MEMO

Date: March 30, 2015
To: Derek Sennes
From: Elizabeth Aaroe
Re: Submission of Additional /Follow Up Testimony – SB 916/Evidence-based Medicine and the ILADS Standards of Care

One of the representatives (Board of Health, Nurse Association, Oregon Medical Board) stated in her comments today that ILADS did not have evidence-based guidelines for the management of patients with Lyme disease. I testified that this was false and that ILADS had, in fact, updated and replaced the guidelines it issued in 2004, making its 2014 guidelines the most current and relevant for both clinicians and patients.

ILADS' evidence-based guidelines for the treatment of patients with Lyme disease were published on July 30, 2014 and are readily available. Healthcare providers who evaluate and manage patients with Lyme disease were and are the intended users.

Evidence–based medicine (EBM) is defined as "the integration of best research evidence with clinical expertise and patient values," however patient values are frequently overlooked. Government institutions, like the Institute of Medicine (IOM) and Patient Centered Outcomes Research Institute (PCORI), represent an important shift and recognition that trustworthy policies, guidelines and research require the participation of patients. Patient groups, like Consumers United for Evidence-Based Medicine (CUE), are helping to define the patient's role in EBM.

If we are basing healthcare coverage decisions on EBM, we need to know where the evidence begins and ends. Public trust is critical to the success of healthcare reform. We need to know whose clinical expertise we are relying on. Is it the clinical expertise of treating physicians or that of researchers who see few patients? We also need to know how patient values are taken into account. Are patients involved? Whose values and viewpoints are represented? Many patients believe that EBM is vulnerable to corruption by stakeholders, like insurers seeking to control costs and panel members who have industry conflicts of interest.

As you heard from many patients, distrust in IDSA Lyme guidelines is high because patients believe they have been fraught with conflicts and self-interest for years and still are. Consequently, patient involvement in EBM is essential to enforce the boundary between evidence and values. The Lyme community wants a seat at the table, wants to be part of the conversation that determines patient healthcare and wants to be heard.

ILADS specifically stated that their EBM guidelines were not intended to be the sole source of guidance in managing Lyme disease, nor should they be viewed as a substitute for clinical judgment nor used to establish treatment protocols.

The guidelines address three fundamental treatment questions: the usefulness of antibiotic prophylaxis for known tick bites, the effectiveness of *erythema migrans* (EM) treatment and the role of antibiotic retreatment in patients with persistent manifestations of Lyme disease.

ILADS' clinical practice guidelines are intended to assist clinicians by presenting evidence-based treatment recommendations, which follow the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system. ILADS adopted the GRADE system to ensure a transparent and trustworthy guideline process. One of the goals of the GRADE scheme is to make transparent the value judgments underlying recommendations particularly when high-quality evidence is not available so that guideline panels don't make recommendations or institute practices that are not in the patient's best interest or which suppress research concerning benefits and risks.

ILADS has placed a high value on the ability of the clinician to exercise clinical judgment and believes that guidelines should not constrain the treating physician from exercising clinical judgment in the absence of strong and compelling evidence to the contrary. Further, the goals of medical care in Lyme disease should be to prevent the illness whenever possible and to treat with the intent to cure the illness when it occurs. When this is not possible, the emphasis for treatment should be on reducing patient morbidity and therefore reducing patient risks for developing the chronic form of the disease. ILADS' and IOM's goals are aligned by treating the treatable wherever and whenever possible and prioritizing prevention by 1) effectively treating a tick bite, 2) treating an EM rash sufficiently to restore health and prevent disease progression and 3) treating patients whose illness may be responsive to additional therapy.

Lyme patients today and those in the broader Lyme community have overwhelmingly supported ILADS guidelines because of its mindfulness of the role of patient preferences and values in GRADE as well as the IOM's call for patient-centered care that is responsive to the needs, values and expressed preferences of individual patients.

The burden of Lyme disease for individuals and society remains high. Despite preventive measures, the incidence of acute Lyme disease is significant. How individual patients fare is an important consideration and ILADS is primarily interested in preventing and reducing the morbidity associated with chronic disease. Although some prospective studies showed that long-term outcomes were good, many had significant limitations and the amount of evidence demonstrating that the severity, duration and cost of persistent manifestations of Lyme disease can be profound, was substantial.