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Written Testimony for the Massachusetts Public Health Committee September 22, 2009

Co-Chairs and Committee Members,

Thank you for the opportunity to testify on this very important legislation, H.1148, Hargraves.

As background: Lyme Disease Association (LDA) is all-volunteer national non profit devoted to education, research, prevention & patient support and has 34 allied organizations nationwide. It's registered in Massachusetts & has a Chapter on Cape Cod, which has presented many Lyme disease in-services in the Massachusetts schools. LDA and TFL, its CT affiliate, opened the first center in the world to study chronic Lyme at Columbia University in 2007. LDA's *LymeAid 4 Kids* fund, developed with author Amy Tan, dispenses money for children without insurance – 17 families here in Massachusetts have benefited from this fund. I have spoken at several public forums here and in 2005 was invited by then Joint Health Chair Koutoujian to sit on an Ayer panel to hear Lyme patient stories and later to testify before the Joint Health Committee in Boston. LDA hosted its 8th scientific conference in Boston in 2007, jointly sponsored with Columbia University. Its 10th on Oct 23 outside DC, features 14 faculty presenters including CDC's Chief of the Vector-Borne Division and two professors from Harvard. LDA is on the federal government approved charities list as part of the 2009 Combined Federal Campaign and is an Environmental Protection Agency PESP partner.

According to CDC, from 1990 through 2008, Massachusetts had 21,196 reported cases of Lyme. CDC states only 10% of cases that meet CDC surveillance criteria are reported,¹ which means that 211,960 Massachusetts residents developed Lyme that met the surveillance criteria over 18 years. Those numbers are only a fraction of cases that probably occurred, since CDC's surveillance criteria numbers are meant for comparing one state to another. They don't include cases clinically diagnosed by physicians – meaning cases without an EM rash or without a positive test.

The situation isn't likely to improve soon. Climate changes are contributing to increased tick populations and expanded tick ranges, increasing disease burden. According to University of Massachusetts NIH-funded researcher Steven Rich who discovered a thriving population of deer ticks halfway up Mount Greylock, one of the coldest areas in the state: "Deer ticks used to be limited primarily to a 15-mile zone along the coast of New England....Now they are moving much farther inland as they seemingly adapt to the cold."² Confirmation of that observation comes from a UN commissioned study which indicates ticks in Sweden have moved almost as far north as the Arctic Circle and are being found in January.

In January 2005, my daughter pulled a fully engorged deer tick from behind the ear of my then 5-year old granddaughter. It was 25°. According to CDC, increased case numbers are hitting our children the hardest—at highest risk combined boys & girls 5-9.³ A CDC study of 65 New Jersey children K-12 with Lyme showed the median number of missed school days was 140, with median duration of home instruction, 153 days. 78% of parents said their children experienced a fall in grade point average during illness. 79% experienced a decrease in friends; "...often, patients spent large blocks of time as semi-invalids, isolated from social groups and missing out on cultural, sports and social activities....School performance of nearly all patients fell sometimes drastically, and in several instances, was said to

interfere with selection by colleges and universities.”⁴ A study at Columbia demonstrated a drop of 22 IQ points in a student with Lyme disease, later reversed with treatment.⁵

Two documents greatly influence the ability and willingness of doctors to treat Lyme patients, including our children – the first is the CDC surveillance criteria. Despite CDC’s warning that Lyme surveillance criteria are NOT intended for diagnosis, treatment, or insurance reimbursement but only for disease reporting, most doctors are inappropriately using them to diagnose and treat. In an endemic region, an EM rash (plus a required test in a non-endemic region), OR major system involvement plus positive blood work meet the surveillance criteria for reporting purposes. Patients who do not meet that criteria scramble to find physicians willing to risk making a clinical diagnosis for Lyme disease, one based on symptoms, history, ruling out other diseases, one which does not require a positive test for diagnosis. Problems about diagnosis are fueled by unreliable Lyme testing that is 40-60% accurate,⁶ and by the fact that less than 50% of people develop the classic bull’s eye rash.⁷

The second document influencing doctors’ ability and willingness to treat is the Infectious Diseases Society of America (IDSA) guidelines (“Guidelines”) which are meant for diagnosing and treating. They recommend **against any long-term treatment for chronic Lyme; against entire classes of antibiotics; against alternative treatments; against some supplements; and against individual physician discretion in diagnosis and treatment.** IDSA says there is NO chronic Lyme disease.

The CDC surveillance criteria are misused for diagnosis, and the IDSA guidelines are misused as being mandatory. Despite a disclaimer that Guidelines are guidelines only and not mandatory, actual experiences demonstrate they have become *de facto* law. The misuse by medical boards, health department, hospitals, insurers, schools, pharmacists, IDSA doctors themselves, is so blatant that Connecticut Attorney General Richard Blumenthal felt compelled to legally investigate the IDSA Guidelines’ process.

He acted because of Connecticut residents inability to get diagnosed and treated in state. The Guidelines created a chilling effect on treatment climate. Why would doctors want to treat a disease knowing their treating peers were being investigated and harassed? The same situation was occurring nationwide, thus to date, 41,000 people have signed an LDA petition opposing the IDSA treatment guidelines on humanitarian grounds. (www.LymeDiseaseAssociation.org)

In May 2008, the AG and IDSA reached a settlement Agreement. Mr.Blumenthal stated: “This agreement vindicates my investigation—finding undisclosed financial interests and forcing a reassessment of IDSA guidelines...My office uncovered undisclosed financial interests held by several of the most powerful IDSA panelists.The IDSA’s guideline panel improperly ignored or minimized consideration of alternative medical opinion and evidence regarding chronic Lyme disease, potentially raising serious questions about whether the recommendations reflected all relevant science...The IDSA’s Lyme guideline process lacked important procedural safeguards....”⁸ IDSA had to form a new panel, which heard testimony in July, re-looking at the guidelines, but it again excluded chronic Lyme treating doctors as panel members.

There are other Lyme treatment guidelines which differ from IDSA’s, which do allow doctor discretion, and do recognize that Lyme sometimes requires more than a short course to make people better. They address early infection and chronic disease. They provide the basis for a second standard of care. Published by the International Lyme & Associated Diseases Society (ILADS), a professional medical and research organization,⁹ they’re ignored by IDSA and often not disclosed as an option by doctors to their patients. They are published on the Department of Health and Human Services National Guidelines Clearing House website, recognizing them as being evidenced-based.¹⁰

ILADS comprehends that patients who are not diagnosed quickly or not treated appropriately can become chronically ill– one study shows that Lyme patients suffer a degree of disability equal to that of patients with congestive heart failure.¹¹ Yet these patients, often multi-members of one family,¹² now have to travel many hours outside Massachusetts to find care for their Lyme. They don’t have the resources nor

the health to fight the vested interests stacked against them, which is why legislation is necessary. It ensures that in-state treating doctors cannot be prosecuted for unprofessional conduct solely for providing long-term treatment based on clinical judgment. Two contiguous neighbors, Rhode Island and Connecticut, have passed protective legislation, as has California. Others have or will introduce soon.

The primary opposition to all Lyme doctor protection legislation comes from the same organization which has created the need for doctor protection, the IDSA. Doctors who don't follow IDSA Guidelines but use their own clinical skills to diagnose and treat face medical board discipline, hospital privilege revocation, insurance plan inclusion revocation, and loss of hospital posts if they do not march lockstep with IDSA, leading to physician scarcity and a "chilled" treatment climate nationwide, even worldwide, where Lyme is now found in about 65 countries.

IDSA sometimes cites development of antibiotic resistance for opposing legislation, despite resistance most often developing due to **under usage** rather than over usage of antibiotics. The Union of Concerned Scientists is concerned that a significant cause of resistant bacteria may be an estimated 70% of antibiotics in the U.S. being fed to healthy pigs, cows, and chickens to promote growth and prevent disease.¹³ Improper hygiene by medical personnel in hospitals often fosters the spread of resistant strains.

IDSA ignores the fact that other diseases are allowed long-term treatment with antibiotics including tuberculosis, Q fever endocarditis, and even acne. With little outcry, healthy animals can be fattened with antibiotics, health care workers can practice shoddy hygiene leading to more resistant strains, acne sufferers can get years of treatment, but terribly sick Lyme patients are singled out to be left without treatment because of undocumented accusations of resistance due to treating sick people.

IDSA even opposes federal legislation (HR 1179, S 1352) which provides much needed funds for research, particularly for an accurate test to help resolve many Lyme-related issues —legislation that the late Senator Ted Kennedy felt so strongly about he signed onto as a co-sponsor this past summer. IDSA indicates they do not like the constitution of a Lyme and tick-borne diseases federal advisory panel created by the bills because it contains patient and treating physician reps, just as other diseases have.

Following IDSA Guidelines can lead to delayed diagnosis and treatment. According to an actuarial study on Lyme costs, "37% of the financial costs of this disease is incurred before the correct diagnosis is made."¹⁴ A delay in diagnosis also leads to more chronic disease since the Lyme bacterium can get into the brain within 24 hours of a tick bite.¹⁵ Chronic Lyme is more costly to patients physically, mentally, and financially. According to a 1998 CDC journal study, early Lyme costs* averaged \$161 per patient and neurologic longstanding Lyme disease averaged \$61,243.¹⁶ Chronic Lyme is also more costly to the state and federal government in terms of disability and education e.g., special services, home instruction, substitute teachers.¹⁷ Allowing doctor discretion can cut costs and most importantly, human suffering.

Massachusetts owes it to patients and physicians to pass a doctor protection bill, leveling the playing field by providing treating physicians with a measure of protection they are entitled to, since there are two standards of care. Doctors should not be penalized for following the standard, which in their clinical experience, best improves patient health. Don't be fooled by rhetoric saying legislators shouldn't be mandating treatment. This bill DOES NOT mandate treatment of any kind. Your Connecticut peers weren't fooled by that argument whispered into their ears behind the scenes, both houses passed the bill unanimously. You should do the same. Thank you.

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Endnotes

¹ Paul Meade, CDC, *Herald News* 5-4-04, Jessica Adler.

² Recorder.com, July 30, 2007.

³ Centers for Disease Control & Prevention, *Average Annual Incidence of Reported Cases of Lyme Disease by Age Group & Sex*, http://www.cdc.gov/ncidod/dvbid/lyme/ld_MeanAnnualIncidence.htm.

⁴ David Dennis, CDC, presented study in Wall Township, NJ, October 1992, Congressional meeting. Later pub. *Lyme Times Children's Educational Issue*, ed. CALDA, Summer 2006.

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- ⁵ Brian Fallon MD *The Underdiagnosis of Neuropsychiatric Lyme Disease in Children & Adult*, The psychiatric Clinics of North America, Vol.21, No.3, Sept.1998.
- ⁶ P. Coulter et al, J. Clin Microbiol. 2005 Oct.; 43(10): 5080-4 *Two Year Evaluation of Borrelia burgdorferi Culture and Supplemental Tests for Definitive Diagnosis of Lyme Disease. Lancet 1990, Journal of Clinical Investigation 1994 & S. Schutzer et al, JAMA Vol 282, No. 20 Borrelia Burgdorferi: Specific Immune Complexes in Acute Lyme Disease, Nov. 24, '99*
- ⁷ R. Smith et al, Annals of Internal Medicine 2002;421:421-428, 477-479; A. Pachner, Reviews of Infectious Diseases-Vol. II, supplement 6 - September-October 1989 Neurologic Manifestations of Lyme Disease, the new "Great Imitator"; J.M. Johnson, Ph.D., Chief, Public Health, NPS Ticks and Disease.
- ⁸ Office of the Connecticut Attorney General, press release, May 1, 2008.
- ⁹ Daniel Cameron, et al, Expert Review of Anti-infective therapy 2(1) Suppl. 2004
- ¹⁰ AHRQ, <http://www.guideline.gov/>.
- ¹¹ Connecticut Agricultural Experiment Station, "Summary of Tick Testing Results for 2003." www.caes.state.ct.us.
- ¹² CDC unpub. study data presented in Congressional forum, Wall NJ Oct 1992 (Later pub. in Lyme Times)
- ¹³ http://www.ucsus.org/food_and_environment/antibiotics_and_food/myths-and-realities.
- ¹⁴ Irwin Vanderhoof, *Lyme Disease the Cost to Society*, Contingencies January/February 1993.
- ¹⁵ Steere, Allen, Mandel, Douglas, and Bennett's *Principals & Practices of Infectious Diseases*, 4th ed. 1995.
- ¹⁶ Martin I. Meltzer *The Cost Effectiveness of Vaccinating against Lyme Disease CDC Emerging Infectious Diseases*; Vol.5, No.3; 1999 May-June;5(3)321-8.
- * This is in 1996 costs not adjusted to 2007. The following additional significant costs to society aren't measured by this table: special education needs for children, disability, increased medical and insurance costs, and livestock losses, etc. Also, there are personal loses: friends, employment, self, esteem, domicile, and breakup of families.
- ¹⁷ Patricia Smith, Wall Township, NJ, Board of Education member *NJ School District Study on Impact of Lyme Disease on School Districts* presented in Washington DC Congressionally hosted meeting with CDC & NIH, March 12, 1992.