TESTIMONY TO OREGON REPRESENTATIVES

Thank you Oregon Representatives for hearing testimony for SB916.

My name is Sharon Lee. I have been an RN for 50 years with a master of nursing education degree. I have been sick with Lyme disease and four other tick-borne co-infections since 1978. I am currently the co-leader of a 200 + member support group called Southern Oregon Lyme Disease (SOLD). As an affiliate of the Oregon Lyme Disease Network, we serve the following counties: Klamath, Jackson, Josephine, Curry, Coos & Douglas.

Lyme disease has been a nationally notifiable condition in the United States since 1991. To help monitor the spread and number of Lyme cases, the CDC put out what is called a surveillance case definition. Their "definition" of Lyme was based on the early findings, and hasn't changed since that time.

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 a case is confirmed. Each county's confirmed cases are reported to ODH who, in turn report them to the Centers for Disease Control (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 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.

Over the years, the CDC has transformed their Lyme criteria, which was developed for surveillance purposes, into diagnostic mandates for physicians. In fact, most physicians believe the patient must meet the criteria of the early CDC definition for a diagnosis of Lyme to be made. This is not true. The CDC definition was never meant to be used as a check list for clinical diagnosis of Lyme, but, unfortunately, that is exactly what has happened. As a result, many patients are not diagnosed early or are misdiagnosed and subsequently go one to a chronic state of disease.

The main reason for this limitation is the current, CDC protocol required for confirmation of each Lyme case. The CDC supports their testing criteria even though many studies have demonstrated the antibody tests lack sensitivity and miss from 50-75% of cases. This protocol requires the following:

1) Presence of a bull's eye (erythema migrans) rash;
2) A culture or a two-tiered testing protocol, and
3) Documentation of several symptoms indicating advanced disease.

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!

The Oregon Department of Health confines confirmation to only two items:

1) A physician documented rash over 2 inches; and
2) A culture or a positive two-tiered testing protocol.

Nothing else is to be taken into account according to their guidelines! 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 can also see that, due to these restrictive guidelines, very few confirmed cases will be reported to the CDC. Be aware that the guidelines set by the Oregon Department of Health are those that have left many misdiagnosed and untreated. It seems odd to me that public health agencies, whose usual importance is on prevention, have actually placed a burden on the medical care system. I suggest the criteria and guidelines for confirming and counting cases of Lyme disease in Oregon should be review and revised. Oregon Lyme Disease Task Force includes public health nurses and other Lyme disease experts that would be willing to be part of this review process.

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. In 2014, one CDC proficient CLIA lab (Igenex) reported to Oregon Lyme Disease Network (OLDN) they had reported 166 positive CDC test results for Lyme disease to the Oregon Department of Health. But during that same year, the Oregon Department of Health only reported 31 cases to the CDC. This is a huge discrepancy! In another survey conducted by SOLD of 56 members, 24 people met the criteria based on lab results alone, but only 4 were contacted by Oregon public health officials for follow up. And none of the positive lab reports that were done by Igenex lab 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 by the Oregon Department of Health when reported.

In Oregon, most physicians still go by the old and unreliable standard: that Lyme is rare and exists only on the East Coast, that a bull's eye rash must be present, that tests using the first tiered test called an ELISA, is reliable. As you can see, that is far from the truth!

If one happens to have a bull's eye rash and a positive ELISA, and a Western Blot test, it will get them about 2 weeks of antibiotics. Any further insurance coverage of treatment is denied. This is the standard recipe that has destroyed countless lives in Oregon and across the nation.

Another reality is that not all Lyme patients test positive on the two-tiered testing, at least not at the levels set by doctors who follow CDC and Oregon surveillance criteria as diagnostic. The reason for this lies in understanding how the Lyme bacteria operates in order to survive.

Once injected into the body, Borrelia burdorferi, the organism that causes Lyme disease, immediately goes to work suppressing the immune system. In addition, the organism keeps changing or morphing into another form. It also will quickly retreat to sequestered places in the body and it essentially hides itself from the immune system.

The initial two-tiered tests are designed to detect one's antibodies produced against the bacteria. The evasive tactics of the Lyme organism prevent immune antibodies from being produced. As a result, there may be little, if any indication from the two-tiered test that a patient is infected with the organism.

Many physicians unfamiliar with Lyme also don't realize that if the patient has been taking steroids, antibiotics, or anti-inflammatory medications (even over-the-counter drugs like ibuprofen or naproxen) the two-tiered test can provide false-negative results. To get an accurate reading, patients should be off all medications of these types for at least six weeks before the test.

To further complicate the two-tiered testing, there is a variation in how the antibody tests are conducted by each lab that makes many invalid. Many conventional testing labs use a lab-generated bacteria that is not found naturally in a wild tick. In addition, there are numerous species of Lyme bacteria in the wild. It is common knowledge that the tests may only account for 50% of those who are infected. That is no better than a coin toss! IGENEX lab in California is a dedicated tick lab. They only test for tick-borne infections. They typically use several wild antigens of the Lyme bacteria in their tests. Therefore, their positive results are much higher than conventional labs.

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

Since only 50% of Lyme cases will even have a bull's eye rash, that decreases the numbers even further. Applying these statistics to 100 lyme cases, half would be eliminated because they did not have a bull's eye rash. Of the remaining 50 cases, only 15-20 people will be possibly counted. Couple that with the more restrictive Oregon guidelines, and the numbers of cases will obviously be low.

These researchers, members of the Infectious Diseases Society of America (IDSA), have developed Lyme clinical practice guidelines that leave patients ill and without treatment options. When guidelines represent "de facto" law to insurers, government agencies like the CDC and the Oregon Department of Health, medical societies and hospitals, there are serious economic, legal and treatment consequences to patients. These small group of researchers have built their careers around a biased view of Lyme disease. They have disregarded patients while pursuing dead- end research using tax payer funded grants.

Unfortunately, many Lyme specialists are now being harassed by medical boards and insurance companies across the country. They are being accused of over-diagnosing the condition, treating the disease too aggressively, and overusing antibiotics. Several practitioners have either lost their licenses to practice or had to close their clinics. That has sent a powerful message to physicians in Oregon, because we have none who currently treat Lyme patients. That bears repeating. Oregon currently has zero (0) MD's who treat patients with Lyme disease! Therefore, patients have had to go outside the state to seek care. And, the out of state physicians who properly treat Lyme are being swamped with patients.

The reality is this: when a physician or nurse practioner, who fully understands Lyme disease, could prescribe about $50.00 worth of antibiotics early on, it would prevent a treatable disease from turning into a permanent, disabling, and life-changing one. And, it would save millions of dollars and countless lives.

Our federal government is aware of the problem, and is trying to take steps to remedy the situation. A US Senate committee report states, that the current state of laboratory testing for Lyme is very poor. The situation has led many people to be misdiagnosed and delayed proper treatment. The ramifications of this deficit--in terms of unnecessary pain, suffering and cost--is staggering. The Committee is distressed in hearing of the widespread misuse of the current Lyme surveillance case definition. While the CDC does state that "this surveillance case definition was developed for national reporting of Lyme: it is NOT appropriate for clinical diagnosis," the definition is reportedly misused as a standard of care for health care reimbursement, product (test) development, medical licensing hearings, and other legal cases. (Senate Appropriations Report (S.1536, SR.107-84))

And, most recently, the Tickborne Disease Research Accountability and Transparency Act was adopted into a larger medical research bill by federal legislators in May of 2015. This bill would create a group of federal agencies and "non-federal partners," including Lyme physicians and patient advocates. The group would be charged with ensuring coordination among federal agencies to maximize research priorities. It would also require the secretary of health and human services to consult with the group and create a strategic plan within three years. That plan would need to include a proposal for improving outcomes of Lyme disease and other tick-borne diseases, including progress related to chronic or persistent symptoms, infections and co-infections. It would also have to include benchmarks to measure progress toward those goals.

In conclusion, SOLD supports the rights of patients to be advised that there is more than one evidenced-based, medically recognized standard of care for Lyme disease, and that they have the right to participate in decisions pertaining to their (or their children's) medical care. SOLD strongly advocates for legislative leadership and investigation into the past and present CDC and Oregon Department of Health practices, which permit the IDSA guidelines to overly influence national and Oregon health care policy on Lyme disease.