

The LYMERix™ Story: FDA Approval to Market Withdrawal □ Learning from History

This is a piece on the Lymerix Vaccine controversy, written by Patricia V. Smith, President, Lyme Disease Association, Inc., in 2013 and published on LDA website.

[2013 version published on LDA website](#)

It was published in the **Lyme Times Special Issue Sept. 2018**
The LYMERix™ Story: FDA Approval to Market Withdrawal – Learning from History

[2018 version published in Lyme Times](#)

FDA Powerpoint on Lymerix Vaccine

This is an FDA powerpoint by Robert Ball, M.D., M.P.H., Sc.M., on the Lymerix Vaccine, *LYMERix® Safety Data Reported to the Vaccine Adverse Event Reporting System (VAERS)*, January 31, 2001.

Robert Ball, M.D., M.P.H., Sc.M., Division of Epidemiology, Office of Biostatistics and Epidemiology, Center for Biologics Evaluation and Research, Food and Drug Administration (FDA), Rockville, MD

[CLICK HERE FOR THE POWERPOINT](#)

Philadelphia Inquirer on Lyme Vaccine and Attorney's Op-Ed

The Philadelphia Inquirer published an article regarding the development of a vaccine for Lyme disease, October 2013. The article is titled, "*It's Time to Develop a Vaccine for Lyme Disease, Doctor Says*" by Ilene Raymond Rush. We are providing a response to that article by Stephen A. Sheller, founding partner of Sheller, P.C., a national whistleblower, plaintiff's product liability, personal injury class action law firm based in Philadelphia. His book including his work on Lyme Disease, *A Nation Betrayed*, is soon to be released.

[Click here for the article in Philadelphia Inquirer](#)

[Click here for the Op-Ed](#)

Neuropathy and Cognitive Impairment Following Vaccination with the OspA

Protein of Borrelia Burgdorferi

[J Peripher Nerv Syst.](#) 2004 Sep;9(3):165-7.

[Latov N¹, Wu AT, Chin RL, Sander HW, Alaedini A, Brannagan TH 3rd.](#)

<https://www.ncbi.nlm.nih.gov/pubmed/15363064>

Abstract

Neurological syndromes that follow vaccination or infection are often attributed to autoimmune mechanisms. We report six patients who developed neuropathy or cognitive impairment, within several days to 2 months, following vaccination with the OspA antigen of *Borrelia burgdorferi*. Two of the patients developed cognitive impairment, one chronic inflammatory demyelinating polyneuropathy (CIDP), one multifocal motor neuropathy, one both cognitive impairment and CIDP, and one cognitive impairment and sensory axonal neuropathy. The patients with cognitive impairment had T2 hyperintense white matter lesions on magnetic resonance imaging. The similarity between the neurological sequelae observed in the OspA-vaccinated patients and those with chronic Lyme disease suggests a possible role for immune mechanisms in some of the manifestations of chronic Lyme disease that are resistant to antibiotic treatment.

PMID:

15363064

DOI:

[10.1111/j.1085-9489.2004.09306.x](https://doi.org/10.1111/j.1085-9489.2004.09306.x)

[Indexed for MEDLINE]

FDA Response to Vaccine Questions

On January 22, 2002 in Bethesda, MD., the LDA was able to get a private meeting with the FDA on the vaccine issue, despite reluctance by the FDA to grant the meeting. Congressman Chris Smith helped facilitate the setup of this meeting. On February 25, 2002, a month after meeting with FDA, LDA received written answers to its questions from FDA and, also, learned that Glaxo SmithKline had quietly pulled Lymerix from the market, citing "poor sales."

[CLICK HERE FOR THE RESPONSE](#)

[Click here for summary of the meeting](#)

Petition

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 allowed 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.

Currently we have over 45,000 signatures.

Lyme Disease Tick Vectors | What Do Deer Ticks Look Like | Info Graphic

Learn more about blacklegged ticks, also known as deer ticks. What blacklegged ticks look like and the diseases they cause.



TICK VECTORS

Ticks are not insects but are arachnids and are thus related to spiders and mites. They have 8 legs, except when they first hatch from eggs (larva), when they have 6 legs.

WHAT DO DEER TICKS LOOK LIKE?

Ixodes scapularis commonly called blacklegged or deer ticks, are generally born uninfected with Lyme disease, i.e., they do not contain the Lyme bacteria, *Borrelia burgdorferi*. Research has shown a small percent may be born infected with the bacteria.



Photo Credit: James Occi, MA, MS



Photo Credit: James Occi, MA, MS

The deer tick does have a two year life cycle and does survive the winter.

The deer tick can carry other disease organisms besides Lyme bacteria. *Babesia*, *Bartonella*, *Anaplasma*, tularemia, *Ehrlichia* and Powassan virus are some examples. One deer tick bite can infect you with one or more of these disease organisms.



Photo Credit: James Occi, MA, MS



Photo Credit: James Occi, MA, MS

Other types of ticks have different life cycles and carry different diseases. Some examples important in human disease are; *Amblyomma americanum* (the lone star tick) which transmits a Lyme-like disease called STARI and can cause a red meat allergy; *Dermacentor variabilis* (American dog tick); and *Dermacentor andersoni* (wood tick).

TICK HABITAT

Tick Habitat Many people think ticks are only present in the woods. However, ticks can be found in many areas.

- Where woods/fields meet lawn
- Wooded areas
- Tall brush/grass
- Under leaves*
- Very small numbers on cut/raked lawns or sports fields
- Under ground cover (plants) in yard *
- Around stone walls and woodpiles where mice & other small mammals live



Lyme Disease Association, Inc. (LDA)

Dedicated to research, education, prevention and patient support.

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Lyme Patients File Civil Suit Against Insurers/IDSA/IDSA Panelists

The Lyme Disease Association (LDA) has announced that on November 10, 2017, twenty-three Lyme patients/estates of patients filed Civil Action No. 17-cv-190 in the US District Court for the Eastern District of Texas, Texarkana Division—4 counts under Racketeer Influenced and Corrupt Organizations Act (RICO) and one count of antitrust violations of the Sherman Act. The plaintiffs are asking for actual damages, treble damages, reasonable attorney's fees, and court costs

and have demanded a jury trial. The defendants are:

- Infectious Diseases Society of America (IDSA)
- Blue Cross and Blue Shield Association
- Blue Cross and Blue Shield of Texas
- Anthem Inc.
- Aetna Inc.
- Cigna Corp.
- Kaiser Permanente Inc.
- United HealthCare Services Inc.
- UnitedHealth Group Inc.
- IDSA Panelists: doctors Gary P. Wormser, Raymond J. Dattwyler, Eugene Shapiro, John J. Halperin, Robert B. Nadelman, Leonard Sigal, & Allen Steere.

Discussion of the investigation of the IDSA by then Attorney General Richard Blumenthal (now Senator) is presented, testimonies before governing bodies of an advocate and a doctor are included, and cases of defendant patients are presented as well as cases of some physicians who were charged by state medical boards.

One excerpt from the Factual Allegations Common to All Counts & Claims is below: (p.23-4)

The acts of the defendants form a 'pattern of racketeering'

99. The IDSA, Insurance Defendants, and the IDSA Panelists, acting through their officers, agents, employees and affiliates, committed numerous predicate acts of "racketeering activity," as defined in 18 U.S.C. §1961(5), prior to and during the period made the basis of this suit, and continues to commit such predicate acts, in furtherance of their scheme to prevent treatment of chronic Lyme disease and to prevent the proper testing of potential Lyme disease patients, including including (a) mail fraud, in violation of 18 U.S.C. §1341, and (b) wire fraud, in violation of 18 U.S.C. §1343. Such predicate acts include the following: mailing, causing to

be mailed, knowingly agreeing to the mailing of various materials and information, and/or wiring information including, but not limited to, correspondence regarding the following: fraudulently and wrongfully claiming lack of insurance coverage for chronic Lyme disease; fraudulently and wrongfully denying insurance coverage to people with chronic Lyme disease; issuing false and misleading EOB's to patients with Lyme disease; fraudulently and wrongfully claiming all Lyme disease patients can be easily treated and cured with short-term antibiotics; fraudulently and wrongfully claiming Lyme disease patients only have Lyme disease if they exhibit an EM rash or test positive with a two-tier serology test; wrongfully and illegally reporting doctors to their medical boards for treating chronic Lyme disease; fraudulently and wrongfully misleading people with Lyme disease, and their doctors, by classifying their chronic Lyme disease as a mental disorder; fraudulently and wrongfully misleading people with Lyme disease, and their doctors, by classifying their chronic Lyme disease as a different physical condition such as chronic fatigue syndrome or fibromyalgia; and fraudulently and wrongfully enforcing the IDSA guidelines even when doctors determine a patient requires long-term antibiotic treatment.

[Click here for a news release on suit](#)

[Click here for complete lawsuit](#)