



International Lyme and Associated Diseases Society

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The Honorable Edward Kennedy
Chairman, Senate Health, Education, Labor & Pensions Committee
United States Senate
Washington, DC 20510

Dear Senator Kennedy:

On behalf of the International Lyme and Associated Disease Society (ILADS), I am writing to support the Lyme and Tick-Borne Disease Prevention, Education, and Research Act of 2007 (S.1708). ILADS strongly supports the bill's intent to improve the diagnosis methods, surveillance, and outcome for acute and chronic Lyme disease.

The number of cases of Lyme disease are staggering despite more than 3 decades of education, surveillance, and research. The CDC finds itself far from the *Healthy People 2010* objective goal to reduce the annual incidence of Lyme disease to 9.7 new cases per 100,000 population in 10 reference states. The average annual rate in these 10 reference states for the 3-year period (29.2 cases per 100,000 population) was approximately three times the *Healthy People 2010* target.

Connecticut is a good example of the challenges these states face. Connecticut's epidemiologist testified in 2004 that the actual number of Lyme disease cases of 34,000 was 24 times higher than the numbers reported through the surveillance system to the CDC. The epidemiologist went on to testify that 20 to 25% of all families had a least one person diagnosed with Lyme disease ever and that 3 to 5% of all families had had someone diagnosed with Lyme disease in the past year. The annual incidence of LD of 1% per year works out to be 1,000 cases per 100,000 population far exceeds the goal of 9.7 cases needed to meet the CDC's *Healthy People 2010* objective goal.

The number of LD patients who do not fit the CDC's epidemiologic definition continues to grow. The CDC's case definition does not include many of the most common neurologic, psychiatric and chronic manifestations including fatigue, headaches, dizziness, irritability, poor memory and concentration, sleep disturbance, arthralgias, numbness, and myalgias. The bill would "evaluate the feasibility of developing a reporting system for the collection of data on physician-diagnosed cases of Lyme disease that do not meet the surveillance criteria of the Centers for Disease Control and Prevention in order to more accurately gauge disease incidence."

The reports of unnecessary delays in diagnosis were confirmed in the Fallon et al trials. The trial revealed that chronic LD patients reported having been symptomatic with Lyme disease for a mean of 1.7 (SD 3.5) years before diagnosis. Delays of a month or more in treatment has been associated with treatment failures. The problems of delays in diagnosis would be addressed by the bill's provision for "surveillance, diagnosis, treatment, education, or prevention of Lyme or other tick-borne diseases, including suggestions for further research and education."

The poor quality of life of chronic Lyme disease has raised concerns since publication of the NIH sponsored trials by Klempner and colleagues. The quality of life of chronic Lyme disease was worse than type 2 diabetes or a recent myocardial infarction. The reports of an average of 4.7 to 9 years of illness of LD patients enrolling in the Klempner et al and Fallon et al trials was equally of concern. Finally, the fact that only 36% of chronic LD patients improved with treatment raised even more concern. The bill supports much needed clinical outcomes research including "the establishment of epidemiological research objectives to determine the long term course of illness for Lyme disease; and determination of the effectiveness of different treatment modalities by establishing treatment outcome objectives."

The cost of chronic LD is an additional incentive for the bill. The average annual economic impact of LD was estimated by experts from the CDC to be \$16,199 per year for clinically defined late-stage Lyme disease in Maryland Eastern Shore. Five percent of the cost was direct medical costs. Ninety-five percent of the cost was indirect medical costs, nonmedical costs, and productivity losses. The author estimated the estimated nationwide annual economic impact of LD to be ≈\$203 million (in 2002 dollars) in the USA based on the 23,763 cases reported to the CDC. Due to underreporting, the actual nationwide annual economic impact of LD could be as much as ≈\$2 billion (in 2002 dollars), assuming that the actual number of cases of LD is ten times higher than CDC records reflect.

ILADS experience diagnosing and treating tens of thousands of LD patients have not been adequately represented by the IDSA. For example, the trials have are far too small. The largest trial to date enrolled 78 LD subjects. Reports of delays in diagnosis of 1.8 years and onsets of illnesses of 4.7 to 9 years before entering trials may not have been a fair test of whether the general population of LD patients can be successfully treated. The risk of use of antibiotics on global resistance has not been assessed against the risk of withholding antibiotics from a LD patient who might benefit from treatment.

The IDSA has suggested the issues be resolved by the Institute of Medicine (IOM) of the National Academies. ILADS does not feel the stakeholders specifically included in the bill will be guaranteed inclusion in the IOM review i.e. 1) scientific community members representing the broad spectrum of viewpoints held within the scientific community related to Lyme and other tick-borne diseases; 2) representatives of tick-borne disease voluntary organizations; 3) health care providers, including at least 1 full-time practicing physician, with relevant experience providing care for individuals with a broad range of acute and chronic tick-borne diseases, and 4) patient representatives who are individuals who have been diagnosed with a tick-borne disease or who have had an immediate family member diagnosed with such a disease.

ILADS feels it is even critical for the medical community to be able to evaluate conflicting positions, the basis for the medical evidence cited, study criteria, professional agendas and conflicts of interests that may exist. Only by airing these different points of view will the medical and scientific community reach a better understanding of controversial topics such as chronic Lyme disease. The Lyme and Tick-Borne Disease Prevention, Education, and Research Act of 2007 will assure a dialogue between all stakeholders and the monies to work together to solve the LD problem.

Please feel free to contact any ILADS members or visit our website at (www.ILADS.org)

Sincerely,

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