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)

Statistics in Oregon

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 , Intractiable 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 professional 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.

Patients currently in Support groups or in email connection with SG around the state: 817		
Hood River 34	Southern Or 203	Portland OR 350
Bend Oregon 37	Corvallis Or 50	Other areas phone 143

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?

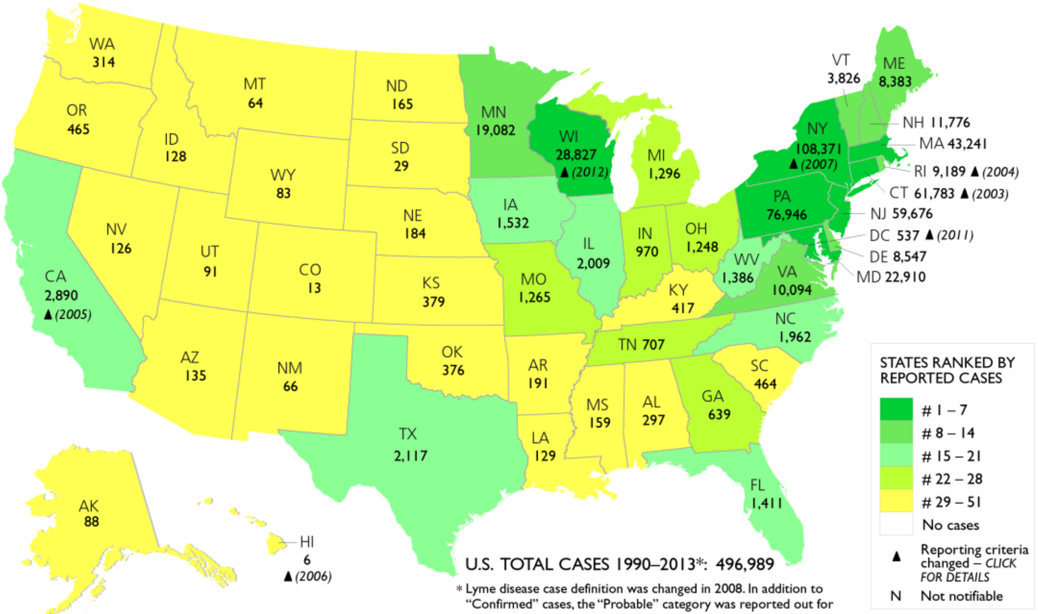
Epidemiology

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

LYME DISEASE ASSOCIATION (LDA)

U.S. LYME DISEASE REPORTED CASES 1990–2013*



U.S. TOTAL CASES 1990–2013*: 496,989

* Lyme disease case definition was changed in 2008. In addition to "Confirmed" cases, the "Probable" category was reported out for the first time. The numbers used for 2008 forward use the CDC "Total" reported cases (confirmed plus probable).

Source: Data compiled from CDC pub. data (MMWR)
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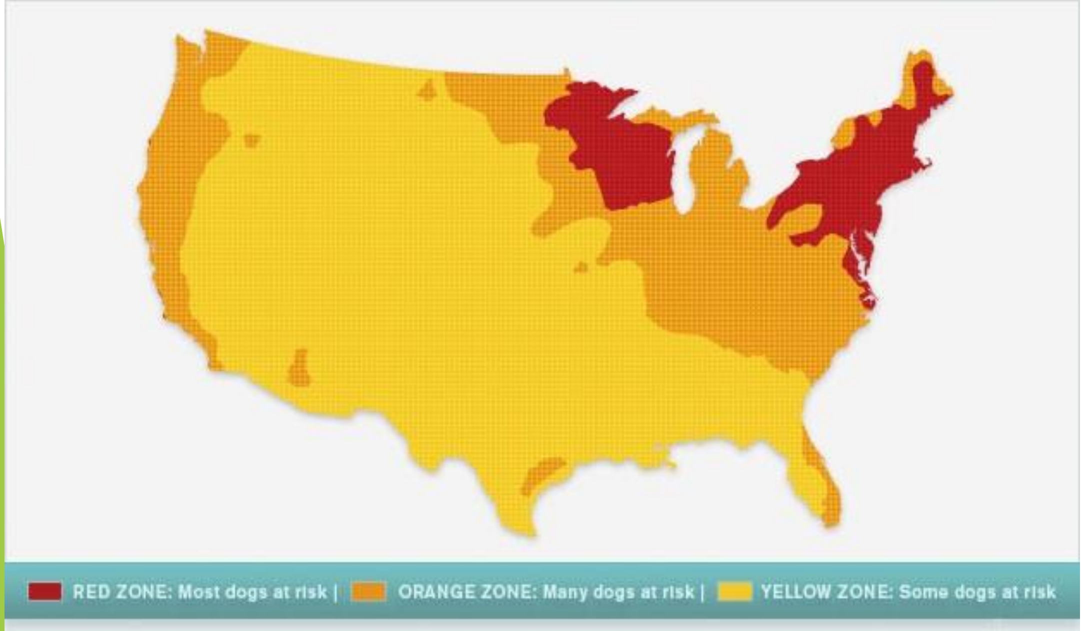
www.LymeDiseaseAssociation.org

Note: CDC states only 10% of Lyme disease cases meeting the surveillance definition are reported – 10,000 cases are reported, 100,000 cases occurred (does not include all the cases falling outside the stringent surveillance case definition). In 2013, CDC announced that about 300,000 cases of Lyme actually occur annually.



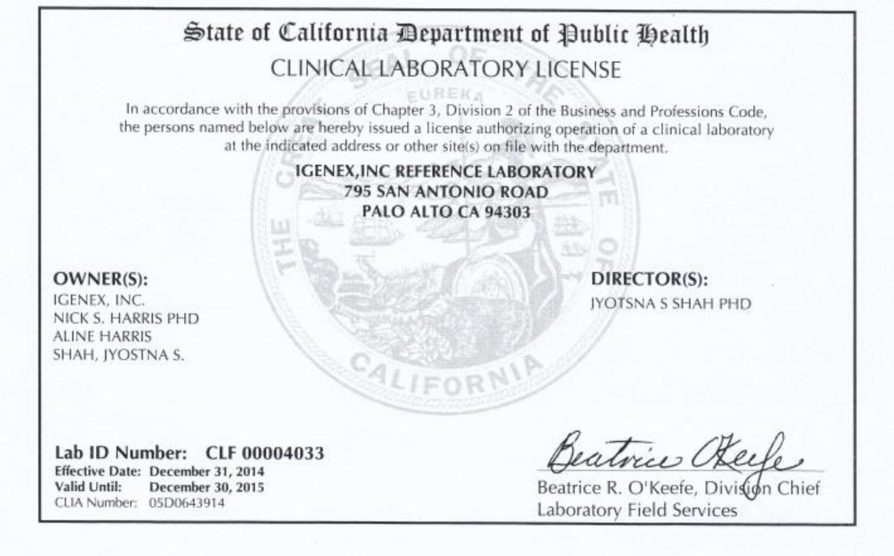
BUT…………

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 phsyicians 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.



State of California Department of Public Health

CLINICAL LABORATORY LICENSE

In accordance with the provisions of Chapter 3, Division 2 of the Business and Professions Code, the persons named below are hereby issued a license authorizing operation of a clinical laboratory at the indicated address or other site(s) on file with the department.

IGENEX,INC REFERENCE LABORATORY
795 SAN ANTONIO ROAD
PALO ALTO CA 94303

OWNER(S):
IGENEX, INC.
NICK S. HARRIS PHD
ALINE HARRIS
SHAH, JYOSTNA S.

DIRECTOR(S):
JYOTSNA S SHAH PHD

Lab ID Number: CLF 00004033
Effective Date: December 31, 2014
Valid Until: December 30, 2015
CLIA Number: 05D0643914

Beatrice O'Keefe
Beatrice R. O'Keefe, Division Chief
Laboratory Field Services

CENTERS FOR MEDICARE & MEDICAID SERVICES
CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF COMPLIANCE

LABORATORY NAME AND ADDRESS
IGENEX INC
795 SAN ANTONIO RD
PALO ALTO, CA 94303-4801

CLIA ID NUMBER
05D0643914

EFFECTIVE DATE
09/20/2013

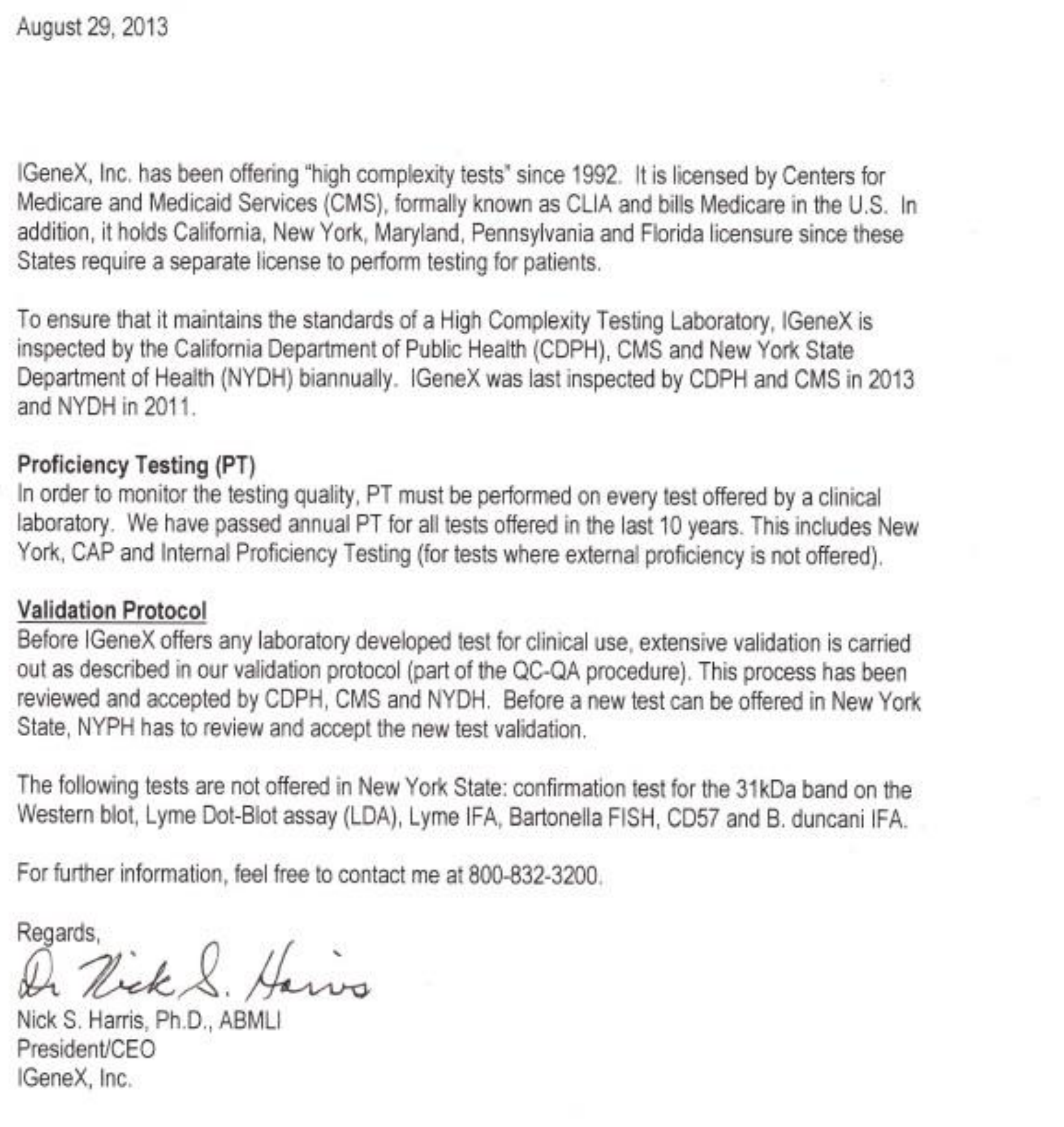
LABORATORY DIRECTOR
JYOTSNA S SHAH DIRECTOR

EXPIRATION DATE
09/19/2015

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.

Judith A. Yost
Judith A. Yost, Director
Division of Laboratory Services
Survey and Certification Group
Center for Medicaid and State Operations



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 (NYDH) 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 NYDH. Before a new test can be offered in New York State, NYPH 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 FISH, CD57 and B. duncani IFA.

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

Regards,
Dr Nick S. Harris
Nick S. Harris, Ph.D., ABMLI
President/CEO
IGeneX, Inc.

“Nationally the direct cost of Lyme disease is $10,769 per case[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 Disabiltiy 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.[2] was conducted and results for Oregon showed annual cost:

Treatment Expenditures: **$3.4B**
Lost Productivity: **$13.1B**
Total Costs: $16.5B

Chronic disease accounted for $1.4 million in hospitalization costs[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%.[5]

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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
2 http://www.milkeninstitute.org/publications/view/321
3 http://www.chronicdiseaseimpact.com/
4 https://public.health.oregon.gov/DiseasesConditions/ChronicDisease/Documents/healthor.pdf
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.

Its 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

Economic Impact in Oregon 2003

(Annual Costs in billions)

Treatment Expenditures: **$3.4B**

Lost Productivity: **$13.1B**

Total Costs: $16.5B

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.

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).9 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.

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

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.

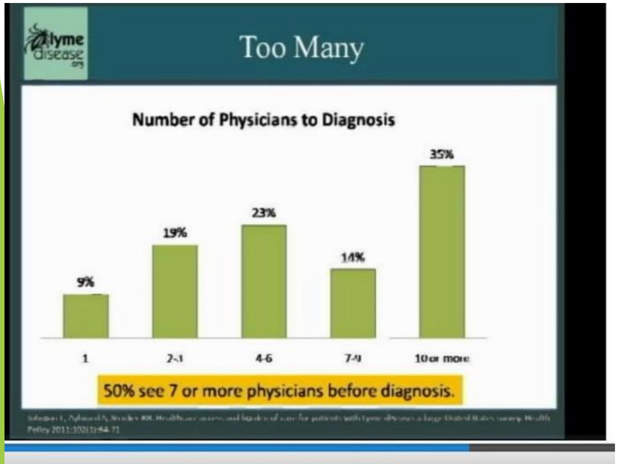
Analysis of Overall Level of Evidence Behind Infectious Diseases Society of America Practice Guidelines
Dong Heun Lee, MD; Ole Vielemeyer, MD

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:

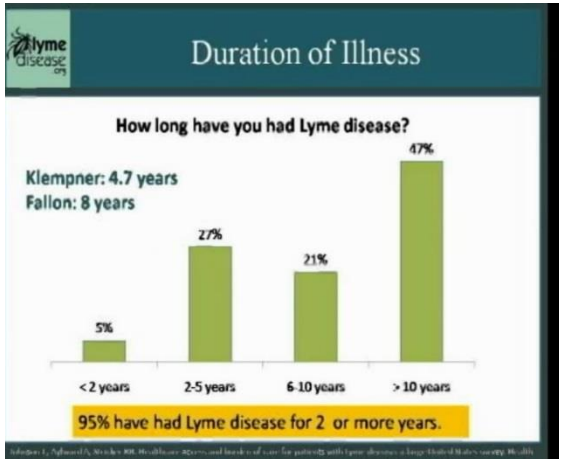


Too Many

Number of Physicians to Diagnosis

50% see 7 or more physicians before diagnosis.

Policy 2011:102(1):64-71



Duration of Illness

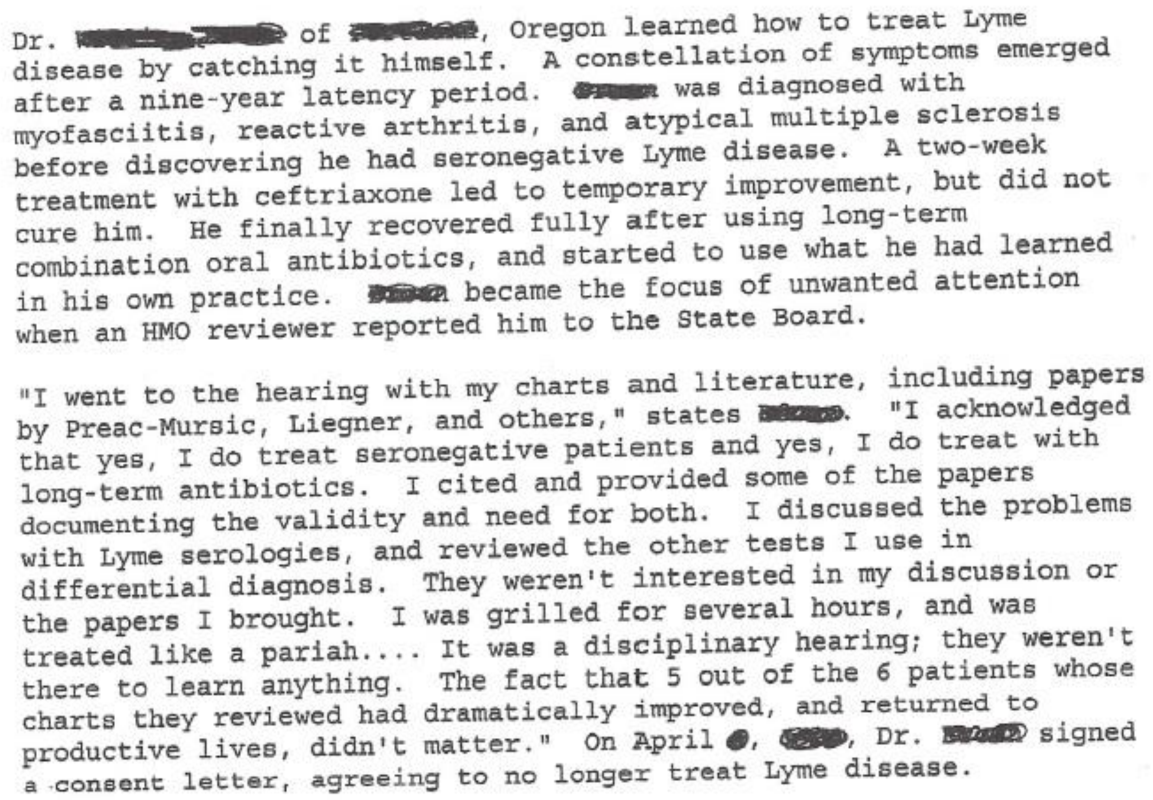
How long have you had Lyme disease?

Klempner: 4.7 years
Fallon: 8 years

95% have had Lyme disease for 2 or more years.

CHRONICALLY ILL PATIENTS that when treated appropriately through ILADS criteria often have a high QOL outcome.

A doctors experience after treating outside the current protocol with evidenced based medicine. These doctors need to be protected



Dr. [redacted] of [redacted], Oregon learned how to treat Lyme disease by catching it himself. A constellation of symptoms emerged after a nine-year latency period. [redacted] was diagnosed with myofasciitis, reactive arthritis, and atypical multiple sclerosis before discovering he had seronegative Lyme disease. A two-week treatment with ceftriaxone led to temporary improvement, but did not cure him. He finally recovered fully after using long-term combination oral antibiotics, and started to use what he had learned in his own practice. [redacted] became the focus of unwanted attention when an HMO reviewer reported him to the State Board.

"I went to the hearing with my charts and literature, including papers by Preac-Mursic, Liegner, and others," states [redacted]. "I acknowledged that yes, I do treat seronegative patients and yes, I do treat with long-term antibiotics. I cited and provided some of the papers documenting the validity and need for both. I discussed the problems with Lyme serologies, and reviewed the other tests I use in differential diagnosis. They weren't interested in my discussion or the papers I brought. I was grilled for several hours, and was treated like a pariah.... It was a disciplinary hearing; they weren't there to learn anything. The fact that 5 out of the 6 patients whose charts they reviewed had dramatically improved, and returned to productive lives, didn't matter." On April [redacted], [redacted], Dr. [redacted] signed a consent letter, agreeing to no longer treat Lyme disease.

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.

Procedure	Average cost per procedure 2014	Tests my daughter underwent prior to diagnosis
MRI	1100-5000	4
SPECT scan	1100	
CT scans	400-600	9
Cardiac Catheterization	7800	3
Echo Cardiagram	2800	5

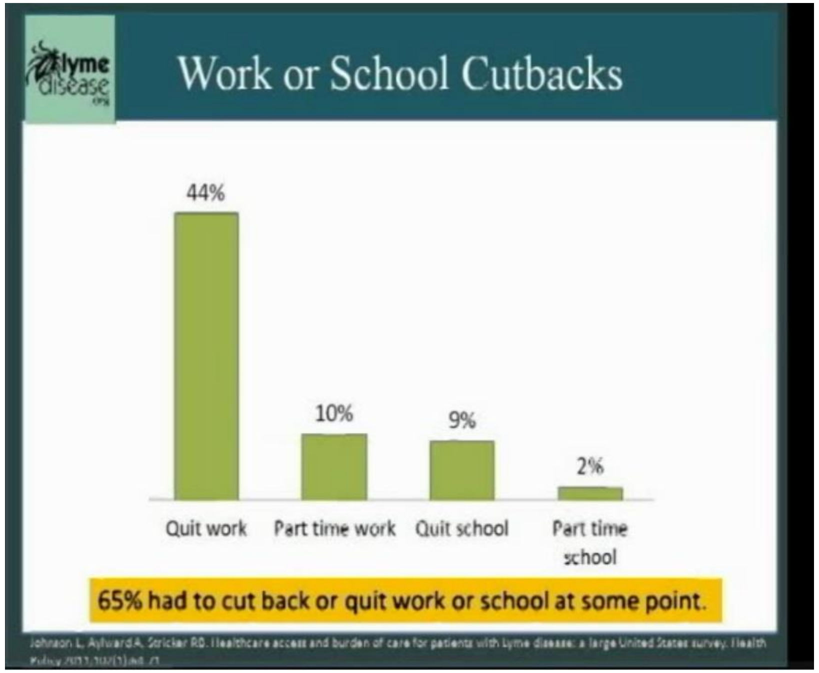
When a Lyme disease patient is not diagnosed, they often end up with many tests to determine what is wrong. Often after an array of expensive test, and the ones in the chart to the right are common for an undiagnosed Lyme patients to unnecessarily undergo

Cost of treating illness per year

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

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**.

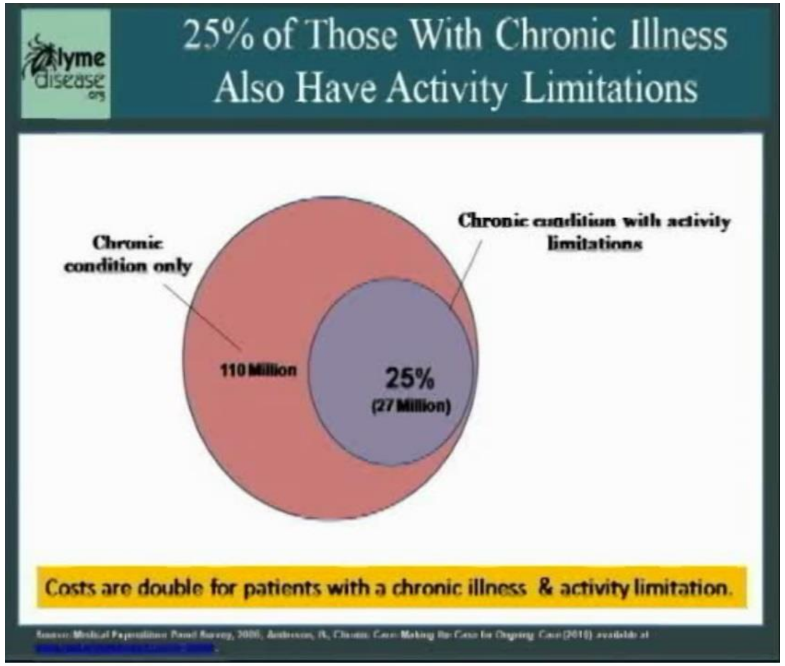
It also fails to recognize the Cost of Chronic Illness and its associated issues (lack of activity, lack of productivity, caretaker reduction in productivity, and the secondary health issues that are created) Untreated Lyme disease causes chronic conditions that also reduce activity in patients



Work or School Cutbacks

65% had to cut back or quit work or school at some point.

Johnson L, Aylward A, Stricker RB. Healthcare access and burden of care for patients with Lyme disease: a large United States survey. Health Policy 2011;102(1):64-71



25% of Those With Chronic Illness Also Have Activity Limitations

Costs are double for patients with a chronic illness & activity limitation.

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 Scleroisi
- Chronic Fatigue Syndrome
- Colitis
- Crohn’s disease
- Early ALS
- Early Alzheimers disease
- Encephalitis
- Fibromyalgia
- Fifth’s disease
- Gastroesophageal Reflux disease
- Infectious Arthritis
- Interstitial Cystis
- Irritable Bowel Syndrome
- Juvenile Arthritis
- Ménières Syndrome
- Osteoarthritis
- Prostatitis
- Psoriatic Arthritis
- Psychiatric disorders (bipolar, depression, etc.)
- Raynaud’s Syndrome
- Reactive Arthritis
- Rheumatoid Arthritis
- Scleroderma
- Sjogren’s Syndrome
- Sleep disorders
- Thyroid disease
- Various other illnesses
- Lupus

968496 dogs

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.

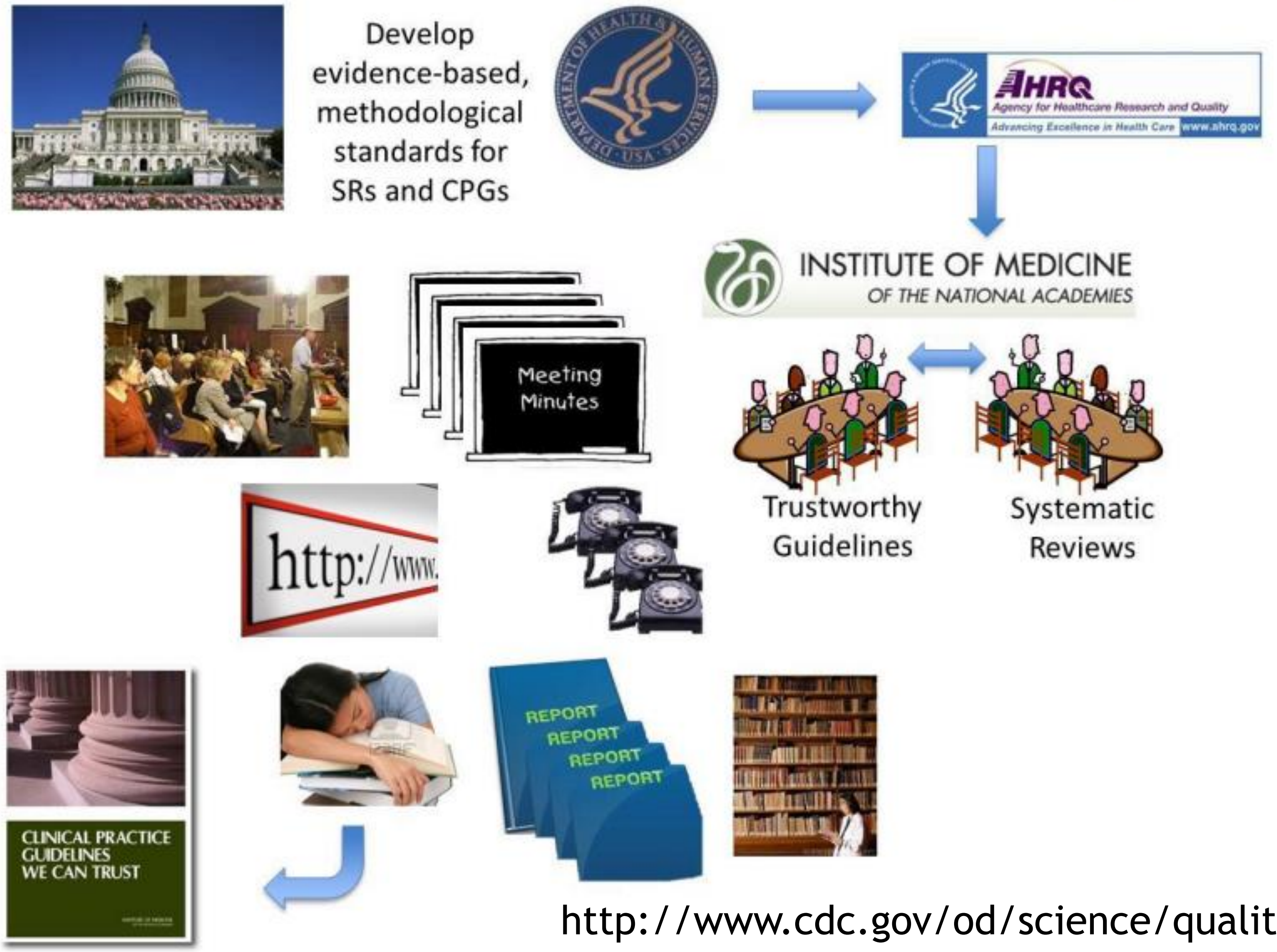
Many of the studies that the IOM undertakes begin as specific mandates from Congress; still others are requested by federal agencies and independent organizations. While our expert, consensus committees are vital to our advisory role, the IOM also convenes a series of forums, roundtables, and standing 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

http://www.cdc.gov/od/science/quality/docs/trustworthy_gls.pdf

Clinical Practice Guideline Development



Develop
evidence-based,
methodological
standards for
SRs and CPGs

Trustworthy
Guidelines

Systematic
Reviews

http://www.cdc.gov/od/science/quality/docs/trustworthy_gls.pdf