

TESTIMONY OF SHARON LEE, RN, MSN FOR SB916

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Thank you Oregon senators for introducing SB916. I encourage you to move this bill to vote without amendment. SB-916 will authorize MD's, DO's, PA's and FNP's to diagnose and treat Lyme disease patients using the guidelines from the International Lyme and Associated Diseases Society (ILADS). In my testimony, I will explain, first, my own long and difficult struggle with Lyme disease. I will then summarize the recent questionnaire of 200 members of our Southern Oregon Lyme Disease (SOLD) support group. And, lastly, I will explain why there are such disparate numbers of confirmed and counted Lyme cases in Oregon with actual cases counted in our SOLD support group.

INTRODUCTION

My name is Sharon Lee. I have been an RN for 50 years with a master of nursing education degree. I started my career in pediatric, medical /surgical, critical care and public health nursing for the first 10 years of my career. I taught associate degree nursing students for 27 years.

MY MISDIAGNOSES

I was bitten by an infected tick in 1978 in northern California. I had the classic "bull's eye" rash but never actually saw the tick. I was never treated because this was way before anyone knew about Lyme disease on the West coast. Several months later, I became very ill with all the classic symptoms of Lyme disease. However, I was misdiagnosed with other diseases. The first was Rheumatic Fever because I had inflammation of my heart. The second was Fibromyalgia because all my joints and muscles ached. The third was Chronic Fatigue Syndrome because I was so extremely fatigued. The fourth was Multiple Sclerosis because I had areas of numbness and vision problems. The fifth was Lupus because my immune system was affected and was attacking various organs in my own body. The sixth was encephalitis & meningitis because I had developed severe headaches and seizures. The seventh diagnosis was rheumatoid arthritis because I had several joints that were painful and swollen. But, as it would be later demonstrated, all of these diagnoses were wrong! Because of overwhelming symptoms, I was no longer able to complete my graduate school education or work as a nursing instructor. I applied for and received disability for several of the diagnoses I had been given. For 13 years I received disability from the California State Teachers Retirement system. During this time, I had five separate screening ELISA tests by five different MD's for Lyme disease which were all reported as negative.

MY CORRECT DIAGNOSIS

In 2002, I consulted an MD in San Francisco who follows the ILADS guidelines. She did a Western blot test for Lyme. This MD reported the test as positive because I had four significant bands that reacted. But, it was not considered positive by the CDC standards because they require five positive bands to be counted. In my case, the right diagnosis occurred 24 years after the initial tick bite. After being on disability for 13 years, proper treatment was finally started. After a few months of antibiotics, I was considerably better and I was able to go back to work--part time for a year. The extended course of antibiotics brought blessed relief from long-lasting and debilitating symptoms. During that first year of treatment, I felt so much better that I simultaneously attended graduate school toward a master's degree in nursing education. Over the next six years (from 2003 to 2009), with continuous antibiotic treatment, my health progressively improved and most of the previous symptoms that labeled me with diagnoses of Rheumatic Fever, Chronic Fatigue Syndrome, Fibromyalgia, Multiple Sclerosis, Lupus, Rheumatoid Arthritis, Encephalitis/Meningitis were nonexistent. And, with graduate degree in hand, I subsequently worked as a full professor of nursing education.

MY RETIREMENT AND MOVE TO OREGON

I retired from teaching nursing in 2009 and moved from San Jose, California to Eagle Point, Oregon. Once established in Oregon, I tried to find a physician who knew how to treat Lyme disease. It was obvious that, after being treated with the proper antibiotics for an extended time of seven years, that I was still not well. But, that is not uncommon for those of us who are diagnosed late in the disease. Finding a physician with knowledge about Lyme disease in Southern Oregon proved to be quite impossible, however. I consulted with five physicians in my area who said they would not even consider treating me. They all said that, according to the guidelines of the Infectious Disease Society of America and the CDC, the few weeks I had of antibiotics in the very beginning of treatment should have been enough and they did not feel comfortable treating me any further. Therefore, I had no other option but to continue with my established physician in San Francisco. At considerable expense and time, I have kept appointments with my physician who is 700 miles away at least three times yearly. I managed to find a local MD who had previous experience treating Lyme disease in New York who said she would monitor me only for the usual blood cell, liver and kidney function tests while I was receiving antibiotics. She indicated that, even though she knew I needed more antibiotics, she would not be treating me in this state because of a fear of medical license review with possible loss of her license to practice medicine.

MY LYME CULTURE

Over the first five years after getting a diagnosis of Lyme disease, I had several Western blot tests (second step of the CDC standard two-tiered tests). Each time, the results were considered negative by CDC standards. Fortunately, my ILADS physician in California continued to treat me with multiple antibiotics for 6 weeks at a time. However, approximately every 4-6 months, I would relapse and require more antibiotics. In March, 2014, after receiving 12 years of multiple courses of oral and IV antibiotics, I had a culture done of my blood. This culture method uses the standard blood smear on an agar plate and an incubator to grow organisms. The usual culture of bacteria takes from 1-2 weeks to grow. The specialty lab that did my culture knew that the spirochete, *Borrelia burgdorferi* (bacterial agent of Lyme disease), takes longer to grow because it is pleomorphic (has the ability to change its form) and often survives in a near hibernation state for weeks to months. The incubation of my blood culture took 16 weeks before a positive growth of spirochetes started growing! The lab then did a monoclonal antibody test to determine that it was, indeed, the *Borrelia burgdorferi* spirochete. This result was further verified by a Polymerase Chain Reaction (DNA test). My physician and I are both convinced that the Lyme bacteria have been living inside my body for 37 years! The antibiotics I received for the past 13 years, while obviously making me better enough to return to work, have not fully eradicated the organisms. ILADS guidelines take into account the activity and growth patterns of the Lyme organism when treating a patient. ILADS supports the premise that all cases of Lyme disease, which are diagnosed late in the disease process, must have access to antibiotics on a long-term basis. And, in Oregon, that is not the case!

SOUTHERN OREGON LYME DISEASE (SOLD) SUPPORT GROUP

While in California, I had attended Lyme disease support group meetings to learn about my disease. I searched for a Lyme disease support group in Oregon. Finding none in the southern Oregon area, another registered nurse with Lyme disease (Judi Johnston, RN, MS) and I decided to start one in 2010. We now have over 200 members concentrated mainly in Jackson, Josephine and Douglas counties. Our support group meets once a month at our local hospital where we offer education and support.

SOLD QUESTIONNAIRE

A recent (March, 2015) survey of SOLD members was conducted. Following is a list of the questions asked:

1. How many years have you been ill before getting a Lyme disease diagnosis?
2. Did you consult with a specialist before you got a Lyme disease diagnosis?
 - a. (Such as rheumatologist, infectious disease, neurologist, cardiologist)
3. Did any previous Southern Oregon physician tell you that you had nothing wrong?
4. Did any previous Southern Oregon physician tell you that Oregon has no Lyme disease?
5. Did you get a previous incorrect diagnosis before getting a Lyme diagnosis? If yes, which ones?
6. Did you have a positive ELISA test for *Borrelia burdorferi*? If yes, which Lab?
7. Did you have a CDC positive Western Blot test for *Borrelia burdorferi*? If yes, which lab?
8. Did you have a positive blood culture for *Borrelia burdorferi*? If yes, which lab?
9. If you had a positive two-tiered test (ELISA & Western blot), were you contacted for follow up by the Oregon Department of Health?
10. If you had a positive blood test by IGENEX (Lyme or coinfections), were you contacted for follow up by the Oregon Department of Health?
11. If you had a positive blood culture for *Borrelia burdorferi*, were you contacted for follow up by the Oregon Department of Health?
12. Has your overall condition improved since starting Lyme disease treatment?
13. Have you received **antibiotics** for longer than three months since being diagnosed with Lyme?
14. Have you been diagnosed with any coinfections of Lyme? If yes, which coinfections?
15. Have you had to take **antibiotics** for Lyme disease and coinfections for more than three years?
16. If you have had antibiotic treatments for longer than 3 months, have they improved your condition?
17. Have you had to discontinue or reduce work because Lyme disease?
18. Have you filed for or received disability or worker's comp. because of your Lyme diagnosis?
19. Since you have received Lyme disease treatment, have you return to work?
20. On average, how much out-of-pocket expenses have you paid per year for Lyme disease and coinfection treatments?
21. What is the approximate amount of overall out-of-pocket expenses you have paid for Lyme disease treatment (adding all the months or years of treatment)?

SOLD QUESTIONNAIRE RESPONSES

There were 56 SOLD who returned the questionnaire. The following is a summary of the respondent's answers.

1. 93% (52 people) were ill more than one year prior to getting a Lyme diagnosis. Of those, 10 respondents were ill for more than 10 years. The average length of time prior to getting a correct diagnosis of Lyme disease was 10.7 years!
2. 83% (47 people) had gone to numerous specialists in the area including rheumatologists, neurologists, infectious disease specialists and cardiologists. The total number of specialists respondents had consulted with their symptoms was 35
3. 79% (44 people) reported that their physician told them they could find nothing wrong with them.
4. 64% (36 people) were told by their physician that there is no Lyme disease in Oregon.
5. 72% (41 people) were given an incorrect diagnosis by their physician prior to getting a correct diagnosis of Lyme disease. The dominant incorrect diagnoses were Chronic Fatigue Syndrome, Fibromyalgia, Depression, Lupus, and Multiple Sclerosis.
6. 32% (18 people) had a positive ELISA test (step 1 of a two-tiered test)
7. 36% (20 people) had a positive Western Blot test (step 2 of a two-tiered test)
8. 43% (24 people) had a positive culture test
9. Only 0.7% (4 people) who had a positive Two-tiered ELISA & Western Blot were contacted by a representative of the Oregon Department of Health. One person was contacted by the CDC. The physician of one respondent was contacted by a Jackson County Public Health representative who was told the patient was not sick (which was not true)!
10. 0% (no people) were ever contacted by the Oregon Department of Health when they had a positive blood test by Igenex Lab in California. This is a recognized CLIA certified laboratory dedicated to doing Tick-borne disease testing. In addition, this lab is required, by law, to notify the health department in the county of patient's residence. Even though there were 9 respondents who had an Igenex positive Two-tiered test.
11. 0.02% (1 person) who had a positive blood culture was contacted for follow up by the Oregon Department of Health. Even though the physician who ordered the culture gave confirmation that he sent the results to the county public health department of the patient's residence.
12. 82% (46 people) have improved since starting Lyme disease treatment.
13. 55% (31 people) have taken antibiotic treatment for longer than 3 months.
14. 93% (52 people) were diagnosed with, at least one coinfection. The majority had been diagnosed with Bartonella (44 respondents) & Babesia (37 respondents). Other coinfections included Anaplasmosis (6), Mycoplasma fermentans (4) Protomyxoa (3) Parvo Virus (2) and Typhus (1).
15. 75% (42 people) had to take antibiotics for more than three years.
16. 100% (42 people) who had antibiotic treatments longer than three months report an improvement of their condition.
17. 64% (36 people) have had to discontinue or reduce their work because of their Lyme disease diagnosis.
18. 29% (16 people) have filed for or have received disability or Worker's Comp because of their Lyme diagnosis.
19. 17% (10 people) have returned to work since receiving treatment for Lyme disease. 11% (6 people) have returned to full-time work and 7% (4 people) have returned to part time work.
20. \$11,000 a year is the average out-of-pocket expenses respondents have paid for Lyme disease treatments. The total for all 56 respondents was \$486,400.00 a year.
21. \$1,688,400 is the total out-of-pocket expenses that 56 respondents have paid since their Lyme disease diagnosis.

COMMUNITY EDUCATION

Since starting the support group, we have begun a community education campaign because we believe that prevention is key. We started with those who work every day in the areas where ticks are prevalent. News quickly spread after our first "Tick Talk" at our local BLM, and we have been requested to speak at other government agencies throughout Oregon. Since 2013, we have given a two hour presentation to government employees of the US Forest Service, Bureau of Land Management, the Oregon Parks Department and the Oregon Department of Forestry throughout Oregon. Feedback from those employees indicates that ticks are becoming more prevalent throughout the area west of the Cascade Mountains. Of 160 government workers who attended those presentations, 30 have been identified as having Lyme disease and other tick-borne infections.

OREGON DEPARTMENT OF HEALTH

Lyme disease has been a nationally notifiable condition in the United States since 1991. Policies regarding case definitions and reporting are determined by each state. Physicians and other clinicians are required to report Lyme disease cases within one working day of diagnosis to Oregon Department of Health (ODH) in their county. Labs are required to report positive test results to Oregon Public Health in the patient's county of residence. County public health officials follow up on cases to determine if case is presumptive or confirmed. Each county's confirmed cases are reported to ODH who, in turn report them to CDC.

Reports of Lyme disease are collected and verified by county health department officials in accordance with their legal mandate and surveillance practices. Follow up should occur with each new patient and they are then classified as a presumptive or confirmed case. If 2 or more confirmed cases are reported in a county, that county is considered to be endemic for the disease. Confirmed cases are then reported to the CDC. Since I am a former California public health nurse, I have often followed policies issued by my state when reviewing infectious disease cases. I retrieved guidelines from the Oregon Department of Health about who should be counted as a positive case of Lyme disease. Much to my dismay, I found the guidelines from Oregon to be even more restrictive than the CDC!

CDC Surveillance Criteria

For instance, the CDC requires the following criteria to be considered as positive:

- A case of (EM) with a known exposure, OR
- A case of EM with laboratory evidence of infection and without a known exposure, OR
- A case with at least one late *Musculoskeletal, Nervous or Cardiovascular system* manifestations with laboratory evidence of infection.

For purposes of surveillance, late manifestations include any of the following when an alternate explanation is not found:

Musculoskeletal system: Recurrent, brief attacks (weeks or months) of objective joint swelling in one or a few joints, sometimes followed by chronic arthritis in one or a few joints. Manifestations not considered as criteria for diagnosis include chronic progressive arthritis not preceded by brief attacks and chronic symmetrical polyarthritis. Additionally, arthralgia, myalgia, or fibromyalgia syndromes alone are not criteria for musculoskeletal involvement.

Nervous system: Any of the following, alone or in combination: lymphocytic meningitis; cranial neuritis, particularly facial palsy (may be bilateral); radiculoneuropathy; or, rarely, encephalomyelitis. Encephalomyelitis must be confirmed by demonstration of antibody production against *Borrelia burgdorferi* in the cerebrospinal

fluid (CSF), evidenced by a higher titer of antibody in CSF than in serum. Headache, fatigue, paresthesia, or mildly stiff neck alone, are not criteria for neurologic involvement.

Cardiovascular system: Acute onset of high-grade (2nd-degree or 3rd-degree) atrioventricular conduction defects that resolve in days to weeks and are sometimes associated with myocarditis. Palpitations, bradycardia, bundle branch block, or myocarditis alone are not criteria for cardiovascular involvement.

<http://wwwn.cdc.gov/nndss/script/casedef.aspx?CondYrID=752&DatePub=1/1/2011%2012:00:00%20AM>

Oregon Department of Health Surveillance Criteria

The Oregon Department of Health, in contrast, requires only the following criteria to be considered to be positive:

- Physician-documented EM rash *and*
- Laboratory evidence of infection

Comparison of CDC and ODH Surveillance Criteria

The Oregon Department of Health requirements for confirmation of a Lyme disease case are not as broad as the CDC criteria. In fact, ODH even stated the following within their guidelines for public health officials:

The case definition for Lyme is restrictive and intended to enhance the specificity of surveillance data. Reduced sensitivity (i.e., exclusion of some reports that seem real) is the inevitable result.

Get over it.

Most reportable cases will be presumptive.

- <http://public.health.oregon.gov/DiseasesConditions/CommunicableDisease/ReportingCommunicableDisease/ReportingGuidelines/Documents/lyme.pdf>

Erythema Migrans (EM) Rash

When comparing the EM rash between the CDC and ODH there is a slight difference that could restrict some cases as being confirmed by Oregon public health officials. ODH says that the rash must be greater than 5 cm. So, if the rash is exactly 5 cm, it will not be counted.

The CDC states the following about an EM rash:

- Physician documented EM is defined as a skin lesion that typically begins as a red macule or papule and expands over a period of days to weeks to form a large round lesion, often with partial central clearing.
- The rash must be greater than or equal to 5 cm (2 inches) in diameter.

The ODH states the following about an EM rash:

- Physician documented EM lesions typically have a "bull's eye" appearance, with partial central clearing. Occasionally, EM may appear as a solid red rash with a vesicular center.
- The rash must be greater than 5 cm (2 inches) in diameter.

Comparison of Laboratory Testing Between CDC and ODH

When comparing the laboratory evidence between the CDC and the Oregon Department of Health, there is little difference. Therefore, when examining a culture, ELISA or Western blot test results either provided by the physician or the lab, the parameters used by the public health officials should be the same as the CDC. The laboratory evidence required by the CDC and ODF are as follows:

- Positive Culture for *B. burgdorferi*, OR
- Two-tier testing interpreted (ELISA and Western Blot) where:
 - Positive IgM is sufficient only when ≤ 30 days from symptom onset
 - at least two IgM bands 22-25, 39 or 41; *or*
 - Positive IgG is sufficient at any point during illness
 - at least five IgG bands (18, 21, 28, 30, 39, 41, 45, 58, 66, or 93)

Researchers from the CDC and New York Medical College recently reported (2015) that 60% to 71% of Lyme disease patients presenting with an erythema migrans rash actually tested negative for the disease by the CDC's (and ODH) two-tier Lyme disease criteria. <http://www.ncbi.nlm.nih.gov/pubmed/25761869>

COUNTING OREGON LYME CASES

It is obvious to me, criteria for confirming and counting of cases of Lyme disease in Oregon is more stringent than even the CDC. Instead of giving physicians the option of diagnosis based on EM rash, positive response on two-tiered tests and involvement of complicating late manifestations involving the musculoskeletal, nervous, or cardiac system like the CDC. The Oregon Department of Health confines confirmation to only two items---a physician documented rash over 5 cm and a positive two-tiered antibody test process. Nothing else is to be taken into account according to their guidelines!

In addition, not all cases reported in Oregon (by either the patient's physician or the testing lab) receive proper follow up by the Oregon Department of Health officials. When I found that 18-24 people from our SOLD members meet the criteria based on lab results alone, but only 4 were contacted by public health officials, I would say that is a huge failing! And none of the positive lab reports from Igenex lab in California were ever followed up. Not one! No wonder physicians are telling their patients that there is no Lyme disease in Oregon. It is because cases are not confirmed when reported.

And, to this day, as a public health nurse who has followed numerous guidelines for other communicable disease surveillance, I have yet to see the language that the Oregon Department of Health outlines for Lyme disease. It was hard for me to read the overtly flippant remark contained in the criteria thus, "Reduced sensitivity (i.e., exclusion of some reports that seem real) is the inevitable result. **GET OVER IT. Most reportable cases will be presumptive**". I can see where these remarks, alone, could set the tone for public health officials to discount criteria to support a confirmed case. I suggest the criteria and guidelines for confirming and counting cases of Lyme disease in Oregon should be review and revised.

SUMMARY

SB 916 is written to enhance options for patients who are seeking diagnosis and treatment for Lyme disease in Oregon. Under Oregon's current accepted medical guidelines, myself and members of our Southern Oregon Lyme Disease support group have experienced great difficulty with timely and accurate diagnosis. Like me, proper diagnosis, often comes in the late stage of the illness. Left untreated, or under-treated, the majority of Lyme-afflicted patients suffer extremely incapacitating illnesses that ultimately lead to exorbitant out-of-pocket health care costs and reduced ability to work and thus, less economic productivity.

The Oregon Department of Health has made counting confirmed cases near impossible. First, by insisting on a two-tiered laboratory confirmation process that often yields less than 60-71% of those infected with the organism that causes Lyme disease. And, second by failing to follow up on reported cases that do have laboratory confirmation. That is why we, who run the six support groups throughout Oregon, have a difficult time with rectifying the numbers. How is it that only 33 cases have been counted in all of Oregon between 2010-2013 when we, collectively, have over 200 members just within our Southern Oregon support group and another 500 members among the other five support groups in Oregon?

I have found that Lyme disease in Oregon is a complicated medical crisis. Since there have been no official survey of the number of ticks that are infected with the organisms that causes Lyme and it's coinfections since 1998, how can we possibly know what the actual risk is? (In 1997-1998, a tick identification and Borrelia isolation study was conducted by the CDC and the Oregon Department of Human Services in Deschutes, Josephine and Jackson counties. The organism was isolated in 3% of Ixodes pacificus ticks tested.)

<https://public.health.oregon.gov/DiseasesConditions/CommunicableDisease/DiseaseSurveillanceData/AnnualReports/arpt2013/Documents/2013-lyme-disease.pdf>

Too many Oregon patients are suffering by being denied access to all acceptable treatment guidelines and modalities of care that are readily available. I have found that a meaningful number of people in our SOLD support group have not gotten better with Oregon's current and very limited standard of treatment. Because of Oregon's severe limitations, patients have sought out and used other states' guidelines not permitted to Oregon physicians, including those of ILADS, and have achieved levels of recovery from the disabling grips of Lyme Disease.

I am asking you to support legislative action that protects patients' rights to receive the treatment of their choice. The bill that I am asking you to sign would allow clinicians to act in the best interest of their patient without fear of punishment from the professional discipline system. Please put your support behind this legislation to ensure that the growing number of sufferers of Lyme receive the treatment and recognition they deserve.