

Rodent-Targeted Bait Vaccine Shows Decrease in Lyme Disease Transmission



Photo credit James L. Occi (PhD candidate) LDA Scientific & Professional Advisory Board

The Connecticut Agricultural Experiment Station (CAES) and US Biologic, Inc. released the publication of a field trial study showing the effectiveness of an orally-delivered anti-Lyme vaccine that targets the white-footed mouse, the major wildlife source of Lyme disease.

The study took place in the residential area of Redding, CT, over a three-year time period and showed substantial decreases in the number of infected mice. One year into the study, test sites that had been treated with the vaccine showed a 13X greater decrease in blacklegged ticks (*Ixodes scapularis*, the primary vector associated with the spread of disease) infected with *Borrelia burgdorferi* (the bacterium that causes Lyme disease) compared to control sites (i.e., 26% drop versus 2% drop).

“Fewer infected ticks mean less infection in the field overall,” says Dr. Kirby C. Stafford, Chief Scientist and

State Entomologist, “So the decrease would be greater year-over-year that the vaccine is applied.”

A second effect, which has been observed in previous laboratory-based studies showed that the vaccine causes the mice to generate antibodies and therefore previously infected ticks act as a ‘xenodiagnostic marker’ of vaccine impact, meaning once they ingest the antibodies, while feeding on vaccinated mice, the ticks then become ‘cleared’ of infection.

Dr. Scott C. Williams, Agricultural Scientist and co-author of the study verified that when non-infected mice feed on vaccine-coated pellets, they are then protected from the *Borrelia burgdorferi* infection. “Non-infected ticks, therefore, cannot pass the disease to other animals, including humans” he says.

The study’s findings were published in the peer-reviewed publication, *Experimental and Applied Acarology*. Click [here](#) to view the press release from The Connecticut Agricultural Experiment Station.

**Torrey vs. IDSA/Insurers
Lawsuit Update: Proceedings
Delayed ‘Till Feb.**

The Lyme Disease Association is providing an update regarding Torrey vs. IDSA/Insurers, the federal lawsuit filed by 24 Lyme patients against six members of the Infectious Disease Society of America (IDSA) and eight insurance companies in the U.S. District Court for the Eastern District of Texas, Texarkana Division.



Recently, two documents were filed electronically by the suit's mediator. [The first](#) announces that Kaiser Permanente, one of the eight insurance company Defendants, has settled with the Plaintiffs. [The second](#) stated that the mediation session, which commenced in February of this year, has been suspended, and that "the undersigned mediator will continue to work with the parties in an effort to settle".

More recently, according to Investigative journalist and author, Mary Beth Pfeiffer, "Proceedings have again been delayed, to 2/14/20. Parties will report by 1/31/20 on 'agreements and/or differences concerning the case schedule, the amount of time necessary to finish discovery and trial timing.'" "

At this stage, this is all the information that has been released to the public. Details regarding the terms or amount of the settlement are currently unknown. The lawsuit was initially filed in 2017 on behalf of the group of Lyme disease patients who claim they have been denied care, as well as harmed, under existing insurance and medical protocols. The litigation proceedings will continue in the U.S. District Court in Texarkana, Texas.

LDA will provide updates when we have them. You can also continue to watch for updates on Mary Beth Pfeiffer's [website](#)

and [Twitter feed](#).

Referenced article:

1. Thefirststepidemic.com. *Patient lawsuit against IDSA and insurers moves forward in Texas*. [Web Article]. Copyright 2019 thefirststepidemic.com. <https://www.thefirststepidemic.com/lyme-lawsuit>.
2. Thefirststepidemic.com. *Amended complaint in Lyme lawsuit; battle lines are drawn*. [Web Article]. Copyright 2019 thefirststepidemic.com. <https://www.thefirststepidemic.com/lyme-lawsuit>.
3. LymeDisease.org. *TOUCHED BY LYME: Latest in anti-IDSA/insurers lawsuit: Kaiser settles*. [Web Article]. Copyright 2019 LymeDisease.org. <https://www.lymedisease.org/torrey-v-idsa-kaiser-settles/>

Research Review Finds IDSA Guidelines Contribute to Mental Health Epidemic



Researchers, including Robert C. Bransfield, MD, Lyme Disease

Association Professional & Medical Advisory Board Member, recently reviewed the proposed new Lyme Disease Guidelines, a [100 page document](#) on the prevention, diagnosis, and treatment of Lyme disease drafted by the Infectious Disease Society of America (IDSA) in collaboration with the American Academy of Neurology and American Academy of Rheumatology. The draft of the IDSA Guidelines was released for public comment in August of 2019 and received a considerable number of responses from the Lyme community, many critical of the proposed Guidelines.

[The review](#) was published in *Healthcare Scientific Journal* and scrutinizes specific sections of the guidelines that are most relevant to psychiatry including the disclaimer, laboratory testing, and adult and pediatric psychiatric sections. The researchers have outlined many issues with the IDSA Guideline draft, most notably, the failure to outline the causal association between Lyme disease and psychiatric illnesses throughout, despite the vast amount of well-founded supporting evidence.

The Disclaimer

According to the researchers, the proposed disclaimer, which was more extensive than the one on past IDSA guidelines, contained many issues, including failure to state that the guidelines cannot be used to establish a standard of care. The analysis found that the disclaimer offered no type of warranty of accuracy or reliability with the methods outlined and that the institutions responsible for creating the guidelines held themselves harmless from any potential losses that may occur when practicing physicians use the guidelines to treat patients. The seriousness of the guidelines issue came to the attention of the US Health and Human Services Tick-Borne Disease Working Group (TBDWG), of which LDA President Pat Smith is a member, and discussion was included in the group's 2018 Report to Congress.

Diagnostic Testing

According to the researchers, one of the most central flaws contained within the guidelines was the recommended use of the scientifically unfounded surveillance case definition as diagnostic criteria. The IDSA Guidelines make the incorrect assessment that patients who do not meet the surveillance case definition for Lyme disease do not meet clinical diagnostic criteria either, and therefore, do not have Lyme disease. Additionally, the review calls attention to issues with the IDSA's arbitrary focus on 2-tiered testing as a reliable method of diagnosis.

Testing Adults with Psychiatric Illness for Lyme Disease

The IDSA Guidelines advise against testing for Lyme disease in adults with diagnosed psychiatric illness, yet a number of studies show a causal relationship between Lyme disease and certain kinds of psychiatric illnesses. Prior research has shown that a low prevalence of mental illness may exist prior to infection while the presence of psychiatric illnesses and comorbidities is more significant post-infection.

The researchers were able to identify 377 unique citations on the ILADS website, supporting an association between Lyme disease and psychiatric illness. However, the IDSA Guidelines include only a small number of articles limited to epidemiologic studies that selectively reported outcomes

Testing Children with Developmental, Behavioral, or Psychiatric Disorders for Lyme Disease

The IDSA Guidelines also recommend against standard testing for Lyme disease in children with developmental, behavioral, or psychiatric disorders, referencing that there is no data to support a causal association between tick-borne infections and behavioral disorders or developmental delays in children. However, as the researchers who analyzed the IDSA Guidelines state, the IDSA included no references to support these claims and in fact, numerous articles demonstrating the causal

relationship between Lyme disease and developmental, behavioral, and psychiatric disorders in childhood do exist.

References:

1. Bransfield RC, Cook MJ, Bransfield DR. [Proposed Lyme disease guidelines and psychiatric illnesses](#). *Healthcare*. 2019;7(3):105.

2. Rheumatologyadvisor.com. Review Indicates Inclusion of Psychiatric Illness Association in Proposed Lyme Disease Guidelines. [Web Article]. Copyright 2019 Rheumatology Advisor.

<https://www.rheumatologyadvisor.com/home/topics/lyme-disease/review-indicates-inclusion-of-psychiatric-illness-association-in-proposed-lyme-disease-guidelines/>

L. Johnson on Meaningful Patient Representation on the next TBDWG

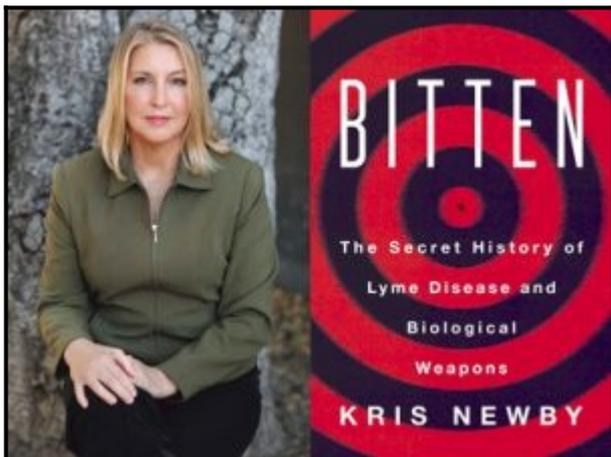


Lorraine Johnson, JD, MBA, Chief Executive Officer of LymeDisease.org delves into the importance of meaningful patient representation on the Federal HHS Tick-Borne Disease Working Group (TBDWG) in her latest blog. This is especially important as we await the announcement of panelists to the new TBDWG charged with the next report to Congress due in 2020. A recent patient survey conducted by lymedisease.org found “To be a meaningful representative, patients chosen for a

panel should: a) have or be a caregiver to a patient with chronic Lyme disease and b) should be an officer or director or someone vetted and approved by a recognized and trusted patient advocacy group (PAG) or someone approved by a PAG.” Read the entire blog by Lorraine Johnson here:

[LYMEPOLICYWONK: Who represents Lyme disease patients? Why it matters.](#)

“Bitten” Book Review



The debate over the prevalence of Lyme disease and whether it exists in a chronic form has raged for decades. Kris Newby’s well researched book provides documented evidence that the suspicions of disease sufferers, their advocates, and treating physicians deserve investigation. The properties of the pathogen itself and its ally, the tick, appear to be part of our nation’s biowarfare studies.

Swiss American scientist Willy Burgdorfer is acclaimed for identifying the spirochetal bacteria which causes Lyme disease. Indeed, the pathogen bears his name, *Borrelia burgdorferi*. Yet as the author discloses through filmed interviews and archival reviews, there were other aspects to Willy’s research. Employed by the US government and headquartered at Rocky Mountain Laboratories, Burgdorfer was enmeshed in biological warfare projects. Ms. Newby discusses

his work in Switzerland for the American government which led to the identification of a new strain of *Rickettsia*, a pathogen if crossed with *Borrelia* might well complicate treatment and thus be a candidate for biowarfare. Interviews by Ms. Newby with American researchers on the topic of the *Rickettsia*, dubbed the Swiss agent by Dr. Burgdorfer, did not shed any light on the mystery pathogen whose existence seems to be buried in the past.

Ms. Newby's discovery of tick drops and the experimental release of ticks document ongoing biowarfare research and questions the consequences if studies go awry. The prevalence of new diseases and the expansion of tick territories are examined in the context of now revealed government studies.

Ultimately, whatever mix of causes is responsible for the Lyme and other tick-borne diseases epidemic in the US, the solutions, as strongly stated by Kris Newby, lie with better science, advanced research and proper funding.

[Click here](#) for YouTube video of Under Our Skin, Director, Andy Abrams and Kris Newby discussing her new book.

[Click here](#) to purchase *Bitten* on amazon.com

[Click here](#) for other purchasing options of *Bitten* on HarperCollins.com

New Book Exposes Secret Lyme

Disease & Bioweapons Link

UNDER OUR SKIN Director Andy Abrahams Wilson interviews Kris Newby, author of “Bitten: The Secret History of Lyme Disease and Biological Weapons.” May 1, 2019

– UnderOurSkin.com

New Lyme Vaccine in Clinical Trials: Update!



An article on a new vaccine for Lyme disease, “New Effort for Lyme Disease Vaccine Draws Early Fire,” by Sumathi Reddy, appeared in the Wall Street Journal on July 9, 2018. The article, which includes a quote by LDA

President, Pat Smith, reports that a European company, Valneva SE, is in clinical trials for a vaccine for Lyme disease, which has been fast tracked by the FDA. **(see 4/28/19 update at end of article)**

A company official estimates it will take at least five years before it becomes commercially available. The vaccine is similar to Lymerix, by Smith Klein Beecham (SKB), now GlaxoSmithKline, which was approved by the Food and Drug Administration (FDA) in December 1998 but was withdrawn from the market in 2002 due to low demand.

“We don’t feel that there has been enough research done to answer the questions as to what occurred with the prior

vaccine,” says Patricia Smith, president of the Lyme Disease Association Inc., a New Jersey-based national nonprofit group, which raises money for Lyme research, education and patient support. “The vaccine that is now in development is something with the same base. There were a lot of patients that thought they were harmed from that vaccine. It’s very problematic.”

Check out the history of Lymerix and efforts by the LDA and others to get the facts behind the vaccine and its withdrawal—individuals who took the vaccine who spoke at the FDA on the problems they felt were related to the vaccine; class-action lawsuits that alleged it caused serious side effects; and a meeting requested by LDA at the FDA where LDA brought in a vaccine expert and physicians who were seeing patients with problems they felt were connected to receiving the vaccine.

Update on Lyme vaccine 4-28-19 On July 2017, Valneva received from the Food & Drug Administration (FDA) a Fast Track Designation for VLA15. On April 4, 2018, Valneva presented Phase 1 interim results of the vaccine at the World Vaccine Congress in DC. In December of 2018, Valneva announced the initiation of Phase 2 Clinical Trial Development to determine the optimal dosage level and schedule for use in Phase 3 field efficacy studies, based on immunogenicity & safety data.

[Click here for a history of the LDA’s involvement with the FDA and the Lymerix vaccine](#)

[Click here to read full Wall Street Journal article](#)

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](#)

Neurological Complications of Vaccination with Outer Surface Protein A (OspA). Marks DH1

Int J Risk Saf Med. 2011;23(2):89-96. doi: 10.3233/JRS-2011-0527.

<https://www.ncbi.nlm.nih.gov/pubmed/21673416>

Abstract

A wide range of neurological complications have been reported via the medical literature and the VAERS system after vaccination with recombinant outer surface protein A (OspA) of *Borrelia*. To explore this issue, 24 patients reporting neurological adverse events (AE) after vaccination with Lymerix, out of a group of 94 patients reporting adverse events after Lymerix vaccination, were examined for causation. Five reports of cerebral ischemia, two transient Ischemic attacks, five demyelinating events, two optic neuritis, two reports of transverse myelitis, and one non-specific demyelinating condition are evaluated in this paper. Caution is raised on not actively looking for neurologic AE, and for not considering causation when the incidence rate is too low to raise a calculable difference to natural occurrence.

PMID:

21673416

DOI:

10.3233/JRS-2011-0527

[Indexed for MEDLINE]

**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.

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15363064

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

[Indexed for MEDLINE]