



# *Lyme Disease Association, Inc.*

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PO Box 1438, Jackson, New Jersey 08527  
888- 366- 6611 [Lymeliter@aol.com](mailto:Lymeliter@aol.com) 732- 938- 7215 (Fax)  
[LymeDiseaseAssociation.org](http://LymeDiseaseAssociation.org)

April 2, 2008

United States Senators  
Washington, DC 20510

Dear Senator,

I am contacting you today on behalf of the Lyme Disease Association (LDA), a non profit organization with 32 partner groups across the country that together represent countless individuals and families nationwide who are concerned about the growing tick-borne disease epidemic. An additional 86 organizations nationwide have joined the LDA groups in support of the Lyme and Tick-Borne Diseases Prevention, Education, and Research Act of 2007, HR-741, and S-1708.

Passage of the bill is vital to addressing numerous unresolved issues that have prevented significant progress in the field of Lyme disease research and treatment despite the “discovery” of this tick-borne disease over thirty years ago, a discovery which was precipitated not by the medical profession, but by a mother with sick children in Lyme, Connecticut.

You recently received a letter from the Infectious Diseases Society of America (IDSA), a medical specialty society.<sup>i</sup> The letter neglected to mention a number of facts germane to IDSA’s opposition to the bill, which is based on a biased view of Lyme disease science, patients, and treating health care professionals.

While the IDSA emphasizes its dedication to helping prevent Lyme disease, IDSA-authored guidelines prevent the sickest patients with the disease from receiving diagnosis and treatment. With minimal clinical experience in chronic Lyme and only “highly selective” science to back its positions, IDSA has taken upon itself to dictate policies that have been extremely detrimental to patients and those charged with providing quality health care across the country.

The IDSA claims that there is no convincing published scientific data that supports the existence of chronic Lyme disease when, in fact, there are numerous studies which report evidence of persistent infection in both animal models and humans after the most extensive IDSA guideline treatment. More than 200 independent scientists and researchers during the later part of the past century published medical literature confirming the persistence of spirochetes in patients and animals that have been treated with what was considered to be “adequate” therapy,<sup>ii</sup> including studies on hamsters, mice, dogs and horses.<sup>iii</sup> Further research needs to be done to determine relevance in humans to chronic infection, studies which would be possible under this bill.

Rational people question why members of a medical society would attempt to stifle research, marginalize patients, and even testify against their own licensed peers in medical board hearings—peers who have chosen to treat patients based on their clinical expertise—and against patients in insurance cases. Insurance denials to patients make it clear that the IDSA writes the rules that the insurers apply and that IDSA members often control the independent medical review processes mandated by state laws to provide patients a fair shake.

Concerns about the IDSA panel’s commercial conflicts, its exclusionary practices, and its guidelines that restrict treatment options available to patients and preclude clinical discretion by physicians, prompted the Connecticut Attorney General, Richard Blumenthal, to launch an antitrust investigation regarding the IDSA’s Lyme disease guidelines.<sup>iv</sup> Not only did the IDSA fail to mention the investigation of its practices in its letter

to Congress, but IDSA also cites new guidelines, touted as “independent corroboration” of the IDSA guidelines.<sup>v</sup> Examining the “independent corroboration,” one finds many of the same IDSA guidelines’ panel members writing guidelines for other medical organizations (*American Academy of Neurology*) and medical journals (*New England Journal of Medicine*), thereby publishing virtually identical Lyme treatment guidelines/reviews. Hence, the appearance of independent corroboration is illusionary—with the same IDSA members disseminating virtually the same guidelines through two additional medical publications.

The federal Lyme bill was designed to overcome the issue of scientific bias so aptly demonstrated by the above examples. The bill provides for research monies which would be coordinated through the Secretary of Health & Human Services, followed by the National Institutes of Health (NIH), Centers for Disease Control & Prevention (CDC), Commissioner of Food and Drugs, and the Director of the Agency for Healthcare Research and Quality and other federal agencies. The Lyme Disease Task Force outlined in the bill, also objected to by IDSA, is advisory only and allows representation from many scientific viewpoints—including the IDSA, the International Lyme & Associated Diseases Society (ILADS), a professional medical and research society whose mission is strictly tick-borne diseases, and other treating physicians, and patients who have been denied any input to date. The IDSA refers to allowing such balanced scientific viewpoints and the participation of deeply affected stakeholders as “slanting toward individuals with unorthodox and potentially dangerous viewpoints,” when in reality, it is overcoming the bias of a single viewpoint—ending IDSA’s monopoly on Lyme disease diagnosis and treatment, which poses a threat to the commercial research interests of the IDSA’s membership.

The IDSA also neglects to point out that other evidence-based guidelines exist, published by its “competitor,” ILADS, which provide a different scientific viewpoint on the disease and the appropriate method of treating it. ILADS guidelines permit doctor discretion and allow patients with chronic disease to be treated.<sup>vi</sup> Both sets of guidelines appear on the National Guidelines’ Clearing House website under the auspices of US Health & Human Services— a website for evidenced-based guidelines.<sup>vii</sup> The omission of this information (and its implication that all non-IDSA approaches are not based on evidence) by IDSA in its assessment to Congress reveals a remarkable lack of candor.

U.S. Department of Health and Human Services also operates Healthy People 2010. David Satcher, Surgeon General’s Office, stated on the launching of the program: “Together, as a nation, we must move toward a balanced community health system — one that ...draws on the involvement of the community, including homes, community schools, churches and other faith-based organizations, and civic and local groups.”<sup>viii</sup> 2010’s goals, then, mandate diverse viewpoints to keep the scientific research moving forward in the US, and thus the bill’s proposed Task Force is directly in tune with the principles of 2010.

Specific to Lyme, Healthy People 2010’s program’s goals were set to reduce the number of tick-borne disease cases over a ten-year period. Efforts to reduce Lyme cases failed; they steadily increased at an alarming three-fold rate. The 10 reference states endemic for Lyme have increased cases to 31.6 (per 100,000) in 2001–2005 instead of their target goal of a reduction to 9.7 (per 100,000),<sup>ix</sup> an occurrence no doubt related to lack of agency coordination and funding priorities. The bill would change that picture, providing for prevention strategies, agency coordination, and stakeholder input to help develop viable strategies for case reductions.

After years of IDSA domination of Lyme disease research, diagnosis and treatment, there is still no test that can conclusively confirm or deny the presence of Lyme infection and other tick-borne diseases. Hundreds of thousands of people may be misdiagnosed or diagnosed late and improperly treated. IDSA’s required tests use antiquated technology, repeatedly shown in research published in prestigious peer review, to allow negative results when patients really have Lyme disease.<sup>x</sup> Additionally, some of the guidelines’ committee members have commercial interests in the tests they mandate in the guidelines.<sup>xi</sup>

Lack of a definitive test is not just a problem in diagnosis, but also a potential problem in the area of the blood supply. Although there have been no known cases of Lyme disease transmitted in that fashion, there is research showing the bacterium survives blood banking conditions<sup>xii</sup> and a recent CDC study demonstrates in the mouse model that transmission through the blood supply is possible.<sup>xiii</sup> Yet there is no real screening process in place; indeed, no definitive test is available, a condition bill passage will move to rectify.

IDSA bases its arguments against the bill on divergent treatment approaches, yet the bill is actually not about treatment but about research, physician education, and prevention. However, it is necessary that we address IDSA's assertion that antibiotic resistance is an issue in long-term treatment of Lyme disease using quotes from IDSA authors themselves who have concluded, "*B. burgdorferi* [Lyme disease bacterium] does not acquire resistance to antibiotics."<sup>xiv</sup> Furthermore, we at the LDA completely support only the appropriate use of antibiotics. Many of the biggest causes of antimicrobial resistance are well-known and manageable with due diligence, i.e., proper infection control in health care facilities, including hand-washing, reduction in prescribing antibiotics for viruses, and ensuring completion of a prescribed course of antibiotics. Denying sick patients access to needed health care is not an appropriate solution.

Notably, in their Principles and Strategies Intended to Limit the Impact of Antimicrobial Resistance, the IDSA points to improved diagnostic testing as one of the key actions to control resistance.<sup>xv</sup> Developing sensitive and accurate diagnostic tools and tests and improving the efficient utilization of diagnostic testing currently available are goals of the bill. Other goals of that bill are establishing epidemiological research objectives to determine the long term course of illness for Lyme disease and determining the effectiveness of different treatment modalities by establishing treatment outcome objectives. We are at a loss as to why IDSA did not recognize any of these goals in their letter.

Scientific integrity, public accountability and social responsibility continue to be exceedingly deficient in the tick-borne disease field. The IDSA has dominated research in Lyme disease, and its intervention in this bill represents its attempt to retain that control by excluding other stakeholders from having a voice in the use of government research funds. In order to attain credibility, those receiving grants and developing health care policies should not have conflicts of interest. The IDSA panel members have disclosed interests in new Lyme vaccines, diagnostic tests, and consulting with insurance companies. Their continued promotion of their self-interests at the expense of patients and public health is not acceptable.

Remember, all 50 states have now reported Lyme disease cases, and children ages 5-14 are in the highest risk age group. Risky behavior can include jogging, playing on the swing set, and walking the dog. You have the opportunity to prevent your family and millions of others in this country from suffering from a debilitating disease whose manifestations are characterized by the National Institutes of Health (NIH) below,<sup>xvi</sup>:

Neurological complications most often occur in the second stage of Lyme disease, with numbness, pain, weakness, Bell's palsy (paralysis of the facial muscles), visual disturbances, and meningitis symptoms such as fever, stiff neck, and severe headache. Other problems, which may not appear until weeks, months, or years after a tick bite, include decreased concentration, irritability, memory and sleep disorders, and nerve damage in the arms and legs. In a few patients symptoms of persisting infection may continue or recur, requiring additional antibiotic treatment. Varying degrees of permanent joint or nervous system damage may develop in patients with late chronic Lyme disease. In rare cases, some individuals may die from Lyme disease and its complications.

Please, support the bill by advocating its placement on the Health, Energy, Labor & Pension (HELP) committee agenda (Kennedy-MA, chair), sign on as a co-sponsor, and vote favorably for the bill when it is brought before you. Thank you.

Sincerely,

Patricia V. Smith

President

Lyme Disease Association

/s/ Stephanie Woolrich Holzman VMD, Rev Claire Longton North, MSS, Co-Founders Lyme Disease Support Group of Southwestern VT Arlington VT	/s/ Pam Dugas, Leader, Wolfeboro/Brookfield Supporters (NH) Brookfield NH	/s/ Nancy Wood, Co-Chair Cape Cod Chapter LDA Cape Cod, MA
/s/ Harriet Bishop, President Texas Lyme Disease Association Colleyville TX	/s/ Lis Heininger, Co-Chair Corning/Finger Lakes Area Chapt. LDA Corning NY	/s/ Ila Utley, President Lyme Assoc. of Greater Kansas City, Inc. Overland Park Kansas (& Missouri)
/s/ J. David Kocurek, Ph.D., President STAND UP FOR LYME Colleyville TX	/s/ Jill Auerbach, Chairperson Hudson Valley LDA Poughkeepsie NY	/s/ Lori Hoerl, Founder Florida Lyme Advocacy Fernandina Beach FL
/s/ Kathleen Liporace Greenville Lyme Advocacy & Support Group Greenville SC	/s/ Ellen Lubarsky, Founder NY Lyme Support Program Manhattan NY	/s/ Virginia Anez, Chair Southeast Florida Chapter LDA Lake Worth FL
/s/ Julie Merolla, Co-Chair, Rhode Island LDA Chapter Warwick RI	/s/ Jeannine Phillips, Leader LymeQuest NJ New Brunswick NJ	/s/ Kim Pappa, Chair Eastern Connecticut Chapter LDA Sprague CT
/s/ Leslie Giardiello, Chair Pennsylvania Chapter LDA Wyomissing PA	/s/ Colleen Nicholson, Moderator Montana Lyme Support	/s/ Maggie Shaw RN, Chair Newtown LD Task Force Newtown CT
/s/ Doug Fern, President, LDA Southeastern Pennsylvania Kennett Square PA	/s/ Laurice Stevens, Coordinator Mid Missouri Tick Coalition Jefferson City MO	/s/ Diane Blanchard, Co-President Time For Lyme, Inc Greenwich CT
/s/ Theresa Denham, Director Oregon Lyme Disease Network Portland OR	/s/ Jean F. Gallbreath, President Harford County LDSG, Inc. Street MD	/s/ Colleen Nicholson, Moderator Alaska Lyme Support

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