Senate Committee On Health Care

Oregon State Legislature 2015 Session

Dear Senator Laura Monnes Anderson,

Please consider adding a bill into the health committee (regarding Lyme Disease) which does three things:

1) Allows inclusion of Standard of Care Guidelines developed by International Lyme and Associated Disease Society (ILADS) using the Institute of Medicine (IOM) criteria using the Grading, Development and Evaluation practices (GRADE) to the Oregon state standard of care for Lyme disease. This guideline is to be included into the acceptable and referenced guidelines for the diagnosis and treatment of for Lyme Disease and other associated viral, bacterial and parasitic infections, for physicians and patients in the State of Oregon.
2) Since the science on the treatment of this illness is still evolving, we would request that additional guidelines that become available using a peer reviewed, evidenced based medicine and sound guideline development practices which fall under the NGC or the IOM GRADE processes be added as allowable patient treatment guidelines.
3) Allow diagnosis and treatment with IOM GRADE guidelines, for Lyme and other associated viral, bacterial and parasitic infections without fear of disciplinary action and censure from the Oregon Board of Medicine, solely for practicing the treatment of Lyme and associated disease outside of the IDSA guidelines Standard of Care (the only allowable guideline at this time). Disciplinary measure must weigh against the choice of guideline the physician is practicing under and cannot be considered experimental in nature providing :
    a) The physician uses approved guidelines
    b) The physician produces written informed consent on both standards of care (or additional standards that may be introduced in the future)
    c) The physician provides documents to support diagnosis and treatment and monitors the ongoing care of the patient receiving therapy.

I have spoken with Senator Tim Knopp (Bend) who is willing to support the writing of the bill in legal language and presenting this bill to committee.

I have enclosed the package of information regarding the need for these legislative pieces to be introduced to help the overall health of patients and counteract the economic impact of undiagnosed and untreated disease in our state finance of health, education, disability and social services

Sincerely

Theresa Denh

Theresa Denham

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STATE OF OREGON ~ LYME BILL

The people of the State of Oregon are proposing a bill which will allow medical practitioners to diagnose and treat Lyme disease, tick borne infections, and other related infections and parasitic diseases, as identified in the IDC–10 Code A69.20 and associated sections, using any standard of care including but not limited to the IDSA Standards, the ILADS Standards, and other pertinent standards of diagnosis and treatment, in accordance to/ with the scope of their practice.

The Institute of Medicine's (IOM's) mandate for patient-centered care is to achieve positive patient outcomes that improve Quality of Life (QoL)The IOM has a GRADE system which is used to rate the stability and strength of medical evidence in patient treatment.

ILADS is the first organization to issue Guidelines on Lyme Disease using the standards set by the IOM for developing trustworthy protocols based on the grading development and evaluation (GRADE) process, a format already used by Cochrane Collaborations and WHO.

Therefore guidelines which incorporate the IOMs GRADE process should be accepted and approved by the Oregon Medical Board and included as an appropriate standard of care.

OREGON STATISTICS FOR LYME DISEASE

TAKEN FROM AN OREGON LYME DISEASE NETWORK SURVEY 2007

According to the late Sen. Ben Westlund, Oregon is running out of money for state services. These services include health, education and disability financing. Lyme Disease affects all of these categories, and is currently a growing problem because it is not being recognized by the very physicians that should be experts in this area.

70% of the patients who responded in our survey were on disability through the ADA

75% of the patients had changed from full time status to part time or unemployed status due to Lyme disease of themselves or a family member.

Of 56 patients who responded all having a CDC positive tests, 22 patients responded with primary symptoms of headaches, stiff neck and myalgia.(common early Lyme disease symptoms)

> Of those 22 with EARLY SYMTPOMS with Only 10 were diagnosed in Oregon (45.45%)
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> Of those Diagnosed by physicians in Oregon 6 cases were told they did not have Lyme Disease by the Oregon Infectious disease physicians (22% diagnosed and confirmed of the early symptoms patients , and only 7% of total positive cases in study group)
>
> All patients in study group were positive by CDC standards and clinical diagnosis; 11 are CDC positive by Western Blot (WB), 7 are CDC positive by ELISA (both false positive and false negative) with confirmatory WB, and 4 are positive by PCR (DNA test) for Lyme disease spirochetes)
>
> All of the 22 showing previous symptoms had previous diagnosis of either ALS, MS or Fibromyalgia, which are debilitating, progressive illnesses which may cause death.
>
> 18 of the 22 are seeing out of state physicians, the other four are not getting treatment due to geographical/financial issues, and one died with cardiac and neurological complications.

56 patients in the group, saw an average of 6.1 specialty doctors were seen prior to being diagnoses with Lyme disease and were ill for a period of 9.2 years before getting diagnosed.

There is not a current study, we do know through Oregon Lyme Disease Awareness campaigns the numbers have dropped, however, patients are still unable to get diagnosis and adequate care in Oregon due to the policies in this state.

SUMMARY OF ISSUES

Oregon issues that prevent patients from getting diagnosis and adequate treatment in Oregon:

1) **Studies in Oregon have shown that tick borne illnesses exist, however, we have yet to fully determine the extent and scope of the problem through rigorous collection and testing of various vectors**

2) **Because of the lack of data, Lyme is not considered endemic within the State of Oregon, therefore physicians are hesitant to recognize the symptoms of vector borne illnesses and early effective treatment is often delayed, leaving long term chronic issues associated with untreated infection.**

3) **There is compelling evidence to demonstrate that treating physicians who use evidence based standards of care that do not reflect the narrow IDSA standard of care have been targeted by the Medical Board for diagnosing and treating Lyme & related vector borne illness under those standards , despite protection provisions offered under ORS 677.190, Section (1) (b) (A) (i).**

4) **Current forms of testing for diagnosis of Lyme Disease under the IDSA standard is the the two tiered CDC surveillance (ELISA & Western Blot) testing developed for surveillance, not diagnosis. This test fails (with both false positive and false negative) in about 50% of cases 1) to discover with adequate diagnostic sensitivity, the reactive antibodies, 2) adequate strain identification 3) and does not recognize that current two tiered methodologies do not take into consideration the instability and time sensitive nature of the antibodies.**

5) **According to the CDC ticks are known carriers of the following diseases: Anaplasmosis, Ehrlichia, Babesia, Bartonella, Rocky Spotted Mountain Fever, Powassan Disease, Tularemia, 364D Rickettsiosis, STARI, Colorado Tick Fever, Relapsing Fever and various Borrelia strains. Due to belief that adequate training is not necessary physicians within the State of Oregon are having difficulty differentially diagnosing the disease due to the complexity of the illness.**

6) Due to this complexity and the confounding variables, medical practitioners are frequently remiss in appropriately treating patients, leading to progressive symptoms which may include: cardiac, neurological, orthopedic and congenital infection, which can be severe, chronic and life threatening.

7) Failure to adequately treat these conditions early often leads to exacerbated symptomatology and disability, costing the State of Oregon large scale financial hardship, including but not limited to: disability, mental health support, special education, loss of productive work, lower tax base, additional street drug use(self- medicating) and increased reliance on the state for basic human needs).

Nationally

Statistics supporting why we need this bill

Thirty-four percent of a population-based, retrospective cohort were ill an average of 6.2 years after antibiotic treatment [1];

Sixty-two percent of a retrospective evaluation of 215 Lyme disease patients from Westchester County, NY, remained ill an average of 3.2 years after antibiotic treatment [8];

A meta-analysis of 504 patients treated for Lyme disease found this group had more fatigue, musculoskeletal pain and neurocognitive difficulties than 530 controls [9]. Additionally, it demonstrated that persistent Lyme disease symptoms were a distinct set of symptoms, which differed from those of fibromyalgia, chronic fatigue syndrome and depression [9];

Among 23 European pediatric patients with objective findings of Lyme neuroborreliosis sequelae, daily activities or school performance were negatively impacted in 10 (43%) [6];

A European study of adults treated for neuroborreliosis found that at 30 months post-treatment, 16% were cognitively impaired [7];

On entrance, patients enrolling in the four NIH-sponsored clinical trials on antibiotic retreatment had experienced poor long-term outcomes from their prior therapy. Participants in the two trials by Klempner *et al*. had persistent symptoms, which were sufficiently severe as to interfere with daily functioning [5];

Using a combined total of 22 standardized measures of QoL, fatigue, pain and cognition [3–5], the investigators of the four NIH-sponsored retreatment trials documented that the patients' QoL was consistently worse than that of control populations [3-5] and equivalent to that of patients with congestive heart failure [5]; pain levels were similar to those of post-surgical patients and fatigue was on par with that seen in multiple sclerosis [3-5]. Table 1 compares the QoL scores of the NIH Lyme disease participants at the time of their study enrollment to those of patients with other chronic diseases, including diabetes, heart disease, depression, osteoarthritis, rheumatoid arthritis, lupus, fibromyalgia and epilepsy [10-15]

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