

THE  
**LYME TIMES**

Volume 27 • Number 2 • 2015

*The Journal of LymeDisease.org*

**BIG DATA IS A BIG DEAL**

WHAT'S THE  
BEST WAY TO  
DIAGNOSE IT?

WHICH  
TREATMENTS WILL  
WORK BEST?

HOW DOES IT  
PROGRESS?



**PATIENT-POWERED RESEARCH NEEDS  
YOUR HEALTH DATA TO HELP FIND A CURE**

***Process for Developing IDSA Guidelines Remains Flawed  
LDo Patient Surveys Expose the High Cost of Illness  
Improving the Sensitivity of Diagnostic Tests***



**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, legal and ethical analysis, education, physician training and medical research.

**LDo** provides a patient-powered research tool — MyLymeData — to enable patients to influence the national research agenda. We conduct national patient surveys published in major journals to inform practitioners and influence policymakers. We network with the patient community through state-based online support groups.

**LDo** communicates in print and online. We analyze and archive information in *The Lyme Times* and provide educational material on [lymedisease.org](http://lymedisease.org). We publish regularly in peer-reviewed medical and healthcare policy publications.

#### **MyLymeData**

MyLymeData is our patient-powered research project that allows people to use today's computer technology to quickly and privately pool diagnosis and treatment experiences. When large amounts of data are combined, we can identify patterns that help determine which treatments work best. Add your Lyme data to MyLymeData to help find a cure for Lyme disease.

#### **Online Support Groups**

Participate in education and advocacy activities in your state. Learn about local resources and receive technical support for your projects. Exchange information conveniently from your home. To find your online statebased group, go to: [groups.yahoo.com/neo/group/YOURSTATE](http://groups.yahoo.com/neo/group/YOURSTATE) NAMElyme. LDo also hosts a support group (LymeUSA) and a parents' group (LymeParents).

#### **Website**

Visit our extensive redesigned website at [lymedisease.org](http://lymedisease.org), now available for viewing on your mobile devices. Discover the basics of Lyme disease, co-infections, protection and prevention. Read our blogs to stay informed on breaking news, analysis and events. Sign up for our free email newsletter.

#### **Facebook & Twitter**

Keep on top of developing news and share your own experiences and opinions by joining the conversation on our Facebook page: [facebook.com/2lymedisease.org](http://facebook.com/2lymedisease.org). Follow @Lymenews to receive our tweets on your phone or computer.

#### **Become a Member**

Make our voice even stronger by supporting our national advocacy efforts. Join online at [lymedisease.org](http://lymedisease.org) or contact JoAnne Vidal: [jvidal@lymedisease.org](mailto:jvidal@lymedisease.org)  
PO Box 1352, Chico, CA 95927, phone 530-570-1811.



## **REDESIGNED LDo WEBSITE UP & RUNNING**

*LymeDisease.org* (LDo) has improved its website. An exciting new feature allows members the option of reading *The Lyme Times* online. You will still reach us in the usual way — by going to *LymeDisease.org*, but it has a revised “responsive” design. What does this mean to you?

You can now read everything easily on a variety of devices — desktop computers, laptops, tablets and smartphones, for example. There is also updated educational information on many topics of interest to the Lyme community. Check it out!

## **IDSA PROTEST IN SAN DIEGO**

When the IDSA meets in San Diego this October, three Lyme advocacy groups will be there as well. *LymeDisease.org*, The Mayday Project, and the San Diego Lyme Disease Support Group are cosponsoring a protest and candlelight vigil outside the Convention Center on Oct. 9-10. Can you join us? Visit [lymedisease.org](http://lymedisease.org) for details.

## **CONFERENCES 2015 — Save the dates!**

October 16-18: ILADS annual meeting in Ft. Lauderdale, Florida.

November 14 & 15: Lyme Disease Association annual conference in Warwick, Rhode Island.

For more information turn to TLT, page 35

## **SEND US YOUR PHOTOS**

Would you like to provide a photo for *The Lyme Times* or our LDo website? It's as easy as 1, 2, 3. Point, shoot, and attach it to an email noting “who, what, where, and when.” Photos need to be high resolution. Give it a try! Contact Sandi Bohle for further details: [sbohle@lymedisease.org](mailto:sbohle@lymedisease.org).

#### **FRONT & BACK COVERS:**

Graphics were adapted from designs and animation produced specifically for LDo's MyLymeData project. Visit [lymedisease.org](http://lymedisease.org) to view the full video explaining the project and how you may participate.

# THE LYME TIMES

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Add your Lyme data to MyLymeData

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# Big Data is a Big Deal

We are excited about MyLymeData — our new patient-powered research tool that lets real patients give meaningful input into the search for a Lyme disease cure. Please learn more about it in this issue because we want you to join in.



MyLymeData builds on the foundation of *LymeDisease.org*'s online surveys, which have collected information directly from patients and published the results in important medical journals. Participation has almost tripled since our first one in 2011 — reaching over 8,000 people this year. MyLymeData will be an even bigger and more powerful project, and its success depends on you.

One of the big problems with mainstream research is that it looks at small numbers of patients in a narrow spectrum of disease symptoms. Lyme specialists complain that the people enrolled in research trials don't look like the average patients they see in a clinical practice. Traditional research also focuses on curiosities of researchers rather than the concerns of patients living with the disease. And sometimes patients find out that their records have been used for a project that actually hurts them!

MyLymeData addresses these problems directly. It allows thousands of patients to pool their medical experiences so we can see how treatments are working, how people have been misdiagnosed, or how many co-infections afflict the average patient. Importantly, each participant will decide who may access their data. *LymeDisease.org* will explain each proposed research project and offer recommendations.

By pooling data, patients and researchers approved by them can learn about the real-life impact of the disease. By asking the right questions, we can give patients a chance to weigh in on issues that matter to them. And *LymeDisease.org* will continue to relay your voices to healthcare policy experts, journalists, and legislators who could actually help patients.

Many are becoming involved in the “big data” movement. John's Hopkins researchers have studied more than 52,000 insurance records of Lyme patients (see story page 24). As a result a very different picture is emerging from the one long held by the Infectious Diseases Society of America (IDSA) and the Centers for Disease Control and Prevention (CDC). Lyme now affects the lives of millions of Americans, and surveys show how it is hurting families and whole communities. It's way past time to change this.

This issue of TLT has other exciting articles, too. More and more people are speaking out and organizing educational events. This spring I attended two conferences on the East Coast. Both played to packed audiences. In March, the Mid-Massachusetts Lyme Disease Foundation hosted its first conference. Hundreds braved icy roads to hear ILADS doctors speak and to participate in a dozen workshops. In May, Connecticut's Lyme Connection organized its ninth annual free patient conference and health fair, where advocates honored Lyme Disease Association President Pat Smith for her years of community service. They also had a full house.

And we have a new film! Andy Abrahams Wilson has come out with a sequel to *Under Our Skin: Emergence*, in which he devotes a big chunk to *LymeDisease.org* CEO Lorraine Johnson explaining the important issues in Lyme science and politics. “Take a Bite Out of Lyme,” also known as the Lyme Disease Challenge, brainchild of Melissa Bell and her Florida colleagues, has proved a big success, bringing many celebrities into the “lymelight” while raising funds for the ILADS Research Foundation.

Read and inform yourself. Then go to *LymeDisease.org* to add your Lyme data to MyLymeData. Learn more about real people with Lyme disease and help find a cure!

*Phyllis Mervine*

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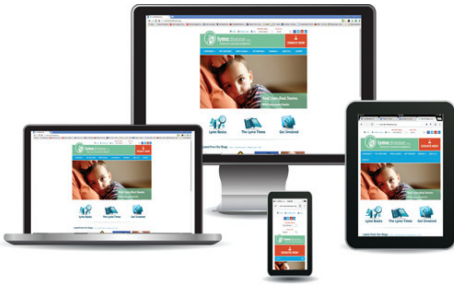
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# LymeDisease.org ONLINE

## STAY CURRENT WITH LDo NEWS AND ANALYSIS

Our recently redesigned LDo website catches changing information as it happens.  
Visit us online at [lymedisease.org](http://lymedisease.org)

We also spread our message via social media:  
youtube: find us at [youtube.com/user/TheLymeTimes](https://www.youtube.com/user/TheLymeTimes)

Twitter: follow us @Lymenews

Facebook: “like” our page, [LymeDisease.org](https://www.facebook.com/LymeDisease.org)

Sign up to be notified by email when new blogs are posted [www.bit.ly/1MrLCud](http://www.bit.ly/1MrLCud)

Visit our homepage if you would like to receive free email newsletters.

On the homepage, click on **News & Blogs** for News, Lyme Policy Wonk, Touched by Lyme, and Focus.

Here are highlights of our recent coverage on [lymedisease.org](http://lymedisease.org)

### NEWS

House passes 21st Century Cures Act with provisions for Lyme disease.

Hidden Epidemic of Lyme is public health fiasco (Business Insider).

Tiny tick, big controversy (30 minute special from WMDT-TV).

Dr. Richard Horowitz, author of *Why Can't I Get Better?* featured on NBC “Today” show.

Is CDC compromised by conflicts of interest?

British medical journal says the agency protects “the private good.”

What really works to prevent tick bites?

Consumer Reports says certain repellents are more effective than DEET.

How Lyme disease subverts the immune system (UC Davis).

### LYME POLICY WONK

Growing number of chronic Lyme patients — still no government action plan?

Delayed diagnosis of Lyme disease has devastating effect on patients.

The LYME POLICY WONK blog is written by Lorraine Johnson, JD, MBA, chief executive officer of LDo. Contact her at [lbjohnson@lymedisease.org](mailto:lbjohnson@lymedisease.org). On Twitter, follow her [@lbjohnson@lymedisease.org](https://twitter.com/lbjohnson)

### TOUCHED BY LYME

Cannabis for Lyme disease and related conditions (book review)

When Lyme disease affects the heart (book review)

The TOUCHED BY LYME blog is written by

Dorothy Leland, LDo vice president.

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On Twitter, follow her [@dleland@lymedisease.org](https://twitter.com/dleland)

### FOCUS

Managing Lyme patients? How about treating them? (Dr. Daniel Cameron)

Watch NY State Senator Serino’s Lyme forum (video)

An unusual presentation of Lyme disease in Georgia.

**Don't miss the special online feature from our recent patient survey  
#Real Lives. Real Stories.**

Thanks to all of you who participated in our March 2015 patient survey! It drew over 6,000 responses. The results were incorporated into LDo’s formal submission to the Infectious Diseases Society of America (IDSA) as it prepares to revise its Lyme disease guidelines.

To read more of the results of our 2015 patient survey, go to <http://bit.ly/1CUuDOh>

# Celebrities Increase Awareness of Millions

Sharing their personal Lyme stories informs and inspires

By Dorothy Kupcha Leland

## Avril Lavigne

When *People* magazine featured Canadian superstar Avril Lavigne on the front cover of its April 13 issue, there was no mention of Lyme disease. Instead, the headlines read:

*Avril Lavigne. Her secret health crisis. 'I thought I was dying.' The singer finally opens up about the devastating disease that kept her bedridden for months — and how she's fighting to recover.*

No matter. Long before any of the weekly's 3.5 million copies actually landed in readers' hands, the news was out. *People's* scoop about the 30-year-old pop star's year-long battle with Lyme disease was widely trumpeted on *Good Morning America*, the *Today Show*,



Avril Lavigne broke down during an interview on ABC's *Good Morning America* June 29, 2015 when speaking about doctors telling her she was crazy when she was looking for a diagnosis.

and other major news outlets, along with Facebook, Instagram and Twitter. Coverage came from such far-flung places as India, Australia, and Africa.

*People's* story rippled throughout the media world for weeks, prompting spin-off articles about Lyme disease in publications as diverse as *Women's Health Magazine* and *Venture Capital Post*.

Then, on June 29, ABC News aired Lavigne's first on-camera interview about Lyme on both *Good Morning America* and *Nightline*. Lavigne tearfully told reporter Jesse Palmer that trying to figure out why her health had collapsed was "the worst time of my life."

The star said after becoming bedridden with a mysterious ailment, she saw many doctors who failed to solve the puzzle.

"They would pull up their computer and be like, 'Chronic fatigue syndrome.' Or, 'Why don't you try to get out of bed, Avril, and just go play the piano?' It's like, 'Are you depressed?'"

Lavigne says she's "80 percent" recovered now. She credits antibiotics and a healthier diet. She now eats organic and avoids sugar, dairy products and gluten. She juices three times a day, does yoga and meditates.

Reviving her musical career after a months-long break, Lavigne also says she wants to help raise awareness of Lyme disease. Telling her story to *People* and *Good Morning America* is an excellent start.

## Costco Connection

*Costco Connection* magazine may not have the razzle-dazzle of *People*. But it has more than double its circulation in the United States. The nation's largest-circulation print monthly, *Costco Connection* is sent free to 8.6 million subscribers.

The May 2015 issue includes an informative article about Lyme disease. It quotes two ILADS doctors, Raphael Stricker, MD, and Steven Phillips, MD, as well as Andrea Caesar, author of the book *A Twist of Lyme: Battling a disease that "doesn't exist."*

The Canadian edition of *Costco Connection* had a similar article by a different writer in its May/June issue. It quoted Jim Wilson of the Canadian Lyme Disease Foundation, as well as Calgary microbiologist Marianne Middelveen, a Lyme disease researcher who has personal experience with the illness. The publication is sent to 2.7 million Costco subscribers in Canada.

## Ashley Olsen

Another celebrity made a big Lyme-related splash in online celebrity gossip columns. Websites *Inquisitr* and *Radar Online* reported that actress Ashley Olsen has been struggling with Lyme disease. Ashley, along with her twin Mary Kate, starred in the long-running TV sitcom *Full House*. These websites attribute the information to unnamed sources, and their stories were widely circulated via social media. As of this writing, however, the 29-year-old Olsen has not confirmed those reports.

## Yolanda Foster

Yolanda Foster, actress on the television series *Real Housewives of Beverly Hills*, continues to use social media to share her search for a Lyme cure. She posts regular updates of her Lyme experience



Yolanda Foster has used all of her social media accounts to share her journey with the Lyme community and her other followers.

to a million followers on Instagram and 486,000 on Twitter. Although she gives few details about her treatments, she has shared pictures of herself hooked up to IVs and using a portable far-infrared sauna.

## Slate

There has been a lot of recent news coverage about ticks and the many diseases they carry. Writing about ticks and their microbes may seem a “safer” subject for many reporters. They don’t have to get bogged down into the question of whether chronic Lyme exists. The online news magazine *Slate* ran a major article under the headline: “Be Very Afraid of Ticks.”

This was followed by the sub-heading: “The threat of tick-borne diseases is serious and growing. And you’re probably not doing enough to protect your family.” The article has been shared on Facebook more than 41,000 times.

## Dear Abby

This advice column, reportedly viewed by 110 million people per day, marked Lyme Awareness Month by running a letter about Lyme disease. It came from a Canadian reader who said, “If someone doesn’t recognize the symptoms and seek treatment immediately, Lyme disease becomes chronic and debilitating.” The

letter included URLs for ILADS and the Canadian Lyme Disease Foundation.

Abby’s response was a real eye-opener. She said her husband had been bitten by a Lyme-infected tick “while sitting in a friend’s living room in California.” The friend’s dog had brought ticks into the house. Abby’s husband developed a bull’s-eye rash and received prompt treatment, which was apparently effective. Then Abby says: “But not everyone is so fortunate, and people with chronic Lyme disease have been known to suffer for life. A word to the wise: be informed.”

# The Lyme Disease Challenge

In 2014, a grassroots initiative called the Ice Bucket Challenge took social media by storm and raised more than \$21 million for the ALS Association. In its wake, a group of five women — some with Lyme themselves, others whose children have Lyme — joined together to plan a similar challenge to raise awareness and funds for Lyme disease.

They enlisted several thousand supporters on Facebook, and in March 2015 launched “Take a Bite Out of Lyme,” also known as the Lyme Disease Challenge. The idea is simple:

Take a photo or video of yourself biting a lime (and perhaps making a sourpuss face). Post it on social media, along with a fact about Lyme disease.

Make a donation to ILADEF (the International Lyme and Associated Diseases Society’s 501(c)(3) non-profit educational fund), and challenge others to do the same.

As of June 2015, the group had raised more than \$77,000 for ILADEF. More

importantly, the campaign has garnered lots of press coverage, in the U.S. and other countries, too. Dozens of media outlets, including the Dr. Oz Show and many local TV stations, have featured the Lyme Disease Challenge. Celebrity participants include Yolanda and David Foster, actor William Shatner, Beastie



Singer Debbie Gibson, right, took part in the Lyme Disease Challenge with Lyme patient, Teresa Ann. Photo by Teresa Ann.

Boys Ad-Rock, international singer-actress Thalia, many Bravo Real Housewives stars, Olympic skier Angeli VanLaanen, many professional athletes, and a large number of local athletes and media personalities across the U.S.

Not all who snap selfies of themselves sucking limes are celebrities, of course. Countless individuals who have Lyme or know someone with it have also joined in.

Melissa Ferwerda Bell, one of the Challenge organizers, says it’s a good way to bring the Lyme community together and bring broader recognition to the issue.



Angeli VanLaanen, professional skier and Lyme patient



Tiki Barber, former NY Giants running back



# Under Our Skin 2: Emergence

Much-awaited sequel follows old friends and introduces new voices

By Dorothy Kupcha Leland

It would be hard to overstate how important the documentary *Under Our Skin* has been to the Lyme community. When released in 2008, it galvanized the Lyme community in a way nothing had before.

Community screenings of *Under Our Skin* sprang up in hundreds of theaters, social halls and living rooms around the country. They often garnered coverage from media outlets big and small. The film was an effective tool for teaching the public about Lyme disease.

It also offered an opportunity for people to recognize themselves in its stories. One was musician Kathleen Hanna, featured in the film *The Punk Singer*. She had suffered for years with Lyme without knowing what she had. Seeing *Under Our Skin* led her to diagnosis and treatment. Many others have had a similar experience.

*Under Our Skin* was shown on national TV, even though the IDSA and its apologists tried to prevent PBS stations from playing it. The film is also now available for free viewing on Hulu.com.

Many in the Lyme community have seen *Under Our Skin* many times. We feel personally acquainted with the patients portrayed: former park ranger Jordan Fisher Smith, rock-and-roll promoter Dana Walsh, new bride Mandy Hughes and several others. We also feel connected to the doctors under fire — Drs. Charles Ray Jones and Joseph Jemsek — as well as Alzheimer's researcher Dr. Alan MacDonald.

Fast forward six years to the much-awaited sequel, *Under Our Skin 2: Emergence*. It updates us about what has transpired on the broader Lyme disease issues and tells us how the individuals we met in Part 1 are doing today. (How heartening to see that most have gotten well and moved on with their lives!)

The physicians are a different story. Drs. Jones and Jemsek, hounded by their respective medical boards, sustained staggering financial losses. They each paid a heavy emotional price as well. And Dr. MacDonald's life has taken several astonishing turns since the filming of Part 1.

Among the new voices in *Under Our Skin 2* is Lorraine Johnson, CEO of *LymeDisease.org*. She cogently lays out how conflicts of interest and medical collusion continue to block progress in the



Producer and director Andy Abrahams Wilson, second from left, with cast members, left to right, Mandy Hughes, Jordan Fisher Smith, and Dana Walsh at the Los Angeles premiere of EMERGENCE Oct. 2, 2014.



Lyme arena.

Part 2 also deals more with international aspects of the disease. It interviews experts from Australia, Canada, Germany and Norway, among others. Coverage of Lyme protests around the world includes footage from Washington DC, Strasbourg, Berlin, Victoria BC, Oslo, Brussels, Sydney, London and San Francisco.

Those protests — which encouraged so many and helped raise global awareness of Lyme disease — might never have come about without the spark provided by the original *Under Our Skin*. Thus the process comes full circle.

Andy Abrahams Wilson, director of both films, says not only is the epidemic emerging, but so is “the reality of Lyme as a complex chronic infection that can no longer be denied.”

Watching these two documentaries is the simplest way to get up to speed on one of the most critical healthcare issues facing America today. Information is power — and we won't fix this Lyme problem without it.

Dorothy Leland, LDo Vice President for Education & Outreach, is TLT Online Editor.



# Advocates in Action

## Protests and events draw attention to compromised patient care

By Sandi Bohle

### The Mayday Project targets IDSA

The Mayday Project held its third annual IDSA protest at IDSA headquarters in Arlington, Virginia, April 29-May 1. Lyme



The May Day Project staff, left to right, Crystal O'Barr, Allison Caruana, Joshua Cutler, Bruce Fries, Saby Mo, along with Monte Skall, Executive Director, National Capital Lyme and Tick-Borne Disease Association (NatCap Lyme). Photo provided by the May Day Project.

patients and advocates from as far away as Montana, Tennessee and California attended the three-day rally, which included a candlelight vigil to honor those who have lost their lives battling chronic Lyme disease. Patients who were too sick to attend the rally shipped their shoes to the IDSA.

"Most Lyme patients are not well enough to travel to Northern Virginia. We wanted to help them send a message, too," said Mayday Project co-founder Josh Cutler, who has been fighting late stage neurological Lyme for nine years. "We are uniting to demand that the IDSA stop its misrepresentation of science, stop its conflicts of interest, and fix its guidelines for Lyme."

The Mayday Project is a non-profit organization working to get Lyme disease recognized as a chronic, disabling illness. They advocate for research and patient rights in the hope that patients will one day have a cure.

Earlier this year, Cutler, along with co-

founder Allison Caruana, met with IDSA President Stephen Calderwood, MD, and asked him to consider a Lyme patient for the patient advocate position on the IDSA advisory committee instead of the recently appointed "patient" advocate with no Lyme experience. Calderwood refused. He also suggested they direct questions about the current Guidelines Review Panel's bias and lack of balance to their public forum.

IDSA spokesman and Johns Hopkins physician Paul G. Auwaerter, MD, is one of the physicians sitting on the panel tasked with updating the IDSA treatment guidelines. Cutler and Caruana are calling for his removal, along with other panelists who co-authored or reviewed the 2006 guidelines. Cutler cited Auwaerter's recent interview with the *Allentown Morning Call* where he suggested that patients with chronic Lyme symptoms are dabbling in conspiracy theories. "When you don't understand something, you try to insert a framework that makes sense to you,"



The Lyme quilt hanging outside the IDSA building during The May Day Project's protest. Photo provided by the May Day Project.

Auwaerter told the interviewer.

Cutler says the problem doesn't lie with patients but rather with denialist physicians, such as Auwaerter, who refuse to consider a large body of science-based evidence supporting the existence of

chronic Lyme.

"When is a Johns Hopkins School of Medicine researcher no longer competent to conduct research and treat patients?" asks Cutler. He then suggested an answer:



Lyme patients unable to attend the protest outside the IDSA sent their shoes in solidarity. Photo provided by the May Day Project.

"When he ceases to have an open, scientific mind and starts to sling mud at the patients he has sworn to care for."

Next up for The Mayday Project is the IDSA's I.D. Week conference October 7-11 in San Diego. For more information, visit The May Day Project's website: [themaydayproject.org](http://themaydayproject.org).

### Michigan family among those at Maine conference

On May 2 the Midcoast Lyme Disease Support and Education group presented their first annual conference at the Community Center in Wiscasset, a small town 45 miles from Portland. According to an article posted on the *Bangor Daily News* website, organizers thought the turnout was phenomenal.

More than 250 people attended the free event. One family came from Michigan with their teenage son who has been suffering from Lyme disease and unable to find anyone to treat him. They were able to connect with one of the Lyme-literate doctors at the conference, and the boy was going to be seen the following week.

The article goes on to state, "That family

drove all the way to Maine with fear and desperation and left with tears of joy and a new found sense of hope. That is the feeling that so many experience when they finally connect with a Lyme-literate doctor and are being heard and believed for the first time — when they are given hope that they can get better.” People from Maine and other parts of New England came with questions and left with answers.

Among the speakers were Pat Smith, president of the Lyme Disease Association; Eva Sapi, PhD, researcher at the University of New Haven; Bob Giguere, IGeneX Laboratories; Beatrice Szantyr, MD; and Katina Makris, author and Lyme Light Radio host. A 2-DVD set of the conference is available. Send an email to [midcoastlymediseasesupedu@gmail.com](mailto:midcoastlymediseasesupedu@gmail.com).

### Massachusetts Foundation conference draws 450 patients

Connecticut LLMD Steven Phillips proved to be a strong draw for the 450 New Englanders who braved snow and icy roads to attend the Central Massachusetts Lyme Foundation’s first conference in Worcester in March. Phillips, a former president of ILADS, was the keynote speaker in the morning; in the afternoon, Eva Sapi talked about her research on biofilms and antibiotics. *Sapi is an associate professor of Biology and Environmental Science from the University of New Haven in West Haven, CT. The day-long event also held break-out sessions covering topics ranging from tick prevention, nutrition, herbal treatment, Lyme disease testing, and patient advocacy.*

Central Massachusetts Lyme Foundation is a non-profit organization created to help those battling Lyme disease as well as other tick-borne illnesses. Ken and Michele Miller started the organization in memory of Michele's mother, Jeanne Cloutier, who passed away in 2013 as a result of late-stage Lyme disease. *For more information on the Central Mass Lyme Foundation and their upcoming events, visit their website at [CentralMassLyme.org](http://CentralMassLyme.org).*

### Connecticut Lyme Connection honors LDA President Pat Smith

An enthusiastic crowd gave Lyme Disease Association president Pat Smith a standing ovation when the patient advocacy group Lyme Connection presented her with their first Courage in Advocacy Award at their patient conference and health fair in May. Several Lyme luminaries attended in Smith’s honor, including CT pediatrician Charles Ray Jones; Columbia Lyme Research Center Director Brian Fallon; NY LLMDs Ken Liegner and Dan Cameron, who is also president of ILADS; CT LLMD Steven Phillips; and family counselor Sandy Berenbaum.

Lyme disease specialist and author Richard Horowitz, MD, the keynote speaker, talked about his book "Lyme Disease: Why Can't I Get Better? Moving from Symptoms to Solutions." Other speakers were New Haven University *Borrelia* researcher Eva Sapi and Dr. William Cowden, author of the Cowden Protocol. All of the speeches from the event are available on YouTube.

Lyme Connection collaborated with the Ridgefield Health Department to develop BLAST, a nationally recognized tick-borne disease prevention program that is offered free to the public at health fairs, schools and community events. The program engages health professionals and trained educators to teach prevention and early symptom identification. The CT legislature is currently considering a bill to fund BLAST. It is now funded by private



Lyme Connection co-founder Karen Gaudian presents Lyme Disease Association President Pat Smith with the first Courage in Advocacy Award at their conference and health fair in May.

donations and grants. *Visit the Lyme Connection website at [lymeconnection.org](http://lymeconnection.org).*

### Ticked Off Music Fest lights up Los Angeles

The Ticked Off Music Fest made its first foray to the West Coast, touching down in Los Angeles at the iconic House of Blues on the Sunset Strip in West Hollywood on March 28. The concert series is dedicated to the prevention, awareness and cure of Lyme disease and other tick-borne illnesses.

The Ticked Off Music Fest was founded in 2012 by Gregg Kirk, who currently lives in the NYC metro area. Kirk is the lead singer/songwriter for the band The Zen Engines and former publisher of the Philadelphia/Delaware-based publication Big Shout Magazine. He has also been dealing with chronic Lyme for almost a decade.

“The fest really picked up momentum in 2014,” said Kirk, “I contracted Lyme disease almost 10 years ago and spent years being too sick to play. Once I got better, I decided I’d rather play music in situations that help people instead of banging my head against the wall and playing the bar circuit trying to make it big. I hooked up with Pat DiNizio of the Smithereens who played a festival in Jacksonville, FL, and have also been working with Les Stroud from the Survivorman TV series who has played festivals with me in Florida and Maryland.” The first three festivals were held in Wilmington, Delaware; Jacksonville, Florida; and Annapolis, Maryland.

Produced by Gregg Kirk alongside line producer Sandi Bohle, the Los Angeles fest was the largest one yet — a full six hours





Singer, songwriter, former X guitarist, and Lyme patient Tony Gilkyson and his band raising the rafters at the LA Ticked Off Music Fest. Photo by Sandi Bohle.

of music and speakers, the majority of whom had Lyme or family members who did. Speakers included Lymedisease.org CEO Lorraine Johnson; Nancy Rollett of The Lyme Light Foundation; Mara Williams, author and founder of Inanna House; and author, speaker, and Lyme Light Radio host Katina Makris.

Headlining the musical portion of the evening were the 90's band Cracker and the Les Stroud band. The remaining acts were incredible musicians who all struggle with Lyme. Gregg Kirk and a West Coast version of his band, the Zen Engines, started off the night led by Jon Alvarez and fellow UCLA music students. Following them were up and coming singer/songwriter Keta, fresh off a tour opening for Sam Smith; Lyme community favorite Alisa Turner from Nashville; singer/songwriter/activist/author Natalie London and her band Hey, King!; and LA native and fan favorite Tony Gilkyson and his band.

The audience enjoyed great food catered by the House of Blues. All the musicians enjoyed playing on the House of Blues stage following in the footsteps of so many top artists who have graced the venue. The event was sponsored by the LA Weekly, InsectShield, the Bay Area Lyme Foundation, and Rightscorp.

Invigorated by the positive feedback the concert series has garnered, Kirk sees 2015 as a time to keep spreading



Lorraine Johnson with Brent Martin and Dana Walsh of Lyme Less Live More, along with Sandi Bohle, LA Ticked Off Music Fest line producer. Photo by Tony Hayman.

the word and making a difference for people suffering from the disease. "We've got four festivals booked this year, and people and locations are lining up so that we may do as many as eight festivals in 2015-16. Every time we play, I have people who are sick with Lyme pull me off the stage and say, 'Tonight you made me forget that I was sick.' I can't imagine anything more rewarding than that. I also want to let people know that Lyme disease is the fastest-growing infectious disease in the country — four times faster than HIV. This kind of stuff is helping to change lives for the better."

Keep your eyes open for upcoming announcements regarding the next Ticked Off Music Fest locations by visiting their website at [tickedoffmusicfest.com](http://tickedoffmusicfest.com).

### San Diego Lyme community holds ninth annual walk

The San Diego Lyme Support Group held its Ninth Annual Lyme Disease Awareness 5k and 1-mile Fun Run on Saturday May 16, 2015 at Ski Beach at the Mission Bay Resort in San Diego. It was a great opportunity for patients, friends and family to network and get some exercise at the same time. Over two hundred people attended the walk. Brooke Landau, Lyme survivor and reporter/news anchor with San Diego Six News, broadcast live from the event. Speakers included Therese Yang, MD, who thanked everyone for helping her keep her non-profit clinic open; and Nicola McFadzean, ND, who spoke about the multi-dimensional treatment approach necessary for recovery from Lyme and its co-infections. An inspirational Lyme success story read by Jenelle Conklin really moved the crowd. Over 150 attendees participated in the Lyme Disease Challenge. Attendees were able to visit health and wellness booths, and eat delicious food from the "O Truck," San Diego's popular organic food truck.



Group photo of participants at the San Diego Lymewalk and Run.

# Guidelines Process Remains Flawed

Despite the antitrust investigation, IDSA priorities remain unchanged: revenues, reputation and reduced liability

By Lorraine Johnson, JD, MBA

Restrictions contained within the Infectious Diseases Society of America (IDSA) Lyme treatment guidelines continue to leave patients sick and without treatment options. Treatment failure rates under their guidelines are unacceptably high — as much as 40% for early Lyme and exceeding 65% for late Lyme.

Insurance companies rely on the IDSA guidelines to deny reimbursement for patient care. Under its first set of guidelines published in 2000, doctors who did not comply were subject to unprofessional conduct actions. Insurance companies denied patients reimbursement for essential treatment, and patients could not find physicians willing to treat them.

In 2005, the IDSA seated a panel to revise their Lyme treatment guidelines. A number of physicians with divergent viewpoints, including some members of the IDSA, applied for a seat on the panel, but were told that the panel was full, even though other panelists whose views aligned with IDSA viewpoints were later seated on the panel. Although the guidelines purport to be “evidence-based,” most of the recommendations in the guidelines are based solely on the “expert opinion” of panel members. Many of those members had extensive commercial conflicts of interest.

## Connecticut AG antitrust investigation

When the 2006 IDSA guidelines were released, *LymeDisease.org* (previously CALDA) spearheaded a national effort with other advocacy groups, including the national Lyme Disease Association (LDA) and the Connecticut-based Time for Lyme (now Global Lyme Alliance). Focusing on antitrust law as a vehicle to address the restrictive guidelines, the groups approached the Attorney General of Connecticut, Richard Blumenthal, who responded by launching an antitrust investigation.

Following an extensive investigation, the Attorney General released his findings in May 2008. Among his conclusions he found: the panel chair “handpick[ed] a like-minded panel without scrutiny by or formal approval of the IDSA’s oversight committee.” Panel members also had financial interests “in drug companies, Lyme disease diagnostic tests, patents and consulting arrangements with insurance companies”

## Settlement review process

As part of the mandated settlement, the IDSA agreed to review its guidelines with a panel free from conflicts of interest. While the

IDSA called the review process “voluntary,” the AG noted that the IDSA “effectively admitted the flaws by agreeing to a review and reassessment of its 2006 guidelines by a conflicts-free panel.” The panel was not independent, however, and the review process was not impartial. The IDSA selected the panel and ran the process, having an interest in preserving its reputation and shielding itself from potential legal liability arising from flawed guidelines.

## Manipulated process

Process irregularities were rampant. The settlement agreement forbade individuals who had previously written Lyme guidelines from sitting on the panel. Nevertheless, the IDSA selected two panel members who had authored previous Lyme guidelines: Dr.

Weinstein and Dr. Baker. Dr. Weinstein was removed from the panel under patient protest, but Dr. Baker remained as the panel Chair despite the violation and despite the fact that she had previously served as IDSA president. Physicians who treat chronic Lyme disease, including members of the IDSA, applied for the review panel and were summarily rejected. As a result, the review panel was essentially stacked in favor of upholding the existing guidelines. Potential panel members were reviewed for



“O.K., let’s slowly lower in the grant money.”

conflicts of interest by an ethicist who, although chosen jointly by the Attorney General and the IDSA, was paid by the IDSA

On July 30, 2009, the panel heard presentations from those opposing and those supporting the guidelines. Evidence submitted to the panel by the International Lyme and Associated Diseases Society (ILADS) included more than 300 pages of analysis and roughly 1,300 peer-reviewed research studies opposing the recommendations in the guidelines.

In the end, the panel — stacked by the IDSA to achieve an intended result — did not comply with the voting process required in the settlement agreement. The violation was spotted by the AG’s office, which was monitoring the minutes of the process.

## IDSA Report

On April 22, 2010, the review panel released its report. Despite the voluminous testimony presented by ILADS, the panel voted almost unanimously to uphold all guidelines recommendations. A particularly important vote — about whether lab tests were required for diagnosis of Lyme disease — ended in a tie. The panel side stepped the implications of the vote, however, by claiming that the lab test requirement was not a “recommendation” subject to the agreement. The AG’s office announced that it would





The 2009 IDSA guidelines panel heard presentations from those opposing and those supporting the guidelines. Evidence submitted to the panel by the International Lyme and Associated Diseases Society (ILADS) included more than 300 pages of analysis and roughly 1,300 peer-reviewed research studies opposing the guideline recommendations. In the end, the panel — stacked by the IDSA to achieve an intended result — did not comply with the voting process required in the settlement agreement and made no changes to their guidelines.

"carefully and comprehensively assess the final report and the review process leading to that report to determine whether the IDSA fulfilled the requirements of our settlement."

### Growing opposition

The IDSA guidelines standardize suboptimal care and harm patients by denying them access to the only treatment option that may alleviate their suffering. Opposition to the IDSA guidelines has continued to grow because of the injustice of leaving patients who are very ill without any treatment options. Over 80,000 people signed LDO and LDA petitions opposing these guidelines.

A number of physician groups oppose the IDSA guidelines and/or support laws to protect physicians. Eight states have already adopted such laws: California, Connecticut, Maine, Massachusetts, New Hampshire, New York, Rhode Island, and Vermont. Minnesota adopted non-legislative physician protection measures.

### Conflicts of interest

Academic research in Lyme disease is controlled by key opinion leaders who consult with industry, run industry trials, take the lion's share of grant dollars, and essentially run a medical business rooted in the concept of commerce, not patient care. Between eight and 12 members of the 14-member IDSA review panel had significant conflicts of interest. When commerce trumps effective patient care, the entire healthcare system loses. Sick patients do not get better when they are ignored and denied treatment that may restore their health. Researchers who ignore the interests of patients while feathering their nests do us all an injustice.

Some people argue that conflicts of interest are simply the price of expertise.

While the Institute of Medicine (IOM) recognizes the value of expertise, it recommends that conflicts be contained (to no more than a minority of panel members) and managed (by prohibiting those with conflicts from holding leadership positions or drafting or deciding specific recommendations).

Industry influence on treatment guidelines is not confined to Lyme disease. An article in the *New England Journal of Medicine* points to treatment guideline panels for the treatment of sepsis, anemia among kidney patients, and high cholesterol as having fallen under the spell of industry influence. A 2006 *New York Times* article spotlighted guidelines that contain an industry-friendly new definition of high blood pressure that "illustrate[d] connections ... among the pharmaceutical industry, academic physicians and societies that formulate opinion."

### Patient interests excluded

Beyond managing conflicts of interest, it is critical that patient interests are held paramount. To protect these interests, patients and their treating physicians should be included in any IDSA guideline development process.

Many hoped that the IDSA review panel would set things right. But while the review panel had been screened for *personal* conflicts of interest, each member had tremendous *organizational* conflicts of interest. Nearly all were members of the IDSA. The panel chair was a past-president of the IDSA; in addition, she had written restrictive Lyme guidelines for the American Academy of Pediatrics. This last should have precluded her from sitting on the panel. Instead, she headed it.

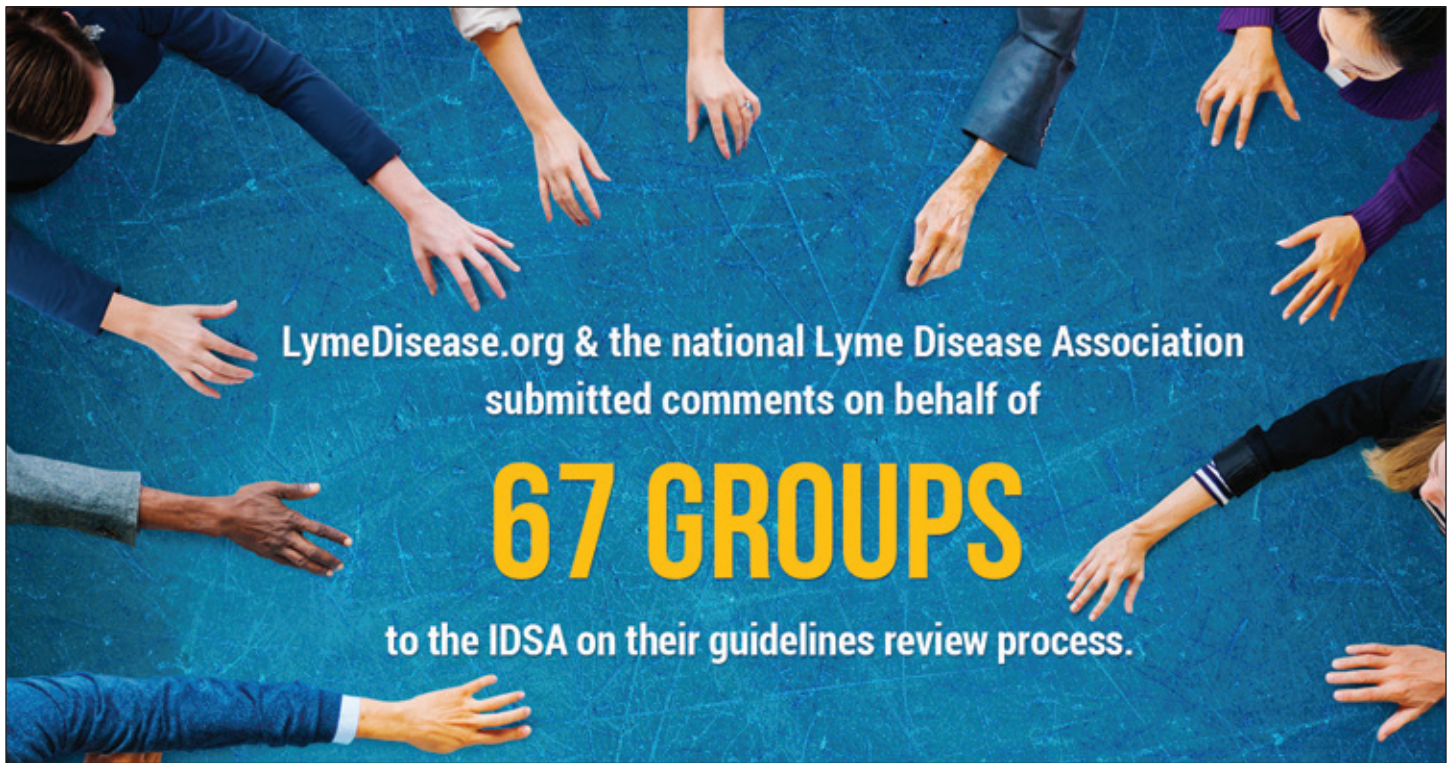
Medical associations do not represent the interests of patients; they represent the

interests of their members. Maintaining and enhancing reputation and reducing liability exposure are their key interests. They also have commercial ties with industry. A recent editorial in the *Wall Street Journal* points out that only 17% of physicians belong to the American Medical Association (AMA), and that it derives most of its income (between \$70-100 million) from a medical coding system that it sells to physicians.

A recent report by the Institute of Medicine (IOM) discusses the institutional conflicts of interest among medical societies. Reviewing the 2006-2007 budget of the American Academy of Family Physicians (AAFP), the IOM found less than 38% of its \$80 million budget came from membership dues and services, while 42% came from the pharmaceutical industry (60% of which from advertising in the academy's journals and 13% from exhibit fees). By my read of the IDSA 2007 IRS Form 990, it follows this theme, too: only 15% of its revenues come from memberships. Since the IDSA does not derive any revenue from patients, their order of interests goes something like this: maintain revenues from industry, enhance reputation, and reduce liability exposure.

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## IDSA Ignores the Institute of Medicine

Guidelines development process violates influential agency's key recommendations

By Lorraine Johnson, JD, MBA

It's been nearly a decade since the Infectious Diseases Society of America (IDSA) published its 2006 Lyme clinical practice guidelines (CPGs). On March 9th of this year, they announced a new guideline development process and invited comments for a 30-day period. Although the IDSA said that they would comply with the new standards for developing guidelines issued by the Institute of Medicine (IOM), a quick glance at their plan revealed that they had not even come close.

On April 9th, *LymeDisease.org* (LDo) and the Lyme Disease Association (LDA) submitted comments about the proposed IDSA process on behalf of over 90 patient groups across the nation. Four international groups weighed in from Canada, Germany, the United Kingdom and Australia. Our comments reflected patient views about healthcare outcomes gathered from a recent LDo survey — opinions and experiences of patients who have suffered great harm from biased IDSA guidelines that ignore the evidence.

### Comments submitted

LDo conveyed many collective objections to the IDSA plan.

Visit [iom.nationalacademies.org](http://iom.nationalacademies.org).

For example, although the IOM states that the guideline development process should include “those affected” by the guidelines, the proposed process leaves out two key groups: Lyme patients or their advocates, and their treating physicians. By suppressing expert viewpoints, the IDSA excludes critical evidence — clinical experience and medical research — from the discussion of what effectively becomes the medical standard of care.

In addition, the IOM states that the process should minimize distortions, biases, and conflicts of interest. Yet several members of the proposed panel have conflicts of interest. For six panel members, those conflicts relate to Lyme diagnostic tests. Gary Wormser, MD, has industry ties with six companies involved with Lyme diagnostic tests.

Read the full comments submitted to the IDSA on my LymePolicyWonk blog at [www.Lymedisease.org](http://www.Lymedisease.org).

### A process unchanged

Patients had hoped that the new guidelines process would be fundamentally different this time because a lot has happened since the IDSA released their 2006 guidelines. That process was subject to an antitrust investigation by the attorney general of Connecticut. Antitrust law is concerned with abuses of power that constrain consumer choice. Although that process did not change the content of the guidelines, it did raise the awareness of the public and legislators about the dubious integrity of the guidelines and the process for developing them.

In fact, in 2010 when the IOM issued its new guidance on developing trustworthy guidelines, it cited the IDSA guideline process as an example of a flawed development process. Many of the IOM's recommendations were intended to prevent the type of abuses that the IDSA guidelines development process exemplified.

The IOM states that the aim of its recommendations is to ensure that group processes “encourage inclusion of all



opinions and grant adequate hearing to all arguments.” How is it possible to achieve this goal when the IDSA excludes from the process those most affected by the guidelines — patients and their treating physicians?

The IOM report explains that “patients and laypersons bring perspectives that clinicians and scientists often lack, and require attention to be paid to those individuals most deeply affected by guidelines ... Sensitivity to what matters most to those living with disease provides important context for decisions about the balance of benefits and harms as well as gaps in scientific evidence.”

IOM Standard 3 calls for two patient representatives, including one from a patient organization. However, the IDSA did not select two patient representatives for its panel. In truth, it has not selected a single patient representative. Instead, it selected one consumer who has no experience with Lyme disease and hails from Nebraska — a state reporting 10 cases of Lyme a year. When contacted, this consumer stated that she has never had Lyme disease and knows nothing about it or the issues facing the community. She stated that she thought this lack of knowledge was why she was chosen — so that she could be “impartial.” How will that person, with no knowledge of what Lyme patients value, help the panel understand patient preferences?

The following chart from LDO’s most recent survey in response to the IDSA

## About The Institute of Medicine (IOM)

The IOM is a division of the National Academies of Sciences, Engineering, and Medicine. A Non-Profit, it operates under an 1863 congressional charter signed by President Lincoln.

It’s aim is to help both government and the private sector make informed decisions, providing evidence that can be relied upon.

Many of the studies undertaken by the IOM are requested by federal agencies, and that is the case with its report “Clinical Practice Guidelines We Can Trust,” which was commissioned by the U.S. Congress and published in 2011.

The IOM report singles out the 2006 IDSA Lyme Treatment Guidelines as an example of flawed guidelines. “This case highlights the need for standardization and transparency...so that these issues do not detract from the science. Guideline developers must be aware of the many, varied observers who will consider their development, particularly when their recommendations are likely to be controversial.”

Guideline process revealed these top concerns of patients.

A token consumer cannot properly represent nor advocate for the concerns of patients and a disease she has no knowledge of. She certainly will not adequately provide the “context for decision about the balance of benefits and harms” that make a patient representative a valuable member of a guideline panel.

Medical boards often target Lyme-

treating physicians for unprofessional conduct actions based on the IDSA guidelines. Under the IDSA process plan, how can clinicians demonstrate any failure of the guidelines in clinical practice? Who will ensure that all science is considered? Who will question the limitations of the research authored by those in the room?

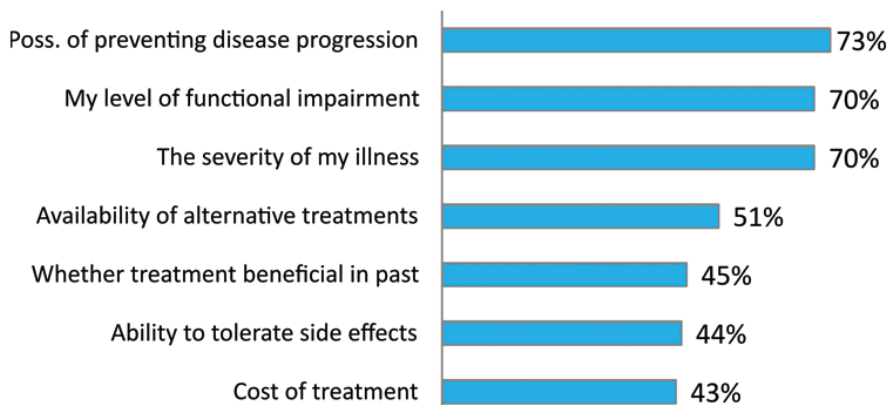
The panel is also filled with the familiar faces of researchers who have built academic careers based on a one-sided view of Lyme disease. The CT Attorney General investigated many of the panel members for antitrust violations in connection with the previous IDSA Lyme guidelines. Some have testified against doctors who treat chronic Lyme disease. How could they possibly create a process free of distortions, biases and conflicts of interest?

### Diagnostic tests

Commercial conflicts of interest related to lab tests are particularly troubling. Six members have received government or commercial grants for lab tests; four have conflicts related to the Immunetics C6 peptide test, and one has commercial ties with six different diagnostic test companies.

*Continued on next page*

### Important factors in treatment decisions



The issue is important to the Lyme community because the diagnostic tests are poor and miss half the cases. In practice this means that requiring a positive blood test leaves many patients undiagnosed and untreated. Further, it is a pivotal point for the guideline recommendations. At the previous antitrust hearing, even with a panel stacked with IDSA members, there was a split vote on whether diagnostic tests should be required for diagnosis. There is no reason why six members with documented conflicts of interest should be on the panel.

### Protecting patients

Unless the IDSA's process has integrity, this will turn out badly for Lyme patients. If the right people are not included in the discussion, the right questions won't be asked. If bias is not checked, it will run amok and taint the entire process. Those sitting in the room essentially will be in an echo chamber listening to their own viewpoints repeated back to themselves over and over. A patient's perspective at the table would ensure process integrity and "act as a safeguard against conflicts of interest that may skew judgment of clinical and scientific experts," according to the IOM. Without changing its current panel makeup, the IDSA guidelines update process will achieve consensus — not by careful deliberation, but by excluding opposing viewpoints.

### What's next?

Pressure has been applied to the IDSA by over 90 Lyme patient groups working together to sign on to the letter sent by *LymeDisease.org* and the Lyme Disease Association during the comment period. The U.S. Congressional Lyme Caucus, established by New Jersey Congressman Chris Smith, forwarded a copy of a patient letter to the IDSA expressing concern about the current process. As a result, the IDSA has indicated it may revisit

## Who is a "Patient Representative"

The Patient-Centered Outcomes Research Institute (PCORI), authorized by the U.S. Congress in 2010, is mandated to produce and promote high-integrity research guided by patients.

PCORI defines a patient representative as "Patients who are representative of the population of interest in a particular study, as well as their family members, caregivers, and the organizations that represent them."

the issue of patient representation on the panel. The question is whether they will again aim for tokenism that denies patients a true and important voice in the process.

## Lab test failure rates—More than 50% false negatives

The IDSA Lyme disease guidelines recommend flawed two-tier testing. The Council of State and Territorial Epidemiologists advises the CDC on testing standards and recognizes the validity of single-tier Western blots—which are more sensitive for detecting Lyme disease.

Two-tiered testing for Lyme disease is no better than a coin toss—missing more than 50% of patients with Lyme disease.

<i>Sensitivity and Specificity of Commercial Two-Tier Tests for Convalescent/Late Stage Lyme disease</i>		
<b>Study/Year</b>	<b>Sensitivity</b>	<b>Specificity</b>
Schmitz (1993)	66%	100%
Engstrom(1995)	55%	96%
Ledue (1996)	44%	100%
Tilton (1997)	45%	100%
Trejejo (1999)	29%	100%
Bacon (2003)	67%	99%
Binnicker (2008)	49%	100%
Steere (2008)	18%	99%
Average	46%	99%



## Real Lives, Real Stories

### Responding to our survey, Lyme patients speak from the heart

When the IDSA announced its guidelines development plan earlier this year, patients were stunned to discover that they had decided *again* to exclude patients and their treating physicians from the process. When they called for formal comments on their plan, *LymeDisease.org* used an online survey to get opinions from the patient community. We also asked them to tell us what treatment outcomes they care about most.

Our survey — conducted in the U.S. between March 24th and April 23rd — drew over 6,000 responses. It included an opportunity to add personal comments beyond the answering standard questions. Over 1,800 respondents took the time to tell us their stories — compelling, articulate and heart-breaking. We were moved to tears as one after another described their struggle and the impact Lyme had on their lives.

We wove these profound personal comments into our final report, “Outcomes Important to Lyme Patients,” which received an overwhelming response. We hope it will be a useful tool for advocates as they inform their legislators and communities alike. You may access and download the report at <http://bit.ly/1GZ>.

Over the last decade, our surveys have uncovered important information about the impact of tick-borne diseases on the lives of patients. From patients that gives voice to patients. As we publish in peer review journals, we add to the collective knowledge about Lyme and inform healthcare policy makers at the state and federal levels. To learn more about our surveys and their results, visit [www.lymedisease.org](http://www.lymedisease.org) and look in the “Research” section.

Now we are extending our survey expertise to a new “Big Data” project — MyLymeData. We will gather information on the health and life experiences of thousands of people living with Lyme throughout the nation. This is a safe and secure way for individual patients to pool their personal data so that we may discover patterns in disease progression and effective treatments.

Please visit our homepage at [www.lymedisease.org](http://www.lymedisease.org) and click on the link to MyLymeData. Watch the informative videos on the project and ask every Lyme patient you know to join us in this effort. Contact the lead author of our survey report, Lorraine Johnson, at [lbjohnson@lymedisease.org](mailto:lbjohnson@lymedisease.org).

## REAL LIVES. REAL STORIES.

### Treatment Options & Choice

*“A patient is the best source providers have to what is happening inside the patient's own body. Therefore, it is imperative that each patient be given as much information as possible and the have a large amount of input into his or her individualized treatment plan. Lyme disease and its coinfections are elusive in diagnosis, treatment and predictability. Patients are the experts of this disease not the physicians. **It is so important that they are listened to, given further education, and taken seriously, or we will never come to better understand this disease in all its complexity.**”*

Female, UT



# Why Big Data is a Big Deal

Beyond the buzz, patients can expect better care from nationwide health data

By Pamela Cocks, MPH, MLS

“Big Data” promises to make the world a better place, according to a recent article in *Forbes* by Bernard Marr. Lyme patients are keenly aware that our healthcare delivery system needs improvement, and this data-sharing effort seems particularly promising.

New technology with massive computing power is letting us collect, analyze and understand a large cache of health information. These systems are especially suited to sorting out the complexities of a disease like Lyme. We are increasingly able to identify patterns and draw comparisons from a large number of individual case histories. We can compare treatment protocols and figure out what works — and what doesn’t.

Although largely siloed in unconnected archives, Marr says the medical industry has already collected huge amounts of data. Being able to access and compare the clinical experiences of many patients can provide an invaluable profile of a disease and suggest effective treatments. The results can enhance a practitioner’s “diagnostic toolbox” by providing ever-growing databases about the public health. For example, a practitioner — your doctor — could assess data from other patients with a similar set of symptoms and determine the likelihood of success of a similar treatment protocol for you.

Shared data is increasingly critical to meeting complicated medical challenges. The opportunity to identify unique applications is already driving private-sector innovations. Several partnerships are emerging to respond to the need for Big Data. One partnership between Apple and IBM is poised to create a Big Data “health platform” — an analytics service to benefit patients and practitioners alike. Apple iPhone and Apple Watch users would be able to share data provided by IBM in “the cloud.” Software can turn smartphones into tools for medical research, capturing patient information more frequently and from more people.

In addition to enhancing medical and

scientific knowledge about treatment options, Marr believes that data-sharing arrangements will inform better research choices on specific diseases. Additional data-sharing arrangements would inspire breakthroughs in research leading to new pharmaceutical discoveries.

The Lyme community could use a concerted research effort to find a cure for tick-borne diseases, and having information based on analysis of a larger clinical data set will advance that cause.

Analyzing an integrated database has other advantages for the healthcare industry, according to a 2014 article in the *Harvard Business Review*. Authors Nilay D. Shah and Jyotishman Pathak see a potential for improving health care by “identifying the right treatment for the right individual or subgroup.”

Many other sectors — business and politics included — have successfully learned to link disparate data sources and “apply advanced analysis and computation to modify existing strategies or create new ones.” According to the authors, the health care sector is finally recognizing the potential value of “identifying the right treatment for the right individual or subgroup.”

Obstacles remain including issues of privacy and security that will need to be addressed. Certainly comparing data collected by so many different sources in so many different forms will be a real challenge. It will require collaboration from both the public and private sectors.

Fortunately, efforts are already underway to solve such challenges with projects like the National Institutes of Health (NIH) Big Data to Knowledge Initiative (BD2K) “to enable the biomedical research community to better access, manage, and utilize big data.” Other collaborations are focusing on bringing together research-driven groups. A special effort is underway through the National Patient-Centered Research Network (PCORnet) for which Lorraine Johnson, CEO of LDo, serves as a patient representative.

Although artificial intelligence may sound a bit futuristic, the use of an IBM “cognitive computer” — known as Watson — is helping a team at the Mayo Clinic analyze proposed clinical trials and find potential patients to participate in specific studies. As Shah and Pathak note, however, the successful application of all this new knowledge depends upon a clear idea of how it would be translated into practice. “Users such as physicians, patients, and policy makers need to be engaged right at the beginning.”

Big Data has the potential to revolutionize the search for new treatments and possible cures. Analyzing utilization patterns within the healthcare system can reveal much about a disease including the cost to the patient and society.

Shah and Pathak speak positively about the future. “The insights from big data have the potential to touch multiple aspects of health care: evidence of safety and effectiveness of different treatments, comparative outcomes achieved with different delivery models, and predictive models for diagnosing, treating, and delivering care.”

Big Data is a game changer, and LDo is already on board on behalf of Lyme patients everywhere as it launches MyLymeData.

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*Pamela Cocks, is a health care planner.*

*Bernard Marr is an expert on business performance, analytics and data. His latest books are 'Big Data' and 'KPIs for Dummies'.*

*Nilay D. Shah is an associate professor at Mayo Clinic, studying and improving the healthcare delivery system.*

*Jyotishman Pathak is an associate professor and director of clinical informatics services at Mayo Clinic.*



# LDo Launches MyLymeData

Add your Lyme data to MyLymeData to make Big Data work for all patients

By Lorraine Johnson, JD, MBA

Over 300,000 people contract Lyme disease in the United States each year. It's six times more prevalent than HIV/AIDS and almost twice as common as breast cancer. Many people with Lyme stay sick for years. Yet there has been little research on how to help people recover from the illness.

*LymeDisease.org* has launched MyLymeData to help change that. Over the last decade, LDo has launched the largest patient surveys on Lyme disease in the U.S. Our surveys have reached thousands living with Lyme disease — as many as 9,000 individuals took part in a single survey. Data generated by our surveys has been published in major medical and scientific journals, helping to inform treating doctors as well as to influence policy makers.

Now MyLymeData raises the concept of patient surveys to a higher level. It's a way for thousands of Lyme patients to contribute specific information about their Lyme disease experience over time. What symptoms? What treatments? What results?

## A new approach

The term “Big Data” is being used more and more in healthcare these days. When massive amounts of information from thousands of patients with the same disease are gathered and analyzed using computer technology, researchers begin to see patterns that help find solutions. With enough data over time, we can find answers to questions like, “What treatments work best?” and “Why do some patients get better and others don't?”

NIH-funded research has not improved patient outcomes. Forty years after the discovery of Lyme disease, we still do not know the best ways to treat it. Traditional research is expert-centered, driven by the questions and curiosities of individual researchers



themselves. These questions may have little relevance to patients.

Traditional treatment trials for Lyme disease have failed to improve patient care for a number of reasons. Their sample sizes are too small to provide meaningful results. Only 55 patients completed the treatment arm of the Klempner treatment trial — the largest one for chronic Lyme disease (CLD). Selection criteria have excluded typical patients from participating. One



NIH researcher screened over 3,368 patients to enroll just 23 in his treatment trial — that's less than 1% of those who applied. None of the NIH trials included patients with co-infections, yet our surveys have found that the majority of patients with chronic Lyme also have co-infections. Most patients do not consider 90 days of treatment to be long-term treatment, but the NIH has never conducted longer treatment trials.

The last NIH-funded treatment trials for chronic Lyme disease closed recruitment over 10 years ago. Because of technological advances in data analysis, patients no longer need to wait for research that may never come. The time has come for patients to press research forward using their own data.

## Patient-centered research

Patient-powered research like MyLymeData puts patients at the center. The LDo project was conceived by patients, is run by patients, and will address issues patients care about. People suffering from Lyme disease want to get well — period. They want researchers to find new and better treatments so they can get their lives back. Research using MyLymeData must address questions important to patients and further their interest in improving quality of life.


Large amounts of patient data will allow researchers to determine the natural progression of the disease, how co-infections affect the course of the illness, and whether Lyme is transmitted sexually or from mother to child. It will also provide information essential to shaping healthcare policy, such as the severity of the disease, the financial toll on families, and its cost to society.

MyLymeData will allow researchers to track patient treatment for years, looking at outcomes that are important to patients. A recent study estimated the cost of CLD based on the assumption that those with the chronic form of the disease are only ill for 4.6 years. Why? Because no one has studied the duration of CLD. We can change that.

Patient-powered research looks at treatment results from real patients. How do co-infections impact patients and their ability to

*Continued on page 20*

# MyLymeData – PATIENT-DRIVEN RESEARCH



**300,000 PEOPLE  
A YEAR**

If you have Lyme disease, you're not alone. More than 300,000 people in the United States develop this tick-borne disease every year. Yet not much is known about Lyme.



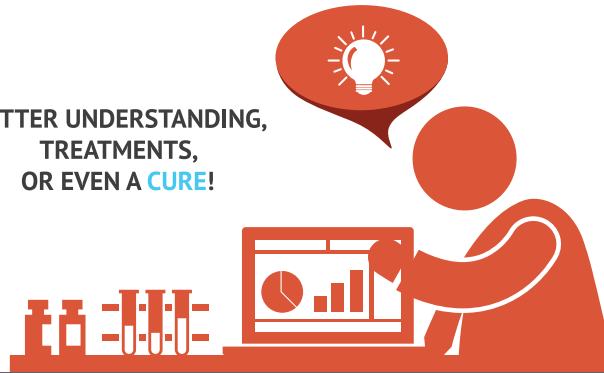
WHAT'S THE BEST WAY TO DIAGNOSE IT?

WHICH TREATMENTS WILL WORK BEST?

HOW DOES IT PROGRESS?

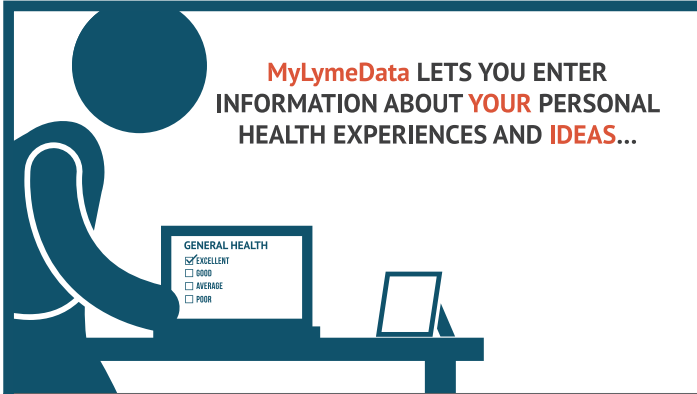
Such as how it progresses. Or the best way to diagnose it. Or why some people get better with treatment and others do not.

## *Add your Lyme data to MyLymeData*



BETTER UNDERSTANDING, TREATMENTS, OR EVEN A CURE!

... and those patterns could lead to better understanding, treatments, or even a cure for Lyme disease.



MyLymeData LETS YOU ENTER INFORMATION ABOUT **YOUR** PERSONAL HEALTH EXPERIENCES AND **IDEAS**...

GENERAL HEALTH

- EXCELLENT
- GOOD
- AVERAGE
- POOR

MyLymeData allows everyone with Lyme disease to confidentially contribute their personal health experiences and ideas.

MyLymeData is a project of [lymedisease.org](http://lymedisease.org)



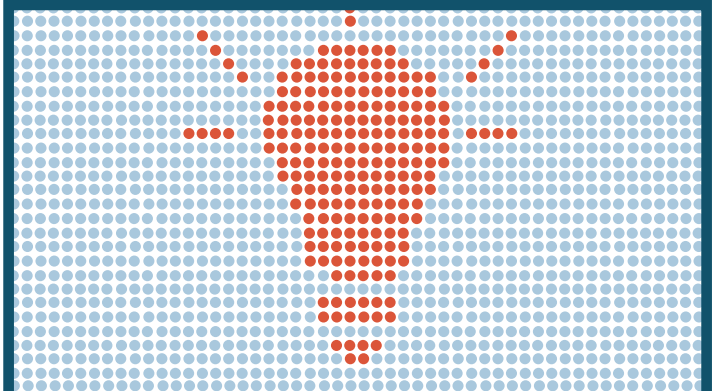
# THAT USES BIG DATA TO SOLVE BIG PROBLEMS

BIG DATA IS A BIG DEAL!

## MyLymeData



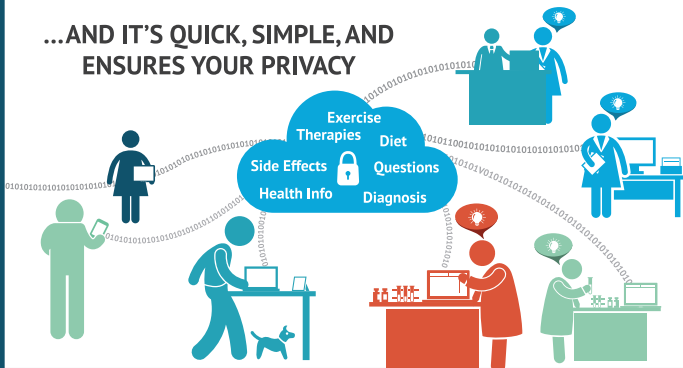
Today, there is a new kind of research that allows you to fight Lyme disease with your own health information. It's called Big Data—and Big Data research is a big deal.



When researchers look at your Lyme data and the data of thousands of others living with Lyme disease, they can see patterns.

*and help find a cure for Lyme disease.*

...AND IT'S QUICK, SIMPLE, AND ENSURES YOUR PRIVACY



It's quick, simple, and ensures your privacy. It's also patient-powered, making sure the voices of those living with Lyme disease are heard—loud and clear.

## HELP FIND A CURE!



Today, with the help of big data, it's within your power to add your voice to the voice of thousands of others. Add your Lyme data to MyLymeData—and help find a cure for Lyme disease.

Watch the video at [lymedisease.org](http://lymedisease.org)

## MyLymeData — from page 20

get well? How do patients respond to treatment that's longer than three months? This project offers a way to answer those questions.

MyLymeData will provide information on treatments people are actually using, whether prescribed by their physician or independently chosen by the individual. Did the patient use IV rocephin? If so, for how long and with what result? What about far-infrared saunas or other alternative treatment approaches?

### How MLD works

Participating Lyme patients share their personal experiences via a secure website designed to protect their privacy. Once an individual is registered with MyLymeData, the person will come back periodically to update his or her progress. What treatments have been tried? Did they help? Have any symptoms cleared up? Have new ones developed? Patients can also see how they compare generally with other patients in the project. For example, a patient who had an EM rash can see how many other patients in MyLymeData had such a rash.

Patients with Lyme disease are justifiably concerned about

privacy. Participating patients control who has access to their data and the purpose it may be used for. Researchers using this information must demonstrate to LDo that it is being used for projects that will benefit patients. MyLymeData puts privacy in the hands of patients where it belongs.

Many patients want to help advance the Lyme disease cause, but are too sick to take on any extra task. Some patients barely make it through the day. But MyLymeData is quick and easy to use. Silver Feldman, who was diagnosed with Lyme at age 13, describes it this way: "People are still suffering unnecessarily given the tools and research possible today. When I was at my sickest I couldn't do much to help, but I could have done this."

To get started, simply visit *LymeDisease.org* and click the *MyLymeData* button. We hope you will add your Lyme data to MyLymeData to help find a cure for Lyme and other tick-borne diseases. And why not go one step further? Invite other Lyme patients you know to participate as well. The more people who take part, the more powerful the database will be.

## Why I will join MyLymeData ... and you should, too!



My name is Jo Anne and I've been involved with LDo for over eight years. I'm usually happy to contribute in the background, and you might never know I'm here doing administrative work that helps LDo help Lyme patients everywhere.

But right now, LDo is launching its patient registry — MyLymeData — and I can't sit back and hope that you take the time to join the registry. I have to jump up (figuratively) and ask you to participate.

You see, in my family it is my mother who has Lyme. She contracted it in her 70's and has suffered a great deal. We caught it early and treated her right away, yet she continues the battle. My mom is in her 80's now, and sadly not much is known about Lyme in geriatric patients — no studies, no research, no experts. Zero. Zip.

On day one, I will be standing in line (with my mom by my side) to enter her history of diagnosis, treatment and ongoing symptoms into MyLymeData. I want her experience to count for something. I want LymeDisease.org and approved researchers to gather information on all of the "over-80's" dealing with Lyme, so that someday soon someone else's little mother will have a better outcome.

Join me. It's safe and secure — we greatly value your privacy. Let's build the body of data that researchers and doctors need to unlock the key to effective testing and treatment. Let's share our health information, so we'll be able to say that, although our families suffered, we did what we could to lead researchers to a cure.

Email me at [jvidal@lymedisease.org](mailto:jvidal@lymedisease.org) if you have questions about the registry.



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# LDo Surveys Support Critical Advocacy Efforts

Large-scale surveys provide patients an important voice in policy debate

By Phyllis Mervine, EdM

During 1998-99 I conducted *LymeDisease.org's* first survey. We were then Lyme Disease Resource Center. It was a simple concept — a follow-up to a 1988-89 comprehensive study of my own rural California community by an entomologist, a veterinarian, and a physician. That study, which was published in the *American Journal of Epidemiology* (Lane *et al.* 1992), had found that 24% of the study participants tested positive for Lyme disease, and 37% had definite or probable Lyme. Of course, I was one of them.

About ten years later I decided to find out what had happened to all those people. Had their symptoms progressed? Had more people been diagnosed? I designed what San Francisco physician Raphael Stricker, MD, called a “standardized questionnaire” to see if there were long-term adverse health outcomes after antibiotic treatment for Lyme disease. I phoned all my neighbors and asked each person the same questions. I tallied their scores on a spreadsheet. The results were sobering.

Of 70 people I contacted from the original 1988 cohort, 29 (41%) had been diagnosed and treated for Lyme disease, while 41 had not. I found that people with a history of Lyme had significantly more complaints than the non-Lyme group. But seven individuals in the non-Lyme group also had very high composite symptom scores, similar to the Lyme group, especially neurologic and musculoskeletal complaints. They also had higher (i.e., worse) scores in all other categories. This led me to speculate that these people might actually have had Lyme as well. Most doctors never suggested testing, however (only two of 50), and so they had never been diagnosed.

I created a poster of the survey that was accepted at the 1999 International Lyme Borreliosis Conference in Munich, Germany, where several people stopped by to talk with me.

## 2003

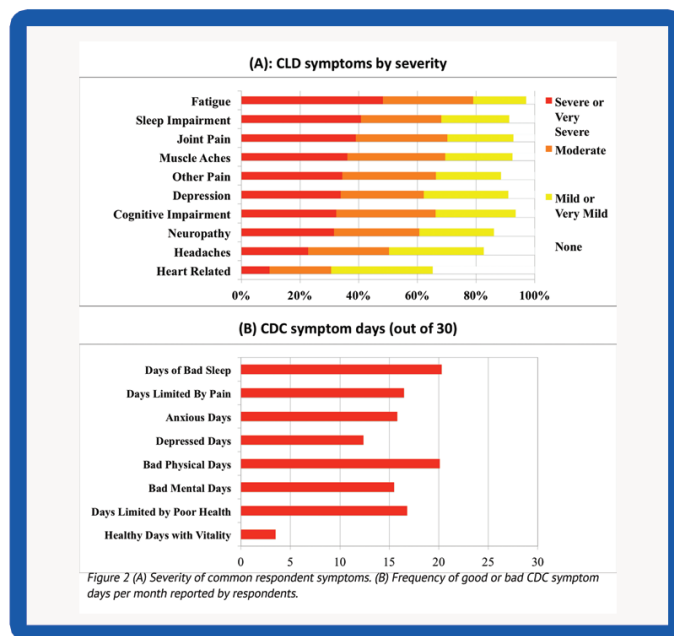
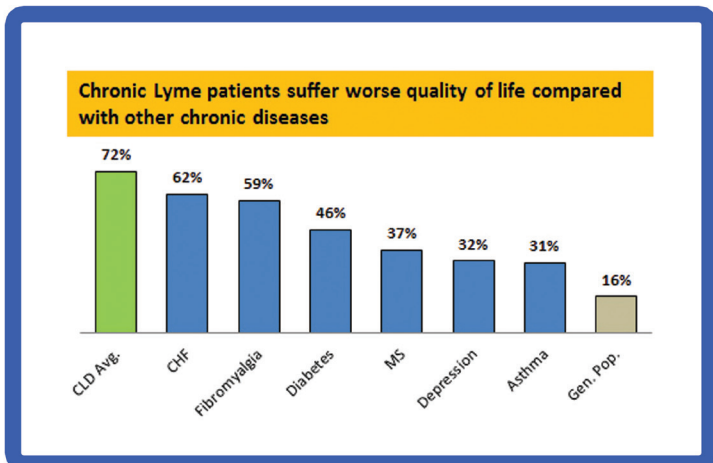
In 2003 *LymeDisease.org* launched its second survey in *The Lyme Times* (issues #35 and #36) and distributed it through selected doctors' offices throughout the nation. We knew doctors were increasingly using the CDC surveillance case criteria for clinical diagnosis — against the CDC's own advice. We wanted to measure

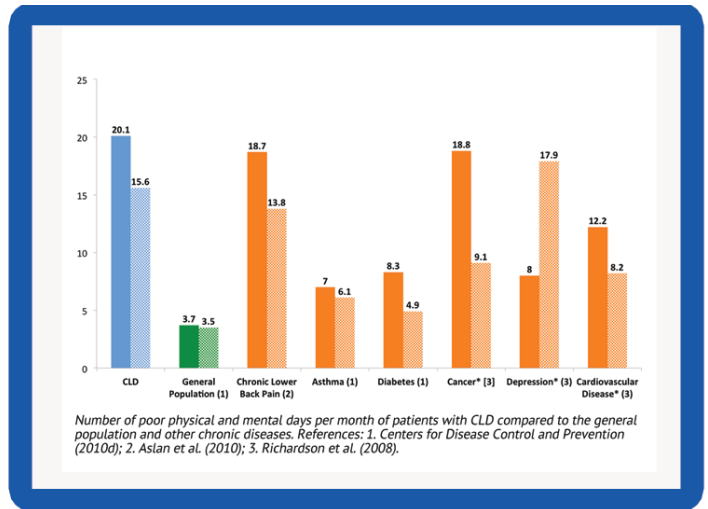
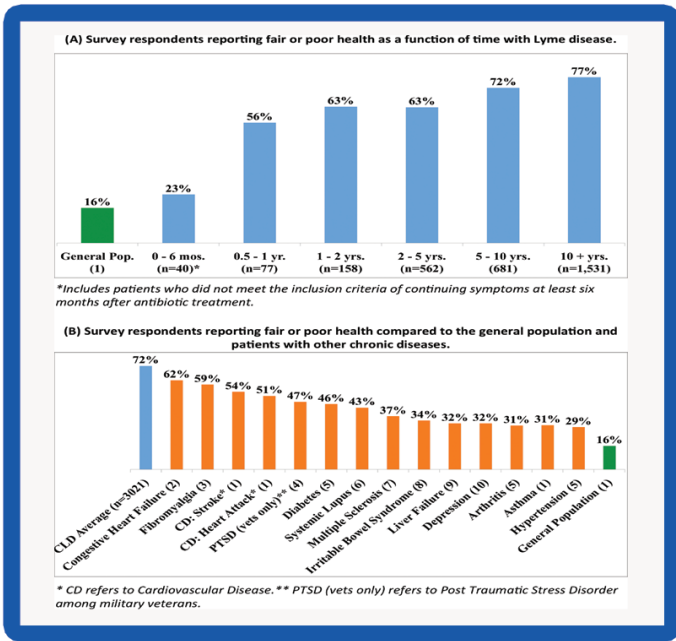
the impact of this trend. The one-page questionnaire asked, “Have you ever been told that you did not have Lyme disease because of a negative ELISA test result, or because a Western Blot did not have the CDC-approved bands?” The questionnaire went on to ask whether people had been denied insurance coverage or disability because they had negative ELISAs or Western blots not meeting CDC criteria.

One hundred people sent in 100 questionnaires during the first six weeks. The results suggested widespread misuse of the CDC surveillance criteria for diagnostic purposes, resulting in significant diagnostic delays. Eventually, we received questionnaires from 182 respondents with Lyme disease. The diagnosis had been missed in 146 (80%). Half had treatment delays of at least one year, and the average delay was 4.4 years. One person waited 18 years to be diagnosed.

Online questionnaires made our third survey much easier. We analyzed the responses of 2,424 patients for our previous healthcare access and burden of care survey, making it the largest survey of Lyme patients ever conducted. The results showed that Lyme patients suffered a significant burden of illness and had difficulty obtaining the healthcare they needed. It was published in 2011 in a highly regarded peer-reviewed journal, *Health Policy*.

Half of the respondents reported seeing at least seven physicians before the Lyme diagnosis was made. Nearly half had Lyme for more than 10 years and traveled over 50 miles to obtain treatment. Most experienced symptoms lasting six months or more despite receiving at least 21 days of antibiotic treatment. A quarter had been on public support or received disability benefits due to Lyme symptoms, and over half had visited an emergency room at least once as a result of their symptoms. The authors concluded that Lyme patients frequently endure extensive delays in obtaining an initial diagnosis, have poor access to healthcare, and suffer a severe burden of illness.





## 2014

Our 2014 study looked at quality of life of >3,000 patients with chronic Lyme disease (CLD) by using health-related quality of life (HRQoL) — the same indicators that the CDC uses to determine the burden of disease, identify health needs, and direct public health policy. This was important because it allowed us to look at Lyme disease on the same basis as the government had studied other diseases — comparing apples to apples. It found that CLD is associated with a worse quality of life than most other chronic illnesses, including congestive heart failure, diabetes, multiple sclerosis and arthritis.

The survey found that patients with CLD reported significantly lower health quality status, more bad mental and physical health days, a significant symptom disease burden, and greater activity limitations. They also reported impairment in their ability to work, increased utilization of healthcare services, and greater out of pocket medical costs.

This survey was published in the online open-access journal *PeerJ*. [ncbi.nlm.nih.gov/pubmed/24749006]

## 2015

Already this year LDo has conducted two surveys. Our most recent occurred over a two-week period to determine what Lyme patients view as important treatment outcomes for their disease.

The survey drew over 6,000 responses in those two weeks. Results were included in comments submitted by *LymeDisease.org* and the national Lyme Disease Association on behalf of 67 Lyme patient organizations to the Infectious Diseases Society of America (IDSA) on its proposed Lyme disease guideline process plan.

We also conducted a survey about the Food and Drug Administration's (FDA) proposed restrictions on Lyme testing. It drew over 8,000 responses within a month and informed our conversations with the FDA regarding the negative impact of the proposed regulations on Lyme disease.

## The patient voice

*LymeDisease.org's* large-scale surveys reflect the experiences of thousands of patients and are one of the few resources researching this critically important population. Too often, healthcare policy makers are unaware of the many ways that Lyme disease seriously impacts patients, families, and communities across the whole nation. We conduct these nationwide surveys of Lyme patients to bring their perspective to the forefront, and to share their information with policy makers, lawmakers, journalists, and others in the healthcare arena. We give the Lyme patient community a voice in the debate.

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# Billion Dollar Price Tag

## Johns Hopkins study of huge insurance database exposes high cost of chronic Lyme

By Phyllis Mervine, EdM

It will come as no surprise to Lyme patients that the biggest Lyme study ever undertaken documents the high cost of the way we currently treat this infectious disease. It also undermines key articles of faith about chronic Lyme disease held by the Centers for Disease Control and Prevention (CDC) and the Infectious Diseases Society of America (IDSA).



While at Johns Hopkins, John Aucott, MD, shared his interest with Emily Adrion in conducting a broad utilization study of the costs associated with Lyme disease.

According to researchers at Johns Hopkins, patients with a history of Lyme disease paid almost \$3,000 more per year for healthcare services than people without any history of Lyme disease. And this was after treatment.

Using a huge database of people enrolled in commercial health insurance plans in the U.S. between 2006-2010, a team led by Emily Adrion, a doctoral candidate at Johns Hopkins Bloomberg School of Public Health, compared 52,795 people with a history of Lyme disease with 263,975 matched controls with no evidence of Lyme.

Looking at costs over a 12-month period, they analyzed 11 measures of healthcare costs: total costs, total inpatient, total pharmacy, total outpatient, outpatient anesthesiology, outpatient evaluation and management, outpatient medicine, outpatient pathology laboratory, outpatient radiology, outpatient surgery, and all other outpatient costs.

They used two measures of utilization, chosen because they hypothesized these categories would most likely be affected by a Lyme disease diagnosis: outpatient management and evaluation

visits, and emergency department visits.

“Lyme patients had 87 percent more visits to the doctor and 71 percent more visits to the emergency room in the year following their diagnosis,” Adrion said in an email response to questions from TLT. “This is quite a bit more than a supposedly easy-to-treat infection should cost.”

Previous studies provide evidence that over half the patients may complain of continuing symptoms after treatment for Lyme disease. The IDSA and CDC estimate is much lower — 10 to 20% — which the IDSA says is similar to the non-Lyme population and nothing more than the aches and pains of daily living. This study undermines their claims.

Adrion said the Johns Hopkins study found that people with Lyme disease were nearly five times more likely to have any diagnosis typically associated with post-treatment Lyme disease syndrome (fatigue, nerve pain, joint pain, cognitive problems) in the year following their diagnosis, and they were 5.5 times more likely to have a diagnosis of excessive fatigue. Adrion notes that the IDSA Guidelines for the treating Lyme disease do not call for follow up visits to document response to treatment in early Lyme disease, suggesting that they actually don’t know what happens to their patients after their initial treatment.

Adrion found that over 63% of the Lyme disease cases had at least one diagnosis associated with post-treatment Lyme disease syndrome, compared to 27.6% of the same symptoms in controls.

The cost was also high.

“We found that among those with Lyme disease, having one or more PTLDS-related diagnosis was associated with health care costs that were about \$3,800 greater than costs for those with no post-treatment symptoms,” Adrion said. “Regardless of what you call it, our data show that many people who have been diagnosed with Lyme disease are in fact going back to the doctor complaining of persistent symptoms, getting multiple tests and being retreated.”

Adrion herself grew up in an endemic state — Massachusetts — and now lives in an endemic area on the East Coast. She is also an avid hiker and has always been very aware of the risks of Lyme disease and the importance of prevention. Her professional background is in health services research, health economics and policy, and one of her major areas of focus throughout her career has been looking at the cost of health care.

Adrion met John Aucott, MD, as she was working on her PhD in Health Services Research and Policy. Aucott had an interest in conducting a comprehensive study looking at the costs of Lyme disease. He recognized a real need for research relating to the costs and health care utilization associated with Lyme disease.

“I was immediately interested and jumped at the chance to get really involved in such an important and necessary study. Very little research on costs existed, and the studies that had been conducted were very small-scale,” Adrion said. “We wanted to do a broader, population-based study that would allow for a better understanding of what patients are experiencing.”

Adrion thinks the public health policy implications of her

findings are significant, particularly with the high number of cases in certain regions of the country and the potential for it to spread into new regions of the United States.

“When you consider that there are somewhere between 240,000 and 440,000 cases of Lyme disease in the United States each year, the total direct medical costs attributable to Lyme disease and post-treatment Lyme disease syndrome-related diagnoses could be somewhere between \$712 million and \$1.3 billion each year,” she said.

Adrian underscores the importance of increased clinical

awareness of potential complications associated with Lyme disease. The effective, cost-effective, and compassionate management of patients with Lyme disease is essential to decreasing costs as well as improving outcomes.

“Our findings highlight the fact that Lyme disease is not necessarily the easy-to-treat infection it is often believed to be,” she said.

It’s expensive, too.

*Phyllis Mervine is the founder and president of LDo and Editor-in-Chief of The Lyme Times..*

### Cost and utilization analyses show unadjusted mean costs are up to two times higher for Lyme disease cases as compared to the control group.

	(I) Unadjusted mean during 12-month study period, Lyme disease group <sup>*.†</sup>	(II) Unadjusted mean during 12-month study period, control group <sup>‡.§</sup>	(III) Welch's t-test (of difference in means)	(IV) Adjusted impact of Lyme disease diagnosis on 12-month health care costs and utilization, (Robust SE)
Total cost	\$ 8,205	\$ 4,421	p<.001	\$ 2,968 (81.9)***
Inpatient cost	\$ 1,710	\$ 1,038	p<.001	\$ 230 (55.9)***
Pharmacy cost	\$ 1,525	\$ 826	p<.001	\$ 612 (16.6)***
Outpatient cost	\$ 4,969	\$ 2,557	p<.001	\$ 2,125 (47.4)***
Cost by outpatient category:				
Evaluation and Management	\$ 904	\$ 412	p<.001	\$ 464 (4.1)***
<b>Medicine<sup>§</sup></b>	\$ 622	\$ 326	p<.001	\$ 275 (7.4)***
Pathology Laboratory	\$ 487	\$ 140	p<.001	\$ 332 (4.4)***
Radiology	\$ 575	\$ 244	p<.001	\$ 294 (9.0)***
Anesthesiology	\$ 100	\$ 58	p<.001	\$ 38 (1.6)***
Surgery	\$ 605	\$ 328	p<.001	\$ 255 (8.4)***
Other (none of the above)	\$ 1,677	\$ 1,048	p<.001	\$ 467 (36.2)***
				<b>Adjusted impact of Lyme disease diagnosis on 12-month health care utilization, (Robust SE)<sup>§</sup></b>
Outpatient management and evaluation visits	6.97	3.65	p<.001	1.87 (0.008)***
Emergency visits	0.35	0.20	p<.001	1.71 (0.020)***

\*\*\* statistically significant at p<.001 level.

<sup>\*</sup> Lyme disease sample includes only those persons with a test order and antibiotic treatment within 30 days of the test order, a diagnosis and antibiotic treatment within 30 days of the diagnosis, or a diagnosis, test order and antibiotic treatment within 30 days. The Lyme disease sample includes only those with 18 consecutive months of enrollment, including a 6-month “clean period” of enrollment prior to Lyme disease episode in which they were neither diagnosed with nor tested for Lyme disease.

<sup>†</sup> Lyme disease and control samples are restricted to persons under 65 years of age, in commercial health insurance plans.

<sup>‡</sup> Controls were matched to Lyme disease cases on age, sex, region, payer and enrollment year. Control group includes only those with 18 consecutive months of enrollment in a commercial health insurance plan. Control group was restricted to persons with outpatient costs greater than \$0.

<sup>§</sup> Medicine includes acupuncture, home health, home infusion and other special services, procedures and reports.

<sup>||</sup> Adjusted impact calculations based on GLM regression analysis using the Huber/White sandwich estimator of variance and adjusting for year, region, age, and sex, and controlling for 44 high-cost conditions

<sup>¶</sup> Adjusted ratio calculations for outpatient and emergency visits are based on negative binomial regression analysis using the Huber/White sandwich estimator of variance and adjusting for year, region, age, and sex, and controlling for 44 high-cost conditions.

doi:10.1371/journal.pone.0116767.t002

# Cost of Chronic Lyme Soaring

Average annual cost exceeds \$10K per patient or \$3B nationally based on new CDC figures

By Lorraine Johnson, JD, MBA

Eventually the CDC is likely to update its official cost estimates for Lyme disease based on their 2014 revised case numbers, but in the meantime, I've pulled together some rough estimates.

In 2002 the annual cost of Lyme disease in the U.S. was estimated at \$203 million according to a study by Dr. Zhang of the Centers for Disease Control and Prevention (CDC). Today, the annual cost is likely to exceed \$3.1 billion. The increased cost reflects the CDC's recent revision of case numbers from 30,000 to 300,000 as well as adjustments for inflation.

According to Zhang's study, the later we intervene with the disease the higher the costs. In today's dollars the societal cost of Lyme when addressed at the time of a tick bite is \$400. If we wait until a diagnosis of early Lyme disease, the cost increases 4-fold — to \$1,658. By the time we are dealing with late Lyme, the cost is through the roof — \$20,502. The average cost per Lyme patient in 2002 was \$8,712 — or \$10,343 in today's dollars.

In late Lyme, only 14% of these costs are medical costs; the remaining 86% are due to indirect medical costs, non-medical costs, and loss of productivity. As Dr. Dan Cameron explained

in his 2010 article, the cost of treating this disease is peanuts compared to the cost of denial. Denial of care merely shifts the burden of the disease from the insurer to the family, caretakers, and ultimately the government through lost tax revenues as people become less productive and lose their jobs.

Zhang's 2002 estimate of annual costs was based on 23,763 cases multiplied by the average cost of Lyme disease, which at that time was estimated to be \$8,172 (in 2002 dollars). The CDC now estimates the number of annual cases to be 300,000 — up from 30,000. Using an inflation adjusted average case cost of \$10,343, the total cost of Lyme disease now tops \$3.1 billion.

When I spoke at the Gibson forum in New York in 2012, I pointed out that it was time to recognize that our “do nothing” policy regarding Lyme disease was a failure. We don't treat the bite aggressively, we don't diagnose and treat to cure in early disease, and we aren't funding research into effective treatments for late disease. How many ways can we fail? And for how long? It's time to wake up and address the problem.

To read Lorraine's speech given at the Gibson Forum, visit the [LymeDisease.org](http://LymeDisease.org) YouTube page: [www.bit.ly/1HSA3pm](http://www.bit.ly/1HSA3pm)

<b>Annual Cost of Lyme Disease in the U.S.</b>		
	<b>Zhang based on 2002 study</b>	<b>2012 Dollars (inflation adjusted)</b>
<b>Late stage per person</b>	<b>\$16,199</b>	<b>\$20,502</b>
<b>Early stage per person</b>	<b>\$1,310</b>	<b>\$1,658</b>
<b>Tick bite per person</b>	<b>\$316</b>	<b>\$400</b>
<b>Per Person Direct Medical Costs</b>	<b>\$2,970</b>	<b>\$3,759</b>
<b>Per Person Indirect Medical Costs Nonmedical Costs &amp; Loss of Productivity</b>	<b>\$5,202</b>	<b>\$6,584</b>
<b>Average Per Person Annual Cost of LD</b>	<b>\$8,172</b>	<b>\$10,343</b>
<b>Number of Cases in U.S.</b>	<b>23,763</b>	<b>300,000</b>
<b>Annual Cost</b>	<b>\$208 Million</b>	<b>\$3.1 Billion</b>



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# FDA Proposal Threatens Lyme Labs

## Restricting independent labs impedes development of critical diagnostic tools

By Lorraine Johnson, JD, MBA

The CDC recommends a two-tiered testing protocol for diagnosing Lyme disease — a series of tests involving the ELISA, which (if positive) may be followed by the Western blot. The CDC reserves recommending new tests only to those that are FDA-approved and whose results are “equal to or better than” existing tests. That currently means those tests identified in the recommended two-tiered testing procedure.

While FDA approval is required for diagnostic tests marketed to other commercial labs, tests used only by a single lab — Laboratory Developed Tests (LDT) — like those offered by IGeneX and Advanced Laboratory Services (ALS), do not currently require FDA approval. Rather, such single lab tests must undergo a rigorous validation process established by the Centers for Medicare and Medicaid Services (CMS) and Clinical Laboratory Improvement Amendments (CLIA). CMS and CLIA require developers to prove their tests are accurate, precise, sensitive, and specific prior to marketing. Both IGeneX and ALS diagnostic tests are approved by CLIA and CMS.

### How does the existing two-tiered procedure perform?

Research shows that the two-tiered testing protocol does more harm than good. While the testing has few false positives (called “high specificity”), it has many false negatives (or “low sensitivity”). The protocol misses 44 of every 100 patients who have Lyme disease. Imagine if that were the case with AIDS!

Consider the table from “Let’s Tackle the Testing.”

### What do the CDC and NIH have in mind for future testing?

The NIH has invested heavily in the C6 test that is commercially marketed by two companies — Immunetics and DiaSorin. Both companies have commercial ties with Dr. Gary Wormser, who authored the IDSA guidelines that require positive lab

tests for diagnosis. In addition, Immunetics receives NIH research grants that fund Dr. Wormser’s research. Dr. Barbara Johnson of the CDC and Dr. Wormser have jointly published a number of articles supporting the C6 test, which, although it is FDA-approved, performs no better than the two-tiered strategy. *So why is the American taxpayer funding C6 research?*

### How do “alternative” tests compare?

In 2005 an official CDC “warning”

Study	Sensitivity	Specificity
Schmitz et al. <i>Eur J Clin Microbiol Infect Dis</i> 1993;12:419-24	66%	100%
Engstrom et al. <i>J Clin Microbiol</i> 1995;33:419-27	55%	96%
Ledue et al. <i>J Clin Microbiol</i> 1996;34:2343-50	50%	100%
Trewejo et al. <i>J Infect Dis</i> 1999;179:931-8	29%	100%
Nowakowski et al. <i>Clin Infect Dis</i> 2001;33:2023-7	66%	99%
Bacon et al. <i>J Infect Dis</i> 2003;187:1187-99	68%	99%
Mean of all studies	56%	99%

cautioned against tests that “interpret Western blots using criteria that have not been validated and published in peer-reviewed scientific literature.” While IGeneX reports individual test results based on the CDC interpretation criteria (i.e., five of 10 IgG bands), they also report results based on two of five Wb bands. Studies show that such an interpretation criteria increases the sensitivity of the test to 93% or higher although the CDC chooses to ignore them.

Culture tests are widely regarded as the “gold standard” of testing, and the CDC surveillance criteria list “culture test” as an acceptable test. Although the Advanced Laboratory Services (ALS) test is relatively new, it has been validated using the CLIA and CMS requirements. A 2013 study of the ALS test published by Eva Sapi *et al* demonstrated that it had sufficient sensitivity and specificity, but these findings should be confirmed in additional studies. *Why isn’t the government funding this type of research?*

### What do patients need?

It’s time for the CDC and the NIH to

abandon the failed two-tiered testing strategy and stop funding tests like the C6, which provide no better results. Patients want diagnostic tests with adequate sensitivity in order to get properly diagnosed and treated. A recent article pegs the number of Lyme tests performed annually at 3.4 million, a market of roughly \$340 million a year. Not only do these numbers suggest that there is a lot more Lyme around than the CDC or IDSA acknowledge, but also that commercially vested interests and the researchers they consult may have a stake in keeping the *status quo* regardless of how bad the tests are. *Could monetary considerations have something to do with opposition to new lab tests?*

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*Lorraine Johnson posts regularly on LymePolicyWonk at [lymedisease.org](http://lymedisease.org). Contact her at [ljohnson@lymedisease.org](mailto:ljohnson@lymedisease.org).*

# New Synthetic Antigen

## IGeneX explores ways to improve sensitivity of Western blots

By Jyotsna Shah, PhD, CMLD, MBA

The diagnosis of Lyme disease is highly problematic if there is no rash or evidence of a tick bite, because current commercially available immunologic assays lack the desired sensitivity. Although the Centers for Disease Control and Prevention (CDC) claims most people with Lyme test positive by their method, published evidence shows that sensitivity averages 50% — not good enough for a screening test. In our paper, “Improved sensitivity of Lyme disease Western blots prepared with a mixture of *Borrelia burgdorferi* strains,” we present a refinement in the immunologic testing in the diagnosis of Lyme.

We selected 364 well-characterized patient samples — 89 known positive along with 275 presumed negative samples for controls — diagnosed using the Western blot (WB) test for Lyme. We used our own less-strict criteria to interpret the banding pattern as well as the CDC recommended criteria. We evaluated both IgG and IgM.

In addition, we prepared the Western blots in our lab from combined lysates (broken down cells) from two different strains grown in culture. We compared results to those obtained from a commercial supplier of strips that used only one strain of the organism.

The CDC criteria, which were formulated over 20 years ago, are particularly narrow in an attempt to reduce the false-positive results. Consequently the sensitivity using the commercial strips and CDC criteria was only 77.1%.

Using the in-house strips, the sensitivity increased to 88.6%, but if both the in-house strips and the in-house developed interpretive criteria were used, the sensitivity increased to 97.1%.

CDC's extremely conservative interpretive criteria are designed to keep the specificity of the assay high; in our samples, specificity was 100% for IgG and 97% for IgM using the in-house prepared strips. If the in-house criteria were used, the specificity decreased to 95% of IgG and 93% for IgM.

### How the Western blots work

Lyme Western blot strips bind *Borrelia burgdorferi* (*Bb*) proteins that are separated by molecular weight. Therefore, non-specific proteins present in the *Bb* lysate co-migrate with *Bb* specific proteins. If antibodies to *Bb* antigens or other antibodies that can cross-react with *Bb* proteins are present in patient serum, they will bind to the corresponding *Bb* proteins on the WB strip. A purple band will appear on the WB wherever there is *Bb* antigen-antibody complex present.

OspA antigen (located at 31kDa position on the WB) is a specific

*Bb* outer surface protein. Antibodies to OspA usually appear late in the disease. Although OspA was once used to vaccinate people against Lyme disease, it is not included in the CDC interpretive criteria because at 31kDa, non-specific *Bb* proteins are present in addition to OspA. Antibodies to non-specific proteins will give a false positive result. Based on CDC studies, some viral antibodies bind to these non-specific proteins. Therefore, if a patient has a band at 31kDa on the WB, there is a 50% chance that it is a false positive band.

While an antibody to OspA is found in patients who have been vaccinated for Lyme disease, it is not included in the CDC criteria because of its known lack of specificity. To improve the specificity, we examined the mostly likely cause of false-positive results of testing patient serum, which is the presence of antibodies to the non-specific *Bb* proteins at 31kDa position with OspA on the WB.

Because the in-house criteria do include the band that migrates where the OspA antigen is located, we developed a WB using recombinant (synthetic) OspA antigen. With this WB, only patient serum with OspA specific antibodies will form a complex with the recombinant OspA antigen and give a positive result.

All patient serum considered positive because of presence of 31 and 41kDa bands on the WB were tested by the OspA recombinant antigen WB. This included 17/29 patients without symptoms who

had a positive WB result. Sixteen of these had negative results on the recombinant antigen WB. Removal of patients with a negative result on the recombinant antigen WB increased the specificity to >97%.

It is possible to improve the specificity of the assay even further by adding testing of recombinant antigens for other gene products. We are currently developing other *Bb*- specific recombinant antigen WBs.

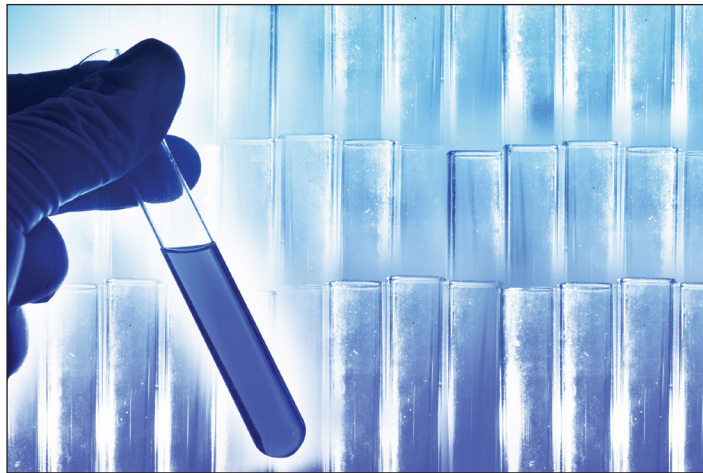
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Jyotsna Shah is the vice president and laboratory director of IGeneX Laboratory, Palo Alto, CA.





# FDA Proposal Threatens Lyme Labs

Increased federal oversight of diagnostic tests limits innovation and compromises care

By Pamela Cocks, MPH, MLS

*Editor's Note: Laboratory Developed Tests (LDTs) are proprietary in vitro diagnostic tests intended for clinical use but designed, manufactured and used only within a single laboratory. The majority of commercially marketed tests are made by private companies and sold to labs, hospitals or physicians' offices. LDTs have not typically been subject to FDA approval.*

It is widely agreed that providers and patients should expect diagnostic laboratory tests to be consistent and of high quality. Inaccurate tests put patients at risk for inappropriate treatment. Recently, the FDA sparked debate by proposing a new regulatory framework to more actively and extensively oversee the quality of LDTs.<sup>2</sup> As usual, the devil is in the details. How exactly will the recent FDA proposal define and guarantee quality in their effort to monitor LDTs?

The question is far from trivial. Thousands of LDTs are currently available, many of which are the standard of care. They directly impact the quality of patient care by informing medical decision-making. The challenge is how to protect the public without restricting innovation, particularly at academic medical centers. To unduly complicate or over-burden the regulatory process may hamper patient access to innovative tests and cutting-edge therapeutics by suppressing competition. This makes this debate of critical interest to clinical labs, researchers and patient groups alike.

## Regulatory rationale

Existing federal laws do not require a quality review or evidence of clinical validity for medical devices, including LDTs. The FDA neither approves Lyme tests nor assures they are safe or effective. Technically, they do “clear” diagnostic tests for sale as medical devices through their 510K process ([www.fda510k.com/approval-process](http://www.fda510k.com/approval-process)). But since new tests are only required to be “equivalent” to previously cleared tests, *all* currently available tests are equally insensitive and ineffective at diagnosing Lyme disease.

Current oversight of such tests is provided by the Centers for Medicare and Medicaid Services (CMS), however, given their authority to regulate labs through the federal Clinical Laboratory Improvement Amendments (CLIA). Judith Yost, director of the laboratory services division for CMS, admits that their reviews for analytical validity are “very narrow and do not address clinical validity at all.”<sup>3</sup>

But since 1976, when the FDA began to regulate all *in vitro* diagnostics, LDTs have evolved along with advances in technology. Increasingly, such tests are being used to assess high-risk diseases and conditions. Public policy is also responding to the call to improve patient outcomes and reduce healthcare costs, both of which depend upon correct diagnoses. Amid many forces, the FDA now seeks to assure that such tests are analytically and clinically valid — both accurate and clinically meaningful. This expanded oversight would allow them to “enforce compliance with the agency’s quality systems regulation pertaining to the design and manufacture of laboratory tests.”<sup>4</sup>

Unfortunately, their proposal would also create a more arduous FDA approval process for LDTs that would impede the search for better Lyme tests.

The greatest concern for patients is whether the framework would deter the development of innovative diagnostics for Lyme and other rare diseases, given that a majority of new tests come from single independent clinical labs. While the FDA may be concerned about potential patient risk from false-positive tests prompting unnecessary treatments, patients require sensitive, accurate tests to prompt beneficial treatment.

## Associations weigh in

As expected, there are conflicting perspectives. The American Society for Clinical Pathology (ASCP) recognizes that all diagnostic tests should be “of the highest quality, reliability, and safety, [to] provide valid and useful information for clinical decision-making.”<sup>1</sup> They understand the

importance of clinical validity.

Some critics maintain that the FDA lacks the statutory authority to regulate LDT services, however. Predictably, the FDA does not accept that premise, leading to a legal controversy. The American Clinical Laboratories Association (ACLA), for example, believes that labs and physicians should be protected from unjustified regulatory action.<sup>3</sup>

One industry group has outlined a new model with less onerous regulation for LDTs. While they propose a “reasonable assurance of ... clinical validity,” they acknowledge the need for “special pathways” for rare diseases, emergency use and unmet needs.<sup>5</sup>

## Advocacy in action

LDo has been following this critical policy debate from day one. Lorraine Johnson, CEO of LDo, has met several times with and submitted extensive comments to the FDA, supported by information gathered from an LDo patient survey. Read Lorraine’s full comment letter to the FDA at <http://bit.ly/1Ndey6n>.

For appropriate diagnosis and treatment of Lyme disease, patients require and deserve accurate direct-detection tests to establish whether there is active infection, whether an infection is responding to treatment, and when the infection is cured. Tests limited to establishing past exposure to an infectious agent do not support quality patient care.

LDo does not believe that the proposed FDA oversight will guarantee safe and effective Lyme tests. It would not benefit Lyme patients.

## Epilogue

Having reviewed public comments earlier this year, the FDA and CMS have established an inter-agency Task Force on LDT Quality Requirements to address a range of issues. No final FDA guidance has been issued.

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# FDA Regulations Undermine Patient Care

Proposed framework favors insurance companies and big pharma at the expense of patients

By Chris Green, MD



Recently proposed rules by the U.S. Food and Drug Administration (FDA) regarding laboratory developed tests (LDT) are a further hijacking of medicine in favor of profits for insurance and drug companies. Such changes in ordering diagnostic tests would undermine patient care by separating the doctor and the patient from the decision-making process. Having the FDA define “legitimate” lab tests would limit treatment approaches.

Years ago I became aware that control of diagnosis was being insidiously and cleverly switched to insurance

companies. Despite the rhetoric, I assumed this would control costs and increase profits, but certainly would not benefit the health of the patient. The first time I was required to get a prior authorization before ordering a diagnostic test, I realized this was a further move to control diagnosis.

As I have said for years, it makes no sense to regulate or legislate the diagnostic process. As a physician, I am trained to ascertain what test is needed for what clinical presentation. I can judge a “legitimate” test. Many of my patients are smart, highly trained individuals, and every one of them is more invested in their case than the FDA. As “consumers” they have learned how to evaluate the quality of a product.

Each patient’s clinical history and picture varies significantly, and lab tests should be selected based on what the examining physician hears and sees. The proposed standardization will hamper diagnosis by compromising clinical judgment and limiting consideration of the larger presenting picture.

With the new FDA regulations, if a headache is the patient’s complaint, the tests for “headache” would be the same, regardless of whether it is a pressure headache, a burning neuropathic headache, or a rigid neck stiffness headache. But you only get to order a “headache” test in whatever order the FDA insurance approves, possibly missing an aneurysm, meningitis or a slipped

disc until it is too late. If the number of “approved” tests and insurance reimbursement are limited, limited treatment follows.

## Policy implications

This FDA action is the second step of an emerging public policy favoring the insurance industry and drug companies.

*First step:* Don’t pay for the tests, which will knock out important coverage for diagnoses and treatment.

*Second Step:* Only diagnose what is generally accepted as the likely cause for an illness. This will boil down to tests that prove the condition is “untreatable” or treatable with medications that generate profit for drug companies, since most research dollars are tied up in products like drugs or medical devices.

For example, Post Lyme Disease Syndrome, a label favored by the IDSA, may be treated with new immune modulators, allergy modulators, pain medications, mood stabilizers and elevators. The search for an effective treatment for Lyme disease has not attracted pharmaceutical interest, and these additional disincentives would discourage the development of cheap, generic medications to solve the problem.

## Future research

In the case of emerging diseases, medical research is often ahead of “usual and customary” treatment. But in the case of Lyme disease, meager research on effective treatment protocols has yielded conflicting evidence and discouraged pharmaceutical interest. With unsettled science, practitioners rely on their diagnostic skill set to identify a complicated disease. The FDA action could remove tests for costly or messy diseases, leaving many ill

and misdiagnosed patients to rely on palliative medications like opiates and antidepressants.

I believe that labs currently have incentives to apply laboratory science to research data and possibly help the people with emerging diseases NOW ... when they are sick ... not in 10 years when everything is worked out. Improving the care of Lyme patients depends on improving our research data and developing better medications. The healthcare system must allow incentives for this necessary research and development to help diagnose and treat Lyme patients NOW ... before the rising number of chronic cases explodes further.

*Chris Green is a practicing physician in California who cares for patients with complex tick-borne diseases. She serves on the boards of LDo and ILADS.*

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As a physician, I am trained to ascertain what test is needed for what clinical presentation. I can judge a “legitimate” test.

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*Pamela Cocks, MPH, MLS, is a health care planner. She chaired a California hospital board committee on quality assurance for several years.*

# 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.



# CONFERENCES 2015

## Save the Dates!



### LDA AND ILADS TO CONVENE THEIR ANNUAL MEETINGS

**October 15: ILADS Lyme Fundamentals**

**October 16-18: ILADS Annual Meeting**

**November 14 & 15: LDA Annual Conference**

### INTERNATIONAL LYME AND ASSOCIATED DISEASES SOCIETY

*Making the difference in the diagnosis and treatment of Lyme disease*

**October 15: ILADS Lyme Fundamentals**

**October 16-18: ILADS Annual Meeting**

ILADS brings its annual scientific conference to the Marriott Harbor Beach Resort, Ft. Lauderdale, Florida. This is an opportunity for medical professionals to learn about the latest developments in research and clinical applications to help patients with tick-borne diseases. ILADS Lyme Fundamentals is a one-day intensive course to introduce and enhance practical knowledge about the diagnosis and treatment of tick-borne disease.

For further information, visit [ilads.org](http://ilads.org)

### LYME DISEASE ASSOCIATION

*Science Bridging the Gap*

**November 14 & 15: LDA Annual Conference**

Sponsored jointly with Columbia University College of Physicians and Surgeons, LDA convenes its 16th annual conference on Lyme and other tick-borne diseases at the Providence-Warwick Crowne Plaza in Warwick, Rhode Island. The conference is designed for medical and health professionals, but is open for the general public to register. CME credits available.

For further information visit [lymediseaseassociation.org](http://lymediseaseassociation.org)

### PHYSICIAN TRAINING GRANTS TO ATTEND ILADS

*Lyme patients need access to proper diagnosis and treatment.*

As part of our mission, LDo provides educational grants for medical professionals to attend the annual conference of the International Lyme and Associated Diseases Society (ILADS). Over the years, we have supported the training of over 100 physicians who returned to their communities with critical current medical and scientific information.

Again this year, we will reimburse qualified medical professionals who attend ILADS for the first time — up to \$500 to attend the 3-day conference or \$150 for the 1-day session on fundamentals.

LDo also reimburses medical professionals 50% of the cost of their first year membership to ILADS.

For more information contact Barbara Barsocchini, LDo senior vice president:

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# A Life on Pause

When Lyme steals everything, you will spend every last cent trying to get well

By Jenny Buttaccio

It's nighttime. Lying in bed wide-eyed and frustrated as the clock ticks, you pray for just a few hours of precious sleep. Insomnia plagues you. Your usual sleep medications have no effect on you tonight. It's as if you just swallowed some candy instead of a sleeping pill. Tears stream down your cheeks. You bury your face into your pillow and weep softly so as not to wake anyone else. Is this really happening again? As the night bleeds into yet another day, time becomes irrelevant as there is never any period of rest. The sleep deprivation is a cruel form of torture for you with no end in sight any time soon.

If you could nap during the day, the constant sleeplessness might be easier to tolerate. Lyme disease wiped out your ability to nap years ago and no one has any solutions for you. Some people want riches or fame, but you, you just want a brain that functions normally. To have a brain that sleeps, isn't foggy, jumbled or forgetful, is your greatest wish.

A streak of bright, orange light bursts through the curtains. Damn it! It's morning now. Utterly depleted, you continue with your idle rest in bed as you wait for the alarm to go off alerting you to take your medications.

Almost every medication prescribed to you requires you to take it on an empty stomach. These are instructions you find particularly challenging to follow. Sometimes, you wait more than two hours before eating breakfast just to squeeze in your morning handful of pills.

Invariably, some medication or supplement gets missed. You panic as you rework your entire medication schedule for the day. There is no room for error anywhere. Hopefully, tomorrow you will get back on track. Treatment for chronic or late-stage Lyme disease is regimented and intense. You persist through these demanding protocols in the hopes of having a normal life again.

With the multitude of symptoms you experience daily, you've become too ill to work. Career advancement is not a realistic option for you anymore. No landing your dream job. No starting your own business. The longer you struggle with Lyme disease, the further away the reality seems that you will ever go back to what you once were.

Lyme disease can be disabling although some medical and political establishments will tell you it's not even real. Oh, how you would love if this disease were fake, a figment conjured up by your wild imagination. That somehow seems treatable and much less expensive.

But it's not an elaborate fabrication or something you've concocted for attention. You're not lazy, unmotivated or a head case.

You are not choosing sickness so you can lie in bed all day. This illness is real and it comes with a hefty price tag.

If you have Lyme disease, you will spend all of your money – every last cent – trying to get well. You will invest tens-of-thousands, if not, hundreds-of-thousands, of dollars on trying to save your life. If you've had this illness long enough, you've maxed out your credit cards, probably drained your savings, pensions, IRAs or 401k's. Evidence of a life before Lyme quickly vanishes.

Physicians most literate in treating Lyme disease are not covered by your insurance. To get well, you will likely need a multifaceted approach to treatment, including regular testing, prescription medications, supplements, and herbal medications.

The effort to repair the damage that chronic Lyme disease has caused is costly, burdensome and at an enormous out-of-pocket expense to you and your family.

Yet, you continually find the strength to persevere. You hold on to hope with fists clenched so tight your knuckles change color. Your hope is in a better quality of life. Your hope is in a future filled with joy and less suffering.

During your battle with Lyme disease, you have not been able to attend weddings, baby showers, family holidays, or outings

with friends. You have had to say "no" more than you say "yes." By now, you feel the pain of isolation. You wish people understood your illness better or, at the very least, that you had some special superpower that allowed you to articulate the torment raging on inside your body.

You will continue to battle this illness with everything you've got, but there's very little energy left (if any) beyond dragging yourself through each day. You need continued help and support no matter how long this journey takes, but you find most relationships cannot endure this level of hardship over the long haul. Your heart badly hurts as you sense relationships beginning to slip away.

Sadly, most aspects of your life are on hold indefinitely due to this illness. Recovery is long. Thoughts about dating, getting married or planning for a family fall to the wayside. You feel this illness stealing some of life's most precious opportunities from you as you wait for the moment when you might one day be well again. The future seems so uncertain.

Like so many other chronic Lyme patients, you constantly feel the slow, suffocating effects of a life on pause.

*Jenny Lelwica Buttaccio, OTR/L, is an occupational therapist and a health and wellness advocate and blogger. She was diagnosed with late-stage Lyme disease in 2013 after nearly a decade of misdiagnoses. She writes about her journey on [lymeroad.com](http://lymeroad.com). Follow her on Twitter (@lymeroad) and Instagram ([jennyxopictures](https://www.instagram.com/jennyxopictures)).*



Photo courtesy of [lymeroad.com](http://lymeroad.com).

# When the Fog Rolls In

My most frightening and frustrating symptoms are invisible to everyone else

By Julie Starling

It was a warm fall evening in Santa Cruz as my husband and I walked the dogs along the beach. Instead of the usual sunset over the horizon, a wall of fog



rolled in, motionless, blocking the setting sun from above. Gazing at the thick fog felt like home. I had just hit a new downturn in my health, so the strange weather brought a kind of comfort. Mother Nature empathized in a way that nobody else could, as she eased the burden of the bright light on my sensitive eyes.

Sometimes when people ask me about Lyme disease, they immediately jump to the most commonly associated symptom of the disease: joint pain. I suppose it's the easiest symptom to notice in a person. I'm glad it eventually ended up in my joints because otherwise I'm not sure I'd have a diagnosis.

Of all the symptoms of Lyme disease, the neurological manifestations frighten me the most. Maybe because they are harder to see from the outside. Or because they feel so utterly uncontrollable and cruelly invasive. They are the hardest to stop. The bacteria burrows deep into brain tissue to avoid being killed by medications that can't cross the blood brain barrier.

It's so hard to explain to someone else without sounding like you've lost your mind. At its worst, neurological Lyme disease can cause paralysis, seizures or schizophrenia. With lesser symptoms,

the victim is plagued with insomnia, nightmares, brain fog, word or song iteration, word loss (tip of the tongue) and hypersensitivity to sound, motion, or bright lights.

Those lesser symptoms sound fairly benign, but piled up and never-ending, they can make daily living grueling. Explaining neurological Lyme disease to someone else can feel like hitting my head against a fog wall.

"Oh! I hate when I can't get a song out of my head," someone will claim. "I forget words and names, too," says another. No, no, no.

Neurological Lyme symptoms are nothing like typical forgetfulness or song earworms (when a song repeats in your head). It's the earworm so extreme, so radically incessant, it leads to a vicious cycle of panic and insomnia. When it first happened to me, it was the unending techno music, which I once listened to while on the stationary trainer. It played in my head 24/7, snowballing into weeks of insomnia, incessant agitation and eventually neurological system shutdown. Today, even on good days when I can listen to music, techno is no longer on my playlist.

Tip-of-the-tongue symptoms in Lyme are also vastly different from occasionally forgetting a word. Instead, it's a daily struggle with common words. I once literally forgot the word "Alzheimer's" (you have to laugh at the irony) and substituted the word "preying" when I couldn't remember "hunting." Those are only two out of hundreds of instances over the last eight years. In the beginning, I chalked it up to being daft, not knowing it was the start of a long journey leading toward more frequent occurrences.

Neurological Lyme can also make it difficult to comprehend written or spoken words. When I recently opened up the user manual for a new camera, I could read the words individually, but I couldn't understand the sentences. This can really rattle a person. Thankfully by then, I knew what was going on and just put the manual

down for another day. None-the-less, the symptoms both fascinate and scare me. It's like learning a new language. Your neurological system has gone haywire. Nothing makes sense, no matter how hard you try.

There's also hypersensitivity to sound and motion. It's hard to explain to my husband — a music lover, who recently installed wireless amps and speakers in every room in the house — that music sometimes feels like an assault on my brain. It mystifies him, even though he knows I have Lyme disease. Why can music suddenly make me agitated, unhappy and downright crazy, when he's always known me to love all kinds of music? For some Lyme patients, loud sounds, music, bright lights or fast motion can trigger seizures. For me, music or action movies can trigger uncontrollable muscle tremors, brain fog, confusion, insomnia, extreme agitation, "brain freeze" pain and even anger, not to mention the ear worm from hell. When I'm in a downturn of Lyme, nothing makes me more furious than a cheerful French song, the twang of a country melody or the pitch of pop music. My husband gets it as best as he can, but since I'm not having a seizure, it's hard for him or anyone else to really understand.

But there's a bright light in all this fog! Recently I discovered that no matter how bad I feel, I can tolerate soft rock music. I don't know why, but it doesn't trigger symptoms. So on my darkest days, if my husband wants music, he must endure Foreigner, Journey, Phil Collins and Brian Adams on Pandora's soft rock station.

Why beat my head against a wall of fog explaining why he can't listen to music when soft rock is enough to send the message that I'm feeling extra Lymie that day?

As for everyone else, it's easier to roll with, "Yah, it's that joint pain disease."

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