

# LDA Position on FDA Laboratory Developed Test Guidance Proposal

The Lyme Disease Association, Inc. (LDA) formulated a response to FDA to be included in its comment period on its testing Guidance which will affect specialty lab Lyme tests. Groups who wanted to support the position taken by the LDA were able to join in on the letter. **Letter was submitted with 73 groups signed on.**

[Click here for LDA letter to FDA](#)

**BRIEF HISTORY:** FDA is moving forward in the process of finalizing its new Laboratory Developed Test (LDT) Guidance proposal. The proposal would move LDTs from under the jurisdiction of Clinical Laboratory Improvement Amendment (CLIA) regulated by Medicare & Medicaid Services to under the jurisdiction of the Food & Drug Administration (FDA). The FDA now regulates non-LDT lab tests under “medical devices,” and “approves” or “clears” tests. Non LDTs are tests which are sold to other laboratories while LDTs are generally tests which are developed and used in one lab, commonly called specialty labs.

Click below for LDA article

[FDA Moves to Regulate All Lyme Tests](#)

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## LDA Position on Amendment in the Nature of a Substitute to HR 4701

The LDA requested Lyme leaders to sign on to a letter against the Amendment in the Nature of a Substitute to HR 4701. Letter

with signups was sent 7/7/14 to Energy & Commerce with this note: "Attached please find a letter stating the position of 154 groups from over 35 states across the US opposing the Lyme disease legislation, 'Amendment in the Nature of a Substitute to HR 4701' that was passed through the Energy & Commerce Health Subcommittee on June 19, 2014. This information was collected over an approximate three-day period over the July 4 holiday weekend. We look forward to your response. Thank you."

As a result of the letter, the bill sponsor, working with LDA and others, was successful in obtaining language that accomplished the goals of having patients at the table with a working group that operates in a transparent fashion. It also includes "chronic or persistent infection and co-infections" language. (Go to top of page to see new version.)

[Click here for LDA letter to Energy & Commerce](#)

## **Bill History**

[Link to Bill History](#)

[House E & C Committee Passes Lyme Bill , HR 4701, July 23, 2014 version](#)

[Victory in the US House of Representatives: Lyme bill, HR 4701 – "Vector-Borne Disease Research Accountability and Transparency Act of 2014"](#)

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# **LDA Position on IDSA 2006 Lyme Disease Guidelines**

The new IDSA guidelines published in October by the Infectious Diseases Society of America (IDSA) are already causing

patients to be denied treatment for chronic Lyme disease. The guidelines have recommended against any long term treatments, listing numerous specific antibiotic classes not to be given, listing alternative treatments and even supplements not to be offered to Lyme patients. Clinical discretion has been removed from treating physicians. We ask that you, your families, and friends across the country sign this petition immediately. Lyme treatment is at stake.

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We, the undersigned, are gravely concerned by the new Infectious Disease Society's (IDSA) guidelines on Lyme disease. These guidelines call for absolute reliance upon either the presentation of an Erythema migrans rash or positive serologic blood tests to diagnose Lyme disease and recommend severely limited courses of antibiotic treatment when either a rash or a positive test are present. They take the place of a longstanding policy of deference to the clinical discretion of the treating physician in both diagnosing and treating the disease. We find it most troubling that the new IDSA guidelines fail to explain the scientific justifications for their absolute reliance upon the rash and current blood testing to diagnose the disease in light of the numerous studies and medical opinions concluding that the rash is either not discovered by or present in many infected persons and that the serologic testing methods recommended by the IDSA are inherently unreliable because they do not even remotely approach a dispositive level of accuracy. Widespread adoption of these guidelines by practitioners, insurers, and government entities will, therefore, cause real and egregious harm to many patients by inhibiting physicians who otherwise would be free to clinically diagnose and treat this disease.

These guidelines fail to meaningfully address the needs of patients with chronic Lyme disease, who are now relegated to the pile of diseases with unknown etiology, like CFS and FMS, and who are provided with only symptomatic relief, while the

underlying infectious disease is allow to progress unabated. Studies have shown that patients with chronic Lyme disease suffer a degree of debility equal to that of patients with congestive heart failure. Failure to address the underlying infectious disease etiology keeps these patients sick, which is inhumane and immoral. There are no chronic Lyme disease patient studies supporting symptomatic therapies, which presumably would be necessary for life at considerable cost to insurers and society. Moreover, the IDSA rejected out-of-hand the requests by patients and their treating physicians to participate in the guideline development process. No medical society should be able to dictate patient healthcare through exclusionary guidelines that ignore considerable scientific evidence and fail to meet the basic goal of medicine-to improve the quality of life of the patient.

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## LDA Vaccine Position Paper

VACCINE POSITION PAPER \* (There are currently no human vacciens on the market in the US. This applied to the vaccine LymeRix which was withdrawn by the manufacturer citing poor sales).

The Association recognizes the need for a safe effective vaccine against Lyme Disease. Several pharmaceutical companies have developed vaccines that are going through the FDA's vaccine approval process. One has been FDA approved.\*

The Association does not recommend for or against products, including the vaccine,

used for the treatment or prevention of Lyme disease. An individual and his/her doctor need to make the decision whether or not to receive the vaccine.

Several questions about the vaccine:

- Since there is no effective test for active Lyme, what happens to individuals who have active Lyme disease and receive the vaccine?
- Since the vaccine is effective against certain strains of the Lyme bacteria, *Borrelia burgdorferi*, what happens if someone is infected with a different strain?
- What happens to individuals who receive the vaccine and become vaccine failures and contract Lyme? After receiving the vaccine, they will now have a positive test for Lyme. Will doctors know enough about the vaccine effects on LD testing to diagnose Lyme, and will insurance companies pay for treatment, or will the record of the vaccine and subsequent positive test prevent diagnosis and treatment?
- Since having had Lyme disease itself does not confer immunity, can one conclude that a positive titer means immunity to the disease? Are positive titer and conference of immunity the same thing?
- What tests have been done to determine the length of protection of the vaccine beyond 2 years?
- In the vaccine trials, people were not challenged with the disease; they were just monitored to see if they came down with it. What happens if someone actually is infected?
- Bacteria inside a tick that is feeding on a vaccinated animal are mostly destroyed. Can the remainder enter the human body and produce disease?
- Some researchers have found that OspA may trigger an autoimmune arthritis in certain susceptible people. Since this vaccine is OspA based, will getting the vaccine produce arthritis in some otherwise healthy individuals?

Adopted: 4/21/98,

Revised: 5/19/98, 2/16/99

[\*Note: This vaccine, *LymeRix*, was withdrawn from the market by manufacturer on Feb. 25, 2002. Currently, there are no vaccines on the market for humans]