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.
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.
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 “powerful 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, 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 Klemper — the Embers study — which was an animal model treatment study. The first [Klemper] study was published in 2001 and was heralded by the IDSA researchers as definitive proof that Lyme disease was 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 Klemper study, 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 primary 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

FEATURES August 26, 2015
LYME IN THE LIMELIGHT
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 ill and lost 30 pounds. Doctors found spirochetes — bacteria — and gave him antibiotics, but he continued to have 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.

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.

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.”
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.

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.

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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.”