COMMENT ON PUBLIC TESTIMONY BY ANN THOMAS (OREGON HEALTH AUTHORITY) PROVIDED DURING 3/30/15 HEARING ON SB 916

RE: PROPER ROLE OF STATE LEGISLATION REGARDING MEDICAL STANDARDS AND PRACTICES

Ms. Thomas made several statements in her written testimony that were either misleading or false. In this rebuttal, I hope to address these misleading and false statements.

Statement by Ms. Thomas	The truth
Lyme disease is relatively rare in Oregon. While there were 36,307 case of Lyme disease in the United States in 2013, there were only 43 cases in Oregon. This translates to an incidence for Lyme disease of 8.6 per 100,000 nationally, as compared to 1.1 per 100,000 in Oregon.	Ms. Thomas relies on old data which the CDC has recognized to be incorrect; furthermore, her statistics for Lyme disease in Oregon misstate the facts. The CDC has recently recognized that the actual incidence of Lyme disease in the United States is in excess of 300,000/year (roughly 100 per 100,000 of population), and that 90% of infected individuals do not know they ever contracted the illness. For Oregon, the 43 cases (roughly 1 per 100,000 of population) represent the number ***reported***, not the true number of infections. The number reported is clearly incorrect with regard to the true incidence of this disease; the committee heard ample testimony from Oregon Lyme patients who were unable to get a proper diagnosis in Oregon despite years of effort. Sharon Lee testified that the surveillance criteria used in Oregon (which lead into the 43 reported cases for 2013) are overly restrictive even compared to the CDC. Thus, Ms. Thomas's statistics are a very poor indicator of the actual incidence of Lyme disease here in Oregon. Veterinarians regularly test dogs for Lyme disease, both nationally and here in Oregon. Nationally, 1 in 16 dogs tested were positive for Lyme disease. In Oregon, the rate is 1 in 86. This is a difference (for rate of infection) of only 86/16 ≈ 6:1, rather than 100:1 as implied by Ms. Thomas's statement of "43 cases in Oregon" compared to the CDC's estimate of 300,000/year nationally.
Lyme disease is diagnosed based on physical symptoms including headaches, fever, fatigue and a skin rash, shaped like a bull's eye in addition to exposure to Lyme disease carrying ticks (blacklegged ticks).	This general statement is true nationally as a theoretical ideal, but is not true as a practical matter here in Oregon. In Oregon, diagnostic guidelines are actually more restrictive than the surveillance case definition applied by the CDC, which the CDC recognizes to be too restrictive for diagnostic purposes. In Oregon, the physician must actually see the rash (which occurs in less than 50% of infections), and confirm the diagnosis with a two-tiered blood test which has been demonstrated to lack the necessary sensitivity for human diagnosis. This overly-strict diagnostic

	criterion is one of the reasons that the number of reported cases in Oregon is so low, and so dramatically under-represents the true rate of incidence in the State. You heard testimony from numerous Oregon citizens who failed to satisfy the narrow Oregon definition for Lyme disease, and who were denied a proper diagnosis and proper care, despite being eventually diagnosed and treated successfully in other states. By citing national guidelines, yet leaving the inference that "there is no problem here in Oregon", Ms. Thomas does a disservice to her patients and the constituents of this State.
According to the Centers for Disease Control and Prevention (CDC), it is not until 4 to 6 weeks post-infection that the test is likely to be positive. This does not mean that the test is bad, only that it needs to be used correctly.	***In fact, the two-tiered test protocol is bad, and fails to properly detect a large percentage of infected individuals even when used correctly.*** Sharon Lee testified that 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)
Approximately 10 to 20% of patients experience fatigue, muscle aches, sleep disturbance, or difficulty thinking even after completing a recommended course of antibiotic treatment. These symptoms cannot be cured by longer courses of antibiotics, but the symptoms generally improve on their own, over time.	Presumably, the "recommended course of antibiotic treatment" to which Ms. Thomas refers is the course recommended by IDSA. ***The committee heard ample testimony that this course of treatment is wholly inadequate for many patients with Lyme disease.*** The statement that "These symptoms cannot be cured by longer courses of antibiotics" is not supported by the scientific evidence (and Ms. Thomas presents none). Again, the committee heard ample testimony of Lyme patients which demonstrates just the opposite – the symptoms can be successfully addressed with longer courses of treatment. There is no credible evidence supporting Ms. Thomas' point of view. Scientific studies (or editorial analysis), which purport to show that longer courses of treatment are ineffective, all suffer from a common flaw – they cannot eliminate the hypothesis of persistent infection as a cause of recurring symptoms.
Senate Bill 916 would require Oregon Medical Board and State Board of Nursing to adopt rules regarding diagnosis and	SB 916 ***does not require*** OMB and SBN to adopt rules regarding diagnosis and treatment of Lyme disease that are consistent with the guidelines developed by ILADS. To the contrary, any doctor or nurse is free to continue treating according to the IDSA guidelines. ***SB 916 is a bill that provides enhanced freedom*** for doctors and

treatment of Lyme disease that are consistent with guidelines developed by the International Lyme and Associated Diseases Society. These guidelines assume a general lack of scientific and clinical knowledge about Lyme disease.	nurses that choose to treat according to a nationally-recognized standard of care, which conforms to the highest standards of evidence-based medicine of the IOM, which is nevertheless not currently recognized in Oregon. Rather than restricting doctors and nurses, or forcing a change in practice, it merely provides enhanced freedom to practice in accordance with the practitioner's best medical judgment. As far as the final sentence is concerned, regarding ILADS guidelines general lack of scientific and clinical knowledge about Lyme disease, this is false and pejorative. As noted, the ILADS guidelines conform to the latest and most stringent standards for evidence-based medicine recognized by the IOM. The CDC recognizes such IOM guidelines as generally authoritative. ILADS itself is comprised of hundreds of doctors and scientists focused on evidence-based care. Ms. Thomas should be ashamed of herself for making this baseless charge, which is clearly false and pejorative.
The IDSA guidelines currently represent the best available synthesis of the medical literature on the diagnosis and treatment of Lyme disease. The IDSA, with input from CDC experts and other doctors, has developed and published Lyme disease treatment guidelines.	This statement is unsupported by the evidence, and in fact, IDSA guidelines have not been substantively revised in many years. While the IDSA certainly has guidelines, that alone is not a reason to exclude the standards of other medical societies that provide evidence-based guidelines. The committee heard ample testimony from numerous patients whose lives were devastated by doctors practicing according to the IDSA guidelines, and who subsequently improved dramatically (or at least avoided further decline) once they found an out-of-state doctor able to treat according to ILADS guidelines. Oregon citizens are suffering while we debate whether doctors and nurses should be allowed to practice according to their best clinical judgment. Clearly, we should be empowering doctors and nurses to practice according to their best clinical judgment.
In addition to the possibility of promoting improper treatment of Lyme disease, the guidelines established by Senate Bill 916 could result in additional and inaccurate reports of Lyme disease that would require follow-up by state and local public health officials.	The IDSA guidelines represent a de facto standard of care in this State – one which has clearly devastated the lives of countless citizens. You heard their testimony. SB 916 actually provides a "relief valve", allowing doctors and nurses to practice according to other evidence-based guidelines. It does not "lock-in" a standard of care; just the opposite. It simply ensures that our medical professionals can practice according to an evidence-based standard that they determine is appropriate. I'm staggered by Ms. Thomas' concern regarding additional follow-up. Today in Oregon, we have large numbers of patients who are not getting care. Their lives are devastated, and in many cases,

	they lose their jobs, stop contributing to the State's economy, and go on public assistance. Against this ongoing disaster, why would Ms. Thomas be concerned about a little extra follow-up in order to confirm or deny the actual presence of infection in a potential patient? At the best, this is penny-wise and pound-foolish. At the worst, it is willful denial of care to a patient in need.
In conclusion, the guidelines that would be established by Senate Bill 916 do not represent the best evidence based treatment options available to treat Lyme disease. Validation of these guidelines as the accepted course of treatment could result in the use of unnecessary and potentially harmful therapies.	Ms. Thomas offers this conclusion without any evidence or analysis. As noted above, SB 916 does not mandate any particular guideline or standard… it merely provides ***freedom*** for our doctors and nurses to practice according to an existing nationally-recognized, evidence-based guideline, which has been proven to be effective (per the personal testimony you heard). SB 916 does not mandate any guideline as the accepted course of treatment – it merely allows the ILADS guideline as an acceptable alternative – to be considered and adopted, or not, by each doctor individually based on their own best medical judgment.

I hope this rebuttal has helped to put some of the issues raised by Ms. Thomas in perspective. She offered no scientific evidence to support her testimony, and her conclusory remarks flew in the face of the personal testimony you heard.

In contrast to Ms. Thomas, the patients and patient advocates you heard, on March 30, 2015, provided scientific evidence along with their prepared remarks, and testified extensively regarding the devastation that this disease is visiting on Oregon and its citizens. Furthermore, they testified to the efficacy of a standard of care, ***available in other states,*** which could improve patients' lives, help them remain as productive members of society, and minimize public assistance expenditures.

We all urge you to do the right thing, and pass this doctor-freedom bill without amendments.

Sincerely,

Stephen B Heppe

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