Lyme Disease In Oregon

Support to Testimony

2015- 78th Session of the Senate Committee on Health

SB916

SUMMARY Directs Oregon Medical Board and Oregon State Board of Nursing to adopt rules regarding diagnosis and treatment of Lyme disease. Declares emergency, effective on passage

Sponsored by COMMITTEE ON HEALTH CARE
(at the request of Oregon Lyme Disease Network)
We surveyed a group of 102 Lyme disease patients in Oregon based on Clinical symptoms and supportive IgG and IgM tests. 56 responded having **CDC positive tests** and symptoms consistent with early or late disseminated Lyme disease.

56 patients in the group, saw an average of 6.1 specialty doctors and were ill for a period of 9.2 years before finally getting diagnosed - usually by out of state MDs.

22 patients surveyed were **CDC positive with early CLASSICAL symptoms:**
- Only 10 were diagnosed by an Oregon MD, DO or FNP (45.45%)
- 6 of the 10 diagnosed by their primary MD were later undiagnosed by Infectious disease doctors. (overturn rate 60%) and refused treatment.

**Missed Diagnosis by Oregon MDs, Do, and FNPs using the current protocol**
- Rate of missed diagnosis was **82%** in the group with classical presentation AND a CDC positive test.
- Rate of missed diagnosis was **93%** with clinical manifestations and supportive laboratory evidence.

**Disability of Oregonians**

75% had lost jobs, homes, or had to have educational IEPs in place due to disabilities associated with this illness.

70% qualified for disability due to untreated Lyme disease causing disabling symptoms. (Lyme induced: Neurological, Cardiac, MS, ALS, Parkinsons, Autism, FMS/CF, Arthritis, Intractable pain, Cognitive and executive function losses)

3 Portland area FM/CFS support groups showed 82%, 87%, and 84% of those patients were CDC positive for Lyme Disease through Western Blot IgG or IgM testing.
There seems to be confusion among professionals in Oregon regarding the rates of Lyme disease.

ONE (of 6 who routinely test for Lyme responded to my request) CLIA certified laboratory with CDC proficiency ratings, reported **166 CDC positive** results on either Western Blot IgG or IgM test for Oregonians in **2014**.

Currently in Oregon Support Groups **817 patients**, a combination of clinical diagnosis with supportive laboratory testing.

<table>
<thead>
<tr>
<th>Patients currently in Support groups or in email connection with SG around the state:</th>
<th><strong>817</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Hood River</td>
<td>34</td>
</tr>
<tr>
<td>Southern Or</td>
<td>203</td>
</tr>
<tr>
<td>Portland OR</td>
<td>350</td>
</tr>
<tr>
<td>Bend Oregon</td>
<td>37</td>
</tr>
<tr>
<td>Corvallis Or</td>
<td>50</td>
</tr>
<tr>
<td>Other areas phone</td>
<td>143</td>
</tr>
</tbody>
</table>

The State of Oregon, Cases of Selected Notifiable Diseases for **2014** -- reported a total of **38 probable cases** and **21 confirmed** in Oregon for the year.
Is Lyme disease in Oregon?

**Epidemiology**
Lyme disease was recognized in 1976 because of close clustering of cases in Lyme, Connecticut and is now the most commonly reported tick-borne illness in the US. It has been reported in 49 states. Most cases occur from Maine to Virginia and in Wisconsin, Minnesota, and Michigan. On the West Coast, most cases occur in northern California and Oregon.

*merck manual-current*
The Oregon MD physician will only (for fear of disciplinary actions by going outside the current standard of care): While the state verbally says there is standard of care in place, it is duly noted that the state ID physicians refer to IDSA being the gold standard and only evidence based guideline (patently untrue) and refuse to even accept east coast “doctors orders” when patients travel to more endemic areas where doctors treat more patients and are up to date on both standards of care available to them.

- Treat the max 28 days then declare a patient cured or refer them to Infectious disease, or some refer to out of state for follow up care. (some of those are currently being investigated for “vague” reasons they don’t know).

- follow restricted surveillance criteria for diagnosis handed down by the health departments (under the authority of the “state expert witness IDSA physicians at OHSU)

- Refer positive patients to an Infectious Disease specialist who refused any care. (it’s a choice- see the audio file we presented and see patient letters)

- only use laboratories the use the ELISA as the first screen despite the poor outcome for that serology test

- Reject IgeneX laboratory telling patients it’s a bad lab (not sure why they say this)

- Refer patient out of state which means hundreds of patients a year will go on to chronic disabling symptoms due to cost
Highly proficient laboratory tests are being thrown out, patients are told this is a “bad lab” by physicians and Oregon Health Dept. This lab specializes in Tick related illness detection.

August 29, 2013

IGeneX, Inc. has been offering “high complexity tests” since 1992. It is licensed by Centers for Medicare and Medicaid Services (CMS), formally known as CLIA and bills Medicare in the U.S. In addition, it holds California, New York, Maryland, Pennsylvania and Florida licensure since these States require a separate license to perform testing for patients.

To ensure that it maintains the standards of a High Complexity Testing Laboratory, IGeneX is inspected by the California Department of Public Health (CDPH), CMS and New York State Department of Health (NVHD) biannually. IGeneX was last inspected by CDPH and CMS in 2013 and NYDH in 2011.

Proficiency Testing (PT)

In order to monitor the testing quality, PT must be performed on every test offered by a clinical laboratory. We have passed annual PT for all tests offered in the last 10 years. This includes New York, CAP and Internal Proficiency Testing (for tests where external proficiency is not offered).

Validation Protocol

Before IGeneX offers any laboratory developed test for clinical use, extensive validation is carried out as described in our validation protocol (part of the QC-QA procedure). This process has been reviewed and accepted by CDPH, CMS and NVHD. Before a new test can be offered in New York State, NYMP has to review and accept the new test validation.

The following tests are not offered in New York State: confirmation test for the 31kDa band on the Western blot, Lyme Dot-Blot assay (LDA), Lyme IFA, Bartonella RISH, CC57 and B. duncan IFA.

For further information, feel free to contact me at 800-832-3200.

Regards,

Nick S. Harris, Ph.D., ABMLI
President/CEO
IGeneX, Inc.
Nationally the direct cost of Lyme disease is $10,769 per case\textsuperscript{1}. A which puts the total US public health burden of Lyme disease in the US at $3.2 billion. This cost does not include the indirect cost incurred in undiagnosed cases requiring excessive medical diagnostics and hospitalizations due to chronic symptoms affecting the heart, CNS and body organs. (MRIs, Cardiac Catheterizations, Reproductive issues, Sleep studies, hospitalizations) or loss of productivity, or the cost of special education involving Lyme induced Autism, Cognitive Deterioration, and Disability from Arthritis.

A study to quantify the economic and business costs of chronic disease: the potential impact on employers, the government and the nation’s economy\textsuperscript{2} was conducted and results for Oregon showed annual cost:

\begin{itemize}
  \item Treatment Expenditures: $3.4B
  \item Lost Productivity: $13.1B
  \item Total Costs: $16.5B
\end{itemize}

Chronic disease accounted for $1.4 million in hospitalization costs\textsuperscript{4} alone--And we have no idea how much that would be reduced if Lyme Disease were diagnosed and treated. We do know Lyme Disease heavily impacts cardiac, skeletal and neurological health of the patients.

Total economic impact of arthritis and rheumatic diseases in Oregon was $1.6 billion ($1.02 billion in direct medical costs and $586 million in indirect costs such as loss of earnings due to disability). The most commonly known symptom of Lyme Disease is Arthritis, however in Oregon it is dismissed out of hand due to current protocol.

Reasonable improvements in preventing and managing chronic disease could reduce future economic costs of disease in Oregon sharply, by 26% ($14.0 billion) in 2023. $11.1 billion of this would come from gains in productivity, and $3.0 billion would come from reduced treatment spending. And the impact on economic output compounds over time. These improvements in health will increase investments in human and physical capital, driving additional economic growth a generation from now. By 2050, reasonable disease prevention and management efforts could add $63 billion to the state’s economic output, a boost of 18\%.\textsuperscript{5}

\textsuperscript{1} The calculation is based on information from the U.S. Centers for Disease Control and Prevention, The Emerging Infectious Diseases Journal, and the U.S. Bureau of Labor Statistics. Xinzhi Zhang, MD/PhD, then an epidemiologist at the CDC co author Dr. Martin Meltzer, the CDC’s Lead of its Health Economics and Modeling Unit
\textsuperscript{2} http://www.milkeninstitute.org/publications/view/321
\textsuperscript{3} http://www.chronicdiseaseimpact.com/
\textsuperscript{4} https://public.health.oregon.gov/DiseasesConditions/ChronicDisease/Documents/healthor.pdf
\textsuperscript{5} http://www.chronicdiseaseimpact.com/state_sheet/OR.pdf
Our dogs get routine Lyme disease tests and are treated more readily than their human counterparts.

Companion Animal Parasite Council Veterinary data shows a rate of 1 out of 84 dogs tested are positive with Lyme Disease (848 tested). *OVMA census shows 968,496 dogs in Oregon. If we were to trend this to the population of dogs that would be 11,261 dogs with Lyme in 2014.*

IddeX laboratory shows 389 cases last year alone in Oregon dogs tested through their laboratory.

When we compare dogs in Oregon to more endemic areas, then compare humans in Oregon to more endemic areas we see significant differences in percentages of human : dog ratios in Oregon versus endemic areas. Our DOGS are higher ratio than endemic areas...and our dogs get treated here.

It's time to recognize there is a skewed problem and we can fix it.

SB916 is the answer to this issues, requiring the adoption of evidenced based standards and ILADS IOM GRADE criteria approved guidelines as state approved guidelines should allow patients access to care while protecting physicians who wish to consider treating patients after the current limiting state protocols have failed that patient.
Keeping Oregonians Healthy is a statewide report that summarizes data and presents information for preventing and managing chronic diseases. Chronic diseases, including cancer, heart disease, stroke, lung disease, diabetes and arthritis, are the major causes of disability and death for Oregonians. In addition to claiming the lives of 19,219 Oregonians in 2005, chronic diseases resulted in hospitalization costs of more than $1.4 billion.

Depression is common among those with chronic diseases; one in ten Oregonians with a chronic condition had active symptoms consistent with major depression, and one in three had clinically relevant depression in the prior 12 months. Lyme disease patients have a high rate of depression due to pain, losses, and fighting the system that doesn’t care.

For unknown reasons, the stroke death rate in Oregon is among the highest in the nation. Lyme Disease and its co-infections are cited in multiple journals as a cause of stroke and seizure.

### Economic Impact in Oregon 2003
(Annual Costs in billions)

<table>
<thead>
<tr>
<th>Category</th>
<th>Cost (in billions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment Expenditures</td>
<td>$3.4B</td>
</tr>
<tr>
<td>Lost Productivity</td>
<td>$13.1B</td>
</tr>
<tr>
<td>Total Costs</td>
<td>$16.5B</td>
</tr>
</tbody>
</table>

During 2003, the total economic impact of arthritis and rheumatic diseases in Oregon was $1.6 billion ($1.02 billion in direct medical costs and $586 million in indirect costs such as loss of earnings due to disability). In 2005, 8,413 of the hospitalizations for osteoarthritis and rheumatoid arthritis resulted in surgical replacement of a major joint (knee, shoulder or hip), with an estimated total cost of $247 million.

Arthritis is the most common chronic disease and affects 27 percent of adult Oregonians. It is a leading cause of disability and is a leading symptoms in Lyme Disease.
Why we need to include additional standards of care and protect our physicians who choose to use additional standards of care for diagnosis and treatment.

Analysis of Overall Level of Evidence Behind Infectious Diseases Society of America Practice Guidelines
Dong Heun Lee, MD; Ole Vielemeyer, MD

Oregons’ Current Standard of Care Guidelines were developed with 4218 individual recommendations,
• Level 1- solid science evidence 14%
• Level 2 - ≥ 1 randomized trial 23%
• Level 3 - expert opinion only 55%

“More than half of the current recommendations of the IDSA are based on level III evidence only. Until more data from well-designed controlled clinical trials become available, physicians should remain cautious when using current guidelines as the sole source guiding patient care decisions”

When using the current protocol we see the following scenario:

CHRONICALLY ILL PATIENTS that when treated appropriately through ILADS criteria often have a high QOL outcome.
A doctor's experience after treating outside the current protocol with evidenced-based medicine. These doctors need to be protected.

Excuses doctors have told patients so they don’t have to treat.

“You’re the first case in Oregon!” (send them to ID specialists who then re-diagnoses)

“Your positive test is false positive”

“There is no Lyme in Oregon”

“You are cured! (forget that the symptoms are still there)”

“I have been told I can’t treat Lyme disease”

“We won’t treat here, you have to go out of the state”
The overall problem with the IDSA cost analysis is that the IDSA is looking at only the cost of treating Late Lyme disease, which is $10,750 per patient per year. When treated the ILADS standard patients average 6 years of treatment when caught in the Late stage.

What it fails to consider is that the cost associated with misdiagnosis is high: MRIs, Cardiac Tests, Spinal Taps, Spect Scans, Drugs to support MS, ALS, Depression, Arthritis.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Average cost per procedure 2014</th>
<th>Tests my daughter underwent prior to diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>MRI</td>
<td>1100-5000</td>
<td>4</td>
</tr>
<tr>
<td>SPECT scan</td>
<td>1100</td>
<td></td>
</tr>
<tr>
<td>CT scans</td>
<td>400-600</td>
<td>9</td>
</tr>
<tr>
<td>Cardiac Catheterization</td>
<td>7800</td>
<td>3</td>
</tr>
<tr>
<td>Echo Cardiagram</td>
<td>2800</td>
<td>5</td>
</tr>
</tbody>
</table>

Cost of treating illness per year

<table>
<thead>
<tr>
<th>Disease</th>
<th>Cost in $ per year</th>
<th>Duration of illness</th>
<th>Other costs to consider</th>
</tr>
</thead>
<tbody>
<tr>
<td>MS</td>
<td>62,000</td>
<td>Lifelong - onset often in late 20s (45 years)</td>
<td>Lost productivity of patient and caregiver</td>
</tr>
<tr>
<td>Parkinsons</td>
<td>2000-27000</td>
<td>Lifelong-onset avg 50 years old (25 years)</td>
<td>Reduced QoL for patient and caregiver</td>
</tr>
<tr>
<td>Autism</td>
<td>17450</td>
<td>Lifelong - onset 2 yrs</td>
<td>Education, lost income and residential care</td>
</tr>
</tbody>
</table>

When a Lyme disease patient is not diagnosed, they often end up with many tests to determine what is wrong. Often after an array of expensive test, and the ones in the chart to the right are common for an undiagnosed Lyme patients to unnecessarily undergo.

Often a diagnosis is made, which is more costly that the treatment and management of Lyme disease, and often has no end point **when a differential for Lyme disease was never considered**.
It also fails to recognize the Cost of Chronic Illness and its associated issues (lack of activity, lack of productivity, caretaker reduction in productivity, and the secondary health issues that are created). Untreated Lyme disease causes chronic conditions that also reduce activity in patients.
Progressive disease resulting from Failure to diagnose and treat

“The Oregon MS Society estimates 6,800 cases”, Cohan said, “but that may be low. Oregon and Washington definitely have higher MS rate”

| Lyme victims are commonly misdiagnosed with other illnesses, such as: |
|---------------------------------|---------------------------------|
| Multiple Sclerosis              | Ménières Syndrome               |
| Chronic Fatigue Syndrome        | Osteoarthritis                   |
| Colitis                         | Prostatitis                      |
|Crohn’s disease                  | Psoriatic Arthritis              |
|Early ALS                        | Psychiatric disorders (bipolar, depression, etc.) |
|Early Alzheimers disease         | Raynaud’s Syndrome               |
|Encephalitis                     | Reactive Arthritis               |
|Fibromyalgia                     | Rheumatoid Arthritis             |
|Fifth’s disease                  | Scleroderma                      |
|Gastroesophageal Reflux disease  | Sjogren’s Syndrome               |
|Infectious Arthritis             | Sleep disorders                  |
|Interstitial Cystis              | Thyroid disease                  |
|Irritable Bowel Syndrome         | Various other illnesses          |
|Juvenile Arthritis               | Lupus                            |
Dr. Guy Webster, a dermatologist at Jefferson Medical College in Philadelphia, said this paper adds to the data suggesting that the odds of acne patients getting a serious, drug-resistant infection are low. People with acne may take antibiotics for months or even years, Margolis said.

AAD implies the risks “Although acne is not a life-threatening condition, it can be painful, particularly when it is severe. It can also cause emotional distress. Acne that appears on the face can impact self-esteem and, over time, may cause permanent scarring.

But at least for now, when doctors are considering treatment for acne, the risks of these antibiotics seem to be smaller than the potential benefits, Webster said.

Are the potential risks of acne really worse than the potential risk of Lyme disease?

- Numbness or pain in the nerve area
- Paralysis or weakness in the muscles of the face
- Heart problems, such as skipped heartbeats (palpitations), chest pain, or shortness of breath
- Abnormal muscle movement
- Joint swelling
- Muscle weakness
- Numbness and tingling
- Speech problems
- Thinking (cognitive) problems
- cranial neuritis
- radicularneuritis
- meningitis
- Encephalitis
- Bells palsey
WHAT IS THE IOM?

The Institute of Medicine (IOM) is an independent, nonprofit organization that works outside of government to provide unbiased and authoritative advice to decision makers and the public. Established in 1970, the IOM is the health arm of the National Academy of Sciences, which was chartered under President Abraham Lincoln in 1863. Nearly 150 years later, the National Academy of Sciences has expanded into what is collectively known as the National Academies, which comprises the National Academy of Sciences, the National Academy of Engineering, the National Research Council, and the IOM.

The IOM asks and answers the nation’s most pressing questions about health and health care.

Our Work

Our aim is to help those in government and the private sector make informed health decisions by providing evidence upon which they can rely. Each year, more than 2,000 individuals, members, and nonmembers volunteer their time, knowledge, and expertise to advance the nation’s health through the work of the IOM. Many of the studies that the IOM undertakes begin as specific mandates from Congress; still others are requested by federal agencies and independent organizations. While our expert, consensus committees are vital to our advisory role, the IOM also convenes a series of forums, roundtables, and standing committees, as well as other activities, to facilitate discussion, discovery, and critical, cross-disciplinary thinking.
What is the Institute of Medicine?

- Health component of the US National Academy of Sciences
- Independent, non-profit, non-governmental organization
- Aims to answer health- and healthcare-related questions posed by government and the private sector
- Provides unbiased advice to health care decision makers and the public
- Generally perceived as authoritative

Clinical Practice Guideline Development