

MA – Combined Health Committee Hearing on Lyme Disease

TESTIMONY TO MASSACHUSETTS COMBINED HEALTH COMMITTEE

By Pat Smith, President, Lyme Disease Association, Inc. 10-12-05

Personal Background: President of the Lyme Disease Association (LDA), Vice President of Political Affairs, International Lyme and Associated Diseases Society, (ILADS), a professional medical society, and former chair of the [New Jersey'] Governor's Lyme Disease Advisory Council, and former president of the Wall Township Board of Education. I also sat on the hearing panel for this committee in Ayer this past summer.

LDA Background: LDA is an all-volunteer national organization whose goals are education, prevention, research and patient support. LDA has supported research projects coast to coast, many published in peer review including JAMA, Infection, Neurology, and Proceedings of the National Academy of Science. LDA has five chapters (including one on the Cape, W. Barnstable), and 7 affiliates, and along with its CT affiliate, TFL, LDA is partnering with Columbia University to open an endowed chronic Lyme disease research center, the first of its kind in the world. 75% of the funds needed to open the center have been raised to date with actress Mary McDonnell, LDA's national spokesperson, supporting the project. LDA has the LymeAid 4 Kids fund for children without insurance to be evaluated for Lyme disease and that is supported by internationally acclaimed author Amy Tan.

Lyme is the most prevalent vector-borne disease in the US today. Research has shown the Lyme bacteria has the ability to enter the central nervous system less than a day's time after a tick bite, yet Lyme is rarely given the weight it deserves to be given. Witness the Center's for Disease Control &

Prevention's (CDC) recent expenditures on Lyme disease: \$7M annually.

Lack of funding and focus have lead to lack of physician education. It has also created a climate of fear for potential treating physicians who are often afraid to diagnose and treat patients due to medical board investigations nationwide of those treating chronic Lyme disease, investigations often initiated by insurers or other physicians who do not recognize chronic disease. Sanctions including supervision, fines, losing ability to treat Lyme patients, and license suspension and revocation have been imposed. This in turn has created a situation where patients are unable to obtain diagnosis, treatment, insurance reimbursement, disability, education or even understanding from their families and peers.

The need for more treating physicians becomes apparent when one examines the CDC reported case numbers which range from 20,000-24,000 annually nationwide, numbers which represent only 10% of actual cases meeting the CDC surveillance criteria according to the CDC, thus up to 240,000 new cases actually occur annually that do meet the CDC criteria.

That represents almost $\frac{1}{4}$ M new cases, a number that does not even include cases that fall outside the CDC surveillance criteria, incredibly, a number no one knows, because the CDC does not require record keeping on those cases. In fact, these physician-diagnosed cases are rejected by health departments if they are reported, because CDC does not accept them.

In 2004, New York (5100), Pennsylvania (3985), New Jersey (2698), and Massachusetts (1532) ranked 1,2,3,4 respectively in reported Lyme cases with Rhode Island 10th (249), New Hampshire 11th (226), Maine 12th (225), and Vermont 17th(50). Massachusetts continues to be 4th in 2005 reported cases (758).

Reported cases meet the surveillance criteria if the patient

has a physician-diagnosed EM (bullseye) rash, or positive blood work and other system involvement. Studies have shown that the EM rash appears less than 50% of the time, and Lyme disease testing, especially the initial required screening test, the ELISA, is highly inaccurate. According to a letter from the NY DOH in 1996 to the CDC, if NY had followed the 2-tier testing requirement for 1995 cases, using first a + ELISA test requirement, 81% of non-EM cases would not have been confirmed. The CDC states that doctors should not use surveillance criteria for diagnosing Lyme, yet many physicians continue to do so.

This creates a controversy which pits physicians primarily from academia who only diagnose based on CDC guidelines and treat short-term against primarily physicians in a clinical setting who diagnose outside the CDC guidelines and treat long-term when necessary and their patients who are experiencing symptom relief from extended treatment. Beyond that controversy is something few dispute: if diagnosed and treated early, Lyme disease can usually be treated rather successfully with a four to six week course of antibiotics. The dispute arises because the tests are not reliable, Lyme mimics other conditions such as MS, ALS, Lupus, even autism and Alzheimer's, and Lyme is often accompanied by other tick-borne diseases, clouding the diagnostic picture further. Thus diagnosis is difficult and does not fit a text book definition, and delaying treatment or providing inappropriate treatment can lead to chronic disease, developed by an estimated 15 to 35% or more of patients.

Patients diagnosed with chronic Lyme disease often cannot buy life insurance policies, nor can they donate blood. Red Cross blood donor guidelines distinguish between Lyme disease and chronic Lyme disease, "Accept persons with Lyme disease if they were treated, the disease resolved and at least one year has passed. Those with chronic Lyme disease are not eligible to donate blood." The American Society of Clinical

Pathologists (ASCP) blood donor guidelines state under "serious illness," "defer indefinitely...Lyme disease." The bacteria that cause Lyme have been shown to survive blood banking conditions, although to date, no cases of Lyme disease transmission have been reported to occur through blood donations.

Doctors are faced with a dilemma: do they treat sick patients who do not meet the CDC surveillance criteria and patients with chronic symptoms? Besides pressure from medical boards, doctors are pressured by insurance companies who often deny coverage to anyone not meeting CDC surveillance criteria, despite CDC's warning that the guidelines are not meant to be used as reimbursement criteria. Doctors indicate that insurance carriers strongly suggest they stop treating Lyme patients long-term or leave the plan. While a few continue to treat, some refer their patients to other long-term treating physicians, while others, fearing reprisals or facing economic hardship, stop seeing Lyme patients.

An insurance company letter to a New Jersey patient typifies what is happening: "Unfortunately, a number of unscrupulous practitioners in this and neighboring states have held themselves out as experts in the treatment of Lyme disease. These individuals have subjected patients to improper diagnoses, excessive treatments, inordinately long courses of intravenous therapy, and other activities not supported by science or generally accepted standards of medical practice. Because our organization has been appropriately vigilant and aggressive in dealing with certain practitioners, they have chosen to leave our network."

While trying to solve the issue of physicians right to treat in NY several years ago, LDA was told by the NYS Office of Professional Medical Conduct (OPMC) that they get some of their best tips from insurance companies. Fortunately, the Lyme treating issue has been resolved in NY by a memo from the OPMC to its staff stating that physicians cannot be

investigated by the OPMC based solely on their long-term treatment of Lyme disease.

In order to better educate physicians and to allow treating physicians and patients to have input into Lyme disease policies at the federal level, companion bills have been introduced into the US House (HR 3427, Smith/Kelly) and US Senate (S 1479, Dodd/Santorum). They provide \$100M over 5 years for Lyme disease research and education to be utilized for well delineated goals. LDA sent a letter to all senators and representatives signed by 90 nationwide groups, including several in Massachusetts, supporting the bills, which also create a patient/ physician/researcher task force with input to Health & Human Services (HHS).

LDA has briefed HHS in DC on doctor patient issues and expects to meet with them soon for further discussion. In September, LDA met with US Army CHPPM (Centers for Health Promotion & Preventive Medicine) at Aberdeen Proving Grounds where they are testing ticks from military bases for Lyme and other tick-borne diseases such as RMSF, Ehrlichiosis, Anaplasmosis, Babesiosis, and STARI (Southern Tick-Associated Rash Illness) a Lyme-like disease carried by the Lonestar tick. The army has also developed a laptop sized testing device which can be used in the field for PCR testing of ticks so that those bitten can immediately know if the tick carries Lyme disease and can receive treatment if necessary. US Army CHPPM has patented the device and is in discussions with a private company to produce the product.

Since the late 80's, CHPPM has mapped all the major military installations in the country for tick populations and has created risk assessments for Lyme disease at each installation. Now CHPPM is doing the same for tick infectivity rates. The information can be beamed to satellites and then eventually to handheld receivers to be carried in the field, advising the troops where the population and infectivity rates of ticks are high, so they may maneuver troops around high

risk areas. CHPPM has recently used the GIS tick data on its Virginia Ft. A.P. Hill installation which hosts the Boy Scout jamboree to determine where ticks were located so they could map and spray those areas for ticks before the Scouts arrived. (map)

Obviously, prevention is the best practice, but that does not solve the problems of those already infected and those with chronic disease which is why we are here today. The physicians' right to freely practice medicine without vested-interest interference and the patients' right to receive timely diagnosis and appropriate treatment need to be considered in the context of a quote from CDC spokesman Paul Meade in Sunday's NH Union Leader. "Can I say chronic infection never, ever occurs? No, of course I can't, and that's where one has to not be dogmatic about these things," says Meade. These are the reasons why today's hearings are necessary and not unprecedented. Connecticut, Rhode Island, and New York have held two hearings and Texas and California, one. Officials in other states such as Pennsylvania, New Jersey, and Maryland have met with LDA to discuss these issues, and New Hampshire Governor Lynch invited me to speak there at a May press conference.

Legislative and policy solutions to Lyme problems include RI's mandatory insurance coverage and doctor protection, CT's insurance coverage with some limitations, California's and NY's Lyme treating physician protection based on existing protections for doctors using non-conventional treatments, NJ's addition of Lyme-literate doctors to its State Board of Medical Examiners Review Board, NJ's mandatory teacher in-services for educators who have students with Lyme disease, and the creation of advisory councils in a half dozen states.

The Lyme Disease Association offers the following relatively low cost easy to implement ideas for consideration by Massachusetts officials. (Full chart distributed) For the Department of Health (DOH):

- send letters to all licensed physicians in the state explaining that CDC surveillance criteria are not to be used for diagnosis and that Lyme is a mandatory reportable disease.
- send a letter to family care agency telling them not to use Munchausen by proxy label against parents who are having children treated long-term for Lyme disease.
- require Lyme disease continuing medical education (CME) credits for state-licensed physicians. Alert physicians about available conferences including those that cover chronic Lyme disease such as LDA/Columbia University conference and the ILADS conference to be held October 28 and the 29th/30th, respectively, in Philadelphia.
- develop a system to track physician-diagnosed cases that do not meet CDC criteria to determine the true incidence of the disease. The DOH already has these reports from physicians.

Department of insurance (DOI):

- alert insurers that they cannot deny Lyme disease treatment based on the CDC . . surveillance criteria.

Department of Education (DOE)

- encourage schools in endemic areas to provide educational forums on Lyme disease . for staff and students, to keep properties maintained, post tick warnings where . . .necessary, and develop trip policies reflecting high risk areas.

The legislature should consider introducing doctor protection measures and mandatory insurance coverage for doctor-recommended treatment like RI has adopted. The adoption of such measures will ensure that patients receive necessary diagnosis and treatment, cutting costs long-term by reducing disability, special education costs, and the other costs associated with chronic Lyme disease. You have the rare opportunity to save thousands of people untold suffering, many of whom may be our children and grandchildren, who run some of the highest risk of acquiring the disease. Playing outdoors, petting the dog, rolling in the leaves, and sitting on a log are all risky behaviors for the development of Lyme disease,

yet are all activities enjoyed by children. Keep that in mind while listening to patient stories today. Thank you.

¹ Dr. Paul Meade, CDC epidemiologist, Lyme: Battles with Illness, Emotions, Insurers, Jessica Adler, (NJ) Herald News
5-4-04

2 Horizon Blue Cross Blue Shield letter to patient, August 24, 1999