NGC Pulls IDSA Guidelines from Website

THE LYME TIMES

Volume 28 • Number 1 • 2016

The Journal of LymeDisease.org

NAVIGATING DISABILITY DENIALS

MyLymeData Reaches a National Audience

Jesse Colin Young Sings About His Lyme Journey

Mayo Clinic Discovers New Species of Lyme Bacteria

lymedisease.org
ADVOCACY, EDUCATION & RESEARCH

LDo advocates nationally for accessible, quality healthcare for patients with Lyme and associated tick-borne diseases. We are committed to shaping healthcare policy through advocacy and education. We fund research critical to improving diagnosis and treatment outcomes. We publish regularly in peer-reviewed medical and healthcare policy publications.

Informing Patients

LDo is the go-to source for news, information, and healthcare policy analysis in the Lyme community. We keep you up-to-date via our website, social media, and The Lyme Times. Visit lymedisease.org and sign up for our free email newsletter. Share your experience and opinion by joining the conversation on our Facebook page: facebook.com/2lymedisease.org. Follow @Lymenews to receive our tweets.

Empowering Patients

MyLymeData — our patient registry and survey tool — enables patients to influence the national research agenda. It is the largest study ever conducted of chronic Lyme disease. This patient-powered research project uses computer technology to collect, combine and assess patient data so researchers can identify successful diagnostic and treatment patterns.

Changing Healthcare Policy

LDo promotes patient-centered care by providing the advocacy muscle to challenge medical societies and protocols that deny treatment. We conduct large-scale patient surveys to inform practitioners and influence legislation. We maintain a national network of online state-based advocacy and support groups, providing online tools like VoterVoice to promote state and federal advocacy efforts.

TLT GOES DIGITAL

After 27 years, this will be the last print issue of The Lyme Times. Starting this summer, TLT will be available online in an all-digital format at our website: *LymeDisease.org*.

All members of *LymeDisease.org* will have convenient access to every issue via their computers or mobile devices so you can read it anywhere. You will be able to download issues and print copies. You can use an online search function to find information easily in any issue. We will publish special issues dedicated to important subjects and update the content as new information becomes available.

ARCHIVE

Features -- Telephone Tree -- News -- Opinion Column

THE LYME TIMES

THE LYME DISEASE NEWSLETTER
OF THE WEST COAST LYME DISEASE NETWORK
CHAPTER OF THE LYME BORRELIOSIS FOUNDATION

*"GOT A LEMON? MAKE LEMONADE!
GOT LYME? MAKE LYME-AID!"*

VOLUME 1, NUMBER 1 FALL, 1989

Introducing the Lyme Disease Newsletter

by Phyllis Mervine, Editor

We, members of the newly formed West Coast Lyme Disease Network, thought it was time to give ourselves a medium for communication, not only among ourselves, but with people all across the country and especially on the West Coast. The goals of this Newsletter are information, support, sharing, and empowerment. We hope to make this a quarterly publication. We were inspired by the recent fruitful efforts of our friends in Minnesota, and hope they will take it as a compliment that we utilize some of their ideas for features, which include: 1) reports of activities, meetings, slide shows, etc. 2) case studies 3) questions and answers about LD, ticks, etc. 4) articles by experts (if we can get any), 5) opinions, 6) telephone tree, and 7) you name it! We are all full of ideas on how to expand and improve our services to you and others. Our program exists to help you, and to help you to help others. It isn't any fun to have a chronic disease, but we sure do have fun working together. We invite you to join us. We welcome your participation on any level, just let us know where you would like to fit in. If you are interested in receiving further issues of this Newsletter, and/or participating in other ways, please return the coupon on page 7.

The Lyme Times is the publication of the West Coast Lyme Disease Network, chapter of the Lyme Borreliosis Foundation, a non-profit national organization founded in 1988 for the purpose of education, research, and patient support.

The Lyme Times is produced on a Macintosh Plus computer using Pagemaker 2.0 software.

The Lyme Times welcomes comments from its readers. Letters may be edited for brevity and clarity and should be addressed to:

Phyllis Mervine, Editor
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Talmage, CA 95481

LDo hopes that making TLT available online will make it possible to provide more up to date information and to communicate our message to an even wider audience. Although stock is limited, back issues of previous print copies may still be ordered.

ILADS GUIDELINES

The 2015 ILADS Guidelines have been downloaded more than 100,000 times! That's in the top 5% of all research articles as scored by a digital science company in London that tracks online interest in scholarly research.

In 2010, another article describing the flawed IDSA Lyme guideline process was also among the top 5% with 30,000 downloads. "The Infectious Diseases Society of America Lyme guidelines: a cautionary tale," written by Lorraine Johnson and Raphael Stricker, was published in the journal Philosophy, Ethics, and Humanities in Medicine (http://bit.ly/1Utx0y3). Together, these articles explain the new ILADS guidelines and why the old IDSA guidelines continue to be so damaging to Lyme patients.

ILADS ANNUAL MEETING

Sheraton Downtown Hotel | Philadelphia, PA
November 3, 2016
The program will include cutting edge research presentations and practical breakout sessions. For more information and to register visit *ilads.org*.

FRONT COVER:
Design by Michele Lott, *MicheleLottDesign.com*
BACK COVER:
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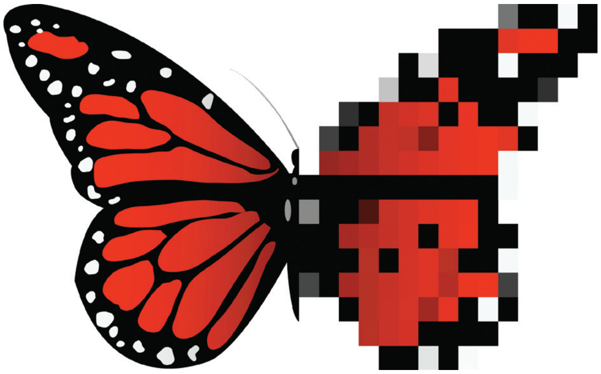
THE LYME TIMES

Volume 28
Number 1
2016



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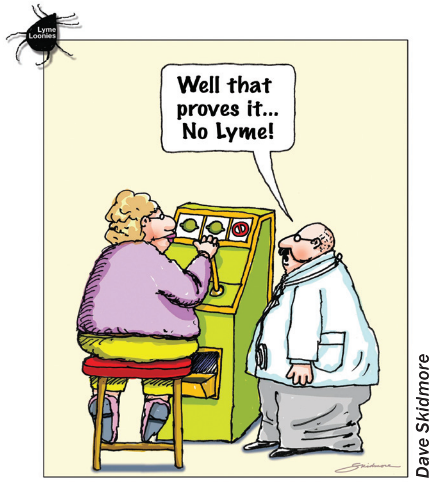

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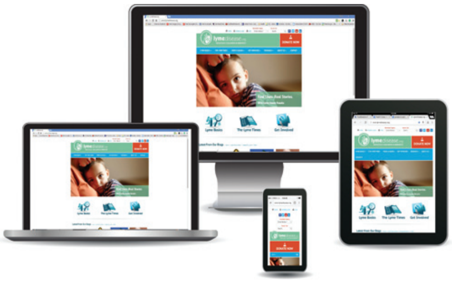

LymeDisease.org ONLINE

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"Like" us on Facebook at *LymeDisease.org*
Visit ourwebsite at *lymedisease.org* aand check out NEWS & BLOGS.

NEWS

Update on young Lyme patient blessed by Pope Francis. 29 MAR Read media updates on Julia Bruzzese, the 12-year old who was thrust into the national spotlight when Pope Francis picked her out from an airport crowd.

Co-infection from ticks is the rule not the exception. 18 MAR According to scientists, *Ixodes* ticks from northern France carried at least two and as many as five pathogens. Study results have been published in PLoS.

Scientists sequence the genome of Lyme-carrying tick. 11 FEB An international team of scientists led by Purdue University has sequenced the complex genome of *Ixodes scapularis*, the tick that transmits Lyme disease — a step towards designing strategies to interfere with the infectious process.

LYME POLICY WONK

Written by Lorraine Johnson, LDo CEO

IDSA guidelines revision to take 2-5 years. 06 APR While their guidelines are outdated and out of compliance with IOM requirements, the CDC continues to post them on their website. It is irresponsible to continue to advise physicians to use these flawed 10-year old guidelines that won't be updated for another 2-5 years.

Are the IDSA's "patient representatives" real or token? 06 APR As the IDSA prepares to revise its 2006 guidelines, advocates are pressing for chronic Lyme patients to be represented on the review panel, clearly a key group that would be affected by the outcome of the process.

TOUCHED BY LYME

Written by Dorothy Kupcha Leland, LDo Vice President

Book Review: Eating Clean, the 21-day Plan to Detox, Fight Inflammation, and Re-set Your Body. 05 APR Amie Valpone, a successful marketing professional, recounts her life-threatening experience and eventual success with functional medicine and her detox diet.

Book Review: How to Heal Yourself When Nobody Else Can. 23 FEB Amy Scher's tale of stem cell therapy in India, Chinese medicine in London, and "energy medicine" in California.

When Your Child Has Lyme Disease: A Parent's Survival Guide Authors Dorothy Leland and Sandra Berenbaum received a "First Place–Adult Non-fiction" award from the Northern California Publishers and Authors association.

FOCUS

I thought I had lost my daughter forever. 05 APR Eliza Hemenway blogs about the book she wrote about her daughter's battle, exposing injustice and hailing perseverance. She joined MLD on behalf of her daughter.

Rapper brings smiles to Lyme community. 8 MAR Sandi Bohle writes about Chris Graber (dba MC Herx) and how many Lyme patients embrace the creative arts during their journey to heal.

I joined MyLymeData because things need to change. 01 MAR Rachel Leland, once wheelchair-bound with Lyme, posts her video blog about why joining MLD is so important.

LDo SYMPTOM CHECK LIST

Does someone you know have Lyme disease?

Check out the Symptom Checklist on the *lymedisease.org* website.

Many people with Lyme (disease) are misdiagnosed. The LDo checklist helps you understand common symptoms and document exposure to TBD infections. It can help your healthcare provider make a proper diagnosis. Identify your symptoms and receive information you can share at your next appointment.

THE LYME TIMES

2016 VOL. 28, NO. 1
Published for members by
LymeDisease.org
www.lymedisease.org
Library of Congress No. 92-595999
ISSN No. 1552-7506

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Printed by Healdsburg Printing, Healdsburg, CA
LymeDisease.org is a 501(c)(3) organization

Ride the Tiger!

So many things happen at once, it feels like we are riding a tiger! Our advocacy efforts took a giant leap forward this winter when Lorraine Johnson was invited to the White House for the Precision Medicine Initiative Summit. This took place after she and I both spoke at the Washington, DC, meeting of the American Association for the Advancement of Science, where we met with government officials, doctors, researchers and other patient advocates. She also spoke at the AAAS annual meeting with Dr. John Aucott, a researcher at Johns Hopkins, and DJ Patel, Chief Data Office at the Office of the White House. Wintry ice and snow outside was offset by everyone's excitement over our Big Data project, MyLymeData, which launched in November. Over a thousand people signed up in the first week (now over 4,000). Read more about it on page 22, and if you haven't joined, join now!

A major development is the removal of the IDSA guidelines from the National Guidelines Clearinghouse website after a five-year free ride (p.13). Also in this issue, Mala Rafik, JD, who wowed the audience at the 2015 ILADS meeting with her talk on disability, begins a series of articles for us. (p.15). And Karen Miller tells you where to send the tick that bites you, if you forget your permethrin-impregnated clothing and insect repellent (p. 27). Also check out our CDC ethics complaint (p.11), the story about Virginia's new doctor protection law (p.14), and my review of Dr. Ken Liegner's encyclopedic new book (p.18).

Last but not least, we're going green! After 27 years as a print publication, this is our last print issue. We have decided to become more ecologically friendly and up-to-date by providing The Lyme Times in a new digital-only format. This will save trees and mailing costs, making your donations stretch further and will be conveniently accessible on your mobile devices and computers.

Starting with the next issue, we will make The Lyme Times available on our website to all *LymeDisease.org* members. You'll be able to read it several weeks earlier than you would receive the print version by mail. You'll be able to download articles to your own computer, tablet or smartphone to read offline or when traveling. You'll have tools to quickly find exactly what you're interested in by searching for text or key words. There will be space for you to comment on articles and discuss important issues with other readers. Another good thing about this switch is that The Lyme Times can become a more effective tool for communication and education over a wider population.

Content will remain the same high quality The Lyme Times is known for. In fact, it will even get better since we will be able to add videos and links to additional resources on the Web. The Lyme Times will continue to be an important part of the toolkit in our mission to improve the lives of people with Lyme and other tick-borne diseases.

Until next time, hold onto that tiger and enjoy the ride! Things are happening!

CONFERENCES

Science Serving Patients

LDA conference presents balanced perspectives from cutting-edge researchers

By Tim Lynagh and Pat Smith

Doctors and patients benefit greatly from knowing and sharing medical and scientific advancements. That is especially important for those facing the complexities of tick-borne diseases (TBD) including Lyme.

Columbia Research Center Director Brian Fallon applauds Pat Smith after her speech.

Over the years, the non-profit Lyme Disease Association Inc. (LDA) has provided continuing medical education (CME) that clinicians and researchers need. Held in various states and most often in partnership with Columbia University, the 2015 conference was convened in Providence, Rhode Island.

Like all CME conferences, the LDA/Columbia program must adhere to strict guidelines in order to award education credits. The guidelines are developed from the Accreditation Council for Continuing Medical Education, the American Medical Association, and, if applicable, the FDA, especially regarding conflicts of interest and ethics. Material and presenters are screened accordingly. Pat Smith, conference organizer, and Brian Fallon, conference director, ensure all guidelines are followed.

As one of LDA's priorities is to educate physicians, we strive to offer depth and breadth of science at our conferences, offering a balanced perspective from cutting edge researchers worldwide. Since Lyme diagnosis and treatment are largely clinical in nature, doctors need to understand the hard science to foster better patient outcomes. We announce the conference to thousands of doctors and representatives from every level of government. The conference reception and faculty dinner provide networking opportunities that often result in fruitful collaborations. More than one now prominent Lyme researcher has begun to focus on Lyme after participating in an LDA conference.

Thanks to a grant from the Steven and Alexandra Cohen Foundation, LDA provided scholarships for medical students and postdocs for the 2015 conference, exposing them to a range of facts and perspectives before they develop misinformed bias.

Precis of Presentations

Patricia Smith, BA, LDA President, opened the conference with a brief overview of the spread of Lyme disease to over 80 countries worldwide and the spread of ticks and TBD throughout the U.S.

William Robinson, MD, PhD, Stanford (CA), presented the keynote "Next Generation Diagnostics for Lyme Disease." He has developed multiplex assays for the early and accurate diagnosis of *Borrelia burgdorferi* (*Bb*) infection and for characterizing inflammatory responses in post-treatment Lyme disease syndrome (PTLDS), as well as the sequencing of B- and T-cell repertoires in acute *Bb* infection and PTLDS.

Charles Chiu, MD, PhD, UCSF (CA) is harnessing genomics to develop new assays for diagnosing Lyme and Lyme-like illnesses. Genetic tools in development include a microarray platform (tick chip) that will enable identifying a range of pathogens; a real-time metagenomics pathogen detection platform with nanopore sequencing; and a Lyme disease gene expression panel obtained by transcriptome profiling of patients.

Kim Lewis, PhD, Northeastern (MA), described the ability of *Bb* to form persisters that are a dormant variant of regular cells and difficult to eradicate. Combinations of antibiotics did not improve killing. An anti-cancer agent killed persisters, eradicating growing and stationary *Bb* cultures, however, and pulse-dosing with selected antibiotics eliminated persisters.

Ying Zhang, MD, PhD, Johns Hopkins (MD), described complex phases of Lyme and persisters as a one of the probable causes of PTLDS. Many other antimicrobials and an anti-cancer drug have better action against *Bb* than current Lyme drugs. Zhang's data indicate that three drug combinations are more effective at eradicating the more resistant form of *Bb* persisters, (i.e., microcolonies), than single or two-drug combinations *in vitro*. Zhang recommended treatment trials with different lengths of treatment.

Public Health England has regular meetings with Lyme Disease Action, the main UK advocacy group, and cross references their literature.

Tim G. Brooks, MA, MB, BChir, LMSSA, MSc, FRCPath, FRSPH, Public Health England (UK), discussed Lyme Borreliosis in England, observing that "the ability to question mantra and share with colleagues" reflects the more open attitudes there. Public Health England has regular meetings with Lyme Disease Action, the main UK advocacy group, and cross references their literature. The UK only has 1,200 laboratory confirmed cases annually, but a much larger number who are treated empirically by family doctors. Roughly 60% of Lyme cases are caused by

Borrelia garinii and 30% by *B. afzelii*; neurological disease is relatively common. He attributes on-going symptoms to a likely combination of persisters, immune mediation, and structural damage. He emphasized that new genetic testing methodologies are critical; more research on pathogenesis and better designed trials are needed. Policy changes are underway.


Ken Liegner, NY physician, exchanging ideas.

Nicholas Komar, SD, CDC (GA), discussed several tick-borne viruses, focusing on Heartland virus, which is more widespread than previously thought. Carried by the lone star tick, 13 out of 19 states sampled were found to have this virus.

Geeta Ramesh, PhD, Tulane National Primate Research Center (LA), presented her work on inflammation in neuroborreliosis, affecting the central and peripheral nervous systems. Treatment needs to eliminate infection and control neuropathic pain and inflammation. Her hypothesis is that *Bb* induces inflammatory mediators in glial and neuronal cells. Experimental treatment of infected animals with different anti-inflammatory drugs had different effects.

Hassan M. Minhas, MD, MB, BS, Yale, reported on a patient presenting with drastic and non-treatment responsive psychiatric symptoms who had Lyme neuroborreliosis. The psychiatric symptoms improved with IV antibiotics. He advised that *Bb* immunoassays should become part of normal testing in hospitals.

Klemen Strle, MD, Harvard, observed that *Bb* does not produce toxins, and clinical features of Lyme disease result from the host immune response to infection. Specific microbial and host factors and their interactions may set the stage for the immune responses associated with severe clinical manifestations of Lyme disease. His key objectives are to develop biomarkers to identify patients at greater risk for more severe disease and to elucidate pathogenic mechanisms to identify better treatments.

> *Bb* does not produce toxins and clinical features of Lyme disease result from the host immune response to infection

Brian A. Fallon, MD, MPH, Columbia Univ. (NY), presented developments in post-infectious neuropsychiatric disorders, focusing on PANDAS (neuropsychiatric disorders occurring after strep in children) and PANS (neuropsychiatric disorders occurring after other microbial infectious triggers). He told about a 10 year-old girl who developed severe obsessive-compulsive disorder overnight, with 4 to 6 hours of rituals daily, who improved when treated for Lyme. He discussed a joint study with Madeleine Cunningham of 200 individuals with a history of Lyme (various stages) who were assessed using the Cunningham Panel of anti-neuronal antibodies and the Cam Kinase Assay. He suggested that when there is a severe onset neuropsychiatric symptoms, an exogenous cause (such as infection or family history of autoimmune disorders) should be considered.


Jyotsna Shah, president of IGeneX Labs, and NY physician Richard Horowitz in discussion.

Philip J. Molloy, MD, FACP, Tufts (MA), discussed the epidemiology of *Borrelia miyamotoi*, an emerging tick-borne pathogen transmitted to humans by deer ticks. The first known cases in N. America were reported in 2013. Dr. Molloy *et al.* recently published (Annals Int Med July 21, 2015) a case series describing 51 patients with acute *B. miyamotoi* infection. Clinical symptoms are nonspecific, but may be severe. They have not been able to culture the organism or to find it in synovial fluid; *B. miyamotoi* serology testing may be cross reactive with *Bb*.

Richard T. Marconi, PhD, Virginia Commonwealth, presented his lab's work on developing human vaccines for TBD. The new vaccine technology centers on the use of linear, protective epitope-based chimeric proteins called chimeritopes. One advantage of this approach is to protect against several pathogens. They have already created three different variants of chimeritopes, and there is nothing that prevents from adding other pathogens to a chimeritope.

> The new vaccine technology centers on the use of linear, protective epitope-based chimeric proteins called chimeritopes.

John N. Aucott, MD, Johns Hopkins (MD), noted that Lyme disease is biologically complicated and measurement is the key to understanding. In his prospective cohort study, SLICE, samples have been taken from over 1,000 different patient visits. Of particular interest, serum cytokine and chemokine biomarkers seem elevated in acute Lyme disease. Levels of most cytokines and chemokines fall to normal values after initial antibiotic treatment. Persistent elevation of these biomarkers, however, may suggest ongoing host inflammation after standard antibiotic therapy. Biomarkers may prove useful in monitoring response to therapy and identifying who may require extended treatment.

Continued on page 5

The Origins of *Borrelia burgdorferi s.s.*

The evolutionary history and structure of *Borrelia burgdorferi sensu stricto*, the infectious agent of Lyme disease, remain obscure. A study published online in *Scientific Reports (*March 9, 2016) indicates that this tick-transmitted bacterial species occurs in both North America and Europe. Researchers sequenced 17 European isolates and compared them with 17 North American strains. They found three distinct genetically differentiated groups: the outgroup species *Borrelia bissettii*; two divergent strains from Europe; and a group of strains from both the U.S. and Europe. They deduced that a European origin of *B. burgdorferi* s.s. is marginally more likely than a U.S. origin. Irrespective of whether *B. burgdorferi* s.s. originated in Europe or the U.S., later trans-Atlantic exchange(s) have shaped the population structure of this genospecies. Further sequencing could clarify the phylogeography of this bacterial species.

For a free full text of this study, visit nature.com/articles/srep22794.pdf.

Science, continued from page 5

Biomarkers may prove useful in monitoring response to therapy and identifying who may require extended treatment.

Edward B. Breitschwerdt, DVM, North Carolina State, presented his research on Bartonellosis. There are 36 named species of *Bartonella*, many of which have been associated with spreading disease to animals and humans. *Bartonella* bacteria are transmitted by arthropod vectors, including fleas, lice, mites, sand flies and ticks. Cat fleas carry 5 or 6 species of *Bartonella*, and there may be inhalation of bacteria from flea feces, making it a risk to veterinary workers. Tick transmission of *Bartonella* to humans is being investigated. Diagnosis is based on PCR, culture, and DNA sequence. Chronic bloodstream infections with *Bartonella* have been documented in healthy and sick animals and in humans.

Erin McGintee, MD, Allergy/Clinical Immunology Practice and Southampton (NY), discussed her clinical experience with the Alpha-gal meat allergy which may be triggered by the bite of the *Amblyomma americanum*, lone star tick. This allergy can appear in a patient who never had a problem eating meat, which is atypical compared to most food allergies.

Raphael B. Stricker, MD, and **Sam T. Donta**, MD, participated in a point and counterpoint discussion of the potential for sexual transmission of Lyme disease. Stricker's information from preliminary clinical, epidemiological and immunological studies in animals and humans, suggests that Lyme could be transmitted by intimate contact from person to person. Donta countered that analyses of epidemiological and clinical data indicate it is most unlikely that Lyme can be sexually transmitted. More determinative research is needed.

William V. Padula, OD, DPNAP, FAAO, FNORA, Western Univ.(CA), presented research findings on the affects of Lyme on vision and visual processing. The visual process affects 70% of the nerves in the body. Dysfunctions of the visual/spatial process cause eyestrain, headaches, spatial disorientation, light sensitivity and blur. The effects of spatial disorientation can be readily observed in rigidity of the body, posture, and unsteady movements. Padula's video demonstrated how wearing prisms can reduce focal binding and improve spatial orientation.

Richard S. Ostfeldt, PhD, Cary Institute of Ecosystem Studies (NY), discussed the amplification of pathogens (such as *Bb*, *Babesia*, and Anaplasma) in communities of hosts. Lacking a vaccine and given problematic diagnosis and treatment, prevention is critical and requires an understanding of the risk of infection. Experimenting with ticks and animal hosts in the Northeast, Ostfeld determined that the white-footed mouse, chipmunk, and shrew were the most highly competent reservoirs for all three pathogens. A lack of biodiversity and a less diverse assemblage of predators increases risk by increasing the abundance of these small mammals.

Lacking a vaccine and given problematic diagnosis and treatment, prevention is critical and requires an understanding of the risk of infection.

Looking forward

Feedback on the 2015 conference was positive. Pat Smith, Brian Fallon, and all who helped organize the conference are extremely grateful to the presenters for taking the time to share their work and expertise to help move the science forward and to equip practitioners and patients with new knowledge and perspectives. LDA and its partners have already begun to track progress, developments, and breakthroughs to present at the 2016 conference. Look for announcements on *Lymediseaseassociation.org*.

LDA Honors Nick Harris, PhD

"This One's For You, Nick," toasted LDA President Pat Smith celebrating his contributions

With gratitude from Lyme patients everywhere we salute you … for your dedication to the Lyme community and your unflagging commitment to helping patients have a better life.

[Excerpted from remarks delivered by LDA President Pat Smith at the LDA conference in Providence, Rhode Island, November 13, 2015.]Every movement has memorable faces that define progress. Not many are better known within the Lyme movement than Nick Harris. In my years of travel, I have heard him mentioned with gratitude and respect by patients, physicians, and researchers alike.

Nick is a true champion of patients. His passion, commitment, and dedication to the science of Lyme are legendary.

First and foremost, Nick is a scientist. His training, experience, and business acumen enabled him to establish IGeneX, a specialty lab for testing tick-borne diseases (TBD). The testing controversy is at the heart of the issue. Outdated testing methods still mandated by the government, cause a vast amount of under-diagnosing and delayed treatment. Because of his expertise, Nick took a dissenting stand in 1994 in Dearborn, Michigan, challenging the Lyme testing decision reached there by a panel that allowed no dissension and decreed the use of only a few specific bands —the only bands approved by CDC ever since.

Understanding the diagnostic dilemma, Dr. Harris developed tests that increase sensitivity by using more than just one lab strain of *Borrelia*. IGeneX also publishes the actual band results from the Western blot, rather than simply a positive or negative conclusion, allowing Lyme-literate physicians to interpret the data for clinical relevance.

Nick is a humanitarian. He has often reached out to patients and their families in need… helping those who lack the financial ability to attend important meetings on TBD, establishing a fund for those who require testing. He's been personally available for patients and their physicians, charting the best course of diagnostic action to address so many new TBD and navigating the waters of immunology, a field he knows so well.

He has helped organizations struggling to spread the word on TBD. He has served uncompensated as a member of the LDA's Scientific and Professional Advisory Board. IGeneX supports publication of the LDA's *LymeR Primer* and *ABCs of Lyme Disease.* He has helped other patient nonprofits in their missions, especially *LymeDisease.org*, an organization with which LDA is proud to be affiliated.

Working with the late Theresa MacKnight, Harris initiated the formation of ILADS, the first professional physician group to help understand the diagnosis and treatment of TBD. It was about time! Over the past 15 years, Nick has helped shape Lyme disease policy. His personable presence has always been an asset and his presentations always articulate and factual.

Above all, Nick is a family man — a devoted husband, proud father and grandfather. He and his wife, Aileen, have generously opened their home to me on my trips to California. Perhaps Aileen thought that might keep me from dragging Nick to meetings all over the U.S!

LDA paid tribute to Nick Harris at a celebration prior to the LDA Conference in Providence, RI.

LDA has always found Nick to be ethical and honest in all his dealings. We have the greatest respect for him as a person and a scientist. He has worked hard to help all those suffering with TBD.

Speaking for the LDA and for patients throughout the world, I say, thank you, Dr. Nick Harris, "he who must be named" and "he who must be honored" for your many contributions toward the health and well-being of so many. And thank you for being our friend and mentor. We love you, Nick.

Editor's note: Pat Smith presented Dr. Harris with an award and letters of tribute, including one from Representative Christopher H. Smith, co-chair of the U.S. House of Representatives Lyme Disease Caucus. Despite retirement, Harris plans to remain active in the Lyme community.

CONFERENCE

Research Review

Addressing ILADS, Ray Stricker critiques the best (and worst) studies published in 2015

Editor's Note: In the closing Plenary session of the ILADS 2015 conference, Ray Stricker, MD, reviewed the best and worst studies published in the Lyme disease literature. He divided them into two groups: evidence-based peer-reviewed articles and opinion-based peer-reviewed articles. This excerpt summarizes the "best" of those studies.

The top entry in the "best" group was authored by Dan Cameron, Lorraine Johnson, and Betty Maloney, all members of the working group who drafted revised ILADS Guidelines in 2014 [see TLT 27-1 published in 2015]. Evidence assessments and guideline recommendations in Lyme disease: the clinical management of known tick bites, *erythema migrans* rashes and persistent disease.

CDC vs IGeneX Western Blot Results

WB Strip Source	Number (percent) positive Interpreted with CDC criteria			Number (percent) positive Interpreted with IGeneX criteria		
	1gG	1gM	Total	IgG	IgM	Total
Marbelet WB (Single strain)	27 (49)	18 (31)	27 (??)	23 (66)	18 (51)	28 (80)
IGeneX WB (Double strain)	22 (63)	27 (77)	31 (89)	36 (86)	28 (20	34 (97)

Shah, et al., *Chronic Dis. Ixt.* 2014;1:7

- First guidelines for Lyme disease developed in accordance with the Institute of Medicine (IOM) standards.
- First guidelines for Lyme disease based on the rigorous Grading of Recommendations Assessment, Development, and Evaluation (GRADE) process.
- Only Lyme disease guidelines that included a patient from the Lyme community as an author or as a member of the guidelines development panel, as recommended by IOM.

A trio of CDC articles indicates 300,000 or more cases of Lyme disease diagnosed per year in the U.S. Hinckley, *et al.* compared testing by large commercial laboratories. Hook *et al.* shared results from national HealthStyles surveys of the public's experience with ticks and TBD. Nelson, *et al.* presented data on the incidence of clinician-diagnosed Lyme in the U.S. 2005-2010.

P.J. Mayne looked at 500 patients and found a considerable presence of Lyme borreliosis and co-infections in Australia. He found Morgellons disease in 6%. Molloy *et al.* found that patients in the northeastern U.S. with *B. miyamotoi* infection presented with nonspecific symptoms including fever, headache, rigors, myalgia, and arthralgia.

Bartonella rash showing typical skin lesions.

M.J. Cook reviewed data on transmission time after tick attachment. In animal models, *Bb* transmission can occur in less than 16 hours, although the minimum attachment time for transmission of infection has never been established. Systemic tick infection and the presence of spirochetes in tick salivary glands prior to feeding could result in rapid *Bb* transmission from ticks to humans.

Zhang, *et al.* examined the composition and transmission of microbiome in hard ticks. The study showed that 237 bacterial genera were commonly detected in unfed ticks, fed ticks, and rat blood samples after tick bites.

Scott and Durden discovered new records of the Lyme bacterium in ticks collected from songbirds in central and eastern Canada, and concluded that migratory songbirds play an integral role in the wide dispersal of *Bb*-infected ticks. They warned that U.S. clinicians must be aware that people can be bitten by infected ticks released by songbirds from Canada.

Middelveen *et al.* cultured and identified *Bb* spirochetes in human vaginal and seminal secretions. These cultures of viable *Bb* spirochetes suggest that Lyme could be transmitted by intimate contact from person to person. The authors concluded that further studies are needed to evaluate this hypothesis.

Adrion *et al.* examined health care costs associated with Lyme. A database of 47 million persons enrolled in a wide range of U.S. commercial health insurance plans. Of the potential 547,993 Lyme cases, 52,795 were analyzed. Over 63% of those had at least one diagnosis associated with post-treatment Lyme disease syndrome (PTLDS), or Chronic Lyme. The presence of this diagnoses after treatment is associated with significant health care costs and patient utilization.

Shah *et al.* of IGeneX Labs presented evidence of improved sensitivity of Lyme disease Western blots prepared with a mixture of *Bb* strains 297 and B31. Testing a total of 364 control and patient sera, they found that using their in-house IgG and IgM Western blot and their in-house interpretation criteria (2/6 positive bands) resulted in a combined sensitivity of 97.1%. Removal of patients who reacted to band 31kDa but tested negative for antibodies to recombinant OspA antigen boosted in-house IgG and IgM Western blot specificity to >97%.

Continued on page 10

From Bench to Bedside

ILADS features breakthrough research to improve patient care

Last October, attendees at the ILADS annual conference learned about scientific and medical discoveries that may improve the care of Lyme patients. Presenters spoke of the potential to help practitioners better diagnose and treat Lyme. Topics included: emerging laboratory testing; integrative, herbal and nutritional treatments; and pediatric TBD. Chris Green, MD, spoke about the epidemiology and ecology of TBD. Betty Maloney, MD, summarized clinical trials on the microbiology and pathophysiology of Borreliosis.

Updates on Lyme co-infections and related diseases included *Babesia*, *Bartonella*, *Rickettsia*, *B. Miyamotoi*, and Morgellons. Rising cases of Lyme in the Southern U.S. was addressed. Joe Burrascano, Jr., MD, moderated presentations on current testing and treatment options; Leo Shea, III, on pediatric neuropsychiatric Lyme; and Ray Stricker, MD, on advances in laboratory testing. There were special sessions for Naturopathic practitioners and non-physicians.

ILADS presented two prestigious awards: its Pioneer Award to researcher Alan B. MacDonald, MD, for tirelessly investigating correlations between TBD and other diseases; and the John Drulle Award to Joe Burrascano, MD, for exceptional dedication to his patients.

Dan Cameron, MD, passes the torch to incoming ILADS President, Sam Shor, MD, at the 2015 annual conference. *Credit: Dan Cameron*

Leo Shea III, MD (right), President of the ILADS Education Foundation, honors Alan MacDonald, MD, with the 2015 Pioneer Award. *Credit: Melissa Bell.*

Dorothy Leland, Vice President of LDo, and Dan Cameron, MD, President of ILADS, enjoy a moment at LDo's exhibitor table.

Joesph Burrascano Jr., MD, was the 2015 recipient of the Research Award in Remembrance of John Drulle for his commitment to patient-centered practice. *Credit: Melissa Bell.*

CONFERENCE

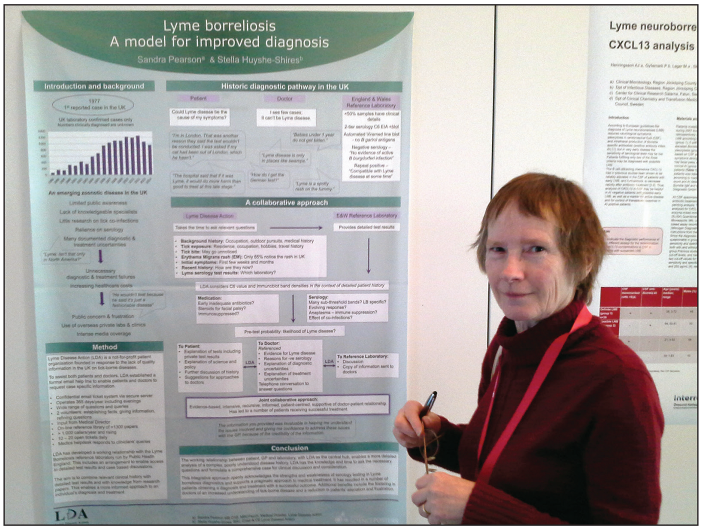
International Collaboration

Nordic scientists create research network and debate guidelines

A February conference on tick-borne diseases held in Sweden brought together leading scientists from Norway, Denmark, Sweden and Finland. It was organized by the Norwegian Tick Research Network (NorTick) and the Swedish tick research network SNÄFF (Sveriges NÄtverk av Fästing Forskare). Scientists, doctors and students from nine countries attended.

Members of the United Kingdom's Lyme Disease Action (LDA) contributed significantly to the conference debate. Awareness of TBD is low among clinicians and the public in the UK. Collaborative efforts are underway, however, among LDA-UK, Public Health England and the National Health Service-England, to improve diagnosis and treatment.

When discussion strayed into ascribing Lyme symptoms to psychiatric disorders, LDA's Sandra Pearson chimed in, speaking as a practicing psychiatrist.



Stella Huyshe-Shires, Chair of LDA-UK, presents their poster reflecting the UK collaboration to improve care for TBD. Photo credit: Sandra Pearson

Highlights

by Sandra Pearson, MD

Presenters addressed issues involving TBD in Europe, including problems with the current case definitions in European guidelines. Among the many topics covered were the spread of Lyme Borreliosis by small rodents in North America; Lyme disease in livestock; tick attachment in roe deer; the incidence of tick bites and EM in four Norwegian counties; *Babesia* species in Norwegian ticks; migrating birds (especially Robins) carrying infectious agents; T-cell responses accompanying continuing symptoms after IV treatment; the sensitivity and specificity of T-cell tests in light of false negatives and positives; approaches to reducing diagnostic and therapeutic uncertainties; doxycycline failures; and ways to improve the diagnostic sensitivity of PCR testing.

The program highlighted progress being made at a central clinic for vector-borne infections in Denmark. This clinic provides coordinated diagnosis and treatment by a team of specialists in neurology, clinical microbiology, rheumatology, immunology and dermatology. They are also creating a research database and biobank.

Despite differences in characteristics of Lyme cases, Sandra recognizes unfortunate similarities shared by the UK and Nordic countries, especially a critical lack of awareness of bTBD and disbelief in chronic Lyme.

Sandra Pearson is the medical director of Lyme Disease Action, the TBD patient advocacy organization in the U.K. For more information, visit lymediseaseaction.org.uk.

Research Review, continued from page 10

Meriläinen *et al.* distinguished different pleomorphic variants of *Bb* by looking at their unique biochemical signatures. These pleomorphic forms are clinically relevant and will influence the development of novel diagnostics and treatment protocols.

Timmaraju *et al.* looked at biofilm formation by *Bb* sensu lato. Using high-resolution atomic force microscopy revealed similarities in the ultrastructural biofilm organization of three *Borrelia* species, suggesting that biofilm formation might be a common trait of *Borrelia* physiology.

Sharma *et al.* found that antibiotic treatment of cell-free *Bb* cultures resulted in a small subpopulation of surviving cells. Upon regrowth, these cells formed a new subpopulation of antibiotic-tolerant cells, indicating that these are persisters rather than resistant mutants. Combinations of known antibiotics did not improve killing of persisters in cell-free cultures.

Feng *et al.* tried drug combinations against *Bb* persisters *in vitro*. *Bb* developed increasing antibiotic tolerance as morphology changed from typical spirochetal form in log phase growth to variant round body and microcolony forms in stationary phase. *Bb* appeared to have higher persister frequencies than E. coli as a control. Further studies could clarify whether combination antibiotics can clear persisters in animal models and human infection.

Middelveen *et al.* explored the association between Morgellons and Lyme and identified *Bb* in Morgellons disease patients. Using multiple detection methods, researchers confirmed that Morgellons is a true somatic illness associated with the *Bb* spirochetes that cause Lyme disease. Further studies could determine the optimal treatment for this spirochete-associated dermopathy.

Stricker concludes that good work is being done on the epidemiology and pathogenesis of tick-borne diseases. He believes that much more research should be directed towards the diagnosis and treatment of TBD.

Meanwhile, the "Lyme Wars" continue.

ADVOCATES IN ACTION

Advocates Accuse CDC of Bias and Favoritism

CDC promotes outdated IDSA guidelines while ignoring new ILADS guidelines

By Debra McGregor

TO: CDC/ATSDR Ethics and Compliance Activity office

FROM: Attendees of the CDC Vector Borne Disease/Lyme Tick Borne Disease Advocacy Meeting June 11, 2013 (Fort Collins, CO.)

RE: CDC Favoritism Toward A Private Association of Physicians Discrimination Toward a Competing Association of Physicians Denial of the Opportunity for Citizens to Chose Their Treatment Plan

DATE: Feb 4, 2016

The Centers for Disease Control (CDC) promotes a single, outdated set of treatment guidelines for Lyme and tick-borne diseases in this country. See below, one example found on their website:

Q: Why does CDC only link to one set of treatment guidelines?

A: CDC believes that the IDSA guidelines currently represent the best available synthesis of the medical literature on the diagnosis and treatment of Lyme disease. The IDSA with input from CDC experts and other doctors has developed and published Lyme disease treatment guidelines. Please note that the CDC does not produce Lyme disease treatment guidelines.

Hundreds of thousands of Americans have been treated for Lyme and tick-borne diseases utilizing the 2006 Infectious Diseases Society of America (IDSA) treatment guideline protocols recommended on the CDC website. Unfortunately, a substantial number of these cases result in treatment failure, often with very serious consequences.

The CDC lends legitimacy to the fact that patients' insurance plans rely heavily on the IDSA guidelines to determine coverage and/or the denial of it.

These 2006 IDSA guidelines:

- Are 10 years old, hence miss hundreds of published research articles
- Do not comply with current IOM standards
- Do not use GRADE process
- Were written by authors who have known conflicts of interest
- Do not meet National Guideline Clearing House (NGC) standards for being listed on the NGC website (although they are listed)

The CDC has been informed on many occasions of the obstacles patients and their physicians face in attempting to return to good health utilizing these old IDSA guidelines, but in particular, at a meeting they convened at their Ft. Collins, CO, office on 6/11/13. This was a meeting initiated by the CDC Vector Borne Disease Group and organized by their staff. The invitees included a list of well-respected advocates from around the country, hand-picked by the CDC employees. At that meeting advocates agreed that their top priority was to end the CDC's bias in recommending the IDSA guidelines and urged the CDC to take steps to correct the situation.

Since that meeting, another medical group who treats Lyme and tick-borne diseases named the International Lyme & Associated Diseases Society (ILADS) has published an updated treatment protocol. The new 2014 ILADS Lyme and associated tick-borne disease guidelines:

- Are current
- Conform with the new Institute of Medicine standards
- Are evidence-based
- Use the GRADE process
- Authors have no conflicts of interest
- Are listed on the National Guideline Clearing House website

On 11/13/15, one of us (DM) sent an email request [attached] to the two CDC employees who arranged the 2013 meeting in Ft. Collins, asking them to add the new 2014 ILADS Guidelines to their website, along side the old 2006 IDSA Guidelines in an effort to give patients/physicians the opportunity to chose another treatment plan. This is common in many disease entities where more than one protocol exists.

The CDC employees (C. Ben Beard, PhD, Chief of Bacterial Diseases Branch of DVB) and (Lyle Peterson MD, MPH, Director of DVB) responded with a denial of our request on 12/2/15 stating:

"At this time, CDC continues to believe that the guidelines published by the Infectious Diseases Society of America remain the best source of evidence-based information for physicians who are diagnosing and treating Lyme disease." [attached]

On 12/23/15 a second email response from the same CDC employees was received further clarifying their positions:

"I assure you that we have read the current ILADS guidelines carefully. We cannot comment further other than to say that for now we respectfully disagree with your position on this issue." [attached]

We have now determined that both Beard and Peterson report to Beth P. Bell MD, MPH (Director, National Center for Emerging and Zoonotic Infectious Diseases or NCEZID) of the CDC, who is a Fellow with the private medical professional association named above — the IDSA.

It is also determined that Beth P. Bell, MD, MPH, reports to Rima Khabbaz, MD (Deputy Director, Office of Infectious Diseases or OID) of the CDC, who is also a Fellow with the private medical professional association named above — the IDSA.

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Borrelia mayonii Discovered

Mayo Clinic identifies new Lyme-like disease

By April Josselyn

Mayo Clinic researchers, in collaboration with the Centers for Disease Control and Prevention (CDC) and health officials from Minnesota, North Dakota and Wisconsin, have discovered a new bacterial species that causes Lyme disease in people.

The new species has been provisionally named *Borrelia mayonii*. Prior to this finding, the only species believed to cause Lyme disease in North America was *Borrelia burgdorferi*.

In the paper published recently in *The Lancet Infectious Diseases*, Mayo Clinic scientists tested samples from U.S. patients from 2003 to 2014 for evidence of Lyme disease using a method called polymerase chain reaction (PCR). From 2012 to 2014, the researchers noticed unusual test results from 6 of 9,000 samples from residents of Minnesota, North Dakota and Wisconsin.

"Using a laboratory-developed test with a method called 'melting temperature analysis,' we detected six specimens that produced a PCR result that was clearly different from *B. burgdorferi*," says Bobbi Pritt, M.D., director of the Clinical Parasitology Laboratory at Mayo Clinic, who is first author of the study.

"Mayo Medical Laboratories, the reference laboratory at Mayo, has tested more than 100,000 patient samples from all 50 states over the past decade using our PCR assay, but we've only recently detected evidence of *B. mayonii*."

Based on these findings, the researchers believe that the organism may have only recently emerged in the upper Midwestern U.S. "It is possible that this species has been present for even longer but at such low levels that it escaped detection," adds Dr. Pritt.

As with *B. burgdorferi*, researchers believe that *B. mayonii* is transmitted to humans by the bite of an infected black-legged tick (otherwise known as the deer tick). Typical symptoms of Lyme disease include fever, headache, rash, neck pain, and arthritis in later stages.

Unlike *B. burgdorferi*, however, *B. mayonii* causes an illness that appears to be associated with nausea and vomiting, diffuse rashes (rather than a single bull's-eye rash), and a higher concentration of bacteria in the blood.

Patients infected with *B. mayonii* will test positive for Lyme disease with currently available U.S. Food and Drug Administration-cleared Lyme disease tests. In some instances, *B. mayonii* bacteria also may be seen on a blood smear.

Dr. Pritt adds, "At this time, there is no evidence that *B. mayonii* is present outside of the Upper Midwest. However, the public should continue to take the recommended precautions against tick bites, as Lyme disease and other tick-borne diseases are well-established in much of the Northeast."

This story was based on a press release issued by the Mayo Clinic February 5, 2016.

CDC Bias and Favoritism,

continued from page 11

It is our belief that these CDC employees, who are making decisions affecting the lives of hundreds of thousands (recent estimates indicate maybe millions) of citizens, are biased by their professional and career affiliation with a private medical group. The CDC cannot, and should not, eliminate treatment options for vast numbers of citizens based on their allegiance to a powerful, private group. This constitutes an unethical abuse of power.

The 2014 ILADS guidelines adhere to a much higher standard than the outdated 2006 IDSA guidelines, which are known to be often ineffective and even damaging to a patient's health. There is NO legitimate reason that they should be eliminated as a treatment option for the American public. Americans deserve the opportunity to obtain a second opinion.

We respectfully request this bias be eliminated by the CDC and either allow:

1. Both sets of guidelines to be posted by the CDC on their website/ literature …
2. Neither guideline to be given sole preferential treatment with a recommendation by the CDC (clinicians/patients can be referenced to the NGC website to chose the appropriate therapy that works for them.)

The Executive Branch employees are required to behave with impartiality.

Signed/

Debra McGregor
(Texas Lyme Disease Association)
Betty Maloney MD (Minnesota
Lyme Disease Association)
Phyllis Mervine (*LymeDisease.org*)
Monte Skall (NatCapLyme)
Kathy White (Kansas Lyme Support)
Linda Lobes (Michigan Lyme
Disease Association)
Jill Auerbach (Dutchess
County Lyme Advocacy)

INFECTIOUS DISEASES SOCIETY OF AMERICA

NGC Delists IDSA Guidelines

The Society's guidelines no longer meet IOM trustworthy standards

By Lorraine Johnson, JD, MBA

The National Guideline Clearinghouse (NGC), a federal database providing treatment information to health care professionals and insurance companies, recently removed the Infectious Diseases Society of America's (IDSA) Lyme disease treatment guidelines from its website. The NGC considers them out of compliance with their current standards.

This means that the only Lyme disease guidelines listed on the NGC are those of the International Lyme and Associated Diseases Society (ILADS) posted in 2014. This is quite good for the Lyme community.

Backstory

In 2006, shortly after the IDSA published its most recent guidelines on the treatment of Lyme disease, then-Connecticut Attorney General Richard Blumenthal filed an antitrust investigation of them. The IDSA settled the investigation by agreeing to review its guidelines in a public hearing, allowing time for the IDSA, patients, clinicians, and scientists who held opposing views.

The hearing panel — of exclusively IDSA members — released its findings in 2010 and endorsed the society's guidelines. Although panelists recommended 25 changes, the Society felt that no changes were necessary. The NGC allowed these guidelines to be posted for an additional five years essentially without having to review and revise them. *LymeDisease.org* protested this extension with the NGC.

In 2014, however, the NGC revised its criteria for listing clinical practice guidelines. To be "trustworthy," they now must conform to standards adopted by the Institute of Medicine (IOM) in 2011, including a rigorous evidence review system. Previously, when the IDSA guidelines did not comply, they had been given a "free pass" because they had been filed before the NGC adopted the IOM standards. The ILADS guidelines now posted by the NGC conform to those high standards.

LDo had been expecting the IDSA to file another "no change" extension and to continue to receive its "free pass." Instead, the NGC recently delisted those guidelines because they had passed their five-year mark and did not comply with their more stringent requirements.

Ongoing revisions

In May 2015 the IDSA announced plans to revise their guidelines and outlined their review process. LDo and the Lyme Disease Association (LDA) encouraged comments from nearly 90 patient groups protesting the process, which (among other things) did not include a chronic Lyme patient on their panel. The IOM maintains that adequate patient representation helps ensure the integrity of the process, including a sensitivity to patient needs and a safeguard against conflicts of interest.

In March 2016 LDo filed another 6,100 comments. Following public protests and pressure from U.S. congressmen, the IDSA indicated it might reconsider seating a Lyme patient on the panel. As we go to press, they have proposed adding three patients and one parent of a child "treated for Lyme." Since the IDSA has not released their names, we do not if they can be trusted to represent the interests of chronic Lyme patients.

Although the IDSA's flawed guidelines are now almost 10 years old, they are still posted on the CDC website while the ILADS guidelines are not. The IDSA expects their revised guidelines to be completed within 2-5 years, and will assign the task of evidence assessment to Tufts Medical Center.

For breaking news on this and other subjects, visit Lorraine's blog LYME POLICY WONK on the lymedisease.org website. You may contact her at lbjohnson@lymedisease.org.

Institute of Medicine (IOM) and National Guidelines Clearinghouse (NGC)

Patients expect their healthcare providers to know what treatment they need for various conditions, but this is not always the case. In 2011 the Institute of Medicine (IOM) adopted standards for achieving trustworthy clinical practice guidelines (CPG). The National Guidelines (NGC) helps improve the quality of patient care by providing a valuable reference for practitioners.

Caring for Lyme patients is far from formulaic. Practitioners face considerable uncertainty and difficult decisions. In addition to their knowledge and experience and the preferences of their patient, they rely on medical and scientific literature to inform their decisions. It is challenging for practitioners to determine the quality of practice guidelines, however.

Patient care recommendations in guidelines posted on NGC are supported by a systematic review of available evidence and a balanced assessment of the benefits and harms of care options. Its mission is to provide health professionals with objective information on clinical practice guidelines and to further the dissemination and use of such guidelines. The NGC is an initiative of the U.S. Department of Health and Human Services housed in the Agency for Healthcare Research and Quality. They partner with the American Medical Association and the American Association of Health Plans.

While we should continue to expect uncertainty in practice standards for Lyme and associated diseases, posting the ILADS guidelines on the NGC and removing the outdated IDSA version should give patients hope for improved patient care and optimized outcomes.

NEWSMAKER

Pat Smith Appointed to Federal Panel

New DoD program sets Congressional priorities for Lyme research grants

The Lyme Disease Association (LDA) has announced that their president, Pat Smith, has been appointed to the Programmatic Panel for the Tick-Borne Disease Research Program (TBDRP), a new program in the Department of Defense's (DoD) Office of Congressionally Directed Medical Research Programs (CDMRP). Under Smith's leadership, the LDA has been pushing Congress to include TBD within the scope of the CDMRP. Funding for the new program became law December 2015.

Given the increasing number of Lyme disease cases and a scarcity of research funding, it's imperative that proper priorities be set and available monies be used judiciously, says Smith. "All programs managed by the CDMRP 'share the common goal of advancing paradigm shifting research,' a much welcomed goal for Lyme disease research, which has suffered from enforcement of a rigid paradigm."

Each year, the CDMRP assesses opportunities to advance scientific research in designated areas. CDMRP strives for breakthroughs in healthcare for the military and the public. They search for innovative approaches and consider research gaps in other agencies.

The CDMRP involves consumer advocates in the review cycle, which applies a two-tier process recommended by the National Academy of Science's Institute of Medicine (IOM). The IOM model values scientific excellence and programmatic relevance. In the first tier — peer review — applications are evaluated based on scientific and technical merits. In the second tier — programmatic review — applications with high scientific and technical merit are compared, using criteria including peer review panel evaluations, programmatic relevance and innovation/impact.

All CDMRP review panels include scientists, clinicians, military members, and consumers from advocacy communities. Consumers play a major role in assuring that the research focus can make a significant impact on the affected community. The Programmatic Panel meets with stakeholders, develops a vision for the annual program cycle, and advises CDMRP staff and program support contractors.

The LDA is especially grateful to Congress–men Smith (NJ-4), Collin Peterson (MN-7), and Rodney Frelinghuysen (NJ-11) for their efforts to get Lyme/TBD included in the CDMRP.

This story was based on a press release issued by LDA on March 14, 2016.

POLITICAL ACTION

Virginia Senate Passes Doctor Protection Bill

Doctors allowed to treat according to any of the NGC guidelines

In February, the Virginia Senate passed landmark legislation affecting a patient's right to treatment consistent with guidelines listed in the National Guidelines Clearinghouse (the "NGC"). The Virginia House is being urged to follow suit.

According to Monte Skall, executive director of NatCapLyme, a Washington, DC-based nonprofit, Virginia doctors are increasingly refusing to accept new patients who present with symptoms of Lyme or other tick-borne diseases. When a patient seems to need extended antibiotic treatment, she says, many physicians believe that the State Board of Medicine will sanction them if they report and treat such cases.

Understandably, physicians are reluctant to risk such exposure, although extended treatment is a recommended option for some patients in the ILADS guidelines published by the NGC. These guidelines recommend an individualized approach to treatment-resistant Lyme.

Virginia Bill SB-671 provides that if a patient chooses treatment in accordance with any clinical practice guideline maintained by the NGC, a health care provider will not be subject to a health regulatory board investigation or hearing based solely on their decision to follow such guidelines.

"Lyme disease has reached epidemic proportions in Virginia," says Skall. "Many Virginians with Lyme disease cannot get the medical assistance they need to adequately deal with the disease."

Many Lyme disease patients and their families helped pass the Virginia bill by bringing their stories to their senators, Skall adds. The bill was introduced in the Virginia House of Delegates February 12 and assigned to Subcommittee #1 of the Health, Welfare and Institutions Committee. A week later that subcommittee recommended continuing the bill to 2017, and the House concurred by voice vote.

"The job is not done yet!" Skall says.

Excerpted from a NatCapLyme press release. For more information about Lyme disease or this bill, please contact Monte Skall in McLean, VA, at 703.821.8822, visit the NatCapLyme website at www.natcaplyme.org, or Facebook and Twitter at NatCapLyme.

FEATURE

Disability Denied

Patients may need a legal advocate to face down insurance gatekeepers

By Mala Rafik, Esq.

Mala Rafik, partner in Rosenfeld & Rafik, consulting in her Boston office. .

For almost twenty years, our firm has represented chronically ill and disabled individuals trying to access health insurance coverage and disability benefits. While every few years there seems to be a new illness upon which insurers focus their attention, no illness in my experience has garnered the level of negative treatment as Lyme disease. In the last five years, the number of chronically ill individuals suffering from Lyme who have called our office has grown exponentially, to the degree that we receive at least two calls a week from individuals seeking health or disability coverage. The numbers are staggering. Even more distressing, however, is the destruction imposed upon the lives of these individuals and their families due to the denial of health or disability coverage.

I have rarely seen an illness faced with as much skepticism as Lyme disease. My clients — hardworking individuals with families and careers — have been called malingerers, mentally ill, addicts … anything but what they are: individuals struck with a disease that the medical community has yet to find a foolproof way to diagnose and cure. Most individuals who contact us follow a similar pattern. They began experiencing flu-like symptoms, including overwhelming fatigue, which soon progressed to joint and muscle pain and worrisome cognitive limitations.

The medical community, while well-meaning, often misdiagnoses their symptoms, attributing them to stress, fibromyalgia, and more commonly, depression. Some are tested for Lyme, but often with the ELISA test not the Western Blot. When the fallible ELISA test comes back negative, treatment focuses on addressing the pain (often with addictive pain medication) and treating the depression, which, while an understandable symptom in the face of progressing debilitating symptoms, certainly is not the cause. While the underlying disease is not treated, the lives of these once productive individuals slowly begin to crumble. Many become addicted to pain medication and/or become increasingly depressed and often suicidal as their physical symptoms fail to abate. Their families watch helplessly as their loved ones become less able to participate in social and family activities. Ultimately, many lose their jobs, their homes, and their financial security.

By the time these individuals come to us, they are in desperate situations. Many finally diagnosed with Lyme have commenced some level of treatment. While the challenge of obtaining a correct diagnosis has finally been met, in many ways their battle has just begun. The first battle is to obtain the treatment recommended by their experienced treating physicians. In countless situations, the recommended treatment is rejected by insurers who fail to appreciate the nature of treatment for the neurological symptoms of Lyme, and who rely upon medical providers who have never examined our clients nor contacted their treatment providers to discuss the need for treatment. This distinction is paramount: Lyme disease is often diagnosed on clinical examination.

Accordingly, the expertise of the treatment provider who has conducted an in-person evaluation is far more compelling when determining the proper course of treatment (or eligibility for disability benefits) for Lyme, than a medical provider who has never examined our patient, or who is relying on limited medical information to render what amounts to a treatment determination. Where diagnosis and treatment relies upon clinical evaluation, deference to the treatment provider is not only prudent, it is the only reasonable course of action. Unfortunately, the law does not see it the same way.

Of course, if treatment is denied, the likelihood of improvement is slim. While these individuals are undergoing an appeals process with their health insurer, they are facing a second battle: the one with their disability insurer and the Social Security Administration ("SSA").

Long-term disability benefits can provide a bridge to an eventual return to work. If treatment and disability benefits are denied, however, return to work becomes less certain. This is the very

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Disbility Denied,

continued from page 15

situation in which the vast majority of our clients find themselves. Their condition remained undiagnosed for an extended period of time, which allowed their symptoms to progress to such a degree that they were forced to cease working. The treatment recommended by their physicians is denied, allowing the disease to take a further hold on their bodies. Unable to work, they turn to the disability coverage for which they have faithfully paid premiums for years, only to be told – again by insurance companies and their medical providers who have never spoken to them, let alone examined them – that they do not suffer from Lyme disease, but rather have untreated Fibromyalgia, or that their symptoms are in their heads. My clients have been called malingerers and told they suffer from somatoform disorder. Their credibility has been challenged. All because they suffer from an illness that is poorly understood and easy to take advantage of.

Each Lyme patient I have had the privilege of representing has been a contributing member of society. They have families, often young children, who depended on their income to survive. When they were ultimately diagnosed, the diagnosis was made through clinical examination, neuropsychological evaluations and often traditional blood tests. Despite the objective evidence supporting their diagnosis and the treatment recommendations of their physicians, life-changing treatment was, at least initially, denied, and only obtained after a prolonged fight. Disability benefits were almost uniformly denied, or their disability was reclassified as mental illness and subject to policy limitations that only permit them two years of coverage before benefits were terminated.

Given the financial devastation wrought by the denial of disability benefits, many of my clients exhaust their life savings before losing their homes and declaring bankruptcy. For others, the support of family members is the only barrier to total financial ruin. In this series of articles, I hope to provide guidance as to how to file a successful application for disability benefits and Social Security Disability Insurance, to challenge a denial of benefits, and hopefully to provide some relief in an otherwise difficult situation.

Employer-Based Disability Policies

Disability policies come in many shapes and sizes. Most individuals have short and long-term disability insurance through group policies, obtained through employment.

Short Term Disability ("STD") insurance provides benefits for a short period of time. The duration is usually six months, although this can vary somewhat from policy to policy. Benefits are provided weekly and pay a varying percentage of a person's salary (often between 60 to 100 percent), again depending on the policy.

Long Term Disability ("LTD") insurance provides benefits for a much longer period of time, typically until the individual turns age 65 or normal retirement age. These benefits are provided monthly and typically pay 60%, 66 2/3 % or 50% of an individual's salary, depending on the terms of the policy. For the most part, you must prove that your illness prevents you from performing the duties of *your* occupation for the first two years, and then *any* occupation after two years.

Employer-based insurance policies — ordinarily STD, LTD, life, health, and pension — are governed by ERISA, the federal Employee Retirement Income Security Act of 1964. Church and governmental policies for city, state and federal employees exempt them from ERISA's reach, however. Unlike traditional laws, ERISA significantly limits the rights and protections normally afforded by the law.

For example, if your benefits are denied by an insurance company, you can't go straight to court. You must go through an internal appeals process, where the very insurance company who is responsible for paying your benefits also gets to decide whether you are disabled. If you lose this appeal, your only option is to go to federal court, where there is no trial available to you. The judge who decides your case will never meet you or hear your story. The court will only review the information you submitted during the internal appeals process — just that paper and nothing else. So, if you appeal without guidance from a lawyer who understands what information needs to be submitted to win your case (the subject of the second of these series of articles), there's a significant likelihood that you will lose in court.

The news only gets worse. There are no damages available to you for what you lost. If you win – and most cases lose because the law is heavily skewed

in favor of the insurance company (or the internal appeal was handled without the guidance of counsel) – then the most the court can order the insurance company to pay you is what they should have paid in the first place: your disability benefits. There are no provisions for you to be compensated for all that you've lost - your home, the retirement benefits you have cashed in, savings you have spent, money you have borrowed from family or friends. You only get your benefits. And, more often than not, you don't even get your benefits when you win. Courts can order a "remand," which essentially allows the insurance company a second opportunity to deny your benefits. So even when you win, you still don't get your benefits. While attorney's fees and costs are up to a court, they aren't guaranteed.

There is some good news. For some people, especially people who work for larger employees, an individual receiving LTD benefits may still remain an employee. Under many plans and employment arrangements, disabled employees receiving LTD benefits are still considered an employee entitled to receive health insurance coverage and continue to participate in pension contributions and other benefits of employment.

Individual Disability Policies

An individual disability policy is generally purchased privately through an insurance agent. These policies generally provide a base monthly benefit that is not linked to your income. They also tend to insure you if you are unable to perform the duties of your own occupation. Benefits tend to last until age 65, although it is possible to purchase riders that will provide for benefits for your lifetime, as long as you remain disabled. Most policies also permit you to purchase a rider that will increase your monthly benefit based on an annual cost of living adjustment.

More good news. Generally, if your benefits are denied under an individual policy, you are not required to undergo an internal appeals process. You can file a lawsuit that provides you with all the protections of state and federal law. You can sue for breach of contract or bad faith, and a jury will decide whether you are eligible for benefits. You may also sue for damages — emotional distress for what you've been through, compensatory and punitive damages to recover what you have lost, and attorney's fees and costs.

The upshot is this: if you haven't purchased an individual policy and are able to do so, you should look into it. It's the best way to protect your income should you suffer from an illness that leaves you disabled.

Policy Limitations

If you're still reading at this point, there's more bad news. Insurance companies selling group policies are permitted to limit the length of benefits provided to people just as long as they don't discriminate against who they sell the policies to (for example, they can't refuse to provide group coverage to people because they suffer from a mental and not a physical disability). As a result, most group policies limit benefits for individuals suffering from mental illness to two years of coverage. As time has passed, insurance companies have begun limiting benefits to one or two years of coverage for other illnesses – Chronic Fatigue Syndrome, Fibromyalgia, musculoskeletal conditions, and now, Lyme disease. This is despite the fact that people who ultimately suffer from these conditions paid the same amount in premiums as people who suffer from conditions that are not limited.

You need to read carefully the disability policy your employer offers to understand what is covered and what is limited. You are entitled to obtain a copy of the policy, referred to as the "plan document" from your employer. Request the plan document in writing, and keep copies of all your correspondence. If you don't receive a copy of your plan document within 30 days of your written request, which is what ERISA requires, contact a lawyer to assist you.

Individual policies are different. Insurance companies may decline to sell you an insurance policy for any reason including your medical history. Often, you may be sold a policy with an exclusion for any disability caused by a pre-existing condition. Most individual policies do not have the same limitations as group policies.

Social Security Disability Insurance (SSDI)

SSDI is a payroll tax-funded, federal insurance program. A portion of your FICA taxes are set aside for SSDI (as well as Social Security Retirement and Medicare). Established in 1954, SSDI provides income if you are unable to work due to a disability until your condition improves and guarantees income if your condition does not improve.

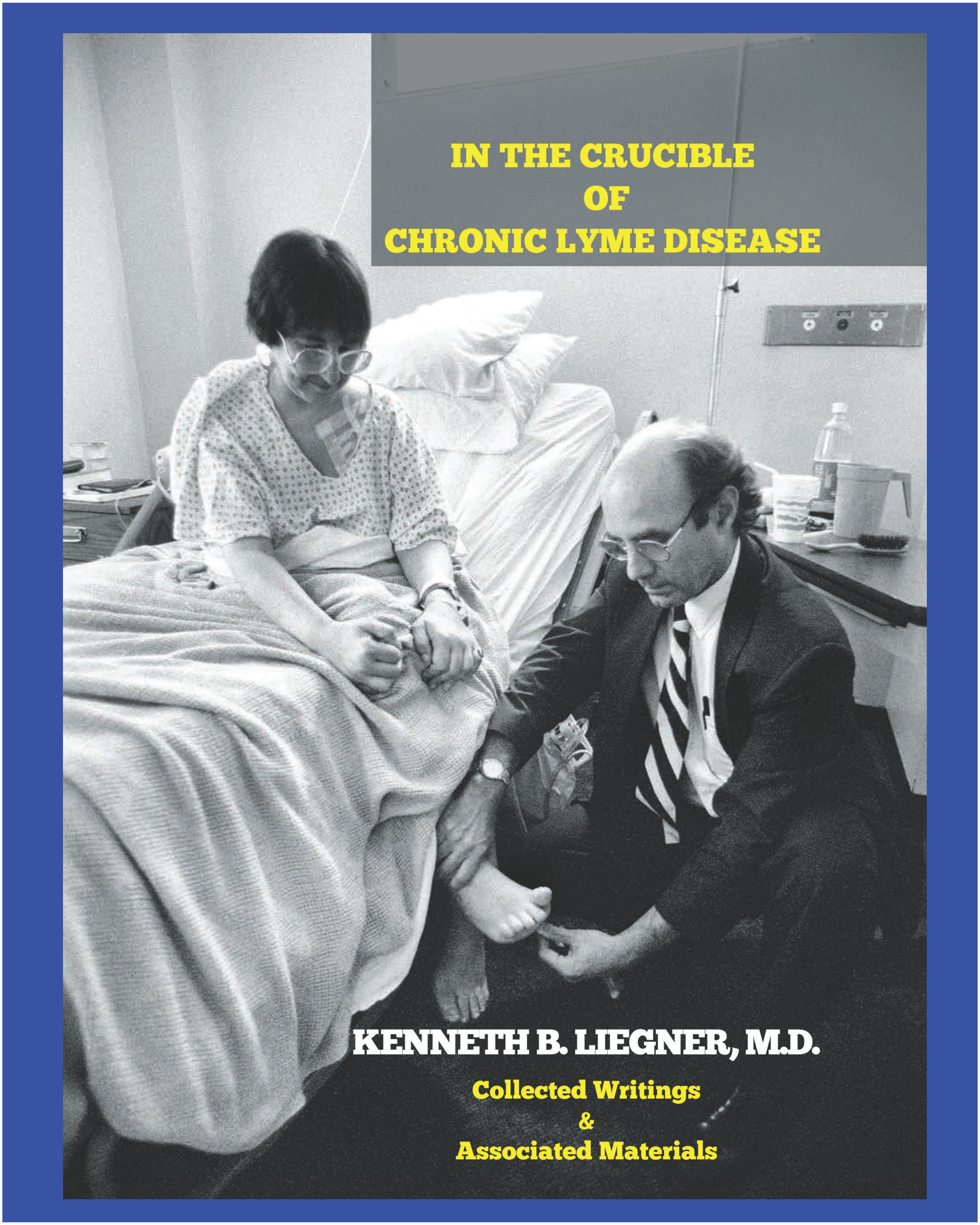
Eligibility for SSDI is based on your inability to work. You are generally considered disabled by the SSA if:

- You cannot do work that you did previously
- You cannot adjust to other work because of your medical condition(s)
- Your disability has lasted or is expected to last for at least one year or result in death.

To be eligible for disability benefits, a person must be unable to engage in substantial gainful activity ("SGA") because of your health and not other factors like being laid off. A person earning more than a certain monthly amount (currently at least $1,100 a month net income) is ordinarily considered to be engaging in SGA. The amount of monthly earnings considered as SGA depends on the nature of an individual's disability (i.e., of you are blind or not).

If approved for SSDI benefits, your earnings freeze so that when you ultimately retire, your SSA retirement benefit is not reduced because you have been unable to work and pay into the Social Security system. Think of SSDI as early retirement as a result of your inability to work. The other good news is health insurance: 29 months after your date of disability, you become eligible for Medicare coverage.

Mala Rafik is a partner at Rosenfeld Rafik & Sullivan, PC, a law firm in New England representing clients denied access to health care as well as those seeking disability, life and long-term care benefits from private insurance carriers. The firm also concentrates on obtaining Social Security disability insurance benefits for its clients. Mala's clients typically have debilitating chronic illnesses and disabilities for whom she has achieved several pivotal litigation victories in state and federal court.



IN THE CRUCIBLE
OF
CHRONIC LYME DISEASE

KENNETH B. LIEGNER, M.D.

Collected Writings
&
Associated Materials

In the Crucible of Chronic Lyme Disease,

by Ken Liegner, MD

Reviewed by Phyllis Mervine

In the Crucible of Lyme Disease, published in 2015, contains an encyclopedic collection of letters, abstracts, articles, speeches and stories, lab results and autopsy reports spread out over the 25 years of the Lyme Wars. In her introduction, Pam Weintraub calls his book "a gift" and says she used Liegner's extensive documents when writing her own book, Cure Unknown.

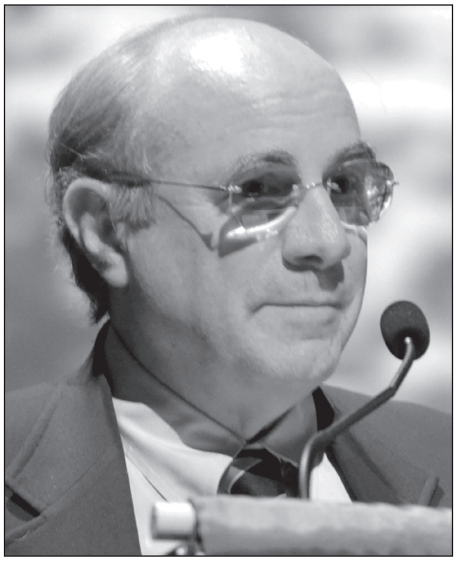
Created over the course of so many decades with such meticulous attention to detail, the book takes us right to the center of action in the way a sculpted, manicured narrative never could.

Weintraub recommends that we read In the Crucible "like scholars read historical documents — one letter, one newspaper story, one record, one artifact and inscription, one report at a time." Indeed, at over 800 pages, that's a smart approach, though I found myself drawn through the pages, remembering people from the early days and marveling at the many platforms where our fight for truth and justice have taken place, and when Ken Liegner was front stage center.

Liegner gives the reader a sense of history and reminds us how many times he has stood up for his patients, putting his career on the line, and always careful and thoughtful, documenting details and referring back to the medical literature for support. One must admire a physician with a busy practice who carved out time to write so many journal articles and letters to editors and attend so many conferences.

One of his early entries is dated 1988. He prepared a review of the literature that shows him to be not far out of the mainstream. In the section on pathology he writes:

The widespread and anatomically remote manifestations of LD and the laboratory abnormalities found suggest and immunologically mediated disease.… Although the advanced stages of Lyme Disease are thought to occur in the presence of the spirochete, there is some concern that the immunologic processes initiated in the disease may be self-perpetuating even after the eradication of the spirochete.



Ken Liegner, MD

In the case of tick bite, the decision about prophylactic treatment should be made on an individualized basis between physician and patient.

Seven of 43 references are to articles written by Allen Steere, who first described the disease. By 1990, however, Liegner is diverging from the research establishment, deploring the practice of selectively withholding antibiotics when the tick has been attached only a short time, subjecting patients to what he terms "a kind of Russian roulette." In a letter to the New England Journal of Medicine, he shows his disdain for "the standard approach" as he argues for prophylaxis of tick bites.

Over the next few years Liegner received a patent for his acaricide dispenser/salt lick; submitted abstracts to several conferences; and published editorials and case reports challenging the academic researchers' conservative views on prophylaxis, diagnosis and treatment. His broad interests reflected the increasingly complicated patients he was seeing in his practice.

We meet Liegner's patient Vicki Logan, whose picture appears on the cover of his book. Logan had a profound effect on Liegner over the course of her tragic story, becoming an iconic figure for him. An article in a contemporary local paper said he was the only doctor willing to consider Lyme, although Logan didn't remember a tick bite or a rash. His abstract about Logan's case, Culture-confirmed treatment failure cefotaxime and minocycline in a case of Lyme meningo-encephalo-myelitis, was accepted at the V International Conference on Lyme Borreliosis (ICLB).

Liegner was one of several people who objected to the approach advocated by David Magid in his article, Prevention of Lyme disease after tick bites. A cost-effectiveness analysis. N Engl J Med.1992 Aug 20;327(8):534-41. The idea of deciding whether or not to treat based on cost rubbed him the wrong way. Clearly, Liegner was seeing the problem from the patient's perspective.

In his 1993 editorial, Sensible pursuit of answers, Liegner calls for a paradigm shift. *Borrelia burgdorferi* can "resist eradication by the powerful antibiotics… [and] presently available chemotherapeutic modalities may be suppressing but not eradicating the infection," he writes. He elaborates on possible mechanisms of persistence and presents evidence on several methods to control the infection. Consistently advocating for patients, he argues for "an open-ended antibiotic approach provided that they are deriving clinical benefit and not experiencing any adverse effects and that they wish to be treated. Seronegativity is a real phenomenon in Lyme disease, occurring in both early and late stages," he states. He practically begs physicians to treat patients proactively and not wait until it

Continued on page 21

Got Lyme?

Join a Patient Online Support Group

Learn more about Lyme and tick-borne diseases
Connect with other Lyme patients in your area

Your state support group allows you to converse online with other Lyme patients in your area - a virtual meeting place – a source of information and emotional support for people with tick-borne diseases.

For help finding a support group in your state, visit

lymedisease.org

or visit your state site directly using the following format:
https://groups.yahoo.com/neo/groups/YOURSTATENAMElyme

Fill in your state name and Lyme as one word,
e.g., newyorklyme, pennsylvanialyme, or dclyme in the case of Washington, DC.

Crucible, continued from page 19

may be too late, although he insists on a careful differential diagnosis. *[J Clin Microbiol.* 1993 Aug; 31(8): 1961–1963]

On August 24, 1993, The New York Times featured an article on Vicki Logan, along with the iconic photograph of the doctor at his patient's bedside. Logan was the case Liegner returned to again and again in his writing. She was his inspiration. He felt for her, he fought for her, he never abandoned her, never gave up trying to restore her to health. He was painfully aware of the insurance provider's life-and-death control over Logan. When they allowed treatment, she improved. When they denied treatment, she declined. With each relapse she deteriorated neurologically even more.

It is heartbreaking to read the correspondence relating to Logan's case. Liegner left no stone unturned, but the reader suspects that there will be no happy ending here, and each step so painfully taken forward will soon be pushed back. Still, Logan and Liegner together were building a case that exposed the dark underbelly of academic medicine: the dogma and rigidity, the callous attitude towards patients, the disregard for human life. Liegner had built his profession on compassion for others and healing the sick. Logan was his muse.

One of the original documents Liegner includes in his book is a consent for disclosure of medical information. Signed by Vicki Logan on June 22,2001, it gave her doctor permission to "disclose any and all information he deems necessary and sufficient about my case." One of her goals was to secure her right — and the right of other persons suffering from chronic spirochetal infections such as Lyme disease — to be treated with the best presently available means at the disposal of medical science to attempt to slow, avert, or reverse the progressive neurologic and multi-system deleterious effects of these infections when they are either not treated at all or treated insufficiently.

The Journal of Spirochetal and Tick-Borne Diseases was a perfect vehicle for Liegner to expand upon his views. Published by the Lyme Disease Foundation (LDF), a now-defunct patient advocacy organization whose readers were a growing group of doctors disenchanted with the standard treatment of Lyme disease, it welcomed Liegner's manuscripts. His eloquent guest editorial in the fourth issue — B. *burgdorferi*, Seek and Ye Shall Find, Expanding the Envelope — reads more like literature than science.

> The idea of deciding whether or not to treat based on cost rubbed him the wrong way. Clearly, Liegner was seeing the problem from the patient's perspective.

Borreliae, present on this earth for eons, evolved alongside mammalian life forms in a host-parasite relationship, no doubt long before the appearance of humankind. It should not surprise us, then, that we have much to learn about the range of diseases that the borreliae may underlie and the true scope of infection of the human inhabitants of this planet.

We are at the threshold of a new and exciting era in the understanding and conquest of Lyme borreliosis. Direct antigen detection methods may strike a discordant note with antibody testing's "perfect music of the Spheres," but when clinically validated and honed to optimal sensitivity and specificity, these will be powerful tools in the exploration of the pathogenesis and clinical manifestations of borrelial disease. Researchers as well as rank and file physicians will be able to diagnose with confidence and will have measurable indices of disease activity as these tests begin to become commercially available. [JSTBD 1060-0051.94:0401-079]

Liegner goes on to call for creation of a tissue repository and more research on problems associated with prolonged antibiotic therapy. He complains that "independent" disease entities are not being traced back to their true cause, which in many cases is infection with *Borrelia*. He calls for Lyme disease to be included in the differential diagnosis of heart disease and a wide range of neurologic syndromes, including MS, Alzheimer's and ALS.

We should be humble before this disease," he states, "Science is all about measuring things. Once objective measures of disease activity are widely available, rational approaches to treatment will replace those based on convention or blind obedience to authority, and the medical neglect now so frequent in chronic Lyme borreliosis will take its well-deserved place in the history of medicine, and not in modern practice.

Where would we be today if we had had no Ken Liegner to fight for patients? Surely his steadfastness and command of the English language have reached some ears that, without him, would have remained deaf to a deeper understanding of Lyme disease. He did not stop there; he continued writing, speaking, working and treating patients. And now we have his book — not only an encyclopaedia, but a testimonial to a highly ethical physician with a deep sense of a wrong he must put right.

When Logan died in 2003 at the young age of 52, her death would not be in vain. Ken Liegner became her posthumous standard-bearer, featuring her in letters, articles and speeches. She was his goddess, whom he had failed to heal, through no fault of his own, for he gave his best. And he is bringing to fruition her wish to help other patients with Lyme disease. Logan's legacy lives on, and now we are blessed with this book, which everyone should read, since he who does not know history is doomed to repeat it.

To order your copy of Ken Liegner's book visit: bookstore.xlibris.com/Products/SKU-000781816/In-the-Crucible-of-Chronic-Lyme-Disease.aspx. For another revealing book review of In the Crucible of Chronic Lyme Disease by Sharon Daniel Kroeger, PhD, visit: themillbrookindependent.com/content/crucible-chronic-lyme-disease

MyLymeData Goes to Washington

Lorraine Johnson presses Lyme message at the AAAS and The White House

In February, on the heels of delivering a speech to the American Association for the Advancement of Science (AAAS), Lorraine Johnson carried her patient advocacy message directly to The White House. Representing Lyme patients everywhere, she joined government officials, academicians, researchers, and other advocacy groups to discuss emerging approaches to improving patient care.

It is significant that the Lyme community was represented at these important events, since the complex and controversial science of Lyme disease has struggled to catch political daylight. "Precision medicine is the pathway to the future of medicine for Lyme disease because it looks at the different factors that affect individual treatment response," says Johnson. "Lyme disease is a complex illness that may involve multiple pathogens. Optimal treatment depends on identifying which pathogens an individual patient has been infected with."

LDo's Lorraine Johnson, (right), with Kristen Honey (left) and DJ Patel (center), representatives of the White House Office of Science and Technology.

MyLymeData

As a leading Lyme research advocacy organization, LDo launched MyLymeData in ??? 2015. In January, President Obama had launched his Precision Medicine Initiative. Aiming to accelerate biomedical discoveries, it can improve healthcare outcomes with targeted diagnostic, prevention and treatment strategies. Precision medicine can provide clinicians with information to help tailor therapies to a patient's unique characteristics. This revolutionary way of doing medicine moves away from a "one-size-fits-all' approach.

In November 2015, Lyme disease received welcome national exposure at the 2015 AAAS Science and Technology Fellows Symposium in Washington, DC. In this national forum, LDo announced the launch of MLD, which is all about precision medicine and big data. [Ed. Note: see *The Lyme Times* Vol. 27, No. 3] As Lorraine Johnson explained, "We are at the forefront of disruptive innovation that is key to providing Lyme patients the care they need. Thousands of patients have already enrolled in MyLymeData. With enough data, we will have better insight into the disease and be able to identify effective therapies."

As a Big Data project, MyLymeData is big news. As the first patient-powered research project to address chronic Lyme disease, it could solve the mysteries of a complex debilitating disease often caused by a stew of pathogens. The promise of these emerging research tools is particularly important for Lyme patients. As Johnson explains, pooling patient healthcare data can help identify effective treatments including why some treatments work for some patients but not others.

The White House

Precision Medicine Initiative Summit

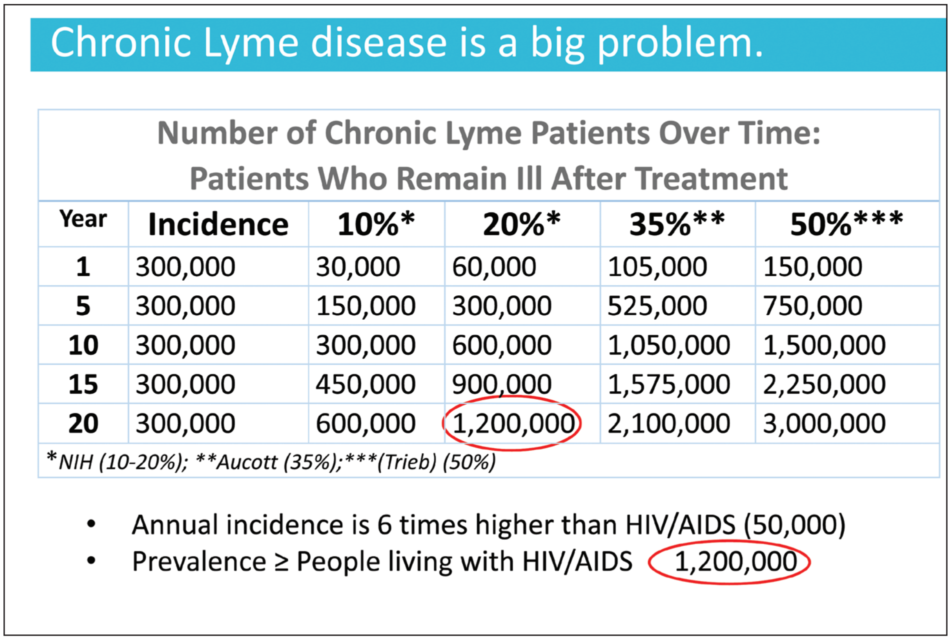
Lorraine was honored to be invited to participate in this intimate event. The President spoke for an hour on a panel with researchers, physicians, and patients about the urgent need to fundamentally change the way we conduct research — using new technological tools to study treatment patterns and tailor treatments to individual patients. The Precision Medicine Initiative holds great promise for Lyme patients stuck with poor diagnostic tests and failing treatments.

To those in the room, it was clear that President Obama "got" the issues. He understood the urgency to move medical science into the 21st century and develop faster cures. He also clearly understood the need to protect patient privacy in the big data era. His viewpoints on some critical issues included: Patients should own and control their data; We should ensure that patient data is not misused; Researchers should not hoard data.

The AAAS Annual Conference

For the last two years, I was privileged to serve on the executive committee of PCORnet, one of the nation's largest big data projects. PCORnet is a project of the Patient-Centered Outcomes Research Institute and has funded over 20 patient-powered research networks in an effort to transform healthcare.

PCORnet pioneered the term "patient-powered research network." This research is conceived by patients and run by patients that is designed to fuel research that will improve patients' lives. It is Big Data done differently by putting patients at the center, usually by using patient registries



Chronic Lyme disease is a big problem.

Number of Chronic Lyme Patients Over Time: Patients Who Remain Ill After Treatment					
Year	**Incidence**	**10%***	**20%***	**35%****	**50%*****
1	300,000	30,000	60,000	105,000	150,000
5	300,000	150,000	300,000	525,000	750,000
10	300,000	300,000	600,000	1,050,000	1,500,000
15	300,000	450,000	900,000	1,575,000	2,250,000
20	300,000	600,000	1,200,000	2,100,000	3,000,000

NIH (10-20%); **Aucott (35%);*(Trieb) (50%)*

- Annual incidence is 6 times higher than HIV/AIDS (50,000)
- Prevalence ≥ People living with HIV/AIDS 1,200,000

and research platforms.

According to the Agency for Healthcare Research and Quality, "A patient registry is an organized system that uses observational study methods to collect uniform data … to evaluate specified outcomes for a population defined by a particular disease …. (Gliklich, 2014)

Patient registries are uniquely suited for enrolling diverse patient populations, evaluating care as it is actually provided in real-world practice, assessing complex treatment patterns, and evaluating patient outcomes when clinical trials are not practical. (Gliklich, 2014)

In November, *LymeDisease.org* launched the first national patient-powered research network for Lyme disease, MyLymeData. I want to tell you why this is so important.

You might have noticed that Lyme disease is getting a lot more press and government attention recently. There's a good reason. The CDC recently revised its estimate of the number of people who contract Lyme annually from 30,000 to 300,000. (CDC 2015) That's six times more than the annual incidence of HIV/AIDS and about 1.5 times the incidence of breast cancer. That's incidence — the number of new cases each year. (CDC 2015)

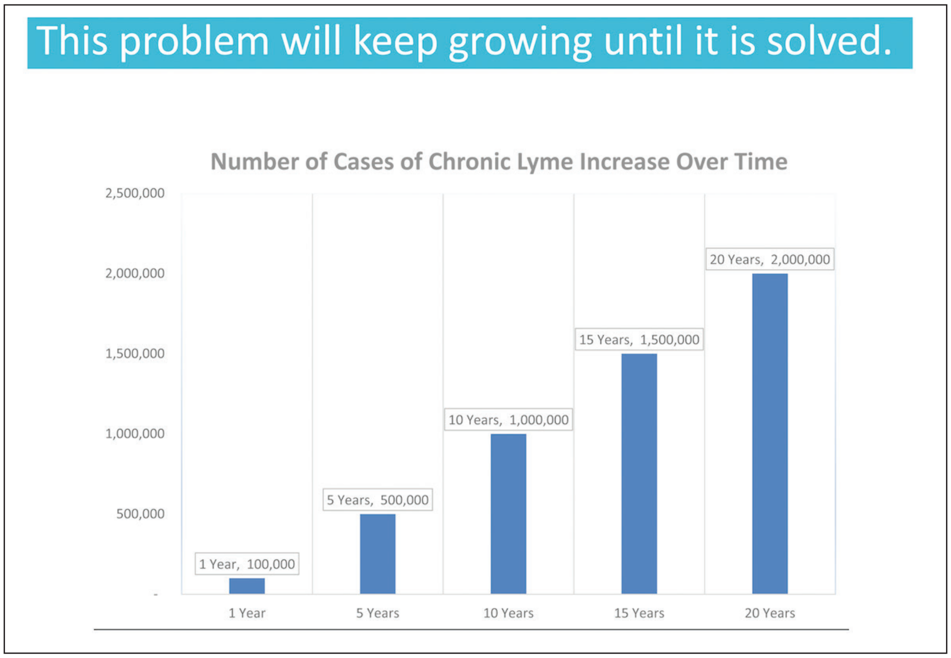
Nobody knows the exact prevalence, that is, how many people contract Lyme disease and remain ill. Prevalence reflects the number of people with "chronic" Lyme — those who do not get better after a short course of antibiotics. The NIH estimates that between 10% and 20% of patients diagnosed with Lyme disease remain ill after treatment. Other studies suggest the number may be even higher, as high as 35% or 50%. (Adrion 2013; Treib 1998)

As you can see, add those numbers up over a 20-year period and you have possibly one to three MILLION people living with chronic Lyme disease. This is a huge number of patients, even when compared to the number of people living with HIV and AIDS, which is estimated to be about 1.2 million. This means that Lyme disease prevalence may actually exceed that of HIV/AIDS. So it's a big problem.

For every year that we do not address the problem and find a cure for those who remain ill, the number of people living with chronic Lyme disease increases. Just taking the average of the treatment failure rate (30%), we add 100,000 patients every year to the number of people living with chronic Lyme disease. It brings to mind the old adage that ignoring a problem only makes it worse. Something needs to be done, and that need is urgent.

Chronic Lyme disease exacts an enormous financial toll on patients, the healthcare system, and society. A study out of Johns Hopkins by Adrion and Aucott analyzed 11 measures of healthcare costs, including inpatient, outpatient, and pharmacy costs and found these costs may be as high as $1.3 billion each year. This study examined only medical costs, which may be just the tip of the iceberg. (Adrion 2013)

It's easy to see why. A study by Zhang at the CDC in 2006 found that medical costs were a relatively small portion of the overall costs. Loss of productivity was by far the largest cost of illness for Lyme disease. (Zhang 2006). Chronic Lyme disease literally stops people in their tracks and prevents them from living full productive lives. We surveyed more than 5,000 patients and found that 43% had to stop working as a result of Lyme disease. This compares to 6% in the general pop-

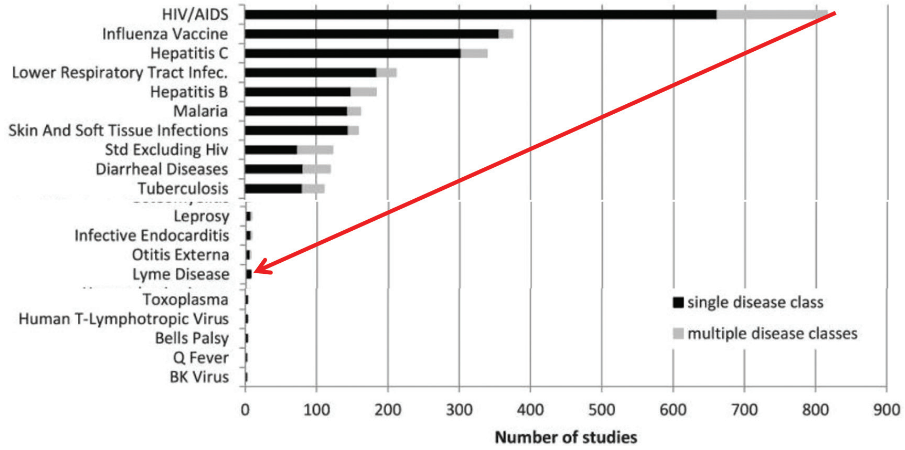


This problem will keep growing until it is solved.

Continued on page 24

MyLymeData, continued from page 23

Chronic Lyme is research disadvantaged.



(Goswami 2013)

ulation. In addition, 26% were forced to reduce their work hours or change the nature of their work. (Johnson, 2014)

This cost is felt not only by the individual but by society for a long time. Nearly half of the patients in our survey reported being ill for 10 years or longer. 24% reported that they were receiving disability payments due to the illness. (Johnson, 2011, 2014). So it's a big problem, but little has been done to address it.

The incidence of chronic Lyme may be over 100,000 cases each year — three times more than Hepatitis C. (Goswami 2013). Yet only three government treatment trials on chronic Lyme have ever been conducted. (Klempner, 2001; Krupp, 2003; Fallon, 2008)

Three trials. That's it.

This chart by Goswami is based on ClinicalTrials.gov data and shows how bleak the research environment is for Lyme disease. Goswami (2013)

As you can see, the research base for HIV/AIDS, Hepatitis C, and tuberculosis are relatively robust, but for Lyme disease the research funding pot is essentially dry. I don't see this changing significantly anytime soon.

The last NIH-funded trial for the treatment of chronic Lyme was funded over 15 years ago and there's nothing in the pipeline. Lyme is truly a research-disadvantaged disease. Now, you might think the obvious solution is more randomized controlled trials, but it's not that simple. Randomized controlled trials can excel at proving cause and effect, but they fall short in key ways. Rob Califf, who has been nominated to head the FDA, used to sit on the Executive Committee of PCORnet with me. He liked to say, "Traditional trials are great, but they take too long, cost too much, and don't apply to most people." These limitations are mainly the result of the highly selective nature of randomized controlled trials.

Highly selective trials take years and are costly. The NIH trials for chronic Lyme were extremely selective — only one in ten people screened were enrolled in the Klempner trial. The Fallon trial was even more restrictive: for every 100 patients screened, only one patient was enrolled.

Science magazine conducted an interview of Klempner at the time and concluded: after a year of advertising, only 57 subjects had been enrolled. The goal is to get 260 by the time the study ends in two years. More than 1200 people have expressed interest, and 700 have come in for screening. But only one in 10 … fits the study's strict criteria. (Marshall 1999)

Screening that is this selective is costly and takes a long time. According to Covance, the per patient cost of clinical trials has risen 70% over the past three years, and 46% of that increase is due to patient recruitment (Covance 2014). The NIH trials took 2-4 years to recruit, while the time to publication was 4- 6 years. This is a long time for sick patients.

There's another cost to consider that's not so obvious but just as significant. Since these trials are highly selective in screening patients, the samples may not reflect the clinical patient population, and the results may not apply to these patients. Traditional trials may exclude people like you and me.

Small samples don't capture heterogeneity. This is particularly concerning when dealing with Lyme disease because the patients are extremely heterogeneous. Ticks can carry many bacteria, viruses, fungi and protozoans all at the same time and transmit them in a single bite. When we say someone has Lyme, we may be referring to a stew of pathogens. Treatment responsiveness may depend on what particular stew of pathogens a patient has. (Swanson 2006)

Small samples don't accurately reflect heterogeneous patient populations. For example, patients who are diagnosed early may have a different course of illness than those who are diagnosed late, or those with a greater severity of illness may respond to treatment differently.

Average treatment effects may overlook important treatment response. To do the type of subgroup analysis that shows these different treatment responses requires Big Data. Kravitz describes the problem:

It should be obvious that treatment effects are not necessarily the same for everyone. What may not be so obvious is that misapplying averages can cause harm, by either giving patients treatments that do not help or denying patients treatments that would help them. (Kravitz 2004)

Traditional research may also fail to reflect real world treatments and outcomes. Traditional treatment studies typically measure only one treatment intervention for a short period of time. For example, the NIH treatment studies used single antibiotics at a time, and the longest duration of treatment was 90 days. Many clinicians believe that Lyme disease is more like tuberculosis than strep throat and, like tuberculosis, may require combination antibiotics taken for a couple of years. These types of complex or longer term treatments generally aren't practical to test in traditional trials.

The three NIH treatment trials conducted were very small, with samples ranging from 37 to 129 people. These small sample sizes can't tell us what we need to know. Because as Dr. Gordon Guyatt, a key voice in evidence-based medicine, explains: "To detect small-to-moderate treatment effects necessitates sample sizes in the thousands or tens of thousands." (Guyatt 2008)

Chronic Lyme patients need answers that won't come from small traditional trials. To get sample sizes in the tens of thousands, we need patient-powered projects, like MyLymeData.

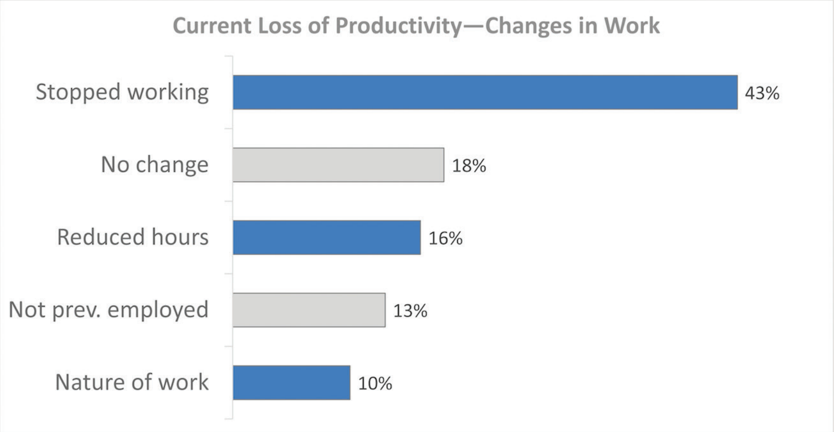
MyLymeData is the first national patient-powered research network for Lyme disease. It provides the tools needed for patients to pool their diagnosis and treatment experiences, and it allows us to track a patient's progress over time.

Patients who are sick today simply can't afford to wait. Chronic Lyme patients have a worse quality of life than patients with congestive heart failure. Many can't work, are on disability (Johnson 2014), have lost their jobs, their families, and their homes. And maybe worst of all, many have lost hope. These patients can't wait for tomorrow's research. They can't wait for traditional research studies to find solutions. They need Big Data projects to bring them the answers they need. They just want to get on with their lives. Lyme disease is an infectious disease, and like Hepatitis C we should be able to solve it. The problem is we're not trying hard enough.

Today patients have enormous power. They have a deep knowledge and understanding of their disease. And they have the most important research asset of all — their health data. Patients are experts with assets. It takes Big Data to solve big problems. Technology now allows patients to pool their data to find answers; it is cheap, quick, and best of all it looks at treatments patients actually receive from their doctors. This is real world research.

Loss of productivity costs exceed medical costs.

Zhang (CDC) study found productivity losses exceeded healthcare costs substantially.



(Johnson 2015; Zhang 2006)

When we analyze mass amounts of data, we can see disease patterns and answer questions that will directly benefit patients. What treatments work the best? Why do some people respond to treatment and others don't? Big data analysis can help us determine which patients are most likely to be cured using standard treatment approaches versus those individuals who may need longer, more aggressive treatment.

Like many patients with long-term illnesses, chronic Lyme patients can feel isolated and powerless. And they ask: Can one person really make a difference? Is it even possible?

Yes, it is. Because with Big Data we're uniting one person with another and another and another. And before you know it, we have a community of patients, all with the same disease, sharing their data. We have patients crowdsourcing their data to find a cure. And I have to tell you, the truth is the people who will cure Lyme disease are the patients. Why? Because they care deeply, are dogged in their pursuit of health, and because they won't stop until they get it right!

Patient-powered research starts with the patients. For over 10 years, *LymeDisease.org* has conducted surveys of patients to increase our knowledge of Lyme disease. Two of our previous surveys have been published in peer-reviewed journals (Johnson 2011, 2014). Our goal is to establish a shared resource of patient natural history information and treatment response to accelerate research on Lyme disease.

It's time for patients to take back the research future. Patient registries and research platforms open a new pathway: They can provide descriptive information. They can conduct observational studies. They can create research-ready populations. They can collaborate on researcher initiated randomized controlled trials. And they can even provide long-term follow-up for traditional trials.

We expect MyLymeData to be the largest study of chronic Lyme disease ever conducted. Sound ambitious? Not when you consider that only 55 patients completed the largest government trial, and that those patients were enrolled over a 3-year period. MyLymeData has enrolled over 3,000 patients in the past three months! That's what patient-powered research looks like! Patients are motivated to find answers quickly.

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FEATURE

The Fine Art of Tick Testing

Knowing the infectious agents in your tick increases the likelihood of proper treatment

By Karen Miller

So you've been bitten by a tick. What do you do? After you've removed the little sucker (immediately *and* safely), it's decision time. Should you test it? Save it in case you get sick and *then* test? Throw it away and hope for the best? To know what to do, you need to find out four things: what tick you have, what pathogen(s) to test for, what type of test to request, and what lab to use.

In the U.S. there are nine ticks generally acknowledged to bite humans and transmit disease-causing pathogens. Currently, there are 17 ticks that cause tick-borne diseases nationwide. Though often ignored in CDC discussions, the west coast is a biodiversity hotspot. Nine of those 17 diseases have been found in northern California, transmitted by six species of ticks. Robert Lane, medical epidemiologist from UC Berkeley, has mentioned four new pathogens recently discovered in this region. Other regions, commonly acknowledged as high-risk areas for TBD, may have fewer pathogens but higher rates of infection in ticks. Inform yourself as to what pathogens occur in your area.

Identifying ticks can be difficult. Technicians in many northern California and some Oregon and Washington county labs often do so for free. I failed to turn up even one county lab in the northeast and midwest that would test ticks, though some would identify them. Some vector control districts and many commercial labs will do so as part of their service (IGeneX does not). Check public health labs, vector control districts, and entomology or veterinary labs at universities for help.

Which test?

If you become sick, testing the tick can tell you what pathogen(s) you were exposed to *by a particular tick*. A negative tick test is not the full story since you may not know if you were bitten another time. Still, knowing which pathogen(s) you were likely exposed to can help you consider a useful treatment approach.

Choosing tests depends on what is available and how much money you are prepared to spend. The chart prepared by Target Lyme of Sonoma County, CA, shows the pathogens *known* to occur in the U.S. These 17 pathogens are correlated with specific ticks known to carry them. Remember, however, that new pathogens are being discovered with some frequency.

Most county public health labs test only for *Borrelia burgdorferi*, strain B31, using an insensitive IFA (immunofluorescence assay) test. A number of commercial labs offer a wider range of tests including the more sensitive polymerase chain reaction (PCR). In the northeast, tick testing is not offered by either state or county labs. A few labs – such as in Duchess County, NY – can identify the tick and estimate engorgement before referring you to the University of Massachusetts for testing. I found no public health lab in the northeast that offered tick testing although a few universities do. Spot-checking in Oregon and Washington elicited no state or county lab that offered tick testing. Vector control districts generally do not test ticks that have been attached to a human.

In California the situation is a bit different. Most northern California regional public health labs will test ticks for about $30-40 and will identify the tick (often for free). However, they will only test *Ixodes pacificus* (Western Black-legged tick) and will only test for *B. burgdorferi*. Unfortunately, they test the ticks using an IFA test, which (according to the Sonoma County lab director) will only test positive if there are a minimum of about 100,000 spirochetes. A PCR test, in contrast, will show positive with fewer than 100 spirochetes. According to the U. Mass lab, their PCR test can detect as few as three molecules of DNA.

Sonoma County uses the less sensitive IFA test because it has "better positive predictive value" for human disease. That is, assuming it takes a certain number of organisms to cause disease, they believe that a dose of 100,000 organisms is more likely to cause infection. Unfortunately, this test may be *too* insensitive. The "infectious dose" varies with the genospecies and strain of

Continued on page 29

PATIENT RESOURCES

Lyme and associated tick-borne diseases (TBD) present complicated challenges for patients. *LymeDisease.org* screens a wealth of information and posts selected sources on our website. Please visit *LymeDisease.org* (click on LYME BASICS - RESOURCES) for recommended books, articles, videos and links to the internet.

ASSESSING MEDICATIONS

In our current healthcare system, access to appropriate medically necessary medications continues to be a challenge for Lyme patients for a number of reasons.

Given the politics of Lyme, the personal financial burden for patients seeking diagnosis and treatment can be overwhelming. Check out these programs that offer assistance.

PHARMACIES

A knowledgeable pharmacist is a pivotal part of your healthcare. These reliable sources are most commonly available at a local pharmacy that provides personalized attention. Independent pharmacies also have greater access to more wholesalers and greater flexibility to order a more effective generic brand. Often it is better to pay a little more at a pharmacy that provides this service.

Outlet stores and supermarkets are generally cheaper than pharmacy chains since they typically use their pharmacy as a loss leader to draw customers into the store. Don't waste time with insurance company approvals given their barriers and manipulations to using their 90-day prescriptions or mail order pharmacies for a generic medication in which the cash price is less or close to the insurance company co-pay.

Be cautious about whether generics are equivalent. Demand generic brands that are known to be equivalent with the medication you need and avoid those known to be inequivalent.

Be cautious when using Internet and foreign pharmacies. Many "Canadian Pharmacies" are not located in Canada, and there are risks of receiving substandard, fraudulent and potentially toxic medications.

DISCOUNTS

If you are having difficulty filling your prescriptions, you may be interested in the following resources:

To access discount coupons, check out the website for the pharmaceutical company that makes the medication you need. These websites are often identified as *(name of the drug).com*.

A number of companies provide discount cards for medications. They are mailed to physicians and also available on the Internet:

Needy Meds: *needymeds.org/index.htm*
Healthcare Alliance: *TheHealtCareAlliance.com*
Half Off: HalfOffRx.com
National Prescription Savings Network: *NPSNCard.com*
Patient Savings Alliance: *PatientSavingsAlliance.com*
Avia Partners: *AviaPartners.com*
PDR card: pdr.net/pharmacy-savings/discount-card-for-patients

Partnership for Prescription Assistance A clearinghouse for patients to network with pharmaceutical companies with patient assistance programs. Many such companies provide discount prices and/or free medication to individuals that meet income requirements. *pparx.org*

GoodRx Gathers millions of current prices, available discounts, and savings tips for prescriptions at major U.S. pharmacies "to make you an informed consumer." The are a small company based in Santa Monica, CA, that does not sell medications. Their posted prices allow you to comparison shop and see whether switching pharmacies or using a discount or savings tip will save you money. They list and provide free discount coupon prices that have no obligations or hidden fee.

Check their website to better understand how prescription prices and discounts work since pharmacies offer more than one price:

- A "cash price" if you don't have insurance or if your insurance company won't cover that drug or it's not on their "formulary."
- A "club price" if you join that pharmacy's club (sometimes free, sometimes requiring a paid membership). Pharmacies don't always tell you when a lower club price is available. No insurance is required.
- A "coupon price" can be confusing as it is negotiated between a pharmacy and an insurance company. Virtually all pharmacies contract with companies called Pharmacy Benefit Managers (PBMs) to provide discounted prices for Americans with insurance. These same contracts also allow people not using insurance to receive a smaller discount when they use a free discount coupon or card. They suggest alternative less-expensive drugs and provide information on manufacturer coupons, drug shortages, recall info, and pill identification tools.

Visit*GoodRx.com* for further information.

Costco Their drug pricing tool is difficult to find on their website. They do not carry every medication but are a useful price guide as they reportedly charge 3% above wholesale. You do not have to be a member to use their pharmacy.

FINANCIAL ASSISTANCE

LymeAid4Kids For those under age 21 who need diagnosis and treatment but lack insurance coverage.
Visit lymediseaseassociation.org

The Lymelight Foundation For those through age 25.
Visit lymelightfoundation.org

Robert C Bransfield, MD, DLFAPA, contributed to this article. His sage advice is designed for patients faced with finding affordable, effective and safe medications.

The Bay Area Lyme Foundation (BALF) offers free tick testing nationwide. In partnership with Northern Arizona University and the Laurel Foundation, data collected from their testing program may help us understand the distribution of TBD and the risk of acquiring such diseases. For more information visit the LDo website, click on News & Blogs - News 18 FEB

Tick Testing, continued from page 27

Borrelia, so the best cut-off point is unknown.

The Sonoma lab tests roughly 1000 ticks per year and gets 1-2 % positive for *B. burgdorferi*.[1] The infection rate of nymphal ticks is even less, which is contrary to local tick survey results where they are *always* infected at a higher rate than adults. So the numbers match (15-20 positive ticks per year vs. approximately 15-20 human cases per year in five counties served by the lab), but they don't necessarily correlate with *who* gets sick. While this lab finds mostly adult ticks infected with *Bb*, it is most often nymphal ticks causing human infection.

In brief:

Results of tick tests should not be used to predict who gets sick. There are too many variables and no apparent correlation.

Don't wait for test results before treating prophylactically. Preventive treatment is most effective when begun in the first 24 hours after a bite and (according to a recent mouse model study[2] less effective if begun more than three days later. Tick testing is unnecessary in deciding to get preventive treatment – that should be based on where you picked up the tick and how much risk you are willing to take.

Tick Testing Laboratories

Lab	Cost	Available tests
N. Arizona U	Free in U.S.	Borrelia burgdorferi & miyamotoi, Anaplasma, Babesia microti, Ehrlichia
IGeneX	$68 ea	Borrelia burgdorferi & miyamotoi, Babesia microti & duncani, Bartonella, RMSF
U Mass LMZ	$50/set *determined by tick species*	*Ixodes Tick*: Borrelia burgdorferi & miyamotoi, Anaplasma, Babesia microti *Dog Tick*: Borrelia burgdorferi, RMSF, Tularemia *Lone Star Tick*: Borrelia burgdorferi, Ehrlichia, STARI
Tickchek	$50 ea	Borrelia burgdorferi, Anaplasma, Babesia microti, Ehrlichia, Bartonella, RMSF, Tularemia, STARI
Clongen	$75 for one or $65 ea	Borrelia burgdorferi & miyamotoi, Anaplasma, Babesia microti & duncani, Ehrlichia, Bartonella, RMSF, Tularemia, STARI
Imugen	$75 or $98 for both	Borrelia burgdorferi, Babesia microti *Ixodes scapularis only*
Analytical Services	$65	Borrelia burgdorferi
U Michigan	Free: for residents only	Borrelia burgdorferi, Anaplasma, Babesia microti, RMSF
U Connecticut	$50, 2/$80, 3/$100	Borrelia burgdorferi, Anaplasma, Babesia microti
Cornell U	$100	Borrelia burgdorferi, Anaplasma
Tic-Kit	$41 for all	Borrelia burgdorferi, Anaplasma, Babesia microti, Ehrlichia, Bartonella

All tests are PCR. RMSF is Rocky Mountain Spotted Fever.

1) **NAU**/Bay Area Lyme Foundation. www.bayarealyme.org/lyme-disease-prevention/tick-testing.
2) **IGeneX.** www.igenex.com/Website/#. Will test up to 20 ticks per test if requested. Contact a Vector Control District for tick ID.
3) **Tickchek.** www.tickchek.com/landing/lyme-disease?gclid=COGC58OJ0sYCFUxqfgodV4sGFw. Bb, Anaplasma and Babesia recommended. Free tick ID.
4) **University of Massachusetts Lab of Medical Zoology** Tick-Borne Disease Network. www.tickreport.com. For tick ID information, refers you to www.tickencounter.org/tick_identification/guide.
5) **Clongen Laboratories.** www.clongen.com/clinical-diagnostics-services/tick-testing. Also offers $175 for Colorado Tick fever, Heartland or Powassan virus; $500 for all three viruses. Will pool up to four ticks from one individual, if requested. Links to ALDF, an organization associated with the IDSA; proceed with caution.
6) **Imugen.** Norwood, Massachusetts.
7) **Analytical Services.** www.analyticalservices.com/tick-testing.html#what_limit.
8) **University of Michigan**: www.michigan.gov/mdard/0,4610,7-125-1566-44271--,00.html.
9) **University of Connecticut.** cvmdl.uconn.edu/service/tick.php.
10) **Cornell University.** ahdc.vet.cornell.edu/Sects/paras/tickID.cfm. Tick ID included.
11) **TIC-KIT.** www.tic-kit.com. Also tests for Borrelia afzelii, B. garinii, Babesia divergens and Babesia. EU1, Ehrlichia ewengii and may soon add Babesia duncani and Borrelia miyamotoi.

Which lab?

Check first! If you decide to use a publicly-accessible commercial lab, you need one that does relevant tests for the region in which your tick was acquired. The directions for mailing the tick varies, so choose a lab *before* you do anything with your specimen. Some labs require a live tick; some ask for the tick to be in alcohol; some will test frozen ticks (important if you want to test the tick *only if* you develop symptoms). Generally, live ticks should be sent within two weeks of removal.

Be aware that doctors may or may not recommend tick testing. Any information that may help untangle the wide array of ensuing symptoms can be useful, however. Of course, preventing tick bites in the first place will spare you having to use the information in this article.

The author is a patient advocate with the TBD Advisory Group in Sonoma County, CA. She may be contacted at hbgkaren@sonic.net.

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[1] sonoma-county.org/health/publications/index.asp#factsheets,

[2] Piesman, *et al*, "Efficacy of an Experimental Azithromycin Cream for Prophylaxis of Tick-Transmitted Lyme Disease Spirochete Infection in a Murine Model," *Antimicrob. Agents Chemother*. January 2014 vol. 58 no. 1 348-351

Blacklegged Ticks Spread Across America

CDC study finds ticks carrying TBD in nearly half of U.S. counties

The number of ticks that transmit Lyme disease to humans is growing in the U.S. According to recent research conducted by the U.S. Centers for Disease Control and Prevention (CDC), the geographic distribution of two blacklegged ticks (*Ixodes scapularis* and *Ixodes pacificus*) has increased since the last comprehensive survey was published in 1998. These two are the primary vectors of the Lyme disease bacteria, *Borrelia burgdorferi,* and other infectious agents.

Over the last 20 years, these two main species of blacklegged ticks have undergone a population explosion, doubling their established range into half of all U.S. counties. Since 1991, when CDC standardized surveillance and reporting began, Lyme disease case counts have increased steadily.

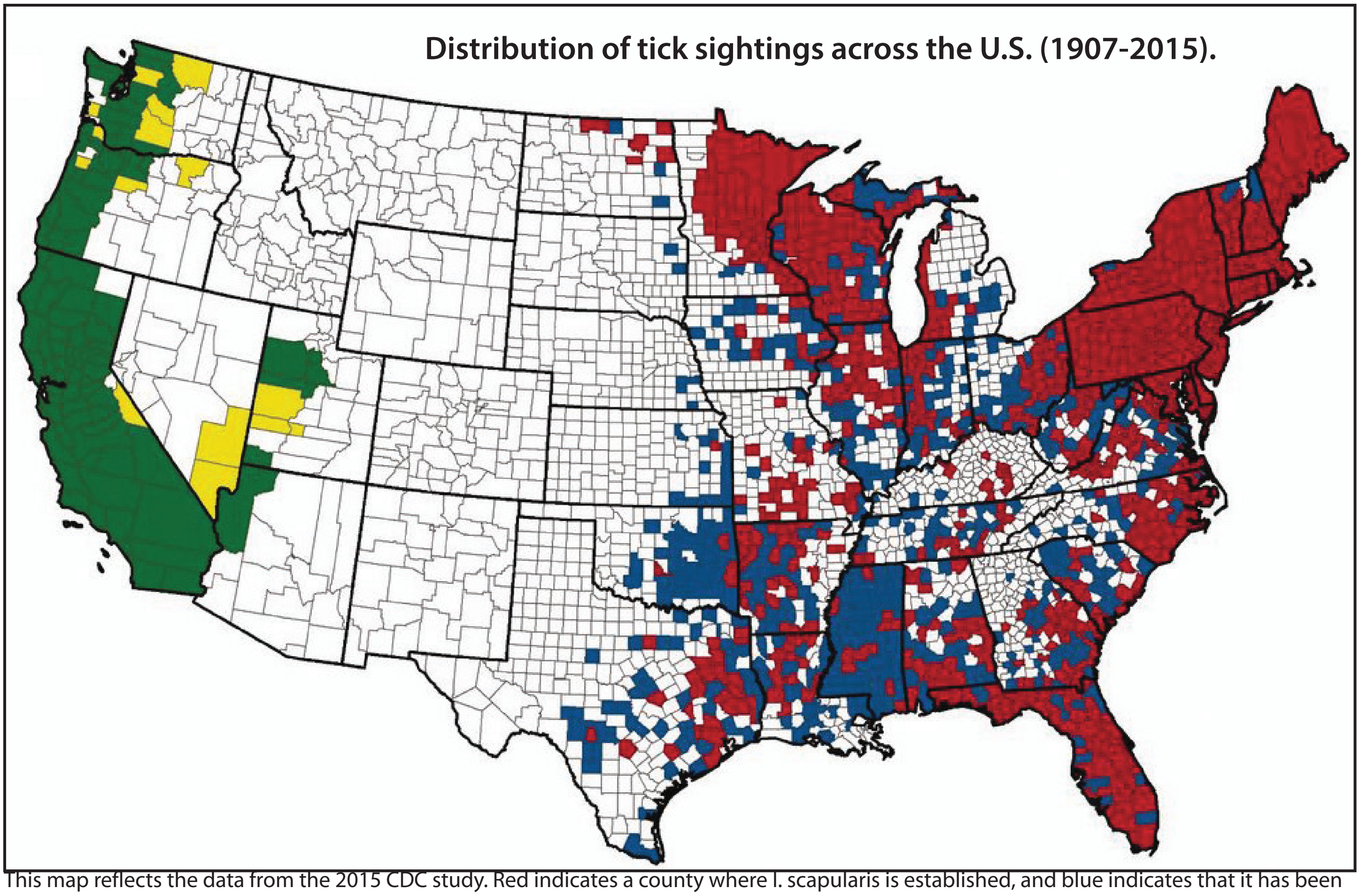
At the same time, cases of Lyme disease in the U.S. have tripled, making it the most commonly reported vector-borne disease in the Northern Hemisphere. Cases of anaplasmosis and babesiosis have been on the rise as well. According to CDC estimates, Lyme disease now affects some 300,000 Americans each year. Other estimates are significantly higher. But the number of "reported" cases may be misleading, however, as Lyme disease is a complex often misdiagnosed illness that can involve multiple pathogens.

Study methods

Since some symptoms of Lyme disease mimic other illnesses, medical practitioners are better able to diagnose TBD if the vector pattern of the disease is understood. A new study by Dr. Rebecca Eisen, a research biologist at the CDC, and her colleagues have clarified the current geographic distribution of those blacklegged ticks involved in transmitting Lyme disease.

The team's surveillance methods were similar to those used in 1998 in order to judge the degree to which the tick distribution had actually changed. Their study was able to identify which U.S. counties had established tick populations, which ones had one or more reports of a blacklegged tick, and which ones had none.

To create a comprehensive map showing where the two species were living, Eisen and her colleagues combined data from pub-



This map reflects the data from the 2015 CDC study. Red indicates a county where I. scapularis is established, and blue indicates that it has been reported. Green indicates a county where I. pacificus is established, and yellow indicates that it has been reported. *R.J.Eisen et al., J.Med.Entomol.* (2016)

lished papers with state and county tick surveillance data going back to 1996. They counted reports of tick sightings in each of the 3110 continental U.S. counties to determine whether those counties hosted an established population or just a few individuals. Ticks were considered "established" when sightings of at least six ticks, or two of the three life stages, had been reported in a year.

Study Findings

Counties

According to this new study, *I. scapularis* has been reported in 1,420 of the 3,110 continental U.S. counties (more than 45%) — compared to 30% of counties in 1998. By comparison, *I. pacificus* is documented in only 111 (3.6%) counties. Even more alarming, the blacklegged tick is now considered "established" in twice the number of counties as they were in 1998. According to Eisen, "The tick is now established in areas where it was absent 20 years ago."

The range of established tick populations in the U.S. has increased modestly — from 3.4% to 3.6% of counties. Combined, these two blacklegged ticks are now found in half of all U.S. counties. "Since the late 1990s, the number of counties in the northeastern U.S., considered high-risk for Lyme, has increased by more than 320%," Eisen adds.

States

Combined, these two blacklegged ticks are now in 1,531 (49.2%) counties spread across 43 states as compared to 41 states in 1998. Despite the wide distribution across states, Eisen notes that the risk of Lyme disease is not equal across the country.

Lyme disease remains most common in the tick-dense northeast. Although blacklegged ticks are found from Florida to Minnesota, 95% of CDC confirmed Lyme cases come from just 14 states in the Northeast and upper Midwest. The distribution of I. scapularis in the South has remained fairly stable. According to this study, most of the tick spread appears to be in the North-Central and Northeastern states. Tick populations in southern states have remained relatively stable. The rarer western blacklegged tick (*Ixodes pacificus Cooley* and *Kohls*) is reported in just six states and 45.7% of counties, up from 30% in 1998.

Conclusion

According to Eisen, "This study shows that the distribution of Lyme disease vectors has changed substantially over the last nearly two decades and highlights areas where risk for human exposure to ticks has changed during that time." Confirmation of the expanding range of ticks in the U.S. highlights the need for continuing and enhancing vector surveillance efforts. Monitoring the spread of the blacklegged tick will allow people to better protect themselves from the risk of being bitten and infected.

The full article was published by the Entomological Society of America in the January 2016 issue of their Journal of Medical Entomology. "County-Scale Distribution of Ixodes scapularis and Ixodes pacificus (Acari: Ixodidae) in the Continental United States." A review of the CDC study by Claire Asher was published in the January 18, 2016 issue of the AAAS journal Science.

PATIENT VOICES

Jesse Colin Young

Singer-songwriter music video reflects on his Lyme experience

By Dorothy Kupcha Leland

In 1995, fire erupted at California's Point Reyes National Seashore, a place of wild beauty about 30 miles north of San Francisco. Fed by hot, dry winds, the conflagration scorched more than 12,000 acres of brush and woods. Forty-five buildings went up in flames, including the home of legendary singer/songwriter Jesse Colin Young and his family.

Young didn't realize it at the time, but the fire and its aftermath would mark a significant turning point in his life. It set in motion forces that pulled him into a downward spiral of poor health and emotional turmoil, before leading to a surprise diagnosis of neurological Lyme disease.

He has endeavored to capture what happened in a song he calls "Lymelife." In it, he distills many years of experience into 30 lines of lyrics.

He and his band the Youngbloods burst into musical prominence during the 1960s with their hit song "Get Together." Just about anybody who lived through that era probably recalls its refrain:

Come on, people now. Smile on your brother.
Everybody get together, try to love one another right now.

Having grown up in New York, Young moved to Point Reyes in 1967 because its natural splendor entranced him. It hadn't yet been named a National Seashore, and few people even knew to go there. He reveled in its solitude and stunning landscape.

"That's where my journey began," Young said in a recent telephone interview. "Hiking in those woods and riding my motorcycle out to the beach. Coming from the lower east side of New York, I felt like I had died and gone to heaven. That's what the beginning of the song Lymelife is about. I had this powerful, beautiful experience of nature...and there were seals that lived right there on the beach at Limontour Spit, and deer running all over, great herds of them, all over the place. I loved it."

As he sings in Lymelife:

I loved the woods and the wildest places
I made trails that had left no traces.
I followed them to the ocean roar
Who on earth could have asked for more?
I spoke with seals and the white deer running
Hawks and owls and a cougar cunning
I breathed with dolphins as they swam by
A blood red sunset in my eye.

During almost 30 years of delighting in the natural world of Point Reyes, Young often pulled ticks off his body and thought nothing of it. Then his house burned down.

"It was a crushing blow for me. I had fallen in love with that area, I made music about it, had been inspired by it. I think that's what brought out the Lyme, that the blow of that fire took me down so far emotionally and eventually physically. However long I had been carrying that Lyme disease in my body, it decided it was time to take over."

But he wouldn't realize that for many years. After the fire, he and his wife moved to Hawaii to live in a house on a small coffee plantation. Soon, Young says, "I thought I was going crazy. I had a lot of anxiety, panic attacks, and strange symptoms of having difficulty swallowing. All these things they just assumed were psychosomatic, because I'd been through the traumatic experience of losing my house like that. The only thing doctors could think of was to put me on antidepressants."

Young suffered for years from cognitive impairment, depression, mood swings, and various pains — not knowing what was really wrong, getting little relief from any treatment his doctors offered.

There's so much to learn, tell me where do I turn?
Now that I've lost my health, my sanity?
I'm angry, I'm sad.
I'm frightened, I'm mad
I'm feeling the bite of inhumanity

"I think that if I had not married such a loving and strong woman as my wife Connie that my family would have blown apart."

Then, another turn of fate.

In the mid-2000s, Young says, his wife went to a family funeral in Ohio. There she saw her cousin, Barbara Buchman, who happens to be the executive director of the International Lyme and Associated Diseases Society (ILADS). Buchman gave her cousin a copy of an ILADS brochure about Lyme and psychiatric symptoms.

"So the brochure ended up on our kitchen counter. (Whether there were angels involved, I don't know.) I read it and thought: this is my biography."

He called Buchman, who suggested that he see Richard Horowitz, MD, in Hyde Park, New York. Horowitz diagnosed him with Lyme disease and prescribed antibiotics.

"And that began my journey to regain my sanity. That, and giving up drinking. Because, when you don't know what's happening, you medicate with whatever tools are at hand. And alcohol became another trap for me. So between my sobriety and entering antibiotic treatment with Dr. Horowitz, I began to see my mind come back to me."

Young said he's not particularly fond of media interviews, but he did a few that mentioned Lyme disease. As a result, he started receiving emails from people talking about their own Lyme struggles. Hearing their stories motivated him to write the song Lymelife.

And when I wake tomorrow morning, who will I be?
A man who's strong and willing, or lost and angry?
Someone's cherished lover, or my lover's enemy?

"As long as the infectious disease doctors in America and the CDC deny the existence of chronic Lyme, those who have been suffering for decades will not get proper treatment. That's what I'm trying to help with. This song is my gift. It's what I do best."

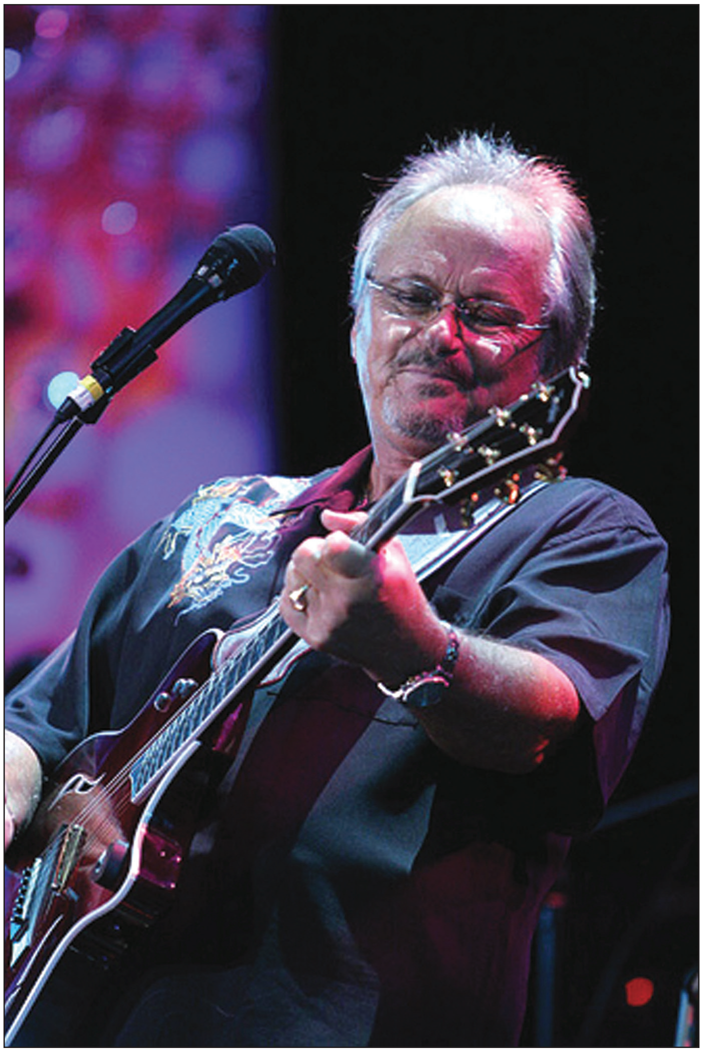
Young now lives in South Carolina, his wife's home state. He's working on an album of songs which won't all be about Lyme disease. However, since he says "I seem to be slow at writing and recording," he has chosen to make Lymelife available as a YouTube video.

It's a simple production, showing Young playing his guitar while perched on the arm of what appears to be his living room couch. A dog dozes at his side. The video was made without a band, studio, or producer. Yet the song exerts a visceral power — the sense that Young is clearly singing from the depths of personal anguish.

"It was important for me to show the pain and confusion and loss of cognitive abilities — and the loss of your sense of who you are. It's a cry for help for our community, a cry for recognition."

Ah, this Lymelife, it cuts like a dull knife.
Ah, this Lymelife, tell me where is my sweet life?
Ah, this Lymelife, the shadow left is me.

Watch the Lymelife video at youtube.com (http://bit.ly/1UywUFR). More information about Young's music is available at jessecolinyoung.com.



MyLymeData Testimonials

What people are saying about their reasons for joining LDo's research effort

MyLymeData
A PROJECT OF LYMEDISEASE.ORG

LymeDisease.org has posted a series of guest blogs on our website written by patients who have added their personal medical data to MyLymeData. As we go to press, over 4,000 patients have enrolled in MLD.

MyLymeData is the first national patient-powered research project for chronic Lyme disease. It was conceived by patients, is run by patients, and addresses the issues that patients care about. Through a secure online portal, patients can share their health information and experiences to help drive research to improve their lives. MLD will allow researchers better understand the disease, what treatments are most effective, and why some people stay sick, while others do not.

Please join the effort to help find a cure! To enroll or learn more about MyLymeData, visit *lymedisease.org/mylymedata.*

Dana Parish began her nightmare on Long Beach Island, NJ. Days later, she woke with a crushing head and neck ache. Seeing a faint red circular rash with a bug bite in the middle, she immediately thought Lyme. From the ER, she received the CDC recommended 21 days of Doxycycline, and was relieved by later reassurances from ID docs. Other severe physical and mental symptoms developed but were dismissed by several specialists. Googling her symptoms, she discovered she had 37 of Burrascano's 60 symptoms. Enraged, overwhelmed and terrified, she found a LLMD in San Diego – her 12th doctor. After a year, she is 95 percent better. She has signed up for MyLymeData to wring some benefit out of her horrific experiences.

Dana is a New York-based singer/songwriter whose work has been recorded by Celine Dion and other stars.

Sandi Bohle enjoyed the outdoors near her home in New York's Hudson Valley until her symptoms began to appear. Her doctor concluded she was just overworked and stressed. Moving to LA, she declined dramatically. Although her classic symptoms screamed chronic Lyme, doctors rejected the possibility. She was misdiagnosed with MS, ALS, Parkinson's, Epstein-Barr, lupus, and fibromyalgia until a Lyme-literate medical group diagnosed late stage CLD and four co-infections. Vindication! But the hard part was still to come. Life had changed.

Sandi is a Lyme activist in Southern California.

Silver Feldman, a bed bound teenager with pain, made out a will when she was sure she was dying. Her suffering became her family's, and in an instant their lives fell apart. Living in Los Angeles, Lyme disease never came up. She never saw a tick bite. She was misdiagnosed, mistreated, and ignored until her quest took her to an east coast doctor. Despite a diagnosis, doctors refused to treat her, telling her there was no Lyme in California. Worse, some were armed with misinformation and ineffective treatments. She was fighting both a debilitating disease and medical ignorance. After eight years devoted to repairing the damage to her body, she is almost pain-free. She understands that we are all in this together and that better research can help identify better tests and life-changing treatments.

Silver lives in Southern California.

Sherrill Franklin knows about suffering with an invisible illness. Her extended Lyme journey began with an engorged tick and a target-shaped, red rash. Despite symptoms, her doctor remained convinced it was not Lyme because she had already been treated for 10 days. She endured years of tests and a dozen doctor visits. Although some diagnosed Lyme and recommended IV treatment, no one would prescribe the actual medication. Overcome with indescribable fatigue, an inability to think clearly, tinnitus, muscle pain, chills, and vision problems, she doubted she would survive. She relied on her committed and capable staff to keep her business going. Eventually diagnosed, she was treated for Anaplasmosis and Lyme. She has learned how difficult it is to cure undiagnosed entrenched Lyme. Although long-term antibiotics help, it has not been a cure. She believes that MLD can help find new solutions.

Sherill is the founder and CEO of Harmonydesigns.com. She lives in Chester County, Pennsylvania.

Sandy Reyes envisioned ambitious dreams. The first woman in her family to graduate from college and go on to law school. As she began her career in Delaware, she became ill. Over time, her doctor misdiagnosed fibromyalgia, sinus infections, Meniere's disease, and IBS. Months stretched into years. Since she had not seen a tick or a rash and her test was negative, her doctor failed to diagnose Lyme and recommended counseling and biofeedback. She resigned her job. When later test results were off the charts, she was admitted immediately to the hospital. Lyme was affecting her central nervous system. She is now returning to her new normal, still living with flare-ups and the stigma of Lyme. She hopes that MLD will save other people from repeating her experience.

Sandy works for the State of Delaware, teaches at Wesley College, and is a member of Delaware's Lyme Disease Prevention Task Force.

PATIENT VOICES

A Hopeless Hypochondriac

A distinguished Air Force career ends in shame because doctors didn't understand Lyme

By Ruben Lee Sims

I have had Lyme disease for 34 years although I only recently began treatment.

I was active duty Air Force when I contracted Lyme disease in Southern California in 1982. I know exactly when, where, and how I was infected. 1982 was the same year Willy Burgdorfer identified the spirochete that causes Lyme.

The experts were claiming that Lyme only existed in endemic areas of the northeastern United States.

Although it was published as fact, there was (and is) no real scientific basis for this statement. It seems purely arbitrary and subjective. However false these statements may be they have caused California Lymies and Lymies outside the so-called "endemic areas" enormous grief and suffering, because so many doctors still believe you cannot get Lyme disease in California and other non-endemic areas.

Military justice

Because doctors identified no disease that caused my many symptoms, I was punished as a military man under the Uniform Code of Military Justice — receiving two Article 15s and nearly court martialed twice. I was committed to secure psychiatric wards three times as a hopeless hypochondriac. I was told I would stay on the psychiatric ward until I got better.

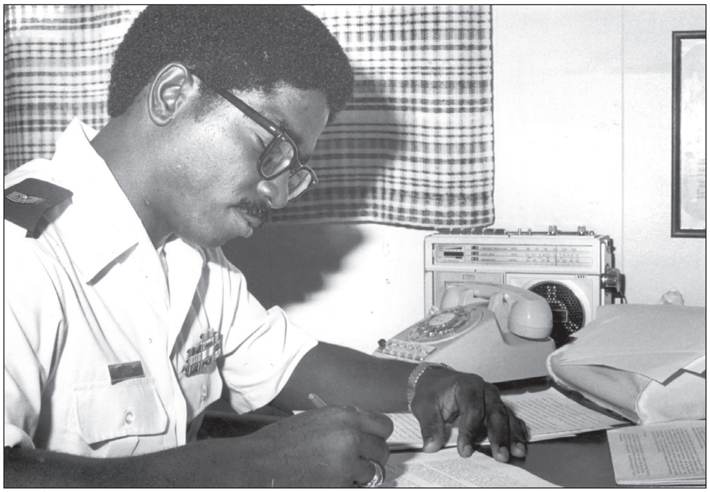
After a congressional investigation, I was finally discharged from the Air Force after 14 years of highly recognized and awarded military service that ended in shame because doctors did not understand Lyme disease. I stood before a military hearing where attorneys laughed and joked as they decided I was no longer fit for duty, discharging me from the Air Force without benefits, pay, or health insurance. I was essentially dumped on the streets homeless, disabled, and unable to work, with a wife and a child to provide for.

Veterans Administration

Three decades after my discharge, the VA still cannot diagnose Lyme disease based upon symptoms. Instead, I learned I had Lyme disease from a May 2015 Costco magazine article that encouraged me to review my medical records and study Lyme disease. That review taught me that the same rash that started three decades ago was the *Acrodermatitis Chronica Atrophicans* (ACA) rash that is caused by untreated Lyme disease.

It took six months of constant confrontation with the VA to get them to bring in someone who understood Lyme disease. I am sero-negative by ELISA and Western Blot, so doctors' over reliance on serology tests nearly left me blind from severe sensitivity to light.

In December 2015, however, the VA finally brought in a Lyme expert from the Hospital of Special Surgeries in New York. Unknown to me, the VA had already confirmed my ACA rash. The expert reviewed my documents and found the confirming skin biopsy in my records. Therefore, even though I was seronegative, the ACA rash confirmed my Lyme disease 34 years after my infection.


Reuben Lee Sims

It is important to know that the VA did not recognize Lyme disease until the mid-1990s. That means that veterans who had Lyme disease before then were misdiagnosed and some may still be homeless and disabled. Our government is no wiser today than before they recognized Lyme disease, however. We are still being misdiagnosed and perhaps dying of other Lyme-related diseases. I cannot sit by and do nothing to change this.

Progress . . . finally

After less than a month of treatment, my photophobia was nearly gone, and the ACA rash was gradually fading. I no longer take daily naps and can sleep 7-8 hours several days a week. I no longer feel totally wasted and out of things every day. I am encouraged by treatment and look forward to setting my records straight and helping others.

As a management/cost/financial analyst for over 30 years, I know that data is a valuable resource. Thus, one of the ways I'm going to help bring about needed change is by participating in MyLymeData.

This important project gives Lyme patients a chance to make a real difference. By pooling our information, we can help build a knowledge base of how real people experience Lyme disease. This will help researchers steer their studies in a more useful direction. No one in the military — or anybody else in this country — should be left to suffer so long without proper medical care.

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