis agent Borrelia burgdorferi sensu lato in East Asia."* ' J Infect Dis. 2004 Dec;57(6):229-35.
2	a	Rudenko, N., et al. (2009). *"Delineation of a new species of the Borrelia burgdorferi sensu lato complex, Borrelia americana sp. nov."* J. Clin. Microbiol. 47**:**3875-3880.
3	a	Kerry L. Clark, Brian Leydet, Shirley Hartman (2013). *"Lyme Borreliosis in Human Patients in Florida and Georgia, USA".* Int J Med Sci 10 (7): 915–931.
	b	Marconi RT, Liveris D, Schwartz I (September 1995). *"Identification of novel insertion elements, restriction fragment length polymorphism patterns, and discontinuous 23S rRNA in Lyme disease spirochetes: phylogenetic analyses of rRNA genes and their intergenic spacers in Borrelia japonica sp. nov. and genomic group 21038 (Borrelia andersonii sp. nov.) isolates".* Journal of Clinical Microbiology ***33*** *(9): 2427–34.*
4	a	Ataliba, Alexandre C.; Resende, José S.; Yoshinari, Natalino; Labruna, Marcelo B. (October 2007). *"Isolation and molecular characterization of a Brazilian strain of Borrelia anserina, the agent of fowl spirochaetosis".* Research in Veterinary Science 83 (2): 145–149.

	b	Magill, A.J., Ryan, E.T., Solomon, T., Hill, D.R., (2013) *"Hunter's Tropical Medicine and Emerging Infectious Diseases",* 9th Edition, Elsevier, p. 602
	c	Dworkin, Mark S. et al. *"Tick-Borne Relapsing Fever."* Infectious disease clinics of North America 22.3 (2008): 449–viii.
8	a	Parola, Phillippe et al. (2011) *"Relapsing Fever Borrelia in Ornithodoros Ticks from Bolivia."* Annals of Tropical Medicine and Parasitology 105.5: 407–411.
9	a	Fraser, C. M., et al. (1997)." *Genomic sequence of a Lyme disease spirochaete, Borrelia burgdorferi.*" Nature 390:580-586.
	b	Qiu, W. G., et al.(2008). *"Wide distribution of a high-virulence Borrelia burgdorferi clone in Europe and North America."* Emerg. Infect. Dis. 14**:**1097-1104.
10	a	Rudenko N, Golovchenko M, Grubhoffer L and Oliver JH Jr (2009) *"Borrelia carolinensis sp. nov., a new (14th) member of the Borrelia burgdorferi Sensu Lato complex from the southeastern region of the United States."* J Clin Microbiol;47(1):134-41.
11	a	Rudenko, Nataliia et al. *"Borrelia Carolinensis Sp. Nov., a New (14th) Member of the Borrelia Burgdorferi Sensu Lato Complex from the Southeastern Region of the United States ."* Journal of Clinical Microbiology 47.1 (2009): 134–141.
12	a	Harris, K.F.(ed) (2012),*" Advances in Disease Vector Research, Volume 6."* Springer Verlag, New York, pp. 128-129.
13	a	LeFebvre, R B, and G C Perng. (1989) *"Genetic and Antigenic Characterization of Borrelia Coriaceae, Putative Agent of Epizootic Bovine Abortion."* Journal of Clinical Microbiology 27.3: 389–393.
17	a	Naddaf SR, Ghazinezhad B, Sedaghat MM, Asl HM, Cutler SJ. *"Tickborne relapsing fever in southern Iran, 2011–2013"* [letter]. Emerg Infect Dis. 2015 Jun [date cited].
17	b	Naddaf, Saied Reza et al. (2012) *"Phylogenetic Analysis of the Spirochete Borrelia Microti, a Potential Agent of Relapsing Fever in Iran."* Journal of Clinical Microbiology 50.9 : 2873–2876.
18	a	Casjens, Sherwood R. et al. (2011) *"Whole Genome Sequence of an Unusual Borrelia Burgdorferi Sensu Lato Isolate ." Journal of Bacteriology* 193.6: 1489–1490.
20	a	Baker J.R. & Muller,R.(ed) (1989), *"Advances in Parasitolog:y Volume 24"*, Academic Press Limited, p. 217.
21	a	Breed,R.S., Murray, E.G.D., Smith, N.R. (1957) *"Bergey's manual of determinative bacteriology Seventh Edition"*, The Williams & Wilkins Company, Baltimore, p. 904
22	a	Schwan TG, Policastro PF, Miller Z, Thompson RL, Damrow T, Keirans JE. *"Tick-borne Relapsing Fever Caused by Borrelia hermsii, Montana."* Emerg Infect Dis [serial online] 2003 Sept [date cited].
23	a	Elbir, Haitham et al. *"Genome Sequence of the Relapsing Fever Borreliosis Species Borrelia Hispanica."* Genome Announcements 2.1 (2014): e01171–13.
24	a	Nakao M, Miyamoto K, Fukunaga M (1994). *"Borrelia japonica in nature: genotypic identification of spirochetes isolated from Japanese small mammals"*. Microbiology and Immunology ***38*** *(10): 805–8.*
25	a	Margos, Gabriele et al. *"Multilocus Sequence Analysis of Borrelia Bissettii Strains from North America Reveals a New Borrelia Species, Borrelia Kurtenbachii." Ticks and tick-borne diseases* 1.4 (2010): 151–158.
	b	Stanek G, Reiter M (April 2011). *"The expanding Lyme Borrelia complex--clinical significance of genomic species?"*. Clinical Microbiology and Infection : the Official Publication of the European Society of Clinical Microbiology and Infectious Diseases 17 (4): 487–93.
28	a	Collares-Pereira, M., et al. (2004). *"First isolation of Borrelia lusitaniae from a human patient."* J. Clin. Microbiol. 42**:**1316-1318.
	b	de Carvalho, I. L., et al.(2008). *"Vasculitis-like syndrome associated with Borrelia lusitaniae infection"*. Clin. Rheumatol. 27:1587-1591.
29	a	Pritt, Bobbi S et al. *"Identification of a novel pathogenic Borrelia species causing Lyme borreliosis with unusually high spirochaetaemia: a descriptive study"* The Lancet Infectious Diseases published online. http://www.thelancet.com/journals/laninf/article/PIIS1473-3099(15)00464-8/abstract
	b	CDC MEDIA RELEASE Monday, February 8, 2016 *"New Lyme-Disease-Causing Bacteria Species Discovered"* http://www.cdc.gov/media/releases/2016/p0208-lyme-disease.html
33	a	Sam R. Telford, Heidi K. Goethert, Philip J. Molloy, Victor P. Berardi, Hanumara Ram Chowdri, Joseph L. Gugliotta and Timothy J. Lepore (2015). *"Borrelia miyamotoi Disease: Neither Lyme Disease Nor Relapsing Fever."* Clinics in Laboratory Medicine, Volume 35, Issue 4, pp 867-882
	b	Sato K, Takano A, Konnai S, et al.(2014) *"Human Infections with Borrelia miyamotoi, Japan". Emerging Infectious Diseases*. ;20(8):1391-1393.

	c	Cosson, Jean-François et al. (2014) *"Genetic Characterization of the Human Relapsing Fever Spirochete Borrelia Miyamotoi in Vectors and Animal Reservoirs of Lyme Disease Spirochetes in France." Parasites & Vectors* 7: 233.
	d	Platonov AE, Karan LS, Kolyasnikova NM, Makhneva NA, Toporkova MG, Maleev VV, et al.(2011) *"Humans infected with relapsing fever spirochete Borrelia miyamotoi, Russia."* Emerg Infect Dis. ;17:1816–23
	e	Gugliotta JL, Goethert HK, Berardi VP, Telford SR III. (2013) *"Meningoencephalitis from Borrelia miyamotoi in an immunocompromised patient."* N Engl J Med. ;368:240–5
	f	Krause PJ, Narasimhan S, Wormser GP, Rollend L, Fikrig E, Lepore T, et al.(2013) *"Human Borrelia miyamotoi infection in the United States."* N Engl J Med.368:291–3
	g	Chowdri HR, Gugliotta JL, Berardi VP, Goethert HK, Molloy PJ, Sterling SL, et al. *"Borrelia miyamotoi infection presenting as human granulocytic anaplasmosis: a case report."* Ann Intern Med. 2013;159:21–7
	h	Hovius JW, de Wever B, Sohne M, Brouwer MC, Coumou J, Wagemakers A, et al. *"A case of meningoencephalitis by the relapsing fever spirochaete Borrelia miyamotoi in Europe"*. Lancet. 2013;382:658
	i	Fukunaga M, Takahashi Y, Tsuruta Y, Matsushita O, Ralph D, McClelland M, et al. *"Genetic and phenotypic analysis of Borrelia miyamotoi sp. nov., isolated from the ixodid tick Ixodes persulcatus, the vector for Lyme disease in Japan."* Int J Syst Bacteriol. 1995;45:804–10.
	j	Branda, John A.; Rosenberg, Eric S. (July 2013). *"Borrelia miyamotoi: A Lesson in Disease Discovery"*. Annals of Internal Medicine 159 (1): 61–62.
	k	Editorial Staff (August 2014). *"Etymologia: Borrelia miyamotoi"*. Emerg Infect Dis [Internet] (CDC) 20 (8). doi:10.3201/eid2008.ET2008. Retrieved 25 July 2014.
36	a	Carly J. G. and Pope J. H. (1962) *"A new species of Borrelia (B. queenslandica) from Rattus villosissimus in Queensland"*. Aust J Exp Biol Med Sci; 40:255-61.
38	a	Masuzawa T, Takada N, Kudeken M, Fukui T, Yano Y, Ishiguro F, Kawamura Y, Imai Y and Ezaki T (2001) *"Borrelia sinica sp. nov., a lyme disease-related Borrelia species isolated in China."* Int J Syst Evol Microbiol; 51(Pt 5):1817-24.
39	a	Fingerle, V., et al.(2007)." *Epidemiological aspects and molecular characterization of Borrelia burgdorferi s.l. from southern Germany with special respect to the new species Borrelia spielmanii sp. Nov"*. Int. J. Med. Microbiol. 298:279-290.
40	a	Masuzawa T1, Suzuki H, Kawabata H, Ishiguro F, Takada N, Yanagihara Y. (1996) *"Characterization of Borrelia spp. isolated from the tick, Ixodes tanuki and small rodents in Japan."* J Wildl Dis. Oct;32(4):565-71.
41	a	McCoy, Brandi N., Ousmane Maïga, and Tom G. Schwan. (2014) *"Detection of Borrelia Theileri in Rhipicephalus Geigyi from Mali."* Ticks and tick-borne diseases 5.4: 401–403.
42	a	Weinman,D., Ristic, M., (1968) *"Infectious Blood Diseases of Man and Animals: Diseases Cuased by Protista, Volume II: The Pathogens, the Infections, and the Consequences"*, Page 205, Academic Press New York and London
43	a	Kalmár, Zsuzsa et al. (2015) *"Transstadial Transmission of Borrelia Turcica in Hyalomma Aegyptium Ticks."* Ed. Brian Stevenson. PLoSONE 10.2 (2015) e0115520.
44	a	Fukunaga M, Hamase A, Okada K, Nakao M; Hamase; Okada; Nakao (1996). *"Borrelia tanukii sp. nov. and Borrelia turdae sp. nov. found from ixodid ticks in Japan: rapid species identification by 16S rRNA gene-targeted PCR analysis"*. Microbiology and Immunology **40** (11): 877–81.
	b	Kang, Jun-Gu; Kim, Heung-Chul; Choi, Chang-Yong; Nam, Hyun-Young; Chae, Hee-Young; Chong, Sung-Tae; Klein, Terry A.; Ko, Sungjin; Chae, Joon-Seok (March 27, 2013). *"Molecular Detection of Anaplasma, Bartonella, and Borrelia Species in Ticks Collected from Migratory Birds from Hong-do Island, Republic of Korea"*. Vector-Borne and Zoonotic Diseases 13 (4): 215–225.
	c	Masuzawa T, Komikado T, Kaneda K, Fukui T, Sawaki K, Yanagihara Y; Komikado; Kaneda; Fukui; Sawaki; Yanagihara (August 1997). *"Homogeneity of Borrelia japonica and heterogeneity of Borrelia afzelii and 'Borrelia tanukii' isolated in Japan, determined from ospC gene sequences"*. FEMS Microbiology Letters 153 (2): 287–93.
	d	Norte, Ana C.; Lopes de Carvalho, Isabel; Núncio, Maria S.; Ramos, Jaime A.; Gern, Lise (2013). *"BlackbirdsTurdus merula as competent reservoirs for Borrelia turdi and Borrelia valaisiana in Portugal: evidence from a xenodiagnostic experiment*". Environmental Microbiology Reports 5 (4): 604–607.
46	a	Scheld,W.M., Whitley,R.J., Marra, C.M. (2004). *"Infections of the Central Nervous System"*, Third edition, Lippincott, Williams & Wilkins, Philadelphia, p. 664
47	a	Diza E, Papa A, Vezyri E, Tsounis S, Milonas I, Antoniadis A. (2004) *"Borrelia valaisiana in Cerebrospinal Fluid"*. Emerging Infectious Diseases.;10(9):1692-1693.
49	a	Margos G, Chu CY, Takano A, Jiang BG, Liu W, Kurtenbach K, Masuzawa T, Fingerle V, Cao WC, Kawabata H. (2015). *"Borrelia yangtzensis sp. nov. a rodent associated species in Asia is related to B. valaisiana."* Int J Syste Evol Microbiol, 2015 Aug 3
50	a	Alexander W. Gofton, Charlotte L. Oskam, Nathan Lo, Tiziana Beninati, Heng Wei, Victoria McCarl, Dáithí C. Murray, Andrea Paparini, Telleasha L. Greay, Andrew J. Holmes, Michael Bunce, Una Ryan and Peter Irwin (2015). *"Inhibition of the endosymbiont "Candidatus Midichloria mitochondrii" during 16S rRNA gene profiling reveals potential pathogens in Ixodes ticks from Australia."* Parasites and Vectors, 8:345, pp 1 - 11.
51	a	Wilhelmsson, Peter et al.(2010) *"Prevalence and Diversity of Borrelia Species in Ticks That Have Bitten Humans in Sweden ." Journal of Clinical Microbiology* 48.11: 4169–4176.
	b	Hao, Qin et al. (2011) "Distribution of Borrelia Burgdorferi Sensu Lato in China." *Journal of Clinical Microbiology* 49.2: 647–650.

ATTACHMENT B – Copy of Correspondence with Westmead

From: [redacted]
Sent: Friday, 18 March 2016 12:51 PM
To: [redacted]
Subject: Queries for your technical team - with the table this time!

This time sent with the table.

From: [redacted]
Sent: Friday, 18 March 2016 12:39 PM
To: [redacted]
Subject: Queries for your technical team

[redacted]

It was lovely talking with you this morning. As discussed, please forward the below questions to your technical staff. I expect they are quick to answer and am hoping to hear back today. If you receive an answer to even one question, please send it to me.

1. I am wishing to ascertain what species of borrelia can be identified by the western blot assay kit used in your laboratory. Please advise either the kit manufacturer (and I will chase this information though them) or indicate on the table below what species can be detected.

2. Borrelia that infects humans is roughly divided into relapsing fever and lyme borrelia groups. Can the ELISA test detect relapsing fever borrelia species?

3. Is there any testing other than ELISA and Western Blot used to detect borrelia infection at your lab?

Thankyou for your assistance.

No.	*Group LD - Lyme Disease Group*	*Borrelia Name*	*Known Association with Human Disease*	*Western Blot can Test for it?*
1	*LD*	*B. afzelii*	*Yes. Lyme borreliosis*	*Yes*
2	*LD*	*B. americana*	*Yes. Lyme borreliosis*	*No?*
3	*LD*	*B. andersonii*	*Yes. Lyme borreliosis*	*No?*
4	*RF*	*B. anserina*	*Yes. Relapsing Fever*	*No?*
5	*RF*	*B. baltazardii*	*Yes. Relapsing Fever*	*No?*
6	*LD*	*B. bavariensis*	*Yes. Lyme borreliosis*	*No?*
7	*LD*	*B. bissettii*	*Yes. Lyme borreliosis*	*No?*
8	*RF*	*B. braziliensis*	*Yes. Relapsing Fever*	*No?*
9	*LD*	*B. burgdorferi*	*Yes. Lyme borreliosis. "Classic Lyme"*	*Yes*

10	*LD*	*B. californiensis*	*No.*	*N/A*
11	*LD*	*B. carolinensis*	*Yes. Lyme borreliosis*	*No?*
12	*RF*	*B caucasia*	*Yes. Relapsing Fever*	*No?*
13	*RF*	*B coriaceae*	*Yes. Relapsing Fever*	*No?*
14	*RF*	*B crocidurae*	*Yes. Relapsing Fever*	*No?*
15	*RF*	*B. dipodilli*	*Yes. Relapsing Fever*	*No?*
16	*RF*	*B. dugesii*	*Yes. Relapsing Fever*	*No?*
17	*RF*	*B. duttonii*	*Yes. Relapsing Fever*	*No?*
18	*LD*	*B. garinii*	*Yes. Lyme borreliosis*	*No?*
19	*RF*	*B. graingeri*	*Yes. Relapsing Fever*	*No?*
20	*Further Research Required*	*B. harveyi*	*Yes.*	*No?*
21	*RF*	*B. hermsii*	*Yes. Relapsing Fever*	*No?*
22	*RF*	*B. hispanica*	*Yes. Relapsing Fever*	*No?*
23	*LD*	*B. japonica*	*No*	*N/A*
24	*LD*	*B. kurtenbachii*	*Yes. Lyme borreliosis*	*No?*
25	*RF*	*B. latyschweii*	*Yes. Relapsing Fever*	*No?*
26	*RF*	*B. lonestari*	*Yes. Lyme borreliosis*	*No?*
27	*12*	*B. lusitaniae*	*Yes. Lyme borreliosis*	*No?*
28	*LD*	*B. mayonii*	*Yes. Lyme borreliosis*	*No?*
29	*RF*	*B. mazzottii*	*Yes. Relapsing Fever*	*No?*
30	*RF*	*B. merionesi*	*Yes. Relapsing Fever*	*No?*
31	*RF*	*B. microti*	*Yes. Relapsing Fever*	*No?*
32	*RF*	*B. miyamotoi*	*Yes. Relapsing Fever*	*No?*
33	*RF*	*B. parkeri*	*Yes. Relapsing Fever*	*No?*
34	*RF*	*B. persica*	*Yes. Relapsing Fever*	*No?*
35	*RF*	*B. queenslandica*	*Yes. Relapsing Fever. More research required.*	*No?*

36	*RF*	*B. recurrentis*	*Yes. Relapsing Fever*	*No?*
37	*LD*	*B. sinica*	*No*	*N/A*
38	*LD*	*B. spielmanii*	*Yes. Lyme borreliosis*	*No?*
39	*LD*	*B. tanukii*	*No*	*N/A*
40	*RF*	*B. theileri*	*Yes. Relapsing Fever*	*No?*
41	*RF*	*B. tillae*	*No*	*N/A*
42	*RF*	*B. turcica*	*No*	*N/A*
43	*LD*	*B. turdi*	*No*	*N/A*
44	*RF*	*B. turicatae*	*Yes. Relapsing Fever*	*No?*
45	*RF*	*B. uzbekistana*	*Yes. Relapsing Fever*	*No?*
46	*LD*	*B. valaisiana*	*Yes. Lyme borreliosis*	*No?*
47	*RF*	*B. venezuelensis*	*Yes. Relapsing Fever*	*No?*
48	*LD*	*B. yangtze*	*No*	*N/A*

Kind Regards,

[redacted]

ATTACHMENT C – Ministerial Correspondence

Attachment C-1 Letter dated 03/09/2015 sent by my family to the Office of the State Member for Mundingburra, Minister for Disability Services, Minister for Seniors and Minister Assisting the Premier of North Queensland, the Hon. Coralee O'Rourke MP The Hon. Coralee O'Rourke advised in writing on 14/09/15 that response to our concerns was being sought from the Office of the Health Minister (Queensland), the Honourable Cameron Dick MP.

Note: This letter provided attachments. Of these attachments:

Test Results [redacted]	These have not been included in the Senate Submission. Can be provided if requested.
Record of Meeting with [redacted]	This has been included in the Senate Submission (4 pages)
Medical Summaries [redacted]	These summaries have not been included in the Senate Submission, but can be provided if requested. Medical histories are provided in my wife's senate submission ([redacted])

[redacted]

The Hon. Coralee O'Rourke MP
Member for Mundingburra, Minister for Disability Services, Minister for Seniors and Minister Assisting the Premier on North Queensland.
Shop 3, 198 Nathan Street
AITKENVALE QLD 4814
T (07) 4766 8100

3rd September 2015

Dear Mrs O'Rourke,

RE: Access to Treatment for Infection Denied by Hospital

We are writing to obtain your representation in a health matter that has, and continues to have extraordinary detrimental impacts on our family. Our family has a Borrelia infection, for which we have been denied treatment at [redacted], because of a somewhat unrelated controversy surrounding "Lyme". We seek your help with obtaining treatment and investigation into the problems surrounding our predicament.

We are a young family with two children; all four of us have positive diagnoses to Borrelia bacteria. We have eleven positive diagnoses to this devastating infection from laboratories in Australia and Germany (appended). Borrelia is epidemic around the world including America, Asia and Europe however is poorly understood and rarely diagnosed, accepted or treated in Australia.

Borrelia is known to be transmitted through tick bite, also by other insect vectors. Sexual and congenital transmission is frequently denied by the authorities, regularly proven in scientific literature and is evidenced by our family circumstances. We have both travelled extensively for work including to regions where this disease is well established however our children have not. Maternal infection with borrelia impacts on foetal brain development and ultimately if the unborn child is infected, contributes significantly to the development of autism. Both our sons are autistic with numerous diagnosis, medical conditions and developmental delays.

[redacted] (mother) has four positive tests including positive blood and serum cultures. She has been symptomatic of neurological borreliosis since approximately 2003 and has suffered significant illness involving diagnosis of limb girdle muscular dystrophy, pancreas, neuromuscular and autoimmune conditions affecting thyroid and heart. In May this year after receiving the first two positive pathology results for Borrelia bacterial infection she presented to the infectious disease specialist (IDS) [redacted] at the [redacted] and was denied service. One of the pathology tests was a positive blood culture. Despite accompanying medical paperwork demonstrating a high degree of correlation with the medically known symptoms of borreliosis it was not the "belief" of [redacted] that [redacted] had a "Lyme" infection. Despite repeated requests, explanation as to the basis of [redacted] "belief" was not provided. The IDS referred to the condition as "Lyme" which we do not accept to be accurate / appropriate as Lyme is Borrelia Burgdorferi Sensu Stricto, and there are numerous other variants of Borrelia that cause the similar symptoms (eg of a few: B. afzelii; B.garinii; B. miyamotoi, B. spielmanii). No such diagnosis can be made without DNA sequencing of the Borrelia bacteria which has not been done. The IDS made it clear the only proof of infection acceptable that would lead to treatment was a positive Westmead North Ryde diagnosis and this further pathology testing was not offered. No further testing was ordered, no further referral provided. [redacted] was up front that she was an American and she would be working to American CDC standards (refer record of conversation).

Months later, following receipt of the tenth diagnosis, our family doctor had a telephone discussion with the [redacted] IDS and was advised that no treatment would be offered as no member of the family would be considered without a positive diagnosis from Westmead hospital. A record of this discussion can be obtained upon request. It was made clear to our doctor that no other positive test from anywhere else would be accepted and without the positive Westmead test result, we were not entitled to public treatment.

Our issues with the denial of service from our hospital are numerous as follows:

1. The borreliosis infection which there is ample evidence of, has been approached as a “Lyme” infection. Failure to comply with specific CDC Lyme criteria has been taken as justification for denial of treatment of borrelia infection. This is about as logical as only diagnosing and treating a person with influenza only if they meet criteria for strain A, and refusing diagnosis and treatment to those that have strain B or other strains.
2. Australia should not be using the American Centre for Disease Control standards for diagnosis of Lyme in place of diagnosis of borrelia. This is incredibly poor practice considering the documented controversy surrounding the corruption of America’s position on the diagnosis and treatment of “Lyme” (patents for vaccine development and insurance industry considerations).
3. It is well accepted that a negative diagnosis does not exclude the presence of this infection as borrelia is a stealth intercellular immunosuppressive infection and is very good at evading the immune system, making it difficult to diagnose, particularly in long term infections (as all members of our family present with).
4. Our family has laboratory tests showing significant immune suppression consistent with Borrelia or other immunosuppressive infection. This is the CD-57 test, normal range is 130 to 360, my 5 yr old son has a CD-57 of just 6. It seems incredible that a child can demonstrate such immune suppression and not be further investigated.
5. The hospital will only accept testing done at one laboratory in the world – Westmead North Ryde. The Westmead hospital is one of many institutions in Australia and the world testing for borrelia, it is certainly not the laboratory used for diagnosing the epidemic around the rest of the world. Test results we have are from InfectoLAB in Germany and would be accepted elsewhere and additionally Australian Biologics which is a Sydney based laboratory has been reliably shown to be accurate and used in many studies.
6. The Westmead test is limited to detection of borrelia burgdorferi and borrelia afzelii – whereas many borrelia strains exist that infect people.
7. The Westmead testing itself is a highly controversial two stage test. The first stage ELISA test is used to screen out, not diagnose patients. This test is diagnostically useless as it relies on normal immune function which is problematic in detection of immunosuppressive disorders and yeids a correct result less than half of the time (45%). In the event a positive is obtained from the ELISA, the Western blot test is performed, however the number and type of DNA bands required to be considered positive to this test is not scientifically a good measure of infection and excludes those infected from obtaining diagnosis. Westmead seldom returns positive test results giving Australia an improbably low infection rate in the face of what is a worldwide epidemic.
8. The problems surrounding use of the two tier Westmead system is long standing and in 2012 a clinical diagnostic committee (first meeting March 2013) was established by Federal government to investigate issues of diagnosis, however was disbanded in July 2014 for unknown reasons. At present this is being reinvestigated at a round table due to meet on 18th September in Parliament House (motion by Jill Hall MP, Gai Brodtmann MP, Andrew Nikolic MP and Stephen Jones, MP in Federation Chamber on 17th August 2015). You may be aware that Senator Claire Moore’s motion in relation to development of a national plan for Lyme was moved in the Senate Thursday 20 August 2015.
9. Diagnosis of, and treatment of borrelia infection is clearly being served on the basis of a singular laboratory using testing (a) limited to two borrelia types only when numerous exist (b) using testing that is inaccurate and controversial and (c) not being diagnosed on the basis of symptoms, other diagnosis and other pathology markers. History (including travel and medical history) and other supporting pathology tests such as immune system should be considered in determining borrelia infection.

Our family did not pass Westmead testing, three of us with very low immune counts did not pass the ELISA, and then the fourth (with better immune function) did not pass the Western Blot. Regardless, every member of my family has a positive Western Blot test from InfectoLAB.

Our family's diagnosis to borreliosis has so far cost us in excess of $8,398. That is additional to years of large medical bills from specialists unable to determine the cause of disability in [redacted] (resulting in incorrect muscular dystrophy diagnosis) and ongoing illness in the children and this has been additional to the extraordinary expense involved with treating our sons' autism which has totalled in excess of $400,000. [redacted] has not been able to work since 2006 due to illness and the children's autism and illnesses and we have been on a single income since this time.

We have had considerable difficulty identifying any practitioner willing to, able to or experienced in treating this disease. There is no such doctor locally. Borrelia infection in Australia is poorly understood and due to punishment of Australian doctor's treating borreliosis, a great deal of fear in the medical community exists.

It is very difficult and grossly unfair to be so very unwell and have to be responsible for unwell and disabled children and to additionally bear the burden of research, education, advocacy and treatment for a disease that is recognised and treated in other countries (in excess of 300,000 new cases in America annually). Our options are to continue identifying and funding expensive treatment (which we can no longer do) or become increasingly more unwell/disabled and potentially spread infection. The impact this infection has had on our children has been horrendous and if no treatment is provided we expect continuation of their suffering with increasing disability. We have attached a medical summary of the children's lives and also [redacted] medical history, however an expanded and far more insightful summary can be provided upon request. [redacted] summary has not been provided due to employment related issues.

Borrelia is not just a problem for our family, through inept medical administration it is a burden society and the government bears. Borrelia infection has been found in a large portion of patients with Alzheimer's, Autism and ALS and the incidence of these disorders is increasing. Without recognition and reporting of this illness, no formal structure can be set in place to prevent anyone continuing to be an organ or blood donor or make informed choices about treatment and family planning. Without accurate diagnosis, the extent of the problem will not become apparent and nor will the solution.

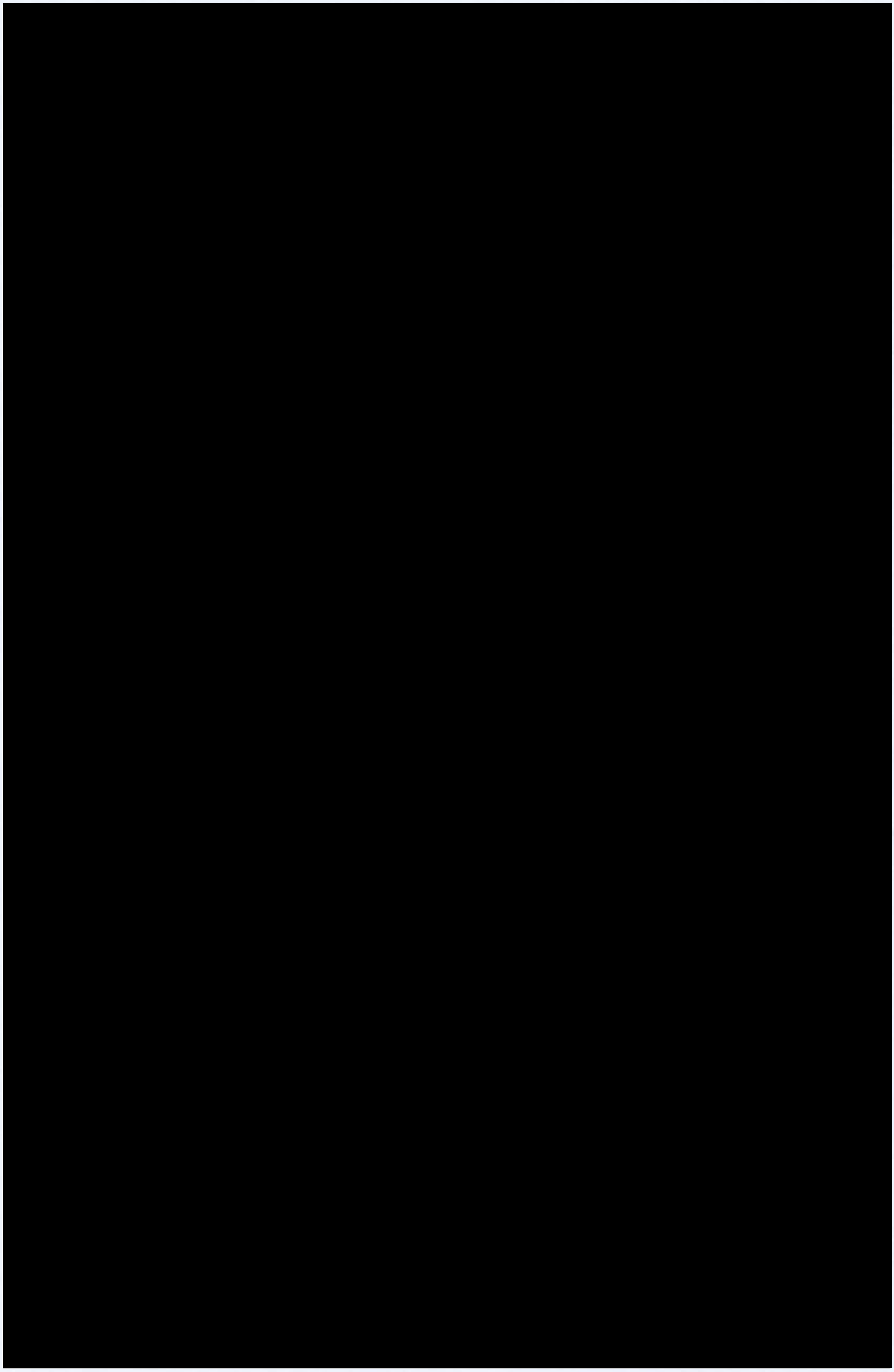
In identifying the underlying cause for our family illness, we did not expect or want to be involved in a government / medical controversy. We are very sick people trying to get better and desperately require medical treatment that is being denied. We cannot understand why we have been treated the way we have been, and we cannot understand how the Government has permitted this situation to remain unanswered for so long. We will not sit quietly and be sick and we will not stop until our children have some hope for their future.

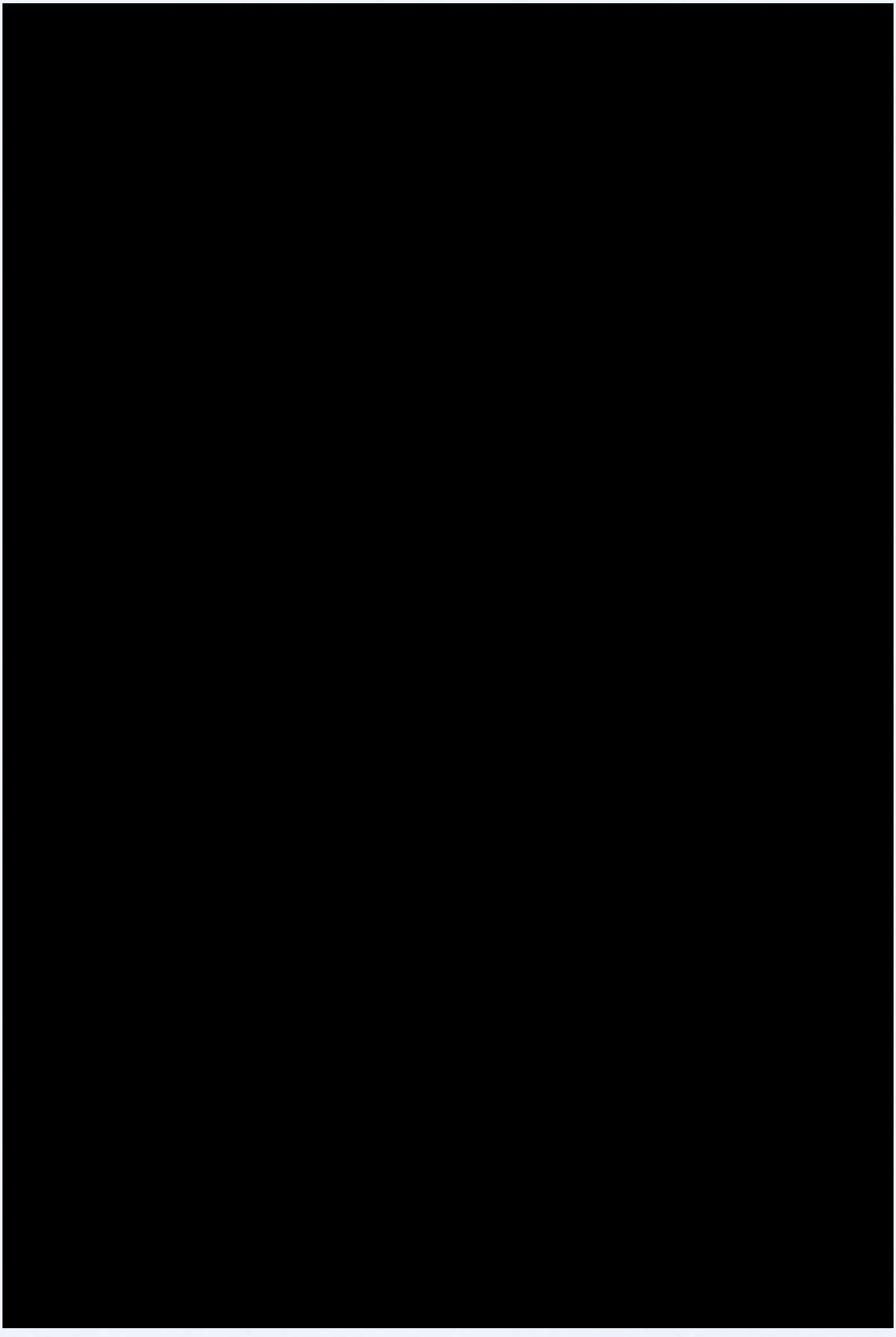
In response to our particular circumstances, we ask for your intervention with our local hospital such that we may obtain some treatment. We look forward to meeting with you and taking this matter forward.

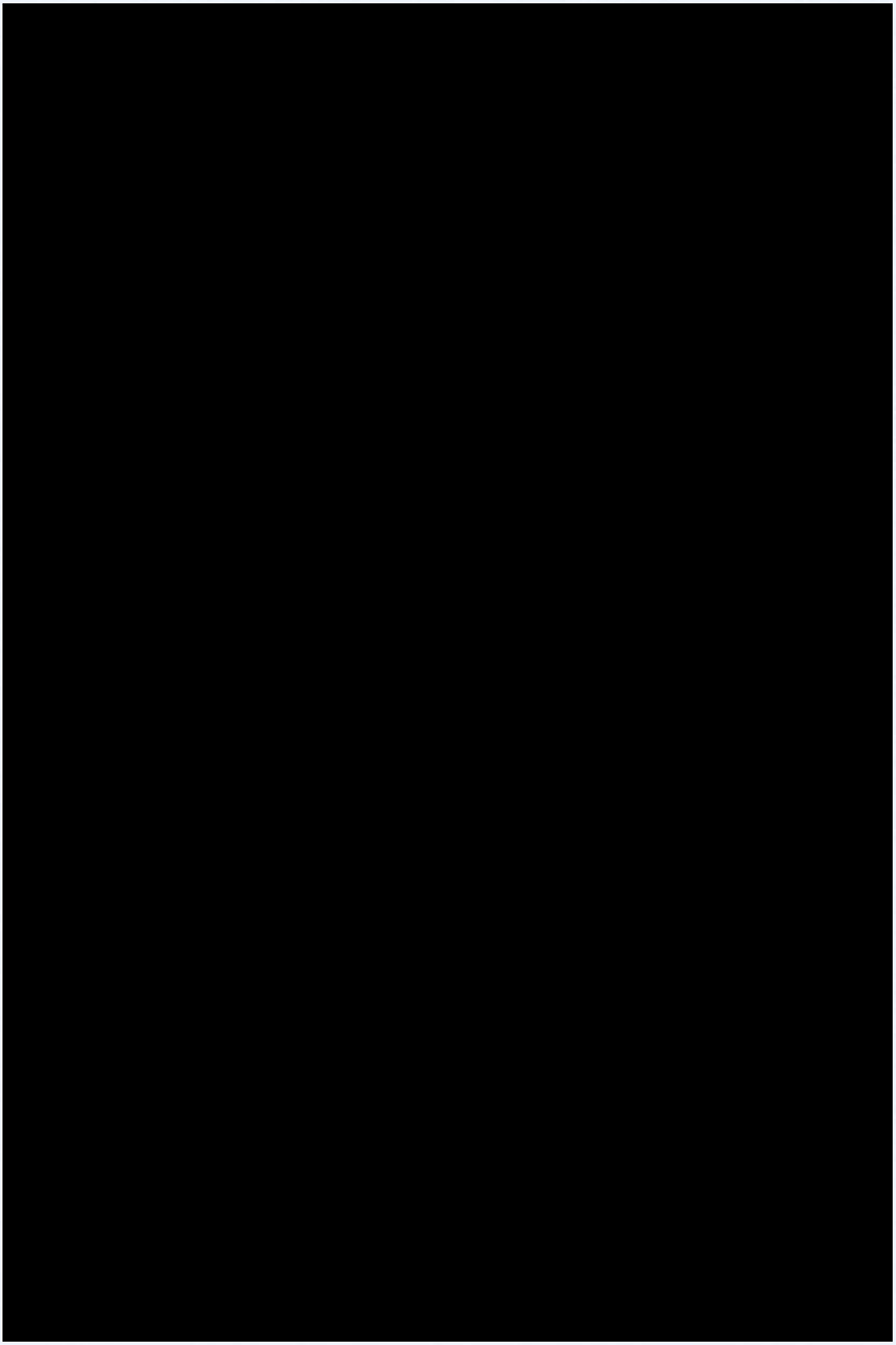
Yours faithfully,

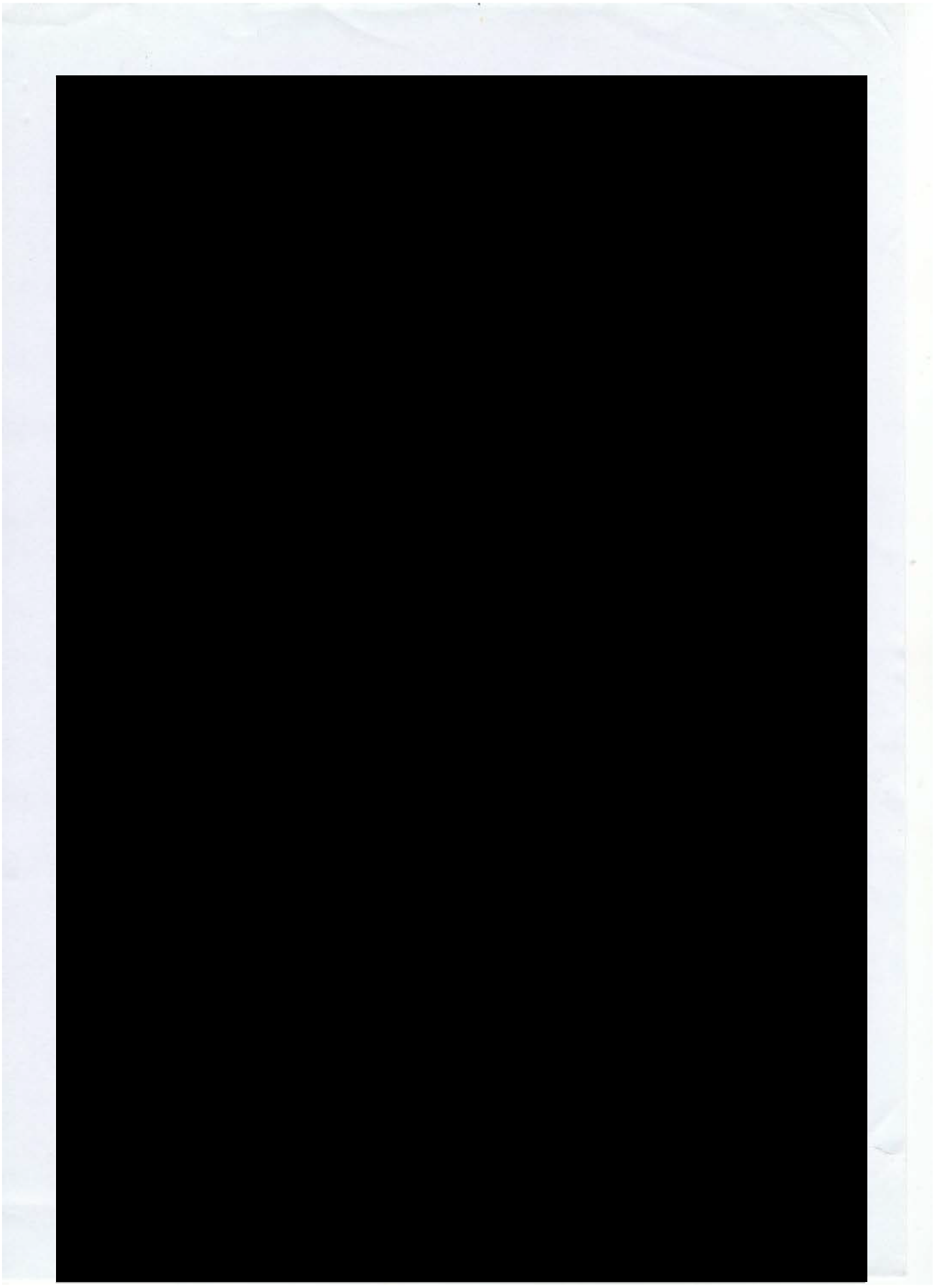
[redacted] [redacted]

Attached: Test Results [redacted];
Record of Meeting with [redacted];
Medical Summaries [redacted].









Attachment C-2

Letter dated 16/10/15 received from the Hon. Coralee O'Rourke MP conveying the response received from the Office of the Health Minister (Queensland), the Hon. Cameron Dick MP.

Coralee O'Rourke MP

State Member for Mundingburra
Phone: 07 4766 8100 | **Fax:** 07 4725 4194
Email: Mundingburra@parliament.qld.gov.au
Office: Shop 3, 198 Nathan Street, Aitkenvale QLD
Address: PO Box 1409, Aitkenvale QLD 4814

16/10/2015

Received 30th October 2015 PM

[redacted]

Dear [redacted]

Re: Lyme Disease and Borreliosis

Firstly, thank you for raising your enquiry with my office. The information you provided my staff was turned over to me and I sought advice from the office of the Minister for Health on your behalf.

I am informed that there are several laboratories that test for Lyme Disease in Australia including Westmead. I understand that Dr [redacted] clinical judgement was that you were not displaying symptoms consistent with a diagnosis of Lyme Disease, in accordance to international guidelines. Additionally, a positive test could indicate a past, resolved infection. Dr [redacted] clinical judgement was that current symptoms were not consistent with active infection.

The test results you provided were not clinically acceptable to Dr [redacted] as they were not from laboratories accredited by the Royal College of Pathologists of Australasia (RCPA). An RCPA position statement approved in February 2014 Diagnostic Laboratory testing for Borreliosis ('Lyme Disease' or similar syndromes in Australia and New Zealand) specifically cautions against the validity of results from non-National Association of Testing Authorities/RCPA-accredited laboratories in Australia and overseas (mainly the USA and Germany) testing for Lyme Disease.

In Australia, diagnostic criteria are very stringent requiring highly specific confirmatory tests at accredited reference laboratories; using laboratory tests from endemic countries would result in a high percentage of erroneous (false positive) results.

I am also informed that while Dr [redacted] was willing to consider other possible medical conditions, that you were reluctant to explore that possibility.

In this instance, I am unable to provide you with further assistance or advice. Should you have any further queries regarding this matter, I suggest you raise your concerns with the office of the Health Minister, the Honourable Cameron Dick MP.

GPO Box 48
Brisbane QLD 4001 health@ministerial.qld.gov.au Ph: 30356100

Warm regards,

[redacted]

Coralee O'Rourke MP
Minister for Disability Services
Minister for Seniors
Minister Assisting the Premier on North Queensland

www.facebook.com/Coralee.Mundingburra
@CoraleeORourke
www.coraleeorourke.com

Putting the community first

Attachment C-3

Letter dated 29/09/2015 from the offices of the Federal Minister for Health and the Federal Minister for Sport, the Hon. Sussan Ley MP, as sent to our local Federal Member for Herbert, Mr Ewen Jones MP.

THE HON SUSSAN LEY MP
MINISTER FOR HEALTH
MINISTER FOR SPORT

Ref No: MC15-015312

Mr Ewen Jones MP
Member for Herbert
PO Box 226
AITKENVALE QLD 4814

Dear Mr Jones Ewen

Thank you for your representations of 28 August 2015 on behalf of [redacted] and [redacted] regarding Lyme disease.

I am sorry to learn that the [redacted] family are suffering from a number of medical conditions.

My Department, through the Chief Medical Officer (Professor Chris Baggoley) has taken an interest in Australian patients who are experiencing and sharing their stories of a chronic debilitating illness which some medical and health practitioners have ascribed to Lyme disease or a Lyme disease like syndrome.

Lyme disease is a common tick-borne illness in the United States of America, Europe and parts of Asia which is caused by an infection with a bacterium carried by ticks. I am advised that, as yet, neither a causative agent nor a vector for Lyme disease has been identified conclusively in Australia, despite research on this topic.

Patients presenting with a chronic debilitating illness for which no cause can be identified, is a particularly difficult situation. I am advised by my Department's medical practitioners that patients should receive treatment based on an accurate diagnosis. When an accurate diagnosis is not available, symptoms should be ameliorated where possible. When a clinician has doubt about the accuracy and quality of diagnostic tests, it is important to first do no harm and where possible relieve pain and suffering. In the situation of patients presenting with a chronic debilitating illness this does not automatically mean long term, multiple antimicrobial therapy. Each patient should be investigated for the cause of their symptoms. For example, the children of the [redacted] family have been diagnosed with disorders on the autism spectrum. This is not caused by an infectious disease and specialist paediatric care is required. My Department is not aware of any verifiable evidence that classical Lyme disease is associated with autism in children. Additionally, there remains no verifiable repeatable evidence for Lyme disease transmission sexually or vertically from mother to child.

The Department of Health welcomes the exciting and ground breaking research publication from Professor Peter Irwin and his team from Murdoch University. This Australian Research Council funded work is published in: www.parasitesandvectors.com/content/8/1/345/abstract, and has revealed amongst the large number of bacteria in ticks at least one new species for further investigation. While no Lyme disease *Borrelia* bacteria were found in Australian ticks, the Murdoch team was able to readily detect Lyme disease bacterial DNA in the ticks from Germany. In one Australian tick collected from a wild echidna, out of a sample of 196 ticks, the DNA from a *Borrelia* species associated with relapsing fever was detected. The clinical significance of this finding is still to be determined and should not be overstated. My Department will remain engaged with Professor Irwin to consider the implications of this research for human health in Australia. It is anticipated that research on ticks taken from humans will be published later in 2015.

The Chief Medical Officer has had the opportunity to speak with Professor Irwin, who emphasised that it is not yet appropriate to link the bacteria that he found in the ticks with them causing disease in humans. Nothing can be assumed without further research.

In a country where the presence of Lyme disease has not been confirmed, such as Australia, it is not possible to reliably diagnose Lyme disease on clinical signs and symptoms alone as there are many other diseases (infectious and non-infectious) that can have similar clinical features.

Tests to diagnose Lyme disease are technically complex and require specialist expertise. They should only be conducted in laboratories that are accredited in Australia and compliant with AS ISO 15189 (accredited laboratories are listed at www.nata.asn.au). Such accredited Australian diagnostic laboratories are able to diagnose Lyme disease by serology in patients who have returned from overseas areas where Lyme disease is endemic.

The medical testing accreditation scheme is run jointly by the National Association of Testing Authorities (NATA), Australia with the Royal College of Pathologists of Australasia based on policy guidance provided by the National Pathology Accreditation Advisory Council. The policy guidance takes the form of standards and guidelines which pathology laboratories must adopt in order to be accredited.

Individual laboratories apply to NATA for accreditation in medical testing and then undergo an assessment by NATA selected assessors. Once accredited, laboratories become members of NATA.

The Institute of Clinical Pathology and Medical Research's microbiology laboratory has medical testing accreditation and is generally regarded as the reference laboratory in Australia for Lyme disease serology.

My Department has recently contracted with the National Serology Reference Laboratory to undertake an evaluation of the serological assays currently used for the diagnosis of Lyme disease in some specialist Lyme disease laboratories in Australia and overseas as well as accredited pathology laboratories in Australia. The specimens for this evaluation have been collected from individuals in Australia and overseas both with and without symptoms of Lyme disease. The results will be used to examine the performance characteristics of these laboratory tests and hopefully resolve the conundrum of discordant results in laboratories in Australia and overseas.

In 2013, a working group of the Communicable Diseases Network Australia (CDNA) assessed the need for the national notification of Lyme disease in Australia. The assessment was made against CDNA and the Public Health Laboratory Network endorsed criteria. These include the outbreak potential of the disease, whether national notification is required to facilitate public health follow-up and the feasibility of data collection.

CDNA considered that that national notification of Lyme disease is not currently warranted given there is currently no definitive evidence of Lyme disease being acquired in Australia and also the difficulties associated with developing an acceptable case definition. Rather they concluded that other methods for monitoring the disease would be more appropriate. One possible way would be for states and territories to work with public health laboratories to improve data on the number of cases and to ensure the appropriateness of laboratory protocols and practices.

CDNA did note that the need for national notification would be reassessed if any new evidence of locally acquired disease and the presence of a competent vector became available.

In terms of access to treatment, GPs in Australia are able to refer their patients to specialist clinics at public hospitals. For example, in a case of suspected Lyme disease, an appropriate referral could be to the infectious diseases clinic at the local hospital. Outpatient appointments at public hospitals are free-of-charge to the individual. In Australia, infectious diseases physicians are the appropriate specialists to support patients with questions and concerns about Lyme disease. If patients are not satisfied with the advice that they are being given they should seek a second opinion from another infectious diseases physician. If Lyme disease is diagnosed, the antibiotics for treating the disease are readily available. Apart from Lyme disease and possible Lyme disease like illnesses, infectious diseases physicians in Australia are knowledgeable about tick-bite associated infections, especially in patients presenting with a rash and fever.

The Chief Medical Officer convened the Clinical Advisory Committee on Lyme Disease (the Committee) to provide advice on the evidence for Lyme disease in Australia, diagnostic testing, treatment and research requirements. The Committee met five times and the outcomes of those meetings are available on my Department's website at www.health.gov.au/lyme-disease. The Committee has now ceased, with the last meeting being held on 15 July 2014. A report that details the progress achieved against each of the Committee's terms of reference is also available on the website.

Even though the Committee has now ceased, my Department's interest is being maintained. My Department continues to:

- consult with members of the Committee;
- monitor progress made in research;
- act as a point of contact within the Australian Government for the Lyme disease community, including medical practitioners and state and territory health authorities;
- seek advice from international partners; and
- write to patient groups and medical practitioners to update them of any progress.

Over the time that my Department has been engaged in this work it has become apparent that many members of the medical profession remain unaware that Lyme disease infection should be considered in Australians returning from travel in endemic areas and tourists from those locations. My Department has developed an *Australian guideline on the diagnosis of overseas acquired Lyme disease/borreliosis* which is now available on my Department's website. The document is focused on infection acquired in endemic areas overseas. It is hoped as we learn more about the chronic debilitating illness affecting Australians we will be able to modify the document to accommodate their situation.

I remain concerned about Australians suffering a chronic debilitating illness with unexplained symptoms that some healthcare practitioners have ascribed to Lyme disease and will continue to monitor the situation and encourage efforts made by Australian medical practitioners and medical scientists to undertake research to define the cause of this chronic debilitating illness.

Thank you for raising your constituents' concerns.

Yours sincerely

[redacted]

The Hon Sussan Ley MP
29 SEP 2015