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Chair and Members of the Committee on Children
Regarding Bill #207

January 26, 2015

Dear Chair and Members of the Committee on Children,

I would like to strongly support Bill #207.

A serious concern is that present and previous information available to the public, healthcare community and government about Lyme and tick-borne diseases, including transmission, the mechanisms that cause clinical symptoms, testing and treatment strategies has since been demonstrated to be incorrect and inadequate and more accurate information needs to be disseminated. An NIH sponsored chronic Lyme disease study by Dr Fallon demonstrated—"Based on objective tests of physical impairment, we found that the patients had levels of: Functional disability comparable to what you would see with congestive heart failure, Pain comparable to what you might expect in patients coming out of surgery, and Fatigue comparable to patients with multiple sclerosis."

Renewed attention to Lyme disease is occurring at a time when medicine is undergoing a paradigm shift. High level researchers and some community physicians recognize the importance of infections and immune reactions to them can cause many previously unexplained chronic diseases. This is recognized in the NIH microbiome project. Just as mathematics shifted from Newton to Einstein, we need to make a similar shift in medicine to use more complex models to understand complex disease.

Historically many policymakers controlling Lyme disease have been microbiologists, rheumatologists, bench scientists and bureaucrats. Their lack of expertise in clinical medicine and psychoimmunology prevents them from understanding the association between Lyme/tick-borne infections and fatigue and the cognitive, psychiatric, subtle neurological and other multi-systemic symptoms.

These individuals continue to advocate for a highly restrictive definition of Lyme disease that is based upon the original definition of Lyme arthritis from 1970s that includes only a few of the neurological symptoms. In their opinion, other symptoms are ignored and are considered subjective, nonspecific, "medically unexplained symptoms" or so called "post disease treatment syndrome." They believe there are no psychiatric symptoms caused by these infections, the severity is no more than the "aches and pains of daily living," two-tiered testing is highly reliable and is needed for diagnosis, tick-borne coinfections are mostly insignificant, if previously treated it is cured and is never chronic and physicians should defer their judgment to the authority of third parties such as the CDC or IDSA guidelines.

In contrast, others support a more comprehensive definition of Lyme/tick-borne diseases that is based upon a more comprehensive and more clinically based definition that includes a through clinical assessment; recognition symptoms that includes psychiatric symptoms, cognitive symptoms, fatigue and other multisystemic symptoms that require pattern recognition and experienced clinical judgment for proper diagnosis. This scientific position also recognizes the illness can be severe, tick-borne coinfections can be significant, it can be chronic with relapses even when previously treated and two-tiered testing is

highly unreliable although certain laboratory findings may at times support the diagnosis and take the position that physician's primary responsibility to patient, clinical judgment and ethics supersedes deference to third party authority and they support informed decision making with freedom of choice. As a result there are currently two standards of care and both viewpoints are reflected in peer-reviewed, evidence-based guidelines and constitute medically recognized standards of care. Since there is conflicting research, guidelines and opinion no one can make any authoritarian dogmatic statements imposed upon physicians or patients. We all strive for more evidence, but physicians who have the responsibility to treat their patients today need to act upon the best evidence available at this time. This has been a tradition and a standard in medicine for thousands of years. In view of this decisions should be made within the physician patient relationship based upon evidence-based practice which is defined by the Institute of Medicine as the integration of best-researched evidence and clinical expertise with patient values which is based upon the long-standing traditions of Hippocrates and Osler emphasizing a thorough exam and individualized treatment with a balanced weight given to best evidence available, clinical expertise and patient preferences. . [Institute of Medicine Committee on Quality of Health Care in America (2001). *Crossing the Quality Chasm: A New Health System for the 21st Century*. Washington, DC: National Academies Press. Institute of Medicine Committee on Quality of Health Care in America (2001). *Crossing the Quality Chasm: A New Health System for the 21st Century*. Washington, DC: National Academies Press.] Clearly there are currently efforts by some to shift decision making authority away from the physician patient relationship towards third party that empowerment jeopardizes the effective treatment of complex, poorly understood conditions.

A major area of confusion is the distinction between diagnostic criteria and surveillance case definitions which "establish uniform criteria for disease reporting and should not be used as the sole criteria for establishing clinical diagnoses, determining the standard of care necessary for a particular patient, setting guidelines for quality assurance, or providing standards for reimbursement.[CDC 2011 Case Definition CSTE Position Statement Number: 10-ID-06 [2] Lyme disease--United States, 2003-2005. *MMWR Morb Mortal Wkly Rep.* Jun 15 2007;56(23):573-576. Brown SL, Hansen SL, Langone JJ. Role of serology in the diagnosis of Lyme disease. *JAMA.* Jul 7 1999;282(1):62-66.]

All medical decisions require individualized potential risk vs. benefit decision making within the physician patient relationship with a proper total clinical assessment while considering the best evidence available and treatment decisions need to be constantly be re-evaluated. Of course all treatments have risks and failing to treat has risks. That is why we need better education in this area. There is a significant body of evidence that extended antibiotics can be beneficial when clinically appropriate just as it is beneficial for other chronic infections.

Medicine is impacted by the legal standard of care for treating a condition, which is determined by the consensus of physicians who actually treat patients, not by treatment guidelines. [Hurwitz, B. Clinical Guidelines and the law. *BMJ*,1995. 311:p.1517-1518.] In view of the uniqueness of individuals; biological heterogeneity; the complexity of conditions and individual differences in safety, tolerability and efficacy; treatment provided by rigid adherence to treatment guidelines without exercising clinical judgment is clearly below the standard of care. [Johnson L, Stricker R. Treatment of Lyme disease: a medicolegal assessment; *Expert Rev. Anti-infect. Ther.* 2(4). (2004) *Wilson v. Blue Cross of Southern California*, 271 Cal. Rptr. 876 (1990).]

The issue of extended antibiotic treatment is dependent upon debate surrounding defining Lyme disease and needs further education since there is much conflicting evidence and opinion in this area. A recent study funded by the Centers for Diseases Control and Prevention (CDC) surveyed a representative sample of people in the US population and found that only 39% of those with Lyme disease were treated in accordance with blanket short term recommendations in the IDSA guidelines. The majority were treated for longer periods. Therefore short term treatment advocated by IDSA now represents the minority position since the actual standard of care is more reflected by the majority of how physicians actually treat a disease.

If you can provide better education and prevention in Connecticut then I hope to see less patients needing to drive to my office in New Jersey for treating late stage symptoms that otherwise could have been prevented.

Sincerely,

Robert C Bransfield, MD, DLFAPA