NIH awards $3.5 Million for Novel Lyme Disease Vaccine Study

With a new $3.5 million grant from the National Institutes of Health (NIH), Utpal Pal, PhD, professor in Veterinary Medicine at the University of Maryland (UMD) will be partnering with Matthias Schnell, director of the Jefferson Vaccine Center at Thomas Jefferson University to develop a novel “next-generation” Lyme disease vaccine.

Pal, a tick immunobiologist, and Schnell, whose lab studies rabies virus as a platform for vaccination, will adapt the rabies virus platform to fight Lyme disease. The inactivated rabies virus, which helps the body produce antibodies to fight rabies, will be repurposed to produce other types of proteins that can fight Borrelia burgdorferi, the Lyme disease bacteria, a technique found effective for other viral vaccinations.

This study will test the four already identified vaccine candidate proteins, as well as the three major types of rabies vaccine platforms—using live attenuated virus, inactivated virus, and the shell of a virus with viral proteins on the outside but no virus inside to trick the body. Pal is also studying both Borrelia proteins and the tick proteins that keep the Borrelia alive so it can be transmitted to humans.

Read more about this project here – (prweb.com)

Utpal Pal, PhD lectured at LDA’s 2018 Annual Scientific Conference – Immune Evasion of Lyme Disease Agents
Read about Pal’s previous research – UMD Research Isolates Bb Protein that Disables Immune System

GAO Investigation of Ticks/Vector-Borne Agents’ Biowarfare Experiments Passes House

Kris Newby, Standford University Science Writer, “Bitten”

Update July 29, 2020: The Bill and passed amendments such as this one (below) has now moved to the conference committee where the House and Senate will work to decide what language goes into the final product. The LDA provided input into the amendment language and has been working to get Senators to champion the inclusion of this GAO Investigation Amendment
into the final bill.

Said LDA president Pat Smith: “We thank Congressmen Smith & Peterson for championing this investigation. Lyme and tick-borne diseases (TBD) patients and the public are entitled to know the truth about what past government research may reveal not only about the documented tick releases along the Atlantic bird flyway but also about research on the mysterious ‘Swiss agent’ which Dr. Willy Burgdorfer identified as a new Rickettsia strain in his work for the US Government— at Rocky Mountain Labs and in Switzerland. Perhaps it may uncover clues to help stop this epidemic of tick-borne diseases.”

Rep. Smith (NJ-04) NDAA FY 2021 Lyme Disease Amendment Floor Speech
Jul 21, 2020

Congressman Christopher H. Smith (NJ-04)

July 23, 2020: The House voted this week to pass a number of amendments to the NDAA, National Defense Authorization Act, including a Chris Smith/Collin Peterson amendment, # 587 –The Comptroller General of the United States shall conduct a review of whether the Department of Defense experimented with

There is information in various publications that such activities did occur, especially in the book “Bitten” by Kris Newby—a science writer at Stanford University—a book, which explores the evidence through actual government documents and interviews with some researchers who were involved that document such experiments.

Said LDA president Pat Smith: “Lyme and tick-borne diseases (TBD) patients and the public are entitled to know the truth about what past government research may reveal not only about the documented tick releases along the Atlantic bird flyway but also about research on the mysterious ‘Swiss agent’ which Dr. Willy Burgdorfer identified as a new Rickettsia strain in his work for the US Government— at Rocky Mountain Labs and in Switzerland. The book indicates there is speculation that this pathogen, if crossed with Borrelia, might well complicate treatment and thus be a candidate for biowarfare.” She added, “There is the possibility that any uncovered information could lead to facts which could shed light on the current epidemic of Lyme and other TBD and help develop solutions. We thank Congressmen Smith and Peterson for their continued push to make the truth known and the US House of Representatives for their vote to approve the amendment.”

Some things author Newby revealed for the first time were: that ticks were developed and deployed as stealth biological weapons during the Cold War, and that Willy Burgdorfer, the scientist the Lyme bacteria, Borrelia burgdorferi, was named after, was at the center of this program. According to Newby, specific revelations she makes in book include:

- A 1962 pilot study where infected ticks were dropped on Cuba sugar workers.
• Releases of hundreds of thousands of radioactive, aggressive Lone Star ticks on the Atlantic coastal bird flyway.
• Omissions of other microbes transmitted with Lyme-carrying ticks during the original outbreak (“Swiss Agent’). 
• Documentation of military studies where live disease-causing bacteria, some which can be spread by ticks, were sprayed from planes, boats and vehicles on the unsuspecting American public.

In 2019, a similar amendment was introduced and passed the House unanimously but there was no senate support for it.

The Lyme Disease Association (LDA) has been encouraging Lyme advocates across the country to contact both of their US Senators to champion and support this amendment. It is being heard in the Senate this week. LDA thanks those leaders who have made calls and sent emails to garner support.

More Information

New Jersey Globe: House passes Chris Smith measure to probe if government turned ticks into bioweapons

Chris Smith website: Chris Smith’s Lyme Disease Amendment Passes House, Tells DOD IG to Investigate the ‘Bioweaponization’ of Ticks


MoreMonmouthMusings.net: House passes Smith’s Amendment which could lead to a Lyme disease cure

Here is a very similar Smith amendment that passed the House unanimously in 2019 but did not make it through the Senate.
Valneva announced that the vaccine candidate against Lyme disease, VLA15-201, showed positive initial results meeting its endpoints in the Phase 2 study. They stated in the July 22, 2020 press release that “compared to Phase 1, the higher doses used in this trial elicited higher antibody responses across all serotypes.” Of particular note was the immunological response found in older adults (50-65 years), one of the main target groups for a Lyme vaccine. The vaccine candidate is described as “generally safe across all dose and age groups tested”, finding no Serious Adverse Events (SAEs) associated with VLA15. This is an important finding given the history of vaccines and serious concerns that have been generated regarding patient safety and vaccines in the Lyme community.
VLA15 is the only active Lyme disease vaccine candidate in clinical development today, covering six serotypes of Lyme disease prevalent in North America and Europe. It was granted Fast Track designation by the U.S. Food and Drug Administration (FDA) in July 2017. In a few months, Valneva expects to report top-line results for the second Phase 2 study, VLA15-202. Valneva and Pfizer are collaborating for development and commercialization of VLA15.

Read full July 22, 2020 press release here

Read Valneva vaccine history and Lyme Disease Association’s concerns here:
https://lymediseaseassociation.org/news/lyme-disease-vaccine-collaboration-announced/

https://lymediseaseassociation.org/about-lyme/controversy/vaccine/new-vaccine-in-the-news/

Johns Hopkins’ Aucott Makes Case for Chronic Lyme Disease

John Aucott, Director, Johns Hopkins Lyme Disease Research
Center and Associate Professor of Medicine, Johns Hopkins University, published a piece in The Conversation providing his insight on the highly controversial topic of chronic Lyme disease.

In the article, Aucott outlines the existence of a population of patients – an estimated 10-20% – with persistent, lingering symptoms months to years after treatment. He details some of his experience treating these patients and provides an explanation of the various challenges that impair the diagnostic and treatment process. Aucott states, “My chronic Lyme patients were sicker and had less hope than the AIDS patients I worked with, but the underlying mechanism of illness remained elusive.”

Aucott emphasizes that while the mechanism of chronic Lyme disease remains unknown, and molecular markers are needed to provide further insights, it is “no longer accurate to simply argue that chronic Lyme disease doesn’t exist.”

Read Aucott’s full article in The Conversation.

Visit LDA’s web page with more information about the chronic Lyme controversy.

Lyme Disease Vaccine Collaboration Announced
Press Release Summary
Specialty vaccine company Valneva SE and Pfizer Inc. announced a collaboration to develop VLA15, Valneva’s Lyme disease vaccine candidate, which is currently in Phase 2 clinical studies.

According to a Pfizer press release, VLA15 is the only active Lyme disease vaccine program in clinical development today. The program covers six serotypes of Lyme disease that are prevalent in North America and Europe. The vaccine’s mechanism targets the outer surface protein A (OspA) of Borrelia burgdorferi (Bb), the bacteria that causes Lyme disease. OspA is one of the most dominant surface proteins expressed by Bb when present in a tick.

Pfizer states that VLA15 has demonstrated strong immunogenicity and safety data in pre-clinical and Phase 1 studies. In July 2017, the program was granted Fast Track designation by the U.S. Food and Drug Administration (FDA). Valneva expects to report on results from the first Phase 2 studies by mid-2020.

“We look forward to working closely with Valneva to continue advancing the VLA15 program and potentially bring a new solution to patients for this significant unmet need,” said Nanette Cocero, Global President, Pfizer Vaccines.

Comments From the Lyme Disease Association
The Lyme Disease Association President, Pat Smith, had this to
say about the announcement: “A safe and effective vaccine for Lyme disease has been a goal for many decades. Unfortunately, many stakeholders, especially some vaccine recipients and providers who were then giving the vaccine, felt there were problems associated with the past Lyme vaccine, perhaps connected to its Osp A base. There are still many unanswered questions about what really happened, and like much that happens with Lyme disease, decades later, we still do not have those answers. The prudent thing for the government and/or vaccine developers to have done would have been to hold public meetings regarding a new Lyme vaccine with all interested stakeholders to hear concerns and answer questions about the development of a new Osp A-based vaccine and what research was done to address the previous concerns and any newly arisen concerns.

In general, much research on Lyme disease has still not been done. In fact, ~46 years into Lyme disease, it ranks below leprosy in the number of clinical trials done in infectious diseases (Goswami et al., 2013). Those who have questioned the safety and efficacy and approval process of the past vaccine have been publicly accused of bringing that vaccine down. When the opportunity for dialogue which engages the Lyme community and all stakeholders has not been offered as part of the approval process, it creates an atmosphere of distrust among those whose trust is necessary to accept a new Lyme disease vaccine.”

Links for You

Read Pfizer’s VLA15 press release.

Read articles on the history of Lyme disease vaccines.
Torrey vs. IDSA/Insurers Lawsuit Update: Cigna Third Insurance Defendant to Settle

The Lyme Disease Association is providing the most recent 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.

According to investigative journalist Mary Beth Pfeiffer, Cigna has now become the third insurance company defendant in the case to settle following Kaiser Permanente in November 2019 and Blue Cross Blue Shield of Texas (BCBST) in January 2020. Pfeiffer reports that, as was the case with the first two, the Cigna settlement is being handled in secret with sealed documents. The public may never know what the plaintiffs received, or what was accomplished during the hearings. The remaining defendants include the IDSA, five other insurance companies, and six Medical Doctors.

At this stage, this is all the information that has been made available. Details regarding the terms or amount of the settlements are 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](https://www.thefirstepidemic.com) and [Twitter feed](https://twitter.com).

Click [here](https://www.thefirstepidemic.com) to view the Notice of proposed settlement of Cigna Health and Life Insurance Company.

Click [here](https://www.thefirstepidemic.com) to view the Notice of settlement of BCBS of Texas.

Click [here](https://www.thefirstepidemic.com) to view the Settlement reached with Kaiser Permenente.

Referenced articles and websites:


---

**Rodent-Targeted Bait Vaccine**
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.

---

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


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]

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.
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: