

# LYME *in the* LIMELIGHT

BY RACHEL ISAACSON

## Part I

---

### **CAUGHT IN THE CROSSFIRE:**

*How illness, ignorance and ego have turned treatment of Lyme disease into a battle zone — turning patients into victims.*

---

Mrs. Eva Wikler\* was uneasy about her daughter, Shaine,\* 18, who had returned to their Midwood residence in Brooklyn, N.Y., several months into her school year abroad. In December 2013, Shaine came home from Israel following the onset of bizarre symptoms which she had never experienced before and could not deal with on her own. She needed her mother's care.

Mrs. Wikler told *Hamodia*, "I was worried because Shaine was having profound weakness, chills, overall body aches and headaches, to the point that she couldn't get out of bed. She was also having trouble with concentration and focusing, and she had always been a top student in school. I didn't know what was happening to her."

Mrs. Wikler accompanied her daughter to her family's pediatrician, who was stumped by her symptoms and referred Shaine to a rheumatologist. That physician drew a panel of blood works, including tests for Lyme disease, and sent it to a lab.

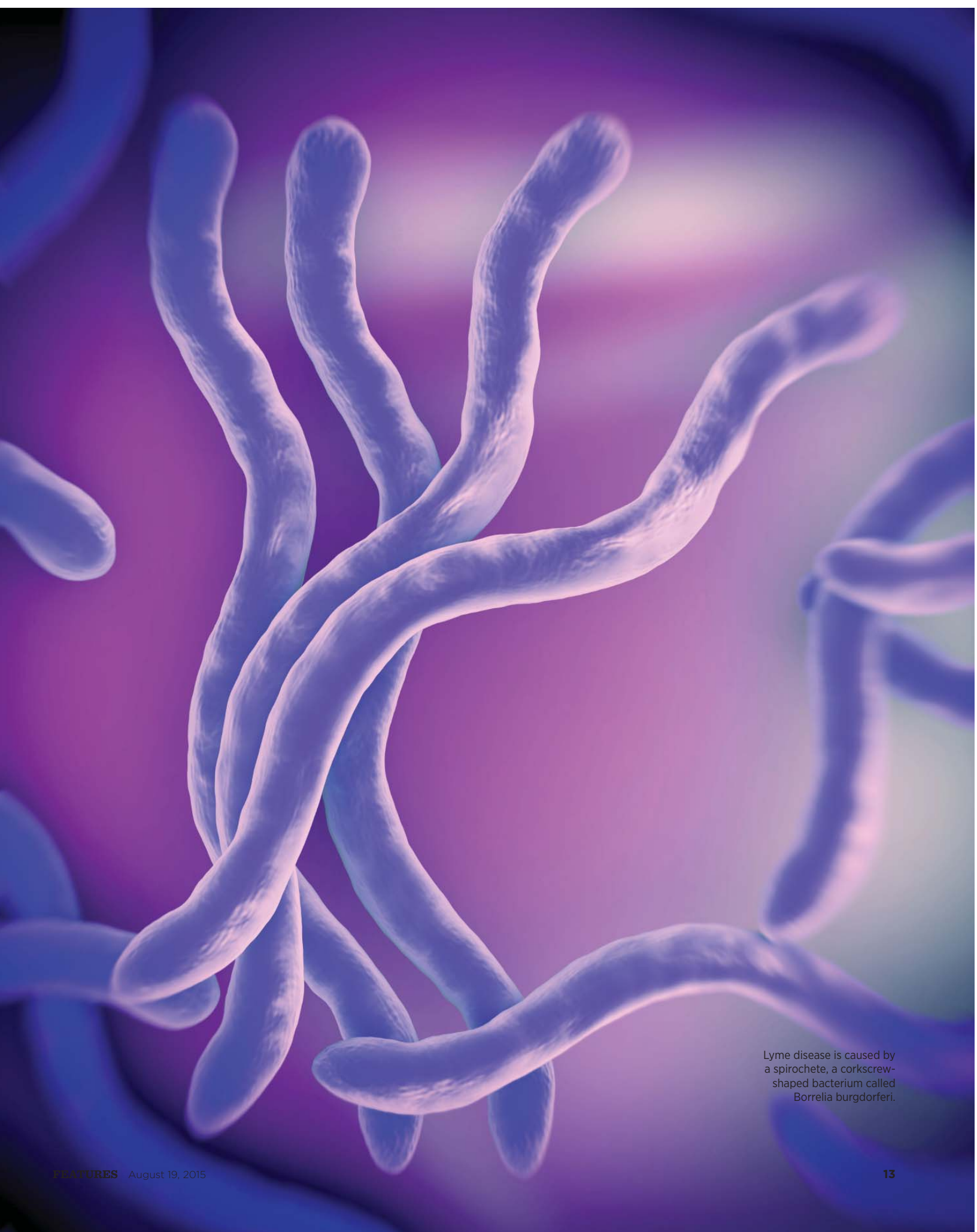
"The possibility of Lyme disease occurred to me. Although Shaine did not have the Lyme rash that doctors say appear with Lyme, I remembered that Shaine was in summer camp about four months before," Mrs. Wikler said. "But when the rheumatologist's Lyme testing proved negative, Shaine's two doctors consulted with each other and advised me not to do anything further. They suggested

to me that possibly Shaine didn't want to go back to school, and was suffering from emotional issues such as depression. I knew my daughter was popular and a high academic achiever and this was not characteristic of her. I also realized that I had to turn elsewhere for help," Mrs. Wikler recalled to *Hamodia*.


Still suspicious of a missed Lyme disease diagnosis, Mrs. Wikler was guided to a Lyme Literate Medical Doctor (LLMD) who specialized in treating Lyme disease patients. The Lyme specialist evaluated Shaine and sent out her bloodwork, this time to a specialty laboratory designed to be more sensitive and specific in detecting Lyme and other tick-borne diseases (TBD). After obtaining a Lyme positive result, the LLMD put Shaine on oral antibiotic therapy.

Shaine, who began feeling improvement after several weeks, flew back to school overseas. Six months later, Shaine was significantly recovered, and with her doctor's consent, stopped antibiotics. She has since resumed her active lifestyle and scholastic studies.

Despite the gratifying outcome, Mrs. Wikler admitted to *Hamodia* that she never confronted the pediatrician who dismissed Shaine's symptoms. "I think that doctors should be made aware of the importance of [Lyme disease] and be educated about this disease," she said, adding, "but I feel uncomfortable saying that to them directly."



Lyme disease is caused by a spirochete, a corkscrew-shaped bacterium called *Borrelia burgdorferi*.



he Wiklers were unwittingly catapulted into the crossfire of an acrimonious debate raging between two poles of medical societies who have authored conflicting guidelines regarding Lyme disease.

The Infectious Diseases Society of America (IDSA) is pitted against the International Lyme and Associated Diseases Society (ILADS). The IDSA showcases the academia of scientific research, whose studies are frequently published in prestigious, peer-reviewed publications. IDSA is composed of scientists, researchers and infectious disease clinicians, who authored IDSA guidelines in 2000, 2006 and 2009. The established IDSA guidelines govern diagnostic and treatment standards [of Lyme disease] which impose the metric of treatment for conventional physicians and at medical institutions across the United States.

Conversely, ILADS is a subset of specialty LLMD-trained clinicians in a growing multispecialty society. ILADS's ranks encompass primary-care physicians, specialists, researchers, nurse practitioners and physicians' assistants. ILADS's approach to clinical treatment is inclusive of patients' multi-systemic symptoms; these doctors evaluate and treat patients by combining their clinical assessment with diagnostic blood work. ILADS scientific research studies are denied entry into the prestigious medical journals and therefore are published online in "open access" medical journals, such as *PLOS ONE*.

The Lyme disease controversy has disenfranchised patients who describe lingering and increasingly ravaging symptoms and are rebuffed by disbelieving mainstream medical practitioners. Struggling patients who grapple with devastating symptoms consequently turn to ILADS physicians, seeking their LLMD's protracted treatment approach for Lyme disease. ILADS terms the constellation of multi-systemic lingering and debilitating symptoms as "chronic Lyme disease."

### Lyme Disease

Lyme disease was discovered in 1975 when a group of children in Lyme, Connecticut, suffered from joint pain symptoms which were originally dubbed "Lyme arthritis." That moniker was soon changed to "Lyme disease" when other symptoms emerged.

In the endemic Northeast and North-central area, Lyme disease is commonly caused by the *Ixodes scapularis* black-legged deer ticks, common in wooded and grassy areas; on the West Coast it is caused by the widespread *Ixodes pacificus* tick. Lyme disease is a corkscrew-shaped bacterial pathogen, called *Borrelia burgdorferi* (Bb) spirochete.

ILADS clinicians, treating in the trenches, claim that Lyme disease can affect any body organ, including the brain, nervous system, muscle, joints and heart. ILADS believes that patients with Lyme disease have often been misdiagnosed with chronic fatigue syndrome, fibromyalgia, multiple sclerosis and various psychiatric illnesses. They dub Lyme disease the "Great Imitator" because of shifting, vague and multi-systemic symptoms that often mimic other diseases.

### Uptick in Ticks

The lower Hudson Valley is a breeding epicenter for

Lyme disease. Other than permanent residents in the area, large sectors of the Orthodox Jewish population are drawn to the bucolic Catskills Mountain region during the summer season, yielding a spike in Lyme cases even once back in their city homes.

Experts warn of a surge in the tick population, which can transmit Lyme disease and other tick-borne diseases. Ticks are hatched as larvae, molt into the nymphal stage and morph into adult ticks after feasting on the blood of white-footed mice — even more than on deer, for which deer ticks are named. When the ticks subsequently bite humans, they inject the bacteria they have absorbed with their blood meals into humans, thereby transmitting the disease. Because ticks are so tiny and their bite is painless, victims are not often aware that they have sustained tick bites, and can go on to contract Lyme disease and other bacterial infections. The longer a tick remains attached to a person, the more likely it is that an infected tick can transmit Lyme bacteria and possibly other pathogens into the person's bloodstream.

Since the reporting of Lyme disease to the New York State Department of Health (NYSDOH) began in 1986, more than 100,000 cases have been documented. Despite annual variations, New York State averages more than 5,500 new cases each year. The NYSDOH provided *Hamodia* with 2013 New York State counts of confirmed Lyme cases. Rates per 100,000 in population indicate that in 2013, Sullivan County residents had 130.2 confirmed diagnosed Lyme cases, while Ulster County residents reported even greater numbers of 236 residents with Lyme disease.

A DOH spokesperson told *Hamodia*, "The New York State Department of Health is currently collecting ticks for testing. In a state as large and diverse as New York, it is extremely difficult to make a prediction about the tick population. However, Lyme disease is endemic across New York, meaning the DOH sees cases year after year. Sullivan County [and Ulster County], because of their location in the lower Hudson Valley, has had several decades of history with ticks and Lyme disease."

When asked by *Hamodia* if wide-scale measures would be implemented to reduce the burgeoning tick population, the DOH spokesperson responded, "Currently, personal protection is the best way to prevent tick bites."

### The Numbers

The CDC has recently estimated 300,000 new cases of Lyme, upward from previous estimates of 30,000, and the controversy engulfing Lyme disease has likewise ratcheted up. According to the CDC, Lyme disease is the fastest-growing vector-borne (transmitted via insects) infectious disease. The CDC has partnered with the IDSA in adopting their guidelines in diagnosis of Lyme disease and treatment standards, although these guidelines were initially intended for CDC surveillance purposes in monitoring definitive new Lyme cases, not for diagnosis and treatment — and regardless of the fact that the CDC had earlier recommended that Lyme should be diagnosed clinically according to doctors' assessment of symptoms.

Dr. John N. Aucott, M.D., Director of Johns Hopkins Rheumatology Lyme Disease Clinical Research Center, concurred with the CDC estimate of 300,000 new Lyme dis-





ease cases. He told *Hamodia* that he had reached a similar estimate in his own studies when researching insurance claims.

When *Hamodia* asked if Lyme disease is epidemic these days, Dr. Aucott replied, "In certain parts of the country, I believe it's reaching epidemic proportions."

*Hamodia* interviewed IDSA guideline co-author Eugene D. Shapiro, M.D., of Yale New Haven School of Medicine. Dr. Shapiro disagreed with the revised CDC estimate of 300,000 new Lyme cases, and said, "There has been a slow and steady increase in Lyme disease, but the 30,000 numbers are still true. Counts in the past have been estimated by doctors submitting 'report cases' which are typically under-reported."

"The CDC, for the past 30 years, has always said the numbers could be 10 times higher. So they [CDC] did a study which nationally studied all positive antibody lab reports. I think that study had errors. I believe there are more than 30,000 cases, but [maybe] there are not 300,000 cases. The CDC is still counting numbers by reported cases, so it's not a surge in numbers, if you use a different system to estimate it. I do believe that there [might] be an increase in Lyme disease, but it's in very limited areas. It's a slow increase but not an epidemic outbreak."

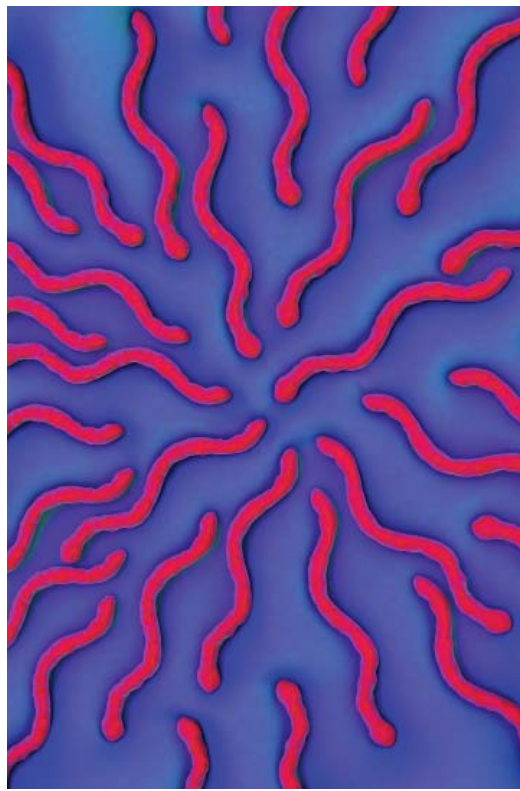
ILADS's board member, Kenneth B. Liegner, M.D., internist and critical care physician, has treated thousands of Lyme disease patients since 1985 and published articles on chronic and neurologic Lyme disease. Expressing views contrary to IDSA's as to Lyme prevalence, Dr. Liegner told *Hamodia*, "Lyme disease is very common and is present in every state of the union and in many continents and countries [around the world]."

Nationally reputed Lyme patient advocate Pat Smith, president of the Lyme Disease Association (LDA), was asked by *Hamodia* about the CDC estimates. She responded, "The [CDC] finally admitted publicly in 2013 to about 300,000 new cases. [But the number] 300,000 may even still be an underestimate due to the lack of a gold-standard test, strain variations [of Lyme and tick-borne disease] and the fact that Lyme in non-endemic areas is vastly under-diagnosed and under-reported." She added, "Some [people] think the numbers are also suppressed."

Lorraine Johnson, chief executive officer of LymeDisease.org and nationally recognized Lyme advocate, was equally outspoken when, at a rally protesting IDSA guidelines, she referred to the CDC count of 300,000 cases reflecting the scourge of Lyme disease. She conjectured that Lyme cases can range from 500,000 to a million, if not more, as "CDC numbers are rigidly defined." She added that many more Lyme cases are clinically diagnosed and do not meet CDC criteria. Johnson underlined, "Numbers are important because numbers drive research funding."

### Diagnostic Tests

Every aspect of Lyme disease is contentious, including its diagnosis — as there are no accurate diagnostic tools which detect the Lyme bacterium itself. The CDC recommends the two-tier diagnostic tests of [the] ELISA and Western Blot testing, which screens the body's immune system reaction of antibodies to indicate Lyme. ILADS and their patients



**“In certain parts of the country, I believe it’s reaching epidemic proportions.”**  
- Dr. Aucott

denounce these standardized tests as missing about 50 to 60 percent of cases, and claim that they are about “as accurate as a coin toss.”

Dr. Shapiro outlined the IDSA stance for new tick bites: “Ticks should be identified if infected [in laboratories]. If the tick is embedded for more than 48 hours, then it can transmit Lyme disease.

“If the tick is in the nymphal stage, a single dose of [the antibiotic] Doxycycline is sometimes indicated. Usually we don’t treat it. Only about 25 to 30 percent of nymphal ticks are infected and most people pull them off before 48 hours. Chances are low for getting Lyme disease.”

He stated that a well-defined case of Lyme disease is one in which the tick has been embedded for 48 hours, and [the patient] presents with an erythema migrans — or “bull’s-eye” rash — which is picked up in a known tick-infested area. “But endemic areas are contained in very limited areas [and only several] states,” he said.

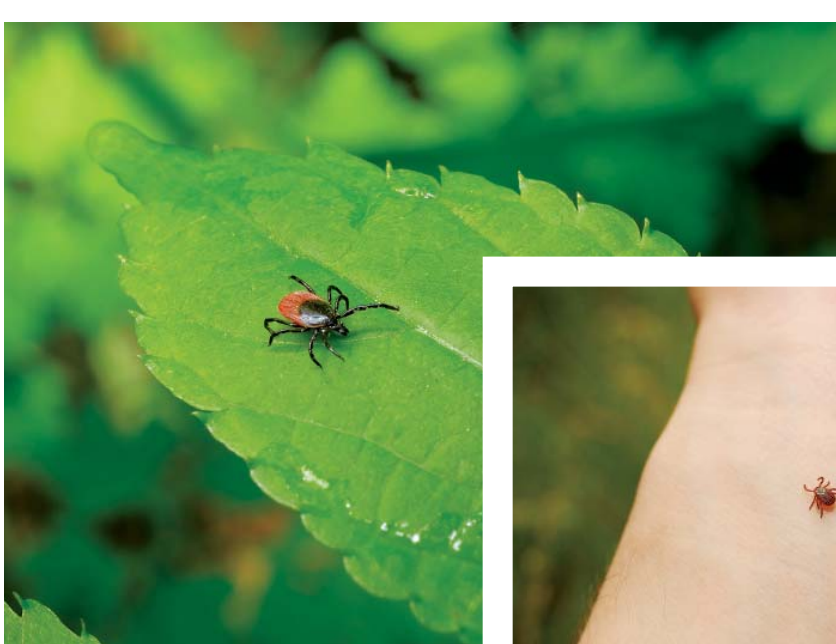
IDSA guidelines recommend treatment for a ‘well defined’ Lyme disease case, consisting of two to four weeks of antibiotics, but not more than 28 days.

Dr. Shapiro noted that “testing for early tick bites makes no sense, because it doesn’t test for the spirochetes; it tests the antibodies of the immune reaction which are too early to have developed, as it takes three to four weeks to develop antibodies, and infection occurs within seven to 14 days.” Dr. Shapiro advised, “I would just tell people to look if the tick is infected, but the risk is low [for getting Lyme disease].”

ILADS’s views on tick bites radically diverge from IDSA guidelines. The IDSA promotes the telling bull’s-eye rash as required evidence of confirmed Lyme disease. Nonetheless, up to 70 percent of patients may never have seen a rash, according to surveys conducted by Lyme advocate Lorraine Johnson of LymeDisease.org [LDo].

ILADS doctors frequently use specialty labs which are touted to be more sensitive in pinpointing Lyme disease. As IDSA-aligned doctors allege that such labs are not FDA approved, Dr. Liegner countered strongly to *Hamodia*, “Laboratories such as iGeneX and their diagnostic methods of testing have been evaluated stringently by the New York State Department of Health and found to be acceptable [by the DOH].”

Dr. Liegner contended, “The CDC-promoted two-tiered testing has been extremely deleterious to the interests of patients, although the CDC asserts it is for ‘epidemiological’ purposes [in surveillance of Lyme cases]. Many, including — and especially — insurers, use it as the gold standard for diagnoses and reimbursement purposes. Insurance companies make ‘payable’ claims disappear ... in a nice sleight of hand.”



Daniel Cameron, M.D., M.P.H., is an internist, epidemiologist and Lyme disease expert affiliated with ILADS, treating Lyme disease since 1987. He is lead author for evidence-based ILADS guidelines in 2004 and 2014, and has published articles, reviewed in peer reviewed publications and presented at national and international conferences.

Dr. Cameron commended ILADS tick bite practice. “ILADS recommends that prophylactic [preventive] treatment should be implemented for at least three weeks, with follow up after a tick bite [as Bb Lyme spirochetes have the ability to penetrate the body and cells in less than 24 hours following an embedded tick bite].” He said, “Whereas IDSA sometimes recommends a one-time 200-mg dose of doxycycline, the only study supporting a single dose of doxycycline demonstrated that it could prevent rashes but did not study whether it could prevent any chronic manifestations of Lyme disease.”

He counseled patients whose physicians balk at providing prophylactic treatment after a tick bite to ask their doctors if they would consider treatment to avoid long-term complications of Lyme disease. “If the doctor does not offer a longer treatment option, you can seek a second opinion from a doctor who might consider longer-term treatment,” he said.

### Chronic Lyme Debate

The most divisive dispute between the feuding societies is centered on the contested existence of disseminated, persistent infection, which, according to ILADS practitioners, is chronic Lyme and necessitates long-term antibiotic treatment. Collaborative insurance companies typically follow IDSA guidelines and often deny payment to patients for oral and IV antibiotic treatment, despite ILADS claims that the treatment is warranted with noticeable patient response.

Dr. Eugene Shapiro, IDSA guidelines co-author, underscored to *Hamodia*, “Lyme disease is not difficult to diagnose and it’s a well-defined entity. It’s generally relatively easy to treat. It’s generally a mild disease and in some cases it’s more severe. In rare cases, it can be very severe. Symptoms of fatigue, muscular and joint pain are very common. So some people [who have these symptoms] decide they must have a disease — and chronic Lyme disease fits the bill. To be clear, I believe that these patients suffer symptoms, but it’s not causally related to Lyme, or even to another medical condition.”

Dr. Shapiro cited a national survey which demonstrated that 10 to 15 percent of the population feels either extremely tired or exhausted most days or every day, for the last three months. “These are the fatigue and aches and pains of daily living,” he maintained, echoing the IDSA position. “There have been numerous studies on Lyme disease and there are no benefits of further antibiotic treatment. There are many side effects and no reasons to take it; there are lots of reasons not to take it.”

Dr. Shapiro contended that patients with symptoms following treatment have “post-treatment Lyme disease symptoms.” If symptoms

remain, they are termed “post-treatment Lyme disease syndrome [PTLDS].”

“Chronic Lyme disease has no definition and no criteria. There is no such thing as chronic Lyme disease. First you need to be diagnosed with Lyme disease — and most people never had Lyme disease to begin with.”

Regarding the controversy, Dr. Shapiro underscored, “Ultimately, science will prevail.”

### ILADS Views

Dr. Cameron, president of ILADS, is among the ILADS clinicians and scientific researchers who charge that their views are banned by the IDSA guideline panel, which bars opposing

representative relevant medical and scientific perspectives that point to evidence-based studies attesting to persistent Bb spirochete Lyme infection.

Dr. Cameron said to *Hamodia*, “There continues to be a network of physicians who push a narrative that there is no evidence of chronic Lyme disease and any illness is nothing more than the aches and pains of daily living. The narrative prevents doctors from working together to treat Lyme disease effectively. IDSA guidelines are too rigid and narrowly defined.”

Dr. Cameron debunked Dr. Shapiro’s assertions that disabling and lingering symptoms are “the aches and pains of daily life.” He described to *Hamodia* that his patients’ lives are derailed by Lyme disease, saying, “Children’s grades and attendance at school can drop precipitously. Adults might need to leave their work and families can fall apart.”

*Yenty Rubin, 33, illustrates the devastation Lyme disease can cause if not given adequate treatment. Rubin offered her account to Hamodia, after waging battle with Lyme disease in 2013. Rubin, who resides in rural Monsey, N.Y., had been an employed, energetic wife and mother. She “suddenly” got sick in January of 2013, elaborating, “It was [as if] I had a physical breakdown.” Recurring infections, crushing fatigue, feeling faint, and intense ‘Lyme brain fog’ assaulted her in rapid succession. Her internist placed her intermittently on antibiotics for the frequent infections, and symptoms receded, but a short time later painfully resurfaced again.*

*Rubin, who had formerly seen her internist only at routine annuals, now shuttled to him regularly and made two emergency room visits. Unable to care for herself or her family, her previously meticulously maintained home was in disarray. “My husband was father, mother and nurse,” she said to Hamodia.*

*Her bloodwork, ordered by her internist, finally yielded a positive Lyme disease result, despite the fact that Yenty Rubin never presented with the erythema migrans (circular bulls-eye rash).*

*Her internist placed Rubin on 28 days of antibiotics. Concluding the internist’s protocol of treatment, her symptoms waned, but resurged again weeks later with terrifying intensity, snowballing to include a stiff neck, bilateral facial numbness, excruciating TMJ and laryngitis, among other symptoms.*

*Rubin was referred to a rheumatologist who diagnosed her with fibromyalgia. When her medical condition further declined, she arrived at her own conclusion, that her symptoms were Lyme related. She found an LLMD who placed her on a combination of oral antibiotics. Rubin improved gradually “with ups and down.” Eight months later, her health mostly restored, she ceased all treatment.*

*Yenty Rubin said to Hamodia, “My internist, who followed the standard protocol, treated me for 28 days. That didn’t work. I think that only ILADS-trained doctors understand how to diagnose and treat Lyme dis-*



ease — and that's why I'm fine today." But she added a caveat: "I do know some people with early-stage Lyme disease who got well after 28 days of treatment. I think I had Lyme disease in my system for six months."

"Chronic Lyme disease includes a wide range of conditions such as Lyme encephalopathy, chronic neurologic Lyme disease, post-treatment Lyme disease and late Lyme disease," Dr. Cameron explained. "Chronic Lyme disease [symptoms] are often severe and chronic, and can include problems with fatigue, memory, irritability, dizziness, joint pain, tachycardia and chest pain. These are just some of the symptoms you will find in Lyme patients. [Studies show] that the symptoms are far worse than the normal population on standardized measures in NIH trials."

Dr. Cameron said, "The Lyme disease patient's quality of life is the same or worse on standardized scales as diabetes, myocardial infarctions (heart attacks), fibromyalgia and chronic fatigue. There are a growing number of doctors who recognize chronic Lyme disease who are professionals with experience in nearly every state and in a growing number of countries. I would encourage doctors who disagree to take a second look at the evidence. I also encourage doctors who disagree with the chronic Lyme disease diagnosis to engage in open dialogue."

Dr. Cameron treats a broad range of patients who respond differently to treatment. "We have patients who remain well after 30 days, and others that do not. We find most of our patients resolve their illness with oral antibiotics. We use IV antibiotics for those who do not resolve their illness with oral antibiotics. We have countless numbers of patients who have recovered and are able to stop treatment. We also have some [chronic] patients who fail treatment who require symptomatic treatment."

The 300,000 cases in the U.S.A. cited by the CDC demonstrate how commonplace it is to contract Lyme disease, Dr. Cameron said. The ILADS physician added that Krupp studies at the National Institutes of Health (NIH) trials demonstrated antibiotics were effective. The Klemmner and Fallon trials [studies which denied persistent infection] only focused on patients who were sick 4.7 to 9 years, and who had failed previous treatment.

Dr. Cameron stated, "The studies were mixed. Chronic Lyme disease remains a clinical diagnosis. The wide range of presentations makes it difficult to come to a consensus on diagnostic criteria. The only exception [in the IDSA disputation] is the post-Lyme disease syndrome proposed by the 2006 IDSA guidelines. Dr. John Aucott of Johns Hopkins Lyme Disease Clinical Research Center demonstrated that PTLDS exists and it can be severe."

Dr. Cameron explained to *Hamodia* the variables which may contribute to chronic Lyme disease. "There is a growing recognition of how complex Lyme disease and co-infec-

tions are. It is unclear what causes these lingering and disabling symptoms in individual patients. Co-infections [diseases other than Lyme which are spawned concomitantly by the tick bite], round bodies [of the bacterium], biofilms, the blood-brain barrier, variable strains of the disease, are only a few of the potential reasons for difficulty in treating Lyme disease. It remains difficult to culture Lyme disease and co-infections in any tissue other than the rash. Therefore it is difficult to prove which mechanism is at play [and the different treatments each requires]."

ILADS's protracted treatment of Lyme patients has led to state medical boards' sanctions against these physicians. LLMs are a subset of beleaguered medical clinicians who aver that they are hounded by state medical boards. These boards investigate complaints and have suspended — and even revoked — the licenses of some of these doctors, following complaints against them which are primarily initiated by insurance companies. ILADS physicians argue that their rightful autonomy to treat their patients has been thwarted. ILADS clinicians therefore maintain a low profile.

In light of maltreatment of ILADS practitioners, Dr. Liegner stressed, "It is desirable for physicians caring for the persons who have, or might have, Lyme or other TBDs to be careful in their evaluations, to document in detail what they are doing, what they are thinking, the rationale for their diagnostic and therapeutic interventions, to be thorough in their assessments — and to be 'humble faced' with so much that we do not know, and with the many uncertainties that attend to this field."

Dr. Liegner said to *Hamodia*, "I have tried to do my best to advocate for my patients in battles with insurers and the 'mainstream' that has insisted there is 'no such thing as chronic Lyme disease.' It has been an uphill battle with heavy propaganda usage to attempt to maintain the 'status quo.' However, things are beginning to change, unfortunately not fast enough."

In his earlier years of his treating Lyme patients, Dr. Liegner had advocated to the insurance carrier for his patient with advanced Lyme disease, Vicki Logan. After consulting with Dr. Liegner in 1989, Logan was hospitalized and administered IV treatment to which she responded. Upon her own request, Logan underwent a spinal tap, which revealed Lyme spirochetal bacteria swimming in her cerebrospinal fluid, despite her prior prolonged antibiotic treatment. Nonetheless, Logan's insurance company continued to reject payment for her critical IV therapy.

In 2003, Vicki Logan died of complications of Lyme disease a while after insurance denial of reimbursement and the ensuing discontinuation of her IV antibiotics. Dr. Liegner has since publicly called for reforms in shielding chronic Lyme patients' treatment and their treating doctors.

Dr. Liegner said, "This field [in treating

## COMPLEXITIES IN TREATING CHRONIC LYME DISEASE

By Dr. Daniel Cameron,  
lead author of ILADS guidelines

Ticks can harbor multiple infections which can be transmitted through a single tick bite and are termed **co-infections**. When a patient's symptoms are severe, persistent and resistant to antibiotic therapy, co-infections are often exacerbating Lyme symptoms.

Scientists have discovered new ways that bacteria can survive in the human body. The spirochetes that cause Lyme disease appear to use these same approaches to survive in people.

A number of bacteria survive antibiotics treatment to form a persister population, which can regrow after antibiotic treatment.

The spirochetes of Lyme disease can stick to each other in a matrix called a **biofilm**. A biofilm can protect the bacteria from the body's defenses and lead to persistent infection.

Lyme disease can change from a spirochetal form to a [dormant] **"cystic"** or round form that can be difficult to treat. These "cystic" forms can revert to spirochetal form, leading to a persistent infection.

Lyme disease can also survive in the brain, which is inaccessible to antibiotics [due to the **blood-brain barrier**, a filtering mechanism that only allows certain substances through]. The persistent cognitive and constitutional symptoms of LD, such as fatigue and headaches, may indicate a subacute brain infection.

Finally, there are **variable strains** of Lyme disease, some of which are more difficult to treat. There is a strain that requires longer treatment.

Lyme disease] is not for the 'faint of heart.' It's the price you pay for being a 'pioneer.' Persons with Lyme disease have suffered greatly from their illness as well as from the ignorance of many in the medical profession; they have been severely discriminated against, aided and abetted by the insurance companies."

Dr. Daniel Cameron summed up, "There are [mainstream] doctors who dismiss Lyme disease (who do not meet ILADS criteria), which leads to needless treatment delays. The delay makes it more difficult to treat. We have not been successful at getting the IDSA to begin the dialogue needed to establish diagnostic criteria. I feel a majority of physicians responsible for their patients will get involved and ignore the IDSA." ■

*\*Name and identifying details changed to protect privacy.*

# LYME *in the* LIMELIGHT

BY RACHEL ISAACSON

## Part II

---

### ***THE GREAT LYME SQUEEZE:***

*Desperately seeking relief, patients are caught  
in middle of a medical turf war.*

---

For Jennifer (Tzivia Bryna) Kramner, 45, who lives in New York City, chronic Lyme disease was the catalyst that upended her life. Kramner recalled to *Hamodia*: “Before I got sick, I used to walk a mile to my dance class and, afterward, I would shop with my friends. I then walked 20 city blocks back to my apartment. I used up a lot of energy, but I never tired. Normal people don’t think about expending energy. Today I think about every step I take ... even on a good day.”

When she was 21 years old, in 1989, Kramner commuted from the city to a day camp job, where camp grounds were situated amid forestry, and campers and counselors frequently slogged through tall grass.

Although Kramner never saw a tick bite or a rash, during the course of that summer her symptoms of extreme dizziness and weakness were sparked. These symptoms flared, waned and intensified again over intervals, but her physician could not determine their cause.

As years passed, her symptoms skyrocketed to include severe vertigo, low fevers, nausea, swollen glands, crushing fatigue, extreme anxiety and intense “brain fog.”

“It felt like my brain was scrambled. I felt like I was underwater and my head was vibrating,” Kramner described to *Hamodia*. “My whole body vibrated from anxiety, too.” Despite using a variety of anti-anxiety medications, her extreme emotional distress was not alleviated. Kramner suffered persistent respiratory infections and “a weird intestinal pain” that was never diagnosed, and she experienced unintended weight gains and losses.

Kramner visited a series of doctors and was evaluated by one specialist as having chronic fatigue syndrome. Between 1994 and 2004, she saw a gamut of “about 20 different doctors” in varying specialties, she said. Nevertheless, Kramner’s baffling symptoms remained elusive and unresolved.







AP Photo/Mike Groll  
Congressman Chris Gibson  
author of "The Gibson  
Bill," which has been  
incorporated into the larger  
"21st-Century Cures Act,"  
prioritizing federal research  
on Lyme disease.

The clash between IDSA and ILADS factions is ignited by IDSA guidelines which regulate Lyme disease diagnostic and treatment standards in the United States. IDSA guidelines mandate a maximum use of 28 days of antibiotic treatment for "well-defined" Lyme disease. ILADS argue that IDSA guidelines generate chronic Lyme disease cases, whose patients consequently require long-term antibiotic therapy. The IDSA unequivocally rejects ILADS's view of chronic Lyme disease.

### S.L.I.C.E.

John N. Aucott, M.D., director of Johns Hopkins Rheumatology Lyme Disease Clinical Research Center, conducts a prospective research study dubbed S.L.I.C.E. — an acronym for "Study of Lyme disease Immunology and Clinical Events." Although the controlled study has been conducted for eight years, the Johns Hopkins center officially opened April 1, 2015.

Dr. Aucott told *Hamodia*, "We don't take sides in the controversy. This center is all about research and we're in the research to find answers." He added, "No one disagrees about acute Lyme disease; what they disagree about is, do persistent symptoms which occur after antibiotic treatment of 21 days indicate post-treatment Lyme disease syndrome (PTLDS)?"

Dr. Aucott said, "I look at the term 'chronic Lyme disease' as a starting point, but it's not a final diagnosis. It's [similar to] when someone comes into the emergency room complaining of chest pains. The chest pains are a starting point for figuring out what's underneath that initial complaint, but it's not a final diagnosis [of a heart attack]. There are multiple final diagnoses for chest pain, and there are multiple final diagnoses which we arrive at when we finish evaluating someone who has a concern about Lyme disease."

Dr. Aucott believes that Lyme disease patients with lingering symptoms following 21 days of antibiotic treatment for "acute Lyme disease" evince a real disease that are not "the daily aches and pains of living," [according to the IDSA] — as is evidenced by his S.L.I.C.E. study.

"I fully believe that many people are disabled and chronically sick with PTLDS. We know that this is a real disease because our study has controls [which demonstrate that]. We know that the post-treatment Lyme disease symptoms of Lyme disease patients are greater and more severe than those in the parallel control panel that do not have Lyme disease."

Dr. Aucott underscored, "Post-treatment Lyme disease syndrome — as indicated by the name — is a disease following treatment for Lyme disease. We don't know what the illness is. We don't claim to know the answers until we do the research to figure it out."

About 10 percent of ideally treated patients in this study go on to develop lingering symptoms after being treated for acute Lyme disease, he said.

### Legal Probe Into IDSA Guidelines

IDSA 2006 guidelines came under scrutiny when, in 2008, former Connecticut Attorney General Richard Blumenthal (today a U.S. senator) launched an unprecedented antitrust investigation into IDSA guidelines. Among other cited misconducts, the attorney general's probe uncovered financial conflicts of interest; the IDSA portrayed another medical association's Lyme disease guidelines as corroborating its own when the two panels shared several authors; the IDSA blocked appointment of scientists and physicians on its panel who had divergent views on chronic Lyme, selecting only like-minded panelists.

Blumenthal called for the IDSA guidelines to be transparent, and for an impartial review panel to reevaluate IDSA guidelines, and mandated that opposing relevant medical and scientific views should be included in the IDSA panel.

Dr. Eugene Shapiro, co-author of IDSA guidelines, censured the probe to *Hamodia*. "I believe it's inappropriate for governmental officials to interfere with medical guidelines based on science," Dr. Shapiro said. "Clearly there are other things going on."

"There was an agreement between Blumenthal and the IDSA that there would be an independent panel set up. The panel chosen by an impartial ombudsman — a medical ethicist — included Ph.D. researchers, clinicians and scientific researchers who had no biased affiliations. [Ultimately, t]he panel concluded that the [IDSA] guidelines were fine and no changes needed to be made," he said.

The 2009 IDSA guidelines remained intrinsically unchanged from the 2006 guidelines.

Dr. Shapiro told *Hamodia* that IDSA guidelines are currently in the process of being revised, and added, “But I don’t predict that there will be any revolutionary changes.”

### National Advocate Lorraine Johnson Of LDo

Lorraine Johnson, chief executive officer of LymeDisease.org, is a nationally-recognized Lyme advocate, campaigning for quality accessible health care for patients with chronic Lyme disease and other tick-borne diseases. Among its other activities, LDo shapes health policy through wide-scale surveys, advocacy, legal and ethical analysis, education, physician training and medical research. “We give voice to the Lyme patient community,” she said to *Hamodia*.

Johnson rhetorically quantified, “Why is this scientific debate so polemical? Because it’s not about science; it’s about values, beliefs and opinions. It’s about who gets to decide, who bears the consequences of those decisions, and who is accountable.”

As an attorney and Lyme patient advocate, Johnson told *Hamodia* that she was involved with the attorney general’s IDSA investigation. She said, “I participated in the [Attorney General] Blumenthal hearing. At the time, we knew the panel was stacked to include just IDSA viewpoints. The ombudsman’s job was to watch for bias [in order to promote opposing views] — but he focused on financial conflicts of interest. The IDSA had a huge institutional conflict of interest among its members — who rooted for their home team.”

She added, “The IDSA does not play by the rules, and runs roughshod over the lives of patients who have no voice in guidelines that profoundly affect them.”

Johnson expressed condemnation that powerful medical societies like the IDSA have “power friends” in other organizations. Many of those guidelines that support the IDSA guidelines were co-authored by members of the same IDSA guideline panel, as was substantiated by the attorney general’s probe into the IDSA guidelines. She asked, “Why would researchers do this? To preserve their grant fund and academic status.” She added, “The IDSA guidelines simply support the research of their authors — they are like an infomercial.”

Johnson said that many (about 40 percent) of IDSA citations are “self-citations” which are regarded as ethically questionable self-promotion by researchers of their own work. Moreover, the majority of their recommendations are supported by the lowest-quality evidence, “which means their guidelines are primarily ‘opinion,’” she said.

“Generally, in evidence-based health care when evidence is weak, patients are provided treatment options. Here the evidence is weak, and the IDSA has left patients without any treatment options. Forty-six percent of these patients have had to quit work or school,



In 2013 Senator Richard Blumenthal introduced the Lyme and Tick-Borne Disease Prevention, Education and Research Act to promote Lyme disease prevention, education and to push to develop better tools for diagnosing and reporting the illness.

at some point. No one knows for sure how to treat cancer, but we try. Here, [Lyme disease] patients are being [essentially] abandoned by a medical society,” Lorraine Johnson said.

### The Embers Study

Lorraine Johnson referred to two NIH studies which were to determine persistent infections and which were funded concurrently. They were intended as parallel studies on Lyme disease.

One study followed the human treatment study by Klempner — the Embers study — which was an animal model treatment study. The first [Klempner] study was published in 2001 and was heralded by the IDSA researchers as definitive proof that Lyme disease was not a persistent infection when patients failed to meet a measure of success in that study. At the same time, the companion Embers study conducted in 1998, which used the same treatment protocol as that of the Klempner study, but whose subjects were non-human primates — rhesus monkeys — contrarily suggested strongly that persistent infection exists, notwithstanding the 90 days of treatment which was administered.

Johnson said, “The Embers study languished on the shelf for 10 years until published in 2012. During the 10 years this primate study was not completed, the door to science should have been held open, as it was clear that the sister study — the Embers study — was still pending.

“But this fact was not publicly acknowledged, and the need for further research was

dismissed. Meanwhile, patients who are very ill have been essentially kicked to the side of the curb and left to suffer without treatment. This is inhuman and a disgrace to science!” she charged.

### The IOM on IDSA Guidelines

The Institute of Medicine (IOM) — an independent panel of scientists and physicians — singled out the IDSA guidelines as guidelines gone awry. Among other recommendations, the IOM advocated that the IDSA include opposing viewpoints in their panel as representation of “key affected groups” (patients who have lived through Lyme disease, such as chronic Lyme patients, and their treating clinicians).

Lorraine Johnson’s name was advanced by a national organization to the IDSA, to be included in the process. The IDSA instead installed on their panel a single token “consumer,” who has stated that she never had Lyme and knows nothing about it, Johnson said.

Lorraine Johnson further alleged, “In Lyme, IDSA peer review for grant funding has been dominated by a handful of IDSA experts who provide biased peer review that leads to the rejection of federal grants for research on persistence [of infection]. This type of sharp-elbowed academic anti-competitive conduct exists in other fields, but it is completely out of control with Lyme disease. Science depends upon the open and free debate of scientific ideas.”

She said, “When one side of a debate holds too much power, abuse of peer review may occur, as it does in Lyme disease. Dr. Stephen Barthold [of the Embers study] testified that those ‘on the wrong side of the tracks’ do not get funded. Patients are essentially victims in a turf war waged by the IDSA against its competitor physician organization, ILADS.”

Lorraine Johnson and ILADS Lyme physician, Dr. Raphael Stricker, co-authored more than 40 peer-reviewed articles and commentaries on Lyme disease, over the past 10 years. These co-authors had earlier submitted a paper to the peer-reviewed *New England Journal of Medicine*, which advised them that their paper would be reviewed by the IDSA.

“We got back a document that bore no resemblance to the one we had submitted,” said Johnson. The *NEJM* stipulated a “take it or leave it” approach to Lorraine Johnson. ILADS scientific research papers are often published in “open access” medical journals, because they are suppressed in conventional peer-reviewed medical journals.

### National Advocate Pat Smith of the Lyme Disease Association (LDA)

Another nationally reputed Lyme patient advocate is Pat Smith, president of the Lyme Disease Association (LDA). Among a myriad of LDA achievements is “raising monies for research, education, prevention and patient

# BEYOND LYME:

## New Illnesses, More Reason to Watch for Ticks

BY LAURAN NEERGAARD

Lyme disease makes the headlines, but there are plenty of additional reasons to avoid tick bites. New research highlights the latest in a growing list of tick-borne threats — a distant relative of Lyme that's easy to confuse with other illnesses.

The study suggests that a kind of bacteria with an unwieldy name — *Borrelia miyamotoi* — should be on the radar when people in Lyme-endemic areas get otherwise unexplained summertime fevers. It's one of several recently discovered diseases linked to ticks in different parts of the country, a reminder to get tick-savvy no matter where you live.

"People need to be aware of what tick-borne diseases are in their area," says Dr. Peter J. Krause of Yale University, a specialist who reviewed the research. "And they should know how to avoid ticks."

### What's This New Infection?

The first U.S. case was reported in 2013 in New Jersey, in an 80-year-old cancer survivor who over four months became increasingly confused, had difficulty walking and lost 30 pounds. Doctors found spiral-shaped bacteria in her spinal fluid that looked like Lyme but caused a relapsing fever more closely related to some other tick-borne illnesses. While treatable by antibiotics, doctors know little about *B. miyamotoi*. (The woman recovered.)

This study offers some clues: Researchers with Imugen Inc., a Massachusetts laboratory, tested blood samples from patients in Massachusetts, Rhode Island, New Jersey and New York whose doctors suspected tick-borne illnesses, using that lab. During the 2013 and 2014 tick seasons Imugen found 97 cases of the new infection. That's roughly 1 percent of samples tested, and close to the lab's detection of a better-known tick disease named anaplasmosis, researchers reported in *Annals of Internal Medicine*. More research is needed to determine just how prevalent the disease is.

Researchers then analyzed medical records from 51 of those patients, and found symptoms typically include a high fever, severe headache, chills and blood abnormalities — decreases in infection-fighting and blood-clotting cells. About a quarter of patients were hospitalized, although Imugen medical director Dr. Philip Molloy cautioned that's probably because doctors are seeking testing only for their sickest, most puzzling patients.

The bacterium is carried by deer ticks, also known as blacklegged ticks, which also can spread Lyme and at least two other

illnesses, such as babesiosis and anaplasmosis.

### It's Not the Only New Worry

Two new tick-borne viruses were recently discovered in the Midwest, and neither has a specific treatment.

The Centers for Disease Control and Prevention has confirmed nine cases of Heartland virus and one death, with other reports under investigation, said CDC entomologist Roger Nasci. Symptoms include fever, fatigue, headaches, muscle aches, diarrhea and low blood counts. The virus, identified in Missouri, was also reported in Tennessee and Oklahoma, although the Lone Star tick that spreads it lives around the East and Southeast.

Then there's the Bourbon virus, with similar symptoms, discovered last year after the death of a Kansas man and named for his home county. Another patient, in Oklahoma, recovered. The Kansas patient had found an embedded tick days before getting sick, and CDC researchers are searching for the culprit species.

Another new and significantly more severe tick-borne disease which is catching CDC attention is the Powassan virus. It is described by medical authorities as a tick-borne rapidly acquired viral infection "that produces symptoms similar to Lyme disease, but more severe, and there's no cure."

### How Many Diseases Can Ticks Spread?

The CDC counts 14 illnesses linked to specific U.S. tick species, not including the Bourbon virus still being studied. Lyme is the most common, with a CDC-revised count of about 300,000 new cases each year.

### Prevention Is Best

No matter where you live, CDC's advice applies:

- Shower soon after being outdoors to spot ticks more easily, and examine pets that can carry ticks inside.
- If you've been in tick-infested areas, carefully do a full-body check, including under arms, behind knees, ears and hair.
- When in the woods, walk in the center of trails, avoiding brush and leaf litter.
- Use bug repellent with DEET, or wear long pants and long sleeves.
- Discourage ticks around homes by keeping grass cut, removing leaf litter and brush, and placing a barrier of wood chips or gravel between lawns and wooded areas. (AP)

support, and political lobbying on behalf of chronic Lyme disease patients."

Smith said that funding for Lyme disease is obtained from the National Institutes of Health (NIH) and The Centers for Disease Control and Prevention [CDC]. In 2014, the CDC had \$8.937 million in its budget and NIH had \$23 million. "Little to none of that funding was allocated [in research] of chronic Lyme, since the position of both agencies has mirrored that of the IDSA, that there is not any chronic Lyme."

Smith said, "The IDSA is influential with federal legislators and has the ability to extensively lobby Congress on the issues. The IDSA has even taken a position against all patient-initiated Lyme legislation, in both federal and state."

### Columbia University Lyme and Tick-Borne Diseases Research Center

Brian Fallon, M.D., psychiatrist and director of the Columbia University Lyme and Tick-Borne Diseases Research Center, established in 2007, said to *Hamodia*, "Chronic Lyme disease is a term that is easy for patients because it's understandable, but for medical purposes we use the term 'post-treatment Lyme disease syndrome.' PTLDS refers to a constellation of symptoms such as pain, cognition impairment and fatigue.

"My view of PTLDS is clearly that this is a heterogeneous [diverse] entity. Some people have a persistent infection and some people have a post-infectious issue. The problem is that we don't have the tools to determine that, primarily because diagnostic tests are insufficient."

As a psychiatrist, Dr. Fallon outlined to *Hamodia* the neuropsychiatric symptoms of Lyme disease. "Primary neuropsychiatric symptoms [of Lyme disease] are short-term memory [loss], word-finding difficulties, and feeling like your brain is in a fog. While depression and anxiety often occur, rarely one might [also] see psychosis or unstable mood disorders," Dr. Fallon said.

### Is the Climate Shifting?

Dr. Fallon, who collaborates with investigators nationwide, reported to *Hamodia* on encouraging findings for Lyme patients now pending, such as a highly accurate diagnostic assay which can detect Lyme disease and an array of co-infections within a single blood sample even within a few short days after a tick bite. "This should be available within the next few years," Dr. Fallon said.

Promising vaccine and treatment approaches are being tested in laboratories and in animal studies, but have yet to be translated into clinical use for humans.



Dr. Fallon said, “There’s great excitement in the Lyme world nationally because tremendous progress has been enabled by advances in technology.”

He summed up to *Hamodia*, “This controversy is based on the inadequacy in current treatment and diagnostic tests. As newer diagnostic tests come to the market, and newer treatment approaches are developed, the controversy will subside.”

When *Hamodia* questioned Pat Smith if the climate may be shifting in favor of chronic Lyme disease, she replied, “Possibly, due to some of the research on chronic Lyme disease [which is not done with government funding], but which demonstrates persistence [of infection] and the reason behind it.” Other reasons may include the organized efforts by Lyme groups such as the LDA which focus on passing laws. Increasing Lyme cases among celebrities have also disclaimed the IDSA views that “Lyme is hard to catch and easy to cure,” as once touted by those who wished to suppress the seriousness of Lyme. This has increased media interest and coverage, and made media and government realize there is more than one position on chronic Lyme that requires further research to develop a better understanding of what is happening to sick patients who cannot get better.

The former “Gibson Bill” is an example of the political influence Pat Smith wields on behalf of the Lyme community. That bill, designed to advocate for Lyme disease patients and their treating doctors, “has included Lyme language” and has, in 2015, been incorporated into a broader health initiative called the “21st-Century Cures Act,” which affects many diseases. It has passed the House and is pending in the Senate.

“The Gibson bill has the potential to benefit Lyme disease patients and their treating physicians, by allowing them a seat at a table with a [Washington] D.C. working group of federal agencies and non-federal partners,” Pat Smith told *Hamodia*. “The LDA has helped write and pass many such initiatives.”

### Dr. Susan Schulman Statement

Leading pediatrician Susan Schulman, M.D., author of *Understanding Your Child’s Health*, provided a statement to *Hamodia* that express her views: “It is obvious that many millions of people are being exposed to ticks carrying Lyme disease by simply living or vacationing in an area where nature is close by to their home environment. The potential pool of affected people is enormous.

“In the early days of this disease, scientific groups battled over the very existence of this disease and the way it is identified. There were many political battles over this matter. Unfortunately, this process resulted in Lyme disease being very narrowly defined by the CDC. These criteria, requiring specific blood tests to be positive, rely solely on immune reaction detected in the blood against Lyme disease.



The tick shown in this article is magnified for easier viewing. However, actual embedded ticks are often tiny and may resemble a brownish-black scab, or even a freckle.

This method is indirect and somewhat lacking scientific precision. I feel that there is room for more flexibility, and that there can be chronic symptoms. Co-infections with other tick-borne pathogens are also a poorly understood, and very poorly addressed, issue.

“There are no clearly defined methods for treating these diseases when they appear outside the narrow parameters of the CDC definition. Science has recently developed more direct ways of identifying a particular pathogen in tissue. When these 21st-century methods are universally available and applied, the mystery and the controversy will be better resolved. For now, a lot of guesswork and trial and error methods are being used. Some are valid and helpful and some are not.”

### Yesh Tickva — Lyme in the Jewish World

In the Jewish community of Brooklyn, N.Y., Chumy Klughaupt, a chronic Lyme disease patient, launched her organization, Yesh Tickva, in 2012, to provide support, referrals and awareness for the Orthodox Jewish sector of chronic Lyme disease patients.

Yesh Tickva has received over 10,000 calls just within the past year, as documented by its phone company. Klughaupt observed, “It is heartbreaking to hear patients who mostly call with the same story. They say, ‘I am suffering from headaches, brain fog, numbness, joint pain.’ Patients say, ‘I have already been to all doctors in town and no one can figure out the cause of my symptoms. All the doctors [can] say is that it’s in my head.’”

Klughaupt said, “An ILADS doctor told me a while back that change will come about, and I believe that I see it. It is amazing to see how some local doctors are now willing to ‘think outside the box’ and encourage patients to

seek doctors that will help them.

“Yesh Tickva’s goal is that all doctors in our community should properly test and treat for Lyme and tick-borne disease in the early stages, so that in the years to come there will be no chronic Lyme disease in our community,” she said.

\*\*\*

During the interim of her unidentified illness, Jennifer Kramner had been employed at a children’s center, but, too ill to work, she felt compelled to resign. She told *Hamodia* about the chance meetings with two friends — in 2004, each on a different occasion — who shared with her a mutual friend’s Lyme account and encouraged her to test for Lyme disease. Kramner acknowledged that their friend’s chronicle of Lyme symptoms meshed with her own. She requested a physician she had seen to draw a blood sample and send it to IGeneX Laboratory; her conclusive results returned as positive.

Kramner said to *Hamodia*, “I didn’t even know about the controversy. I was just starting to learn about Lyme.” She finally discovered a Lyme specialist in 2004, who ramped up her antibiotic treatment gradually, putting her on an oral antibiotic for a co-infection of Lyme, and “my anxiety just disappeared. It was like night and day. It was as if I had a part of myself back again.”

After IV antibiotic treatment was initiated, Kramner noted improvements. “My brain was almost back to normal. I could read again and process the information,” Kramner said. “My stomach felt fine. I was mostly on different combinations of medications, alternating IV and oral antibiotics, and herbs. I felt so much better. I had more energy, my brain cleared and I had no pain.”

Kramner was a patient at Rusk Institute of Rehabilitation (an affiliate of NYU Langone Medical Center in NYC), in therapy for “cognition remediation,” during the phase when she began Lyme treatment. She told *Hamodia*, “They [Rusk] were amazed and called my ILADS doctor about the positive change they saw in me cognitively, and marveled at how my anxiety was dispelled. Lyme and co-infection can cause psychiatric symptoms and I had several co-infections with Lyme. When I was treated, these symptoms went away.”

Nonetheless, she is a chronic Lyme disease patient, and when Kramner stops treatment, she relapses. She is now on Social Security Disability because she is too sick to work.

Kramner has in the past two years turned to the holistic realm for curative therapies. However, she observed to *Hamodia*, “I couldn’t have gotten to this point without the antibiotic treatments I underwent.”

Jennifer Kramner concluded, “My struggles with chronic Lyme disease could easily have been prevented, and happened because I was diagnosed and treated too late. No one should ever have to suffer with chronic Lyme disease, as I do.” ■