COVID-19 Patients Can't Wait (and Neither Can Chronic Lyme Patients)

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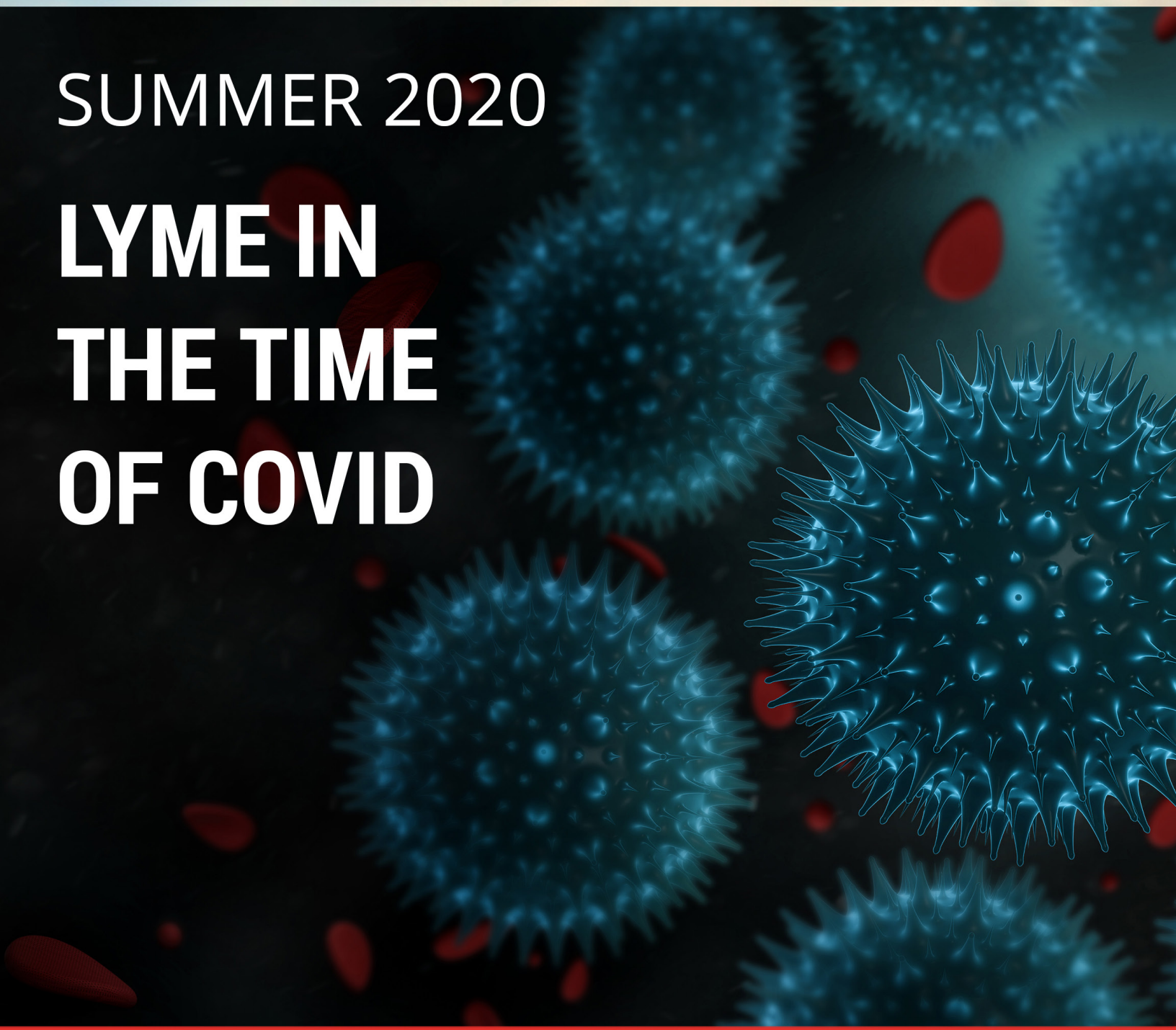

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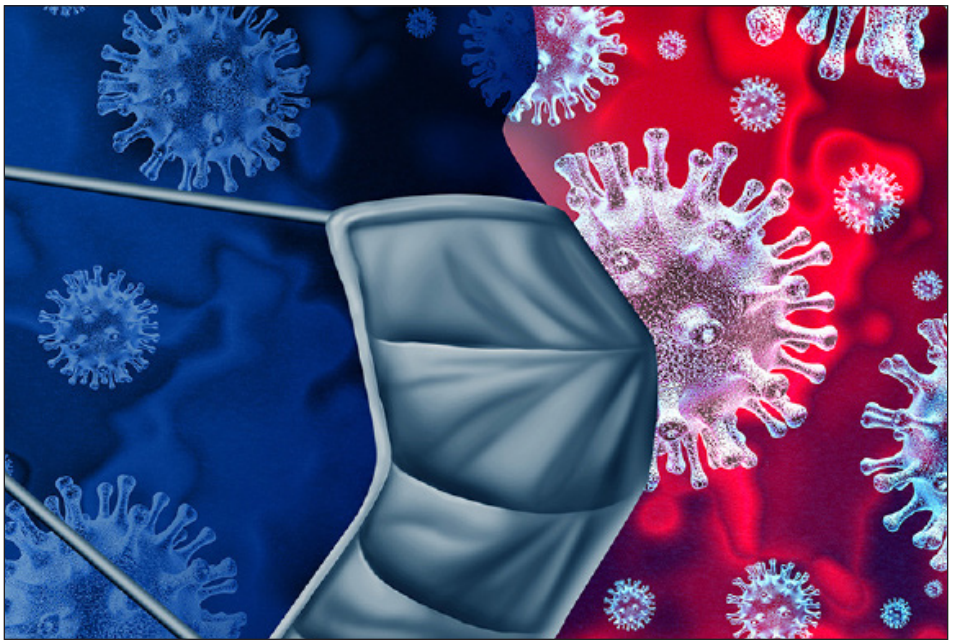

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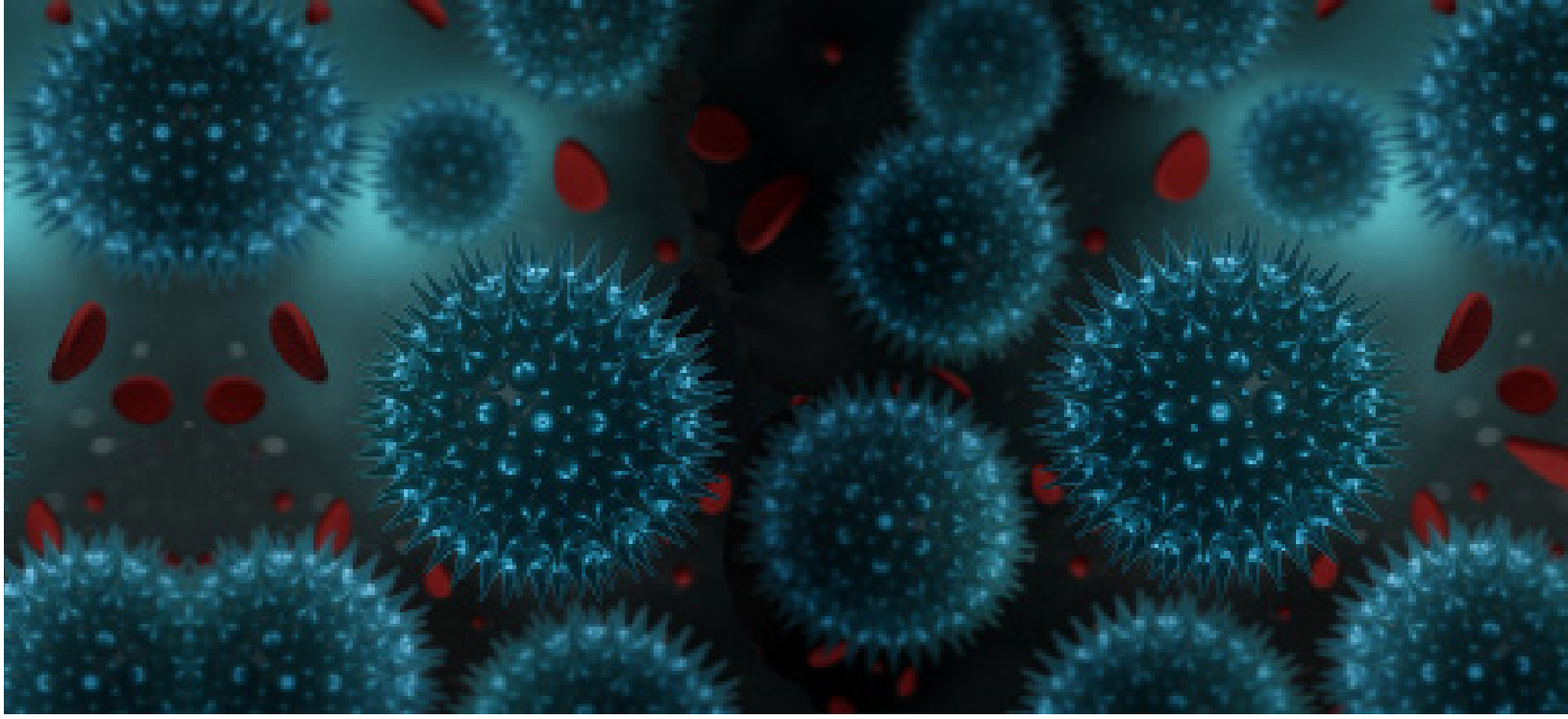


Surviving in the Time of a Pandemic

Tips on how the Lyme community can avoid getting sick in times of widespread viruses.

By Lonnie Marcum

We are living in unprecedented times. Not a day goes by that we don't hear something new about the COVID pandemic. Much of it contradictory. This virus is so new that scientists are scrambling to find answers.

Like so many of you this year, as spring was approaching, I assumed the biggest thing I'd have to worry about was ticks. Boy, was I wrong.

When word of the novel coronavirus spreading to the U.S. hit the news, I became concerned for my daughter, who has been immunocompromised since the beginning of her illness in 2012. So, as I am wont to do, I started researching. Here is what I learned.

What Is COVID-19?

The first human coronavirus was discovered in the 1960s as one of the causes of the common cold. There are hundreds of other viruses linked to upper respiratory infections, including rhinoviruses and flu viruses.

The current coronavirus, named SARS-CoV-2, causes coronavirus disease 2019, which is abbreviated as COVID-19. At its worst, COVID-19 can cause pneumonia in both lungs, multi-organ failure, stroke, and, in some cases, death.

Anyone who interacts with others is at risk for catching this coronavirus. And like with the flu, certain people are at a higher risk for developing severe illness.

According to a research team led by the National Institutes of Health, SARS-Cov-2 can remain infectious for several hours in aerosols (liquid droplets floating in the air after an infected person coughs or sneezes). It can stay infectious much longer than that on cardboard, plastic, hard surfaces, or stainless steel.

Furthermore, roughly half of the people with COVID-19 will show no or mild symptoms. These people, as they go through their daily lives, touching things and other people, can unknowingly pass on the infection.

How to Protect Yourself from Viruses

Because of my daughter's illness, we've made it a habit to practice strict hygiene in our household. If you or your child are immunocompromised, or you simply

want to protect yourself from the common cold and other viruses, you may want to adopt a few of my flu season protection tips.

Wash your hands frequently. We've heard this again and again, but I cannot stress the importance of this enough. Proper handwashing involves scrubbing with soap for a full 20 seconds and turning off the faucet with a paper towel. A simple way to time yourself is to sing "Happy Birthday" twice. (But sing it silently to keep from getting awkward stares from others!) And remember, hand sanitizer works most effectively if you rub your hands together until they are completely air dry.

Avoid sick people. First and foremost, stay away from anyone showing signs of sickness—runny nose, coughing, sneezing, fever, or cold- or flu-like illness. Imagine you are protecting a newborn baby. Likewise, if you are showing signs of illness, stay home. If you live with someone who is sick, they should be isolated and required to wear a mask at all times. Imagine everything the sick person breaths on or touches has glitter on it. The key is for you to avoid breathing glitter or getting glitter on your hands or face.

Start every day with a clean slate. Wipe everything in the kitchen: counters, refrigerator handle, all doorknobs, light switches, faucet handles … essentially everything someone may have touched with dirty hands. This rule also applies to hotel rooms (the phone, TV remote, doorknobs, etc.).

Keep germs out of the house. Never place mail, boxes, or purses on counters where food is prepared or served. Place grocery bags on the floor and clean food as you put it away. I have a TV table at my front door with cleaning supplies and a sign reminding everyone, prior to entering my house, to please:

- spray shoes,
- wipe cell phone, and
- clean hands.

Protect yourself in public. Keep a bottle of hand sanitizer in your purse, pocket, or backpack and car at all times. Wash your hands before you eat or touch your face. Use hand sanitizer after pumping gas or touching anything the public touches (doorknobs, handrails, pens, credit card terminals, etc.). Wear a face mask if you must enter a crowded space or use public transportation during a pandemic. (Some locations mandate face masks any time you are in public.)

Protect yourself at work. At the beginning of every workday, you will want to clean everything you touch to reduce or eliminate as many of the microbes as you can (doorknobs, phone receiver, number pad, keyboard, mouse, light switches, pens, pencils, calculator, etc.). If possible, ask others not to use your work-

station. Some jobs may require you to wear a mask, especially if you work in a space that is frequented by the public (a grocery store, medical facility, restaurant, etc.).

Take extra precautions if you are immunocompromised or vulnerable. Carry hand sanitizer, disinfecting wipes, disposable gloves, and masks everywhere you go. Wash your hands frequently. If you can't remember if you washed your hands, wash them again. Enforce a strict "no visitors" rule for anyone who has a fever, cough, sneeze, or runny nose or who has been exposed to someone else who is sick. You want all visitors to be symptom-free for at least 24 hours (preferably longer) without using cold, flu, or fever-reducing medications.

How to Prepare for a Crisis

California has its share of disasters, so I'm kind of used to preparing for emergencies. During fire season, we keep an evacuation plan taped to the fridge. And because earthquakes happen occasionally, we always have a three-day supply of water and non-perishable foods.

Earlier this year, knowing that COVID-19 was coming, I prepared for my family to hunker down.

Here are the steps we took:

1. Order a three-month supply of prescription medications.
2. Stock up on two to three weeks' worth of dried and non-perishable foods (rice, pasta, beans, nuts, and canned or frozen veggies, fruit, and meat).
3. Replenish household and cleaning supplies, pet food, batteries, etc.
4. Replenish emergency supplies (fever reducers, antihistamines, Band-Aids, masks, gloves, rubbing alcohol, etc.). Make sure you have a thermometer and a pulse oximeter.
5. Create a plan of action in case any family member becomes ill:
   - Who will take care of that person?
   - Who will take care of their kids and/or pets?
   - Who will shop for food, prepare meals, clean, etc.?
6. Have an emergency contact list that includes numbers for your doctor, personal emergency contacts, emergency services, the public health department, etc.

Finding the Silver Linings

Along with hardships, a crisis can also bring silver linings. We will see new policies and learn new strategies for dealing with pandemics. Parallels are being drawn about how the CDC's initial test for COVID-19 failed and how the test for Lyme disease continues to fail. Maybe knowledge gleaned from COVID research into COVID testing will ultimately benefit Lyme disease research?

Maybe people have become more aware of the emotional pain and frustration felt by those who have disabilities or chronic illness, like Lyme disease, and are stuck at home for months to years.

Here's how some people are making use of their quiet times. Mitch Hoggard, a pharmacist by training, treasurer, and board member of LymeDisease.org, has taken advantage of newly acquired solitude by looking for subjects and good composition for taking photographs in nature.

Mitch told me, "During these trying times, we have so much to be thankful for. As is often said, stop to smell the roses. Attitude isn't everything, but it certainly plays a huge role in how we live our lives. We can stay home and complain, or we can find beauty."

Here is a sampling of Mitch's spectacular photography. Learning how to use technology to stay connected during tough times has benefited all of us. Moreover, accommodations for telemedicine and for more people


@ Mitch L. Hoggard


@ Mitch L. Hoggard

working from home will be good for the environment in the long run.

As Dorothy Leland wrote in her Touched by Lyme blog, "Yes, in the interest of everybody's health, we need to sequester ourselves in the coming weeks. But we must do our best to stay socially connected with our families, neighbors, and larger communities. We need each other more than ever in such trying circumstances! Luckily, social media and other technologies help us do that. Personally, I'm making a special effort to keep in touch with my tribe using the best "remote" tools for the job—phone calls, text, Facebook, email, etc."

Renewed Focus on Health

If nothing else comes from this pandemic, people have become acutely aware of how important handwashing is for their health.

I hope the need for wearing masks in public comes to an end soon. However I think cleaning our cell phones, wiping the shopping cart handles, and generally increasing our cleanliness will have a positive effect come next flu season. And, hopefully, we will all think twice about what we've been exposed to and take extra precautions before visiting our elderly friends and relatives.

I see it as a good sign that the FDA is fast-tracking clinical treatment trials, allowing off-label use of medications, and granting emergency use for newly developed tests for COVID-19. We can only hope this type of urgency and innovation will continue and also be employed for tick-borne diseases.

And maybe, just maybe, people have become more aware of the emotional pain and frustration felt by those who have disabilities or chronic illness, like Lyme disease, and are stuck at home for months to years.

Now, wouldn't that be a wonderful silver lining for the Lyme community?

Staying Safe and Well During the COVID-19 Pandemic

Out-of-the-box treatments and physical distancing are helping.

By Dorothy Kupcha Leland

With the coronavirus pandemic, we're learning the importance of staying home and avoiding public spaces—and physical encounters with other people.

But the term social distancing grates against my sensibilities like fingernails on a chalkboard.

Yes, in the interest of everybody's health, we need to sequester ourselves for the time being.

But we must do our best to stay socially connected with our families, neighbors, and larger communities. We need each other more than ever in such trying circumstances!

Luckily, social media and other technologies help us do that. Personally, I'm making a special effort to keep in touch with my tribe using the best remote tools for the job—phone calls, text, Facebook, and email.

I'm also a member of Nextdoor (www.nextdoor.com). The social networking site connects me with neighbors who I may not personally know but with whom I share common concerns (like what's open and what's closed in our community during rapidly changing scenarios).

I also believe that staying in touch with your fellow members of the Lyme community is as important as staying in touch with the neighbors where you live.

One option is to join LymeDisease.org's online support group network. It is hosted on the IO network, which offers more privacy protections than many other social media platforms.

Everyone who joins automatically becomes part of the U.S. National Lyme Group and will receive daily digests of messages posted in the previous 24 hours. (You can change your settings to see them more or less often, as you prefer.) And there are subgroups for individual states, as well as one for parents of children with Lyme disease.

You can join LymeDisease.org's online support group by going to: https://groups.lymedisease.org/g/Lyme

If you haven't done so yet, I also recommend you sign up to receive LymeDisease.org's free weekly email newsletters.

We all must physically distance ourselves from others for the foreseeable future. But, please, let's commit to staying socially connected to family, friends, neigh-

bors—and others in the Lyme community.

With everybody's help, we'll make it through this difficult time.

Lyme Patients and COVID-19

I think it's fair to say that Lyme patients are used to having their concerns ignored by the medical community at large. Therefore, interest was high when Lyme-literate doctors started talking about how COVID-19 was affecting Lyme patients.

In the following webinar, five well-known Lyme doctors discuss coronavirus and its effect on their patients: https://www.lymedisease.org/members/lyme-times/2020-summer-features/lyme-patients-staying-well-covid-19/

The panel discussion was hosted by Dr. Sunjya Schweig of the California Center for Functional Medicine.

He was joined by Dr. Steven Harris, Dr. Jacob Leone, Dr. Ilene Ruhoy, and Dr. Richard Horowitz.

They discussed some of the basic science about the virus, whether patients with tick-borne infections are at higher risk of infection, and potential treatments based on the present scientific literature.

Dr. Horowitz also briefly recounted his experience treating three COVID-19 patients and what regimens have been working to date.

A Lyme Patient's Experience with COVID-19

About a week later, Dr. Horowitz produced another video, this time with Lyme activist/recovered COVID-19 patient David Roth.

David Roth is a New Yorker who became quite sick with Lyme disease and Babesia about 10 years ago. He went through grueling treatment under the guidance of Dr. Horowitz and eventually recovered.

Since then, he's been a strong advocate for Lyme disease legislation and now heads the executive committee of Project Lyme.

Recently, he had dinner with a friend shortly before that person got terribly sick with COVID-19. (Remember that people can infect you even before they start showing symptoms.)

Within a week, Roth also became terribly sick and tested positive for the virus.

He turned to Dr. Horowitz again, who treated him with several "out-of-the-box" approaches that helped considerably.

As Dr. Horowitz explains in the video, the "cytokine storm" that often proves fatal to COVID-19 patients is similar to the Herxheimer reactions that can afflict people with Lyme disease. He believes that the steps he and David took to address the cytokine storm could prove helpful to other people with COVID-19.

COVID-19 Patients Can't Wait (and Neither Can Chronic Lyme Disease Patients)

Will Lyme disease benefit from COVID-19 research innovation?

By Lorraine Johnson, JD, MBA

Even a few short weeks ago, who would have thought we'd be wearing face masks and gloves to visit a grocery store? Or that any shopper would sport a get-up like the one in this picture?

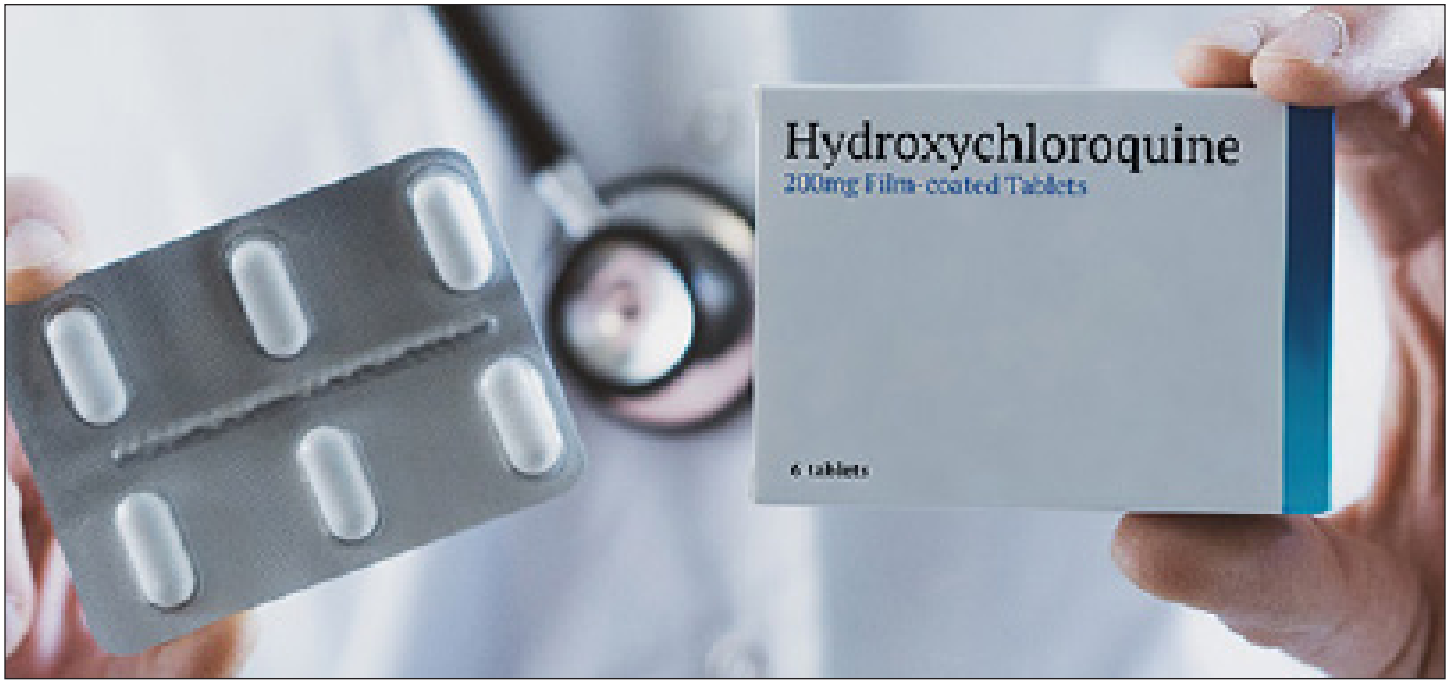
COVID-19 is changing the world as we know it. This coronavirus will change the world for patients with chronic Lyme disease too.

U.N. Secretary-General Antonio Guterres now warns that with COVID-19, the world faces its most challenging crisis since World War II in terms of human suffering, deaths, and economic disruption.

Patients need treatments and they need them now. The grindingly slow pace of traditional research won't do. We need guerrilla research that is fast, agile, and "good enough" for now. Research innovation is long overdue. It will benefit all patients everywhere, including those who have Lyme disease.

In a recent Forbes interview about COVID-19, I said, "It is important right now to take the gloves off clinicians and give them access to all available tools; patients are dying and can't wait for clinical trials."

My comment to Forbes about the need to act quickly drew some heat. Some people countered that we need evidence before we can treat, and that phy-



sician reports of what treatments they see working in hospitals are mere anecdotes.

Sound familiar? Since 2006, that's what the Infectious Disease Society of America has been saying in its guidelines to deny treatment to Lyme patients who remain ill. The COVID-19 pandemic shines a spotlight on the need to act in the face of uncertainty. Same issue, different disease.

For patients without treatment options, like those with COVID-19 and persistent Lyme disease, the amount of risk that they are willing to take on typically depends on the severity of their illness or the degree to which their quality of life is impaired.

Evidence-Based Medicine, COVID-19, and Chronic Lyme Disease

Evidence-based medicine is the combination of scientific evidence, clinical judgment, and patient preferences. Researchers tend to focus on the evidence piece of the puzzle. They contend that treatment be validated in randomized controlled trials (RCTs) before anyone can use it.

That's fine for researchers who aren't sick with the disease. But for patients and the doctors who treat them, the question is what treatments are worth trying? Specifically, are the risks of any given treatment worth it, given the potential benefits? The answer to that depends in part on how sick the patient is and what their treatment alternatives are.

For patients without treatment options, like those with COVID-19 and persistent Lyme disease, the amount of risk that they are willing to take on typically depends on the severity of their illness or the degree to which their quality of life is impaired.

Real-world data collected at the bedside by clinicians, their institutions, or patients provides valuable information. Yet, it can't demonstrate cause and effect. It can't tell us whether a patient got well because of a particular treatment. This patient might have had a milder form of the disease, he or she might have had a better immune system, or the doctor might have only given the treatment to certain patients.

To demonstrate cause and effect, RCTs are required. The problem with RCTs, Dr. Rob Califf, former head of the FDA explains, is that "they take too long, cost too much, and don't apply to most people." In a crisis, barriers like these cost lives.

Anecdotes vs Evidence: The Hydroxychloroquine Controversy

The issue of how much evidence is enough for a doctor to act takes on new urgency with COVID-19's mounting death toll. It has erupted in full force over the innovative use of hydroxychloroquine (HCQ; also known as Plaquenil), sometimes in combination with azithromycin (H&Z). (Doctors sometimes use these drugs to treat persistent Lyme disease, although not necessarily in combination.)

The tone of the debate around H&Z is heightened by its political overtones. President Trump has encour-

aged people to use the treatment, asking rhetorically, "What can it hurt?" Meanwhile, others have derided H&Z as "scientifically unproven." They note that (like all medical treatments) there may be side effects—some serious.

LymeDisease.org is not weighing in on this debate one way or the other. Instead, we look at the healthcare policy arguments advanced generally to see how they apply to persistent Lyme disease.

COVID-19 highlights the tension between doctors in the trenches battling illness and researchers sitting in ivory towers focusing on abstract concepts that don't land in the real world with patients whose lives are at risk.

The clinical experience of doctors is an essential form of scientific knowledge that is being dismissed by researchers who don't bear the consequences of failing to intervene when people are sick. These researchers don't have to tell the families who have suffered a loss that they didn't do everything they could to help.

We see the divide between academic researchers and physicians who treat Lyme disease every day, but the story has not resonated with the media or the public in the way the COVID-19 crisis does.

When the IDSA says, "Let's wait for the evidence," patients need to push back — because COVID-19 patients can't wait, and neither can patients with Lyme disease.

COVID-19 underscores the importance of clinical innovation to save lives. New therapies may take a year or so to develop.

In contrast, doctors can repurpose off-label FDA-approved drugs for use with COVID-19 today. Some doctors have reported success treating COVID-19 with HCQ or H&Z—reports that some researchers dismiss as mere "anecdotes." However, a survey of over 6,000 doctors found that azithromycin and hydroxychloroquine are among the three most commonly prescribed treatments (included in 41 and 33 percent of treatment plans, respectively) for COVID-19.

Embrace Evidence-Based Medicine

In a recent article, Dr. Perry Wilson, Associate Professor at Yale School of Medicine, called out the false dichotomy of framing the HCQ debate as "evidence vs. anecdote":

"The bottom line is that we don't need to abandon evidence-based medicine in the face of the pandemic. We need to embrace it . . . [and] realize . . . evidence-based medicine is not just about randomized trials; it's about appreciating the strengths and weaknesses of all data, and allowing the data to inch us closer and closer toward truth." In the same article, he stated, "We don't have the luxury of waiting for [RCTs]. We need to act on the data we have. . . . As more data come in, we can revise those estimates of efficacy, iteratively and transparently" (Wilson, 2020; emphasis added).

Wilson's piece garnered over 129 comments about whether doctors should provide treatment that "might work" before the evidence is settled.

One clinician put the need for doctors to act in stark terms: "This is war. In war, we do not wait for an RCT to see if a particular new weapon will work. If it works and kills the enemy, good. If it does not work, bad luck. If it works adversely, bad luck—the soldiers were going to die of enemy fire anyway. In [this] case, the new weapon is in fact, an old weapon established as effective against another type of enemy, so no harm in trying it." This is the approach many Lyme doctors take.

These arguments should sound familiar. Lyme patients and their treating clinicians have been saying this for years. We make these arguments in the context of Lyme disease in my subcommittee's report to the federal Tick-Borne Disease Working Group (TBDWG). This spells out the need to make decisions in Lyme disease even when science is uncertain.

Shared Medical Decision-Making

Putting aside the political theatrics in the H&Z controversy, the full spectrum of the debate on what to do when science is uncertain is represented on the president's own COVID-19 team. Trump's encouragement of the use of H&Z has been branded as anti-science. At the same podium, his advisor Dr. Anthony Fauci (director of the National Institute of Allergy and Infectious Diseases) calls the treatment unproven. Dr. Deborah Birx (coronavirus response coordinator) says that the decision does not belong to either President Trump or Dr. Fauci, but rather belongs to the individual patient and their doctor. This is known as shared medical decision-making.

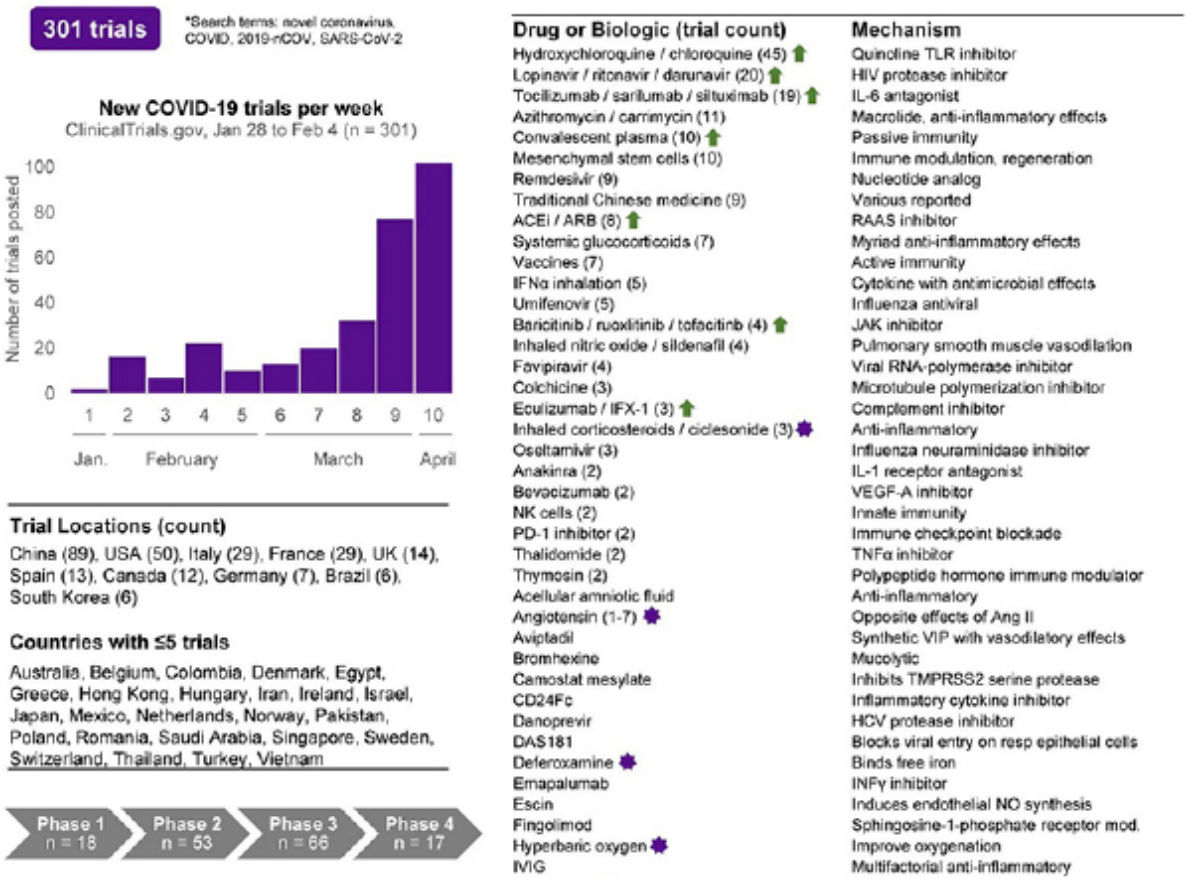
We see this same range of views in the treatment of persistent Lyme disease, with ILADS physicians being accused of using "unproven treatments" and the IDSA asking patients to wait until the science is in. But the Lyme disease treatment research boat has not set sail for over 20 years, when the last clinical trial for treating persistent Lyme disease was funded.

Unlike COVID-19, Lyme disease is a research-disadvantaged disease—with very little government or industry interest in developing new treatments. If COVID-19 research is a fire hose that's full blast right now, then Lyme disease research is a parched desert. The sad fact is that without incentives for research, Lyme disease is unlikely to achieve scientific certainty any time soon, and patients who are sick today need treatment.

In his article, Wilson says that where the evidence is not yet in and the patient outcome is uncertain, "the key to evidence-based medicine during this epidemic is being transparent about what we know and what we don't. If we want to use hydroxychloroquine, that is a reasonable choice, but we need to tell the public the truth: We're not too sure it will work, and it may even be harmful."

That sounds like the calls in the Lyme community for shared medical decision-making with patients. This is one of the recommendations contained in my subcommittee's report to the TBDWG. The Working Group adopted it and will submit it to Congress as a call to action.

Recommendation 7.1: Recommend Federal government websites and educational materials and seminars for clinicians, the public, and public health departments, which discuss Lyme disease, provide information that the state of the science relating to persistent symptoms associated with Lyme disease, is limited, emerging, and unsettled; and increase public awareness that there are divergent views on diagnosis and treatment. Consider that shared medical decision-making may be appropriate in some circumstances.



Lyme disease has always played David to the IDSA's Goliath in terms of power. The urgency of COVID-19 has moved the debate about the need to act when patients are ill and science is unsettled and the importance of shared medical decision-making into the mainstream. Shining the COVID-19 spotlight on these issues may help Lyme disease patients obtain the treatment they need.

The COVID-19 Research Renaissance

The COVID-19 crisis is transforming the speed and way that research is conducted. One physician commented to the article by Wilson saying, "This pandemic can be a real eye-opener . . . [on] the need to revolutionize regulatory infrastructure and come up with innovative solutions for the benefit of our patients." This is a call for research to enter the 21st century and begin using big-data tools, including the use of research registries.

Clinician and institutional registries are being used to capture data about COVID-19 cases. For example, a preprint of a study with over 4,000 patients at one New York center conducted from March 1–April 2, 2020, was published within just seven days! That study analyzed patients who were diagnosed, were admitted, or became critically ill during that month.

This is why LymeDisease.org launched the MyLymeData registry, which has enrolled over 13,000 patients. Patients have long recognized the need to accelerate research and to recognize all forms of data as useful. Data from the registry has helped determine the ground truth for Lyme patients.

There has also been a virtual explosion in the number of research trials being conducted for COVID-19. More than 160 COVID-19 treatments and vaccines are either under development or consideration.

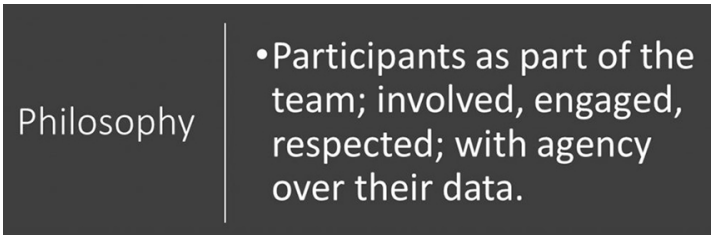
These include antivirals, antibiotics, anti-inflammatories, antibody-based treatments, and vaccines. They include drugs currently being developed as well as FDA-approved drugs that might be repurposed for treating COVID-19. And 300 clinical trials are listed on ClinicalTrials.gov as of April 4, 2020, with more listed every week.

COVID-19 is accelerating changes in the way trials

are conducted and in the use of innovative research tools, like big data. For example, Yale, Rush University in Chicago, and the University of Washington have proposed a trial called INSPIRE, which would use real-world evidence in a national registry. The study is unique because it would allow data to be entered about treatment outcomes by many different stakeholders, including patients, emergency rooms, institutions, clinicians, and lab test sites.

This proposed study was presented at the NIH Collaboratory on April 3, 2020 (which focused on creating a rapid-cycle learning research system where research is conducted quickly and implemented into clinical practice).

The importance of patient participation was captured in the slide below:



Another study, presented on April 17, 2020, at the NIH Collaboratory, called HERO, seeks to enroll over 15,000 healthcare workers (who are at high risk of contracting COVID-19) to track their symptoms and challenges dealing with COVID-19.

It would also use 40 clinical research networks—institutions like Kaiser, for example—to see if using HCQ in healthcare workers prevents them from contracting the illness.

A recent commentary in the New England Journal of Medicine correctly points out that "it is a false dichotomy to suggest that we must choose between rapid deployment of treatments and adequate scientific scrutiny."

COVID-19 is showing us that we do not need to settle on a single evidence-building approach. Instead, we can and must use all the tools at our disposal to solve this problem at the same time. These tools include:

- Encouraging frontline clinical innovation on a patient-to-patient basis
- Using registries to capture results of innovative clinical approaches where possible/li>
- Conducting multi-site clinical trials, including RCTs, to evaluate treatment outcomes
- COVID-19 has ushered in a brave new world of research and heightened debates around the role of the doctor and patient in making health care decisions when evidence is uncertain. As COVID-19 is showing us, the full range of evidence, encompassing patient experience, clinical experience, registry-gathered data of outcomes, and RCTs, exists along a continuum.

Valuing one does not mean devaluing the other forms of evidence. This type of innovation is a good model for Lyme disease. When the IDSA says, "Let's wait for the evidence," patients need to push back — because COVID-19 patients can't wait, and neither can patients with Lyme disease.

Lorraine Johnson, JD, MBA, is the chief executive officer of LymeDisease.org. You can contact her at lbjohnson@lymedisease.org. On Twitter, follow her @lymepolicywonk.

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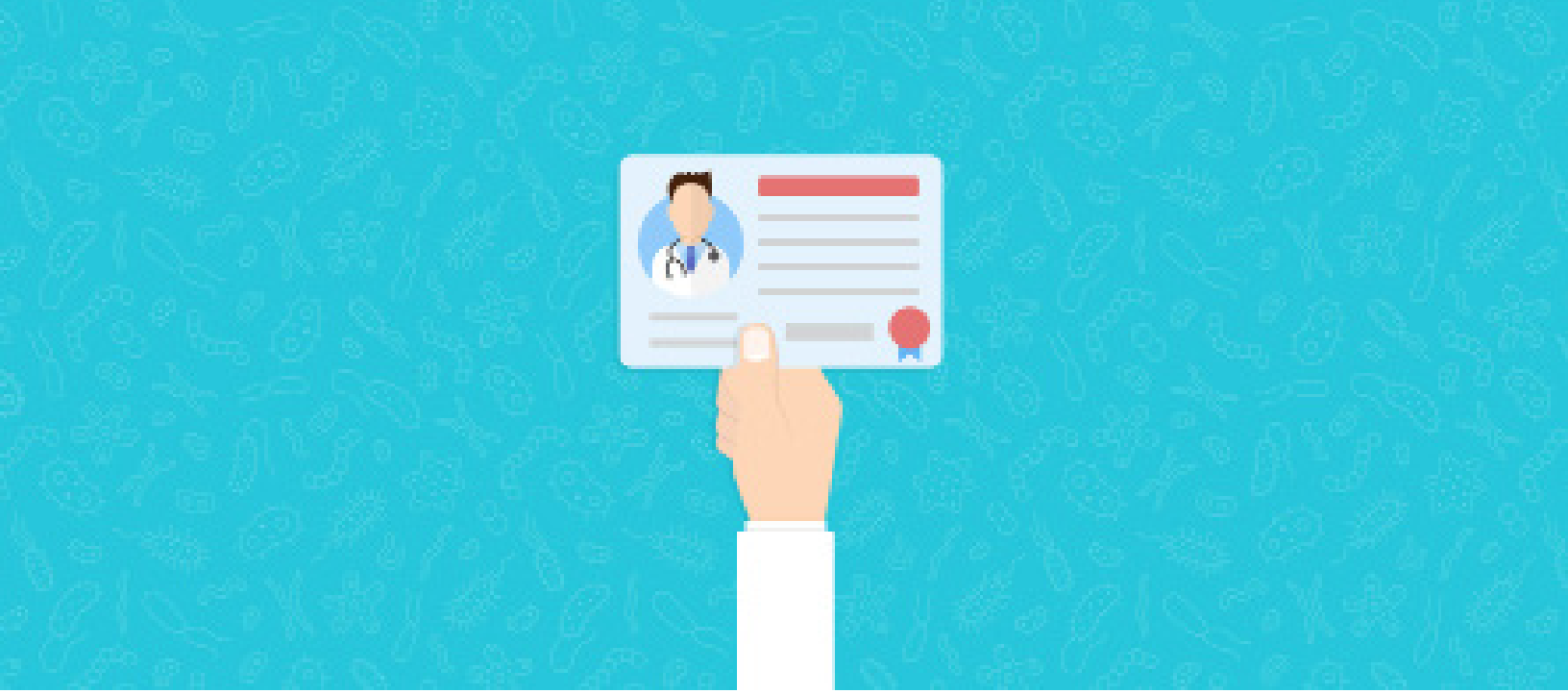


NC medical Board Lifts Restrictions on Prominent Lyme-treating Physician

Dr. Joseph Jemsek thanks North Carolina for it's newly acquired insight and appreciation of Lyme.

By Dorothy Kupcha Leland

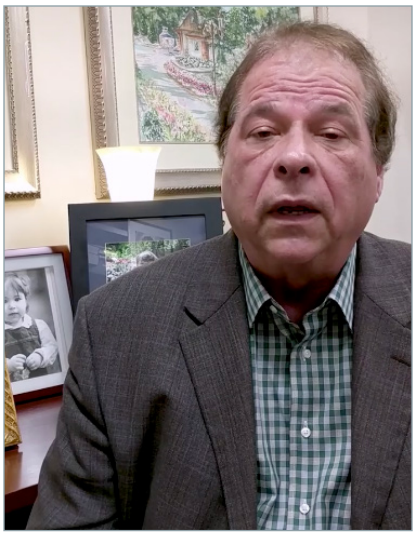
Dr. Joseph Jemsek, whose case with North Carolina medical authorities has been widely followed by the Lyme community, received good news from the board this week.

In a statement widely shared on social media, Jemsek said:

"In 2006, the North Carolina medical board restricted my medical license due to my longer-term therapy of Lyme Borreliosis Complex in this very sick, politicized and marginalized population. Now, well over 13 years later, these North Carolina medical board orders have been rescinded and abolished. This rarely happens."

Dr. Jemsek's troubles with the medical board were prominently featured in the Lyme documentary "Under Our Skin," released in 2008.

After North Carolina restricted his license, he moved his practice out of state, establishing the Jemsek Specialty Clinic in Washington DC.



Dr. Joseph Jemsek

In the following Facebook video, Dr. Jemsek says he thanks the North Carolina medical board for its "newly acquired insight and appreciation for this dreadful illness."

View the video at: https://www.lymedisease.org/members/lyme-times/2020-summer-news/restrictions-lifted-dr-joseph-jemsek/

Virginia Medical Board Revokes License of Lyme-Treating Physician

Many LymeDisease.org's members are Dr. Zackrison's patients and strongly believe that she has been instrumental in helping them recover.

By Dorothy Kupcha Leland

In September 2019, the Virginia Board of Medicine summarily suspended Dr. Leila Zackrison's medical license for treating Lyme disease, pending a hearing.

"My suspension stems from the political rift between IDSA (Infectious Disease Society of America) and ILADS (International Lyme and Associated Diseases Society) where IDSA contends that Lyme Disease is simple to treat and not chronic," Dr. Zackrison stated on a GoFundMe page raising money for her legal defense.

"Unfortunately, the Virginia Medical Board favors IDSA over ILADS," she continued. "Many

ILADS doctors like myself have suffered medical board investigations because they treat outside the IDSA guidelines…. The board has accused me of over-treating these patients, despite the fact that hundreds of my patients have improved under my care and returned to normal activity.

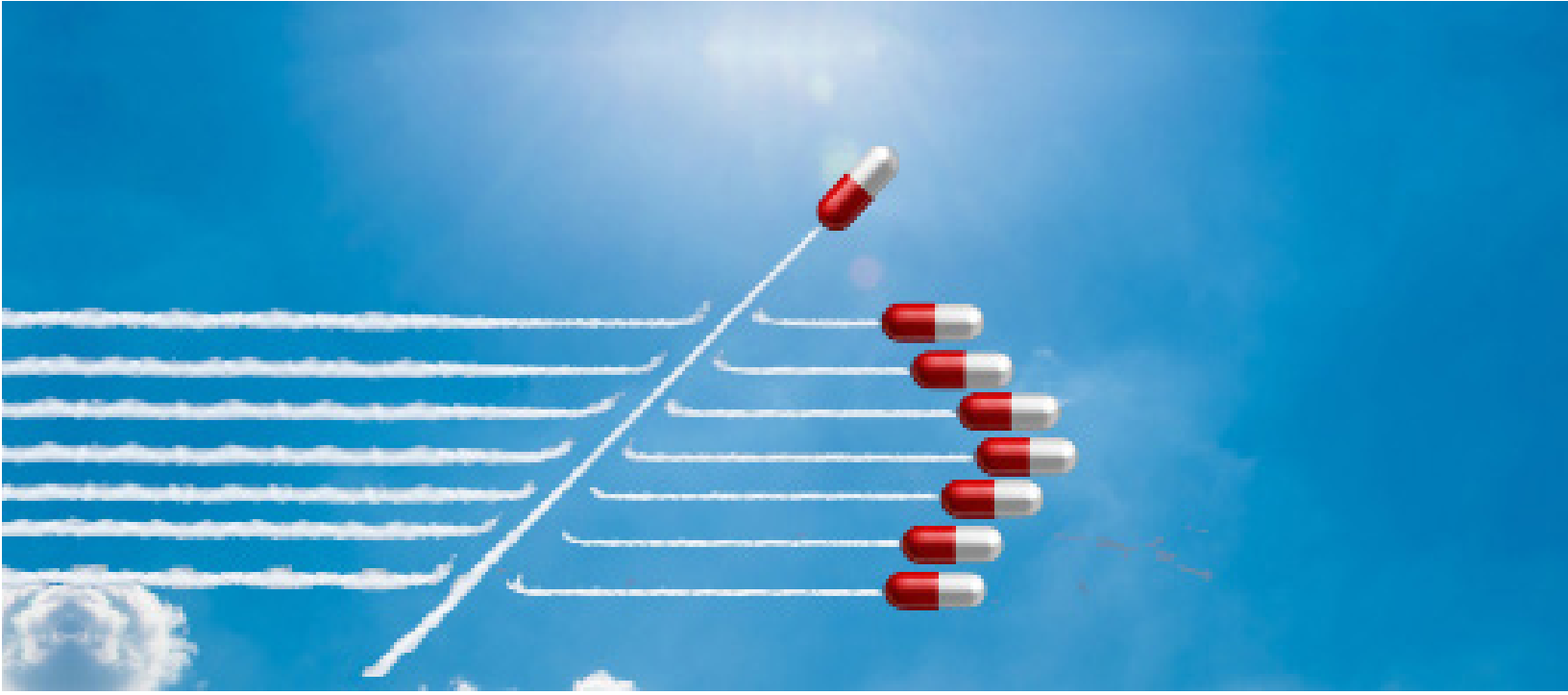
Dr. Leila Zackrison

A group called "Friends of Dr. Zackrison" helped in the fundraising efforts. It also organized patients to participate in a peaceful show of support when the medical board met to decide the case on February 20-21, in Henrico, Virginia.

However, despite their efforts, the medical board voted at that meeting to revoke Dr. Zackrison's license. Under Virginia law, she can seek re-instatement in three years, if she meets certain requirements of the board.

We will keep you posted on any noteworthy developments as the process unfolds.

Go here for more background on Dr. Zackrison's case: https://www.lymedisease.org/patients-rally-zackrison-virginia/



Lyme Disease Bacteria Eradicated by New Drug in Early Tests

Azlocillin appears to kill drug-tolerant persisters very effectively

By Kris Newby

In 2002, my husband and I became seriously ill after a vacation to Martha's Vineyard. It took ten doctors and a year to discover the root cause: We'd been bitten by unseen ticks harboring the parasites that cause Lyme disease and babesiosis, a malaria-like disease.

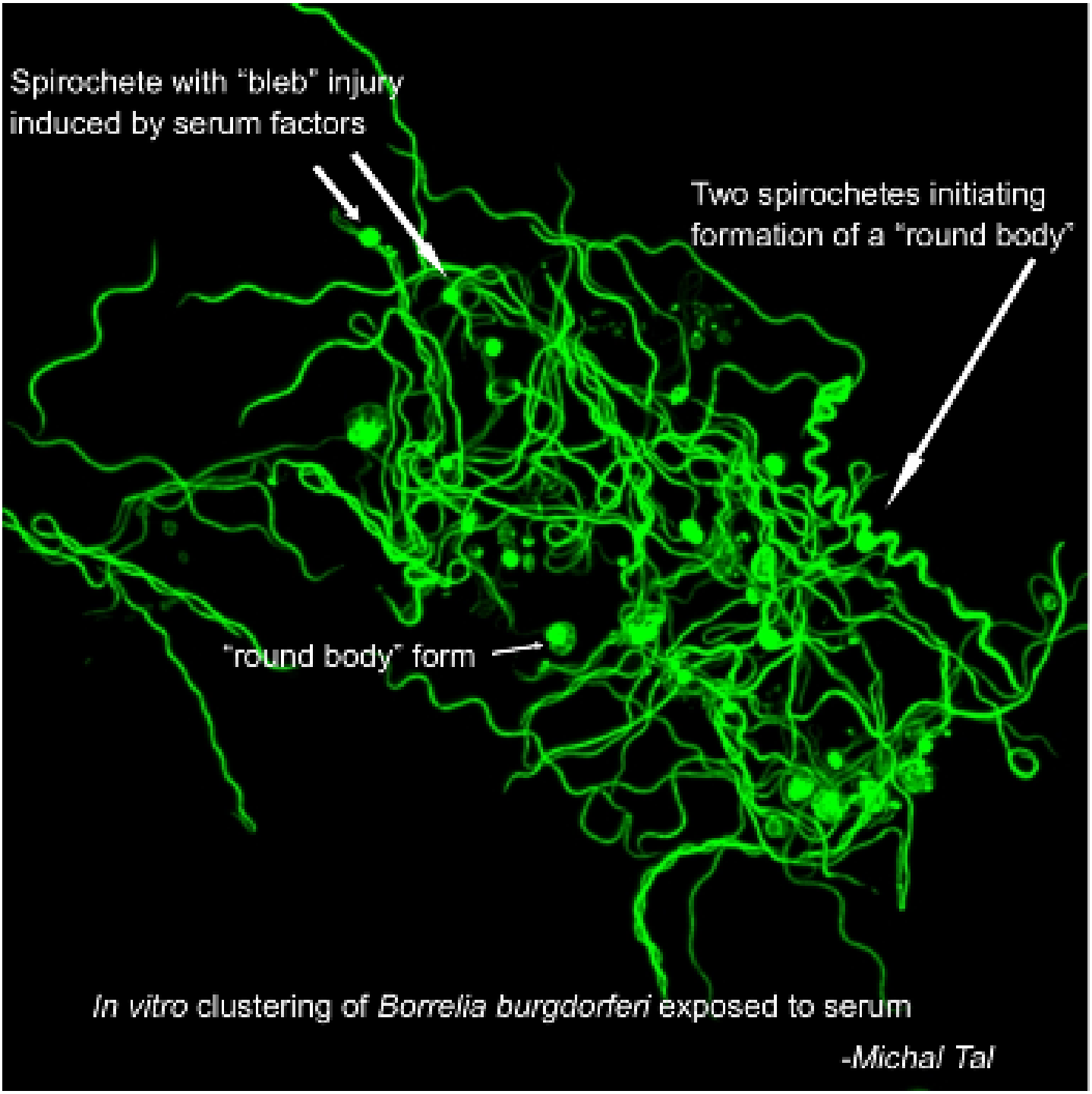
Our road to recovery was grueling, requiring five years of intermittent antimicrobial treatments. Later, I discover that my situation wasn't all that uncommon. About one in five Lyme patients continue to suffer from ongoing symptoms after being treated with the recommended course of antibiotics. After that experience, it was abundantly clear that we need better treatments.

That's why I was excited to hear about a study from Stanford Medicine researchers and their collaborators that provides evidence that the drug azlocillin eliminates the bacteria that cause Lyme disease at the onset of infection in lab mice and cultures.

Lyme disease, the most common vector-borne disease in the United States, affects more than 300,000 people a year. It is caused by the bacterium Borrelia burgdorferi, which is transmitted to humans through the bite of infected blacklegged ticks. If the disease isn't treated promptly, it can lead to life-threatening heart issues and chronic neurological problems. Common persistent Lyme symptoms include fatigue, joint pain, muscle pain, numbness, tingling, burning pains, and changes in mood, memory or mental clarity.

Drug-tolerant bacteria causing symptoms

Standard treatment of Lyme disease is oral antibiotics, typically doxycycline, in the early stages of the disease; but for reasons that are unclear, the antibiotics don't work for up to 20% of people with the tick-borne illness. One possibility is that drug-tolerant bacteria



This image shows how the Lyme bacteria, *Borrelia burgdorferi*, form protective round body "persisters" when threatened by defensive immune system biochemicals in blood serum.

cause the lingering symptoms.

This drug study, published online in Scientific Reports, was conducted by a team led by Jayakumar Rajadas, PhD, assistant professor of medicine and director of Stanford's Biomaterials and Advanced Drug Delivery Laboratory, and research associate Venkata Raveendra Pothineni, PhD.

Azlocillin appears to kill drug-tolerant persisters very effectively. These protective persisters form when the bacteria are threatened with defensive immune system biochemicals or antibiotics.

Azlocillin is a Promising drug candidate

The team zeroed in on azlocillin as a promising drug candidate through the use of high throughput

drug screening. This process entails acquiring "libraries" of thousands of known chemical compounds and drugs, then mixing Lyme bacteria with each in tiny wells to see which ones are best at killing the organisms. The best drug candidates were retested in larger culture dishes, then the safest of these were tested in vivo in seven mice.

Early results of this team's screening process, first published in 2016, led to the discovery of another promising Lyme drug candidate, disulfiram, which is approved by the Food and Drug Administration for the treatment of alcohol abuse disorder. This drug is currently being evaluated in a clinical trial with previously-treated Lyme patients. The trial coordinators are still looking for volunteers.

According to the recent study, azlocillin shows promise because it appears to be able to kill the two morphological forms of the Lyme bacteria — the actively replicating spiral forms and the semi-dormant round-body forms.

Azlocillin appears to kill drug-tolerant persisters

Azlocillin also appears to kill drug-tolerant persisters very effectively. These protective persisters form when the bacteria are threatened with defensive immune system biochemicals or antibiotics. After the threat has passed, the bacteria can reemerge to cause active disease. Many researchers believe that doxycyline's inability to clear the persisters may account for the ongoing symptoms of some Lyme sufferers.

Although azlocillin is an FDA-approved drug, more research needs to be done before it is used to treat Lyme patients. Rajadas and Pothineni have patented the compound for the treatment of Lyme disease and are working with a company to develop an oral form of the drug. Researchers plan to conduct a clinical trial.

As Pothineni said in the Stanford Medicine news release:

"We have been screening potential drugs for six years … We've screened almost 8,000 chemical compounds. We have tested 50 molecules in the dish. The most effective and safest molecules were tested in animal models. Along the way, I've met many people suffering with this horrible, lingering disease. Our main goal is to find the best compound for treating patients and stop this disease."

A former science writer with Stanford Medicine, Kris Newby is the author of Bitten: The Secret History of Lyme Disease and Biological Weapons. She is now working on a documentary based on the book.

Seven Herbal Medicines Can Kill Lyme Disease Bacteria in Test Tube

A new collaborative study shows promise for botanical remedies that could treat Lyme disease.

By Bay Area Lyme Foundation

Bay Area Lyme Foundation, a leading sponsor of Lyme disease research in the U.S., today announced the publication of new data finding that seven herbal medicines are highly active in test tubes against B. burgdorferi, the bacteria that causes Lyme disease, compared to the control antibiotics, doxycycline and cefuroxime. Published in the journal Frontiers in Medicine, the laboratory study was funded by the Bay Area Lyme Foundation and supported in part by The Steven & Alexandra Cohen Foundation.

The study was a collaboration between researchers at Johns Hopkins Bloomberg School of Public Health and colleagues at the California Center for Functional Medicine and FOCUS Health Group, Naturopathic.

"Since traditional antibiotic approaches fail to resolve symptoms in up to 25% of patients treated for Lyme disease and many suffer disabling effects of the disease, there is a need for novel treatment proven effective against B. burgdorferi," said the paper's co-author Sunjya K. Schweig, MD, CEO and co-director, California Center for Functional Medicine and Scientific Advisory Board Member, Bay Area Lyme Foundation.

Patients Turning to Herbal Remedies

"Because patients are currently turning to herbal remedies to fill the treatment gaps left by antibiotics, this research is a critical step in helping clinicians, as well as patients, understand which ones may offer the most potential benefit."

According to this laboratory study, carried out by Professor Ying Zhang's group at the Johns Hopkins Bloomberg School of Public Health, the seven herbal medicines that have the ability to kill *B. burgdorferi* in test tubes are:

It is important to note that each of these products

Cryptolepis sanguinolenta

Juglans nigra (black walnut)

Polygonum cuspidatum (Japanese knotweed)

Artemisia annua (sweet wormwood)

Uncaria tomentosa (Cat's Claw)

Scutellaria baicalensis (Chinese skullcap)

Cistus incanus

have the potential to produce significant side effects in patients, and should be taken only under advisement of a clinician knowledgeable of their capabilities and toxicities.

Of these products, the Cryptolepis sanguinolenta extract caused complete eradication, while doxycycline and cefuroxime and other active herbs did not. This extract has been used for the treatment of malaria as well as the tick-borne infection Babesia, a malaria-like parasite. This study is believed to be the first time this extract has been documented to have a potential impact on B. burgdorferi, and additional laboratory and clinical studies should be conducted to investigate the potential role Cryptolepis sanguinolenta could play in the treatment of Lyme disease.

Further, Cryptolepis sanguinolenta and Polygonum cuspidatum (Japanese knotweed) showed strong activity against both growing B. burgdorferi (MIC = 0.03–0.06% and 0.25–0.5%, respectively) and non-growing stationary-phase *B. burgdorferi*.

In contrast, Stevia rebaudiana, Andrographis pa-

niculata, grapefruit seed extract, colloidal silver, monolaurin, and antimicrobial peptide LL37 had little or no activity against stationary-phase B. burgdorferi.

New Therapeutic Options

"Our hope is that findings from this study could point to new therapeutic options for doctors and their patients, and pave the way for clinical research to help patients with persistent Lyme disease," said Linda Giampa, executive director, Bay Area Lyme Foundation.

New data finds that seven herbal medicines are highly active in test tubes against B. burgdorferi, the bacteria that causes Lyme disease, compared to the control antibiotics, doxycycline and cefuroxime.

These data may provide a basis for the clinical improvement of patients who take herbal medicines, particularly those whose chronic symptoms may be due to persistent bacteria that are not killed by conventional Lyme antibiotic treatment. However, it is critical to note that additional studies are needed to further evaluate the seven active botanical medicines identified in the study. Patients should not attempt to self-treat with these herbal medicines due to potential side effects and lack of clinical trials with these products.

About the Study

For the study, the researchers tested 14 natural products in test tubes against B. burgdorferi. Plant extracts selected for the study included herbs or agents that

- have been previously used to manage the symptoms of patients who do not respond to standard Lyme antibiotic treatment;
- have favorable safety profiles; and
- can be absorbed systemically.

Additional criteria for selecting compounds included anti-biofilm effects and ability to cross the blood–brain barrier. To conduct the study, the plant extracts in concentrations of 1 percent, 0.5 percent, and 0.25 percent and antibiotic controls were each tested on growing as well as non-growing B. burgdorferi cultures. The study found that seven of these natural product extracts at 0.25–0.5 percent had better activity against the stationary-phase B. burgdorferi culture than the control antibiotics doxycycline and cefuroxime, both of which are commonly used to treat Lyme disease.

The paper titled "Evaluation of Natural and Botanical Medicines for Activity against Growing and Non-growing Forms of B. burgdorferi" was written by Jie Feng, PhD, Jacob Leone, ND, Sunjya Schweig, MD, and Ying Zhang, MD, PhD.

SOURCE: Bay Area Lyme Foundation

Tick Attachment Time Guidelines Misleading

There's no grace period for tick bites. Let's quit implying that there is.

By Lonnie Marcum

I delivered these comments to the federal Tick-Borne Disease Working Group on 4 March, 2020.

My name is Lonnie Marcum. I am a physical therapist and health and science writer for the non-profit organization LymeDisease.org. I'm also a member of the Tick Biology, Ecology and Control Subcommittee.

One of the biggest problems we face today is misinformation—Lyme and tick-borne diseases are no exception.

One piece of misinformation I'd like to talk about today is tick attachment time.

Anaplasma, Babesia, Borreila mayonii, Borrelia miyamotoi, Ehrlichia, and Powassan virus are all transmitted by the same tick that transmits Lyme disease. And that last one—Powassan—can be transmitted within 15 minutes.

Currently, the CDC's website states, "In most cases, the tick must be attached for 36 to 48 hours or more before the Lyme disease bacterium can be transmitted" (https://www.cdc.gov/lyme/transmission/index.html).

Unfortunately, this sends the false message that there is no risk if any tick is removed within 36 to 48 hours of attachment.

This simply is not true!

In fact, there is ample evidence showing the risk for transmission with adult ticks begins at 24 hours in mice. But there are no studies showing the minimum attachment time for transmission of Lyme to humans—especially from nymphal ticks.

One European study documented six cases of culture-confirmed Lyme disease where tick attachment lasted less than 6 hours and another nine cases where transmission occurred in less than 24 hours.

While Lyme disease may be the most prevalent tick-borne infection, it is not the only pathogen carried by blacklegged ticks. Anaplasma, Babesia, Borreila mayonii, Borrelia miyamotoi, Ehrlichia, and Powassan virus are all transmitted by the same tick that transmits Lyme disease. And that last one—Powassan—can be transmitted within 15 minutes.

In addition, there are at least nine other tick species in the U.S. known to transmit pathogens to humans, many of them within 24 hours. Furthermore, many pathogens in the Rickettsia family, like Rocky Mountain spotted fever, can be deadly if not treated within the first few days.

Members of the public, as well as many healthcare professionals, are not skilled at identifying ticks or knowing how long they have been attached. Add to

that the studies showing most people with Lyme never even saw the tick.

Why Give the Public a False Sense of Security?

A better message would be to simply inform the public that the chance of disease from infected ticks increases the longer they are attached and feeding. Why not just tell people to keep the tick and send it for testing if they come down with symptoms?

There really is no such thing as a 36 to 48 hour grace period. Let's stop promoting this misinformation.

LymeSci is written by Lonnie Marcum, a licensed physical therapist and mother of a daughter with Lyme disease. Follow her on Twitter @LonnieRhea. Email her at lmarcum@lymedisease.org.

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Venturing out? Watch for ticks

Many of us are escaping social isolation into the ticks' home territory. Protect yourselves.

By Gazette Editorial Board

As government limits our movement due to the coronavirus outbreak, many of us are going to make our way outdoors to get some exercise, relieve stress and get a little alone time for ourselves.

More of us will be taking walks in the woods and fields. Many of us will be taking our dogs with us. We'll be going out back and clearing fallen winter branches and brush. We'll be going into the tall grass to clean up trash or fix damaged fences or just to wander around.

But just as we practice social distancing from one another, we need to remember to distance ourselves from another danger — the threat of Lyme disease, viral Powassan and other tick-borne illnesses.

Tick season never really ends.

But spring is when we venture out from our homes into theirs to cope with being homebound all winter.

It's even more imperative that we take precautions against Lyme disease, as the state and national health systems are going to be so overwhelmed with coronavirus in the coming weeks

In 2018, state and local health departments reported nearly 48,000 cases of tick-borne diseases to the U.S. Centers for Disease Control and Prevention. Of those, about 33,600 were for Lyme disease.

Protect yourself as if every tick was carrying a disease

Experts say this year is no different than past years, in that the ticks will be waiting for us when we go outside.

And we need to take steps to protect ourselves.

It's even more imperative that we take precautions this spring and summer, as the state and national health systems are going to be so overwhelmed with coronavirus in the coming weeks that we don't want to inconvenience ourselves, and further burden our hospitals and medical centers, with our tick-related illnesses.

Self-protection is the only way to keep out of the doctor's office.

"Pretty much everywhere in New York, it's an issue," said Dorothy Kupcha Leland, a nationally recognized Lyme disease activist, vice president of lymedisease.org, and parent of a child with Lyme disease.

Ticks, she said, are oblivious to coronavirus.

"You just want to make sure they don't do it to you," the California resident said in an interview on Friday.

While it's difficult to predict where infestations of ticks will be most prevalent, Leland said that in general, tick habitats are spreading into areas where they haven't been before.

And it's difficult for the ordinary walker or hiker to know where they're most likely to be infected with a tick-related illness.

She said one could find an area populated with ticks that are heavily infected with disease, while just a few hundred yards away, relatively few ticks could be carrying illnesses.

You just don't know. So you need to protect yourself, your family members and your pets as if every tick was carrying a disease.

"There's a lot that still isn't known," Leland said. "But in general to the person that's just walking around, you need to protect yourself. You can't look at [a tick] and see which one is safe."

Steps to protect yourself

Protection includes wearing protective clothing, including clothing treated with Permethrin (brand name Nix, Rid and Elimite); spraying insect repellent containing Deet on your skin; and checking yourself regularly for the presence of ticks after venturing outside. That includes checking your pets for ticks.

Many people take their dogs for walks with them, and a tick doesn't have to bite a dog to be dangerous

to a person. Ticks can easily migrate from a dog's fur to people. So when you're checking your pet for ticks after a walk in the woods, make sure you're still wearing your protective clothing and that you're checking yourself regularly after checking your pet. Ticks can even move from people into homes, cars and clothing.

Once you come inside, you can protect yourself by leaving backpacks and other clothing outside until you have time to check them. Putting clothing into a hot dryer for 10 minutes prior to washing it will help kill ticks and stop the spread inside your home, Leland said.

The Tick Act has yet to be funded

As for the national fight against Lyme disease and tick-borne illnesses, progress was made last year in Congress with the passage of the Kay Hagen Tick Act. The act is named after a North Carolina U.S. senator who died last October from Powassan virus, a rare tick-related debilitating disease.

But the Tick Act — which includes an allocation of $150 million over the next five years for education, awareness, detection and treatment of tick-borne illnesses — has yet to be funded, Leland said.

Lawmakers need to recognize that just because another disease has come to the forefront of our attention, it doesn't mean they can neglect funding for other health issues like this that affect so many lives.

Yes, the coronavirus should be foremost on your mind these days.

But if you're venturing outside to get away from it all, don't forget about the hidden danger lurking in the woods and the grass, and take steps to protect yourself.

For more information on ticks, tick-related illnesses and how to protect yourself from harm, visit www.lymedisease.org.

This editorial was originally published by the Daily Gazette of Schenectady, New York.

Is Your Child Crazy … or Sick? Mental Illness vs. Medical Disorder

Many symptoms of tick-borne diseases can easily be misidentified as mental illness.

By Daniel A. Kinderlehrer, MD

Brad's* parents brought him to see me when he was eleven years old. He was scratched by a cat at age two and developed enlarged lymph nodes in his neck. As a toddler, he began experiencing episodes of inconsolable crying and rocking. By age five, he clearly had problems focusing and was not interested in reading.

His symptoms worsened around age eight. The boy became agitated and easily overwhelmed, with outbursts of anger and rage. His father often had to hold Brad so that he didn't destroy the house.

Brad described dark episodes when he had obsessive, intrusive thoughts, such as hurting himself and others. He had severe anxiety and refused to go to school. He had pseudo-seizures, when he would suddenly flop to the ground but be totally conscious.

Brad had other symptoms, including sharp chest pains with shortness of breath; abdominal pain with nausea, constipation, and flatulence; knee, neck, and spine pain; lightheadedness; sound sensitivity; fatigue; and sugar cravings.

His mood issues were so severe that he underwent two psychiatric hospitalizations. His psychiatrist tried several medications. There was some improvement on Prozac and Trileptal, an anti-epileptic drug that is also prescribed as a mood stabilizer.

We'll get back to Brad. But first, I want to describe one way that microbes can cause psychiatric symptoms.

Dr. Susan Swedo is a researcher in the field of pediatrics and neuropsychiatry. Since 1998, she has been chief of the Pediatrics & Developmental Neuroscience Branch at the U.S. National Institute of Mental Health.

**Patient's name has been changed to protect his privacy.*

PANDAS and PANS

In 1994, Swedo was the lead author on a paper characterizing PANDAS—pediatric autoimmune neuropsychiatric disorders associated with streptococcus. Swedo described children who experienced the sudden onset of obsessive-compulsive disorder, tics, and other mood and behavior problems following a strep infection.[1]

Since then, it has become clear that strep is not the only microbe that can trigger psychiatric symptoms. Accordingly, this syndrome is now referred to as PANS—pediatric acute-onset neuropsychiatric syndrome.

Herpes simplex virus, influenza A virus, varicella zoster virus, Epstein-Barr virus, HIV, recurrent sinusitis, mold, and the common cold have been identified as triggers.[2–4] Tick-borne infections, including *Mycoplasma pneumonia*, *Bartonella heneslae*, and probably *Borrelia burgdorferi,* the Lyme pathogen, have also been identified as triggers.[2,4,5] PANDAS, caused by strep, is now considered a subset of PANS.

PANS may be a lot more common than we realize. In 2018, Dr. Nancy Brown and I did a pilot study in which we tested 10 adolescents at a residential treatment center in Colorado.[6] None of the teens had a known organic illness. All 10 were diagnosed with major depressive disorder and 7 with generalized anxiety disorder. They were too symptomatic to stay at home or go to public school.

According to testing, 6 of the 10 kids had antibodies to tick-borne infections—Lyme disease, bartonellosis, and tick-borne relapsing fever. Three had antibodies to Streptococcus. What was most surprising was that 9 of the 10 teens had elevated antineuronal antibodies.

Antineuronal Antibodies

Elevation of these antibodies, along with activation of a specific enzyme (the calcium calmodulin-dependent protein kinase II, or CaMKII) is the laboratory hallmark of PANS.[7] In the 1990s, Dr. Madeleine Cunningham and colleagues performed groundbreaking research to demonstrate the association of these lab abnormalities in kids with this disorder.8

It turns out that antibodies that target some microbes attack neuronal tissue and activate CaMKII, which disrupts dopamine transmission.9 The result is "brain on fire"—neuroinflammation that triggers a host of neuropsychiatric symptoms.

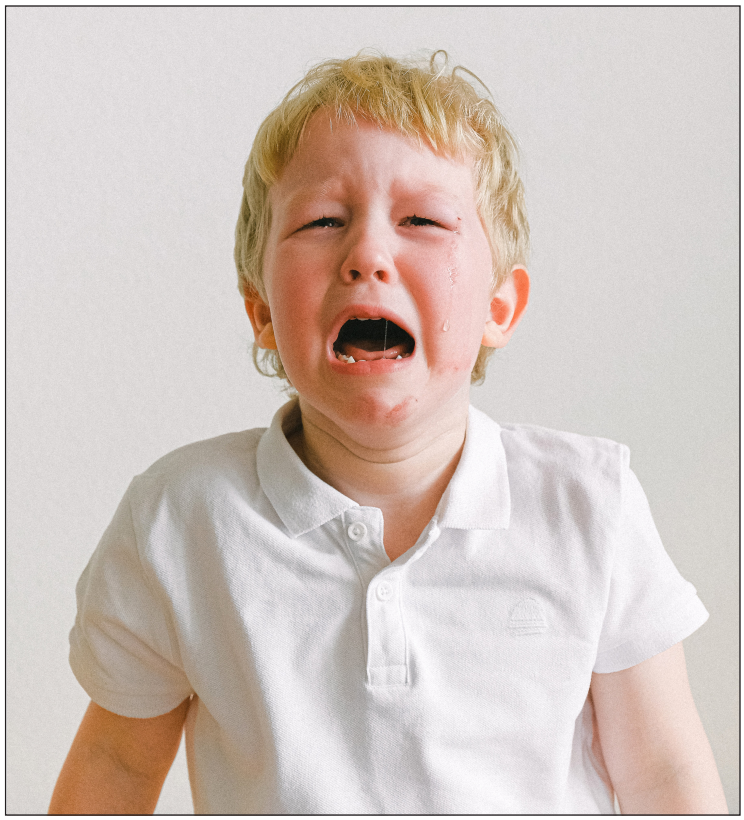

Photo by Anna Shvets

Children with PANS display a wide array of mood and behavior issues, especially anxiety, obsessive-compulsive disorder, depression, and irritability/oppositional/anger issues, which can reach epic proportions like Brad's. Interestingly, many outbursts are followed by remorse.

Children with PANS often fall behind developmentally and academically. Other common symptoms include involuntary movements, tics, and eating disorders. While the case definition of PANS limits the diagnosis to symptoms that have a sudden onset,[10] most of my patients' symptoms have come on gradually.

In my medical practice (which is limited to patients with tick-borne infections), I see many children and teens. I have been surprised by how many suffer from PANS. While they all have Lyme disease, it appears that Bartonella and Mycoplasma may be the worst offenders in triggering PANS.

What Are the Best Treatments?

It is important that these kids be treated with antibiotics,11 although careful titration is necessary because Herxheimer reactions can be severe.

Dr. Amiram Katz, a neurologist in Connecticut, has found that low-dose penicillin injections have been

Photo by Andrea Piacquadio

very effective.[12] I have had the same experience. Katz recommends long-acting penicillin injections (LA Bicillin), 1.2 million units once weekly if the patient weighs less than 100 lbs. and 2.4 million units once weekly if more than 100 lbs. If there is no significant improvement after 10 doses, then there is no reason to continue.

Intravenous gammaglobulin (IVIG) has helped many kids with PANS.[13] IVIG is composed of human antibodies and has the paradoxical function of stimulating the immune system while decreasing inflammation. It is administered intravenously or subcutaneously, often every three weeks. However, it is quite expensive and insurance coverage is difficult to procure—except for residents of Illinois.

Other interventions are often helpful. Many kids with PANS have mast cell activation syndrome (MCAS), which contributes to inflammation.[14] In these cases, interventions such as antihistamines can be helpful. Cromolyn, which inhibits the release of histamine and other inflammatory mediators from mast cells, is particularly beneficial.

Problem Foods

Food sensitivities can also contribute to inflammation,15 so parents should consider specialized testing or an elimination/challenge diet. Be particularly suspicious of food cravings—the foods people crave are often the worst offenders.[16]

In my practice, sugar, yeast, gluten, and dairy products are the most common culprits. Mold can trigger inflammation as well. Even though I live in Colorado, a low-humidity state, I am amazed at how many of my patients suffer from mold issues.

Other interventions are occasionally beneficial. Anti-inflammatory agents, whether ibuprofen or natural products such as curcumin, may help. Some people find that low-dose naltrexone decreases symptoms. Family counseling and support groups are also a good idea. Occasionally, antidepressants—particularly sertraline—can lessen symptoms.

Other modalities that sometimes prove helpful include biofeedback and plasmapheresis, a procedure in which blood is removed and antibodies are filtered out before the blood is replaced.[12]

Back to Brad

Brad suffered from several tick-borne infections: Lyme disease, babesiosis, and bartonellosis. He likely acquired Bartonella from the cat scratch at age two, which then activated a congenital infection with Borrelia burgdorferi and Babesia.

He is sensitive to gluten, dairy, and yeast, which I suspected from the pattern of his food cravings. He had a positive Cunningham Panel consistent with PANS. After major improvement on antimicrobials and intestinal support, he suffered a relapse triggered by a mold exposure. Now on disulfiram, he is doing much better.

I think that once the immune system gets triggered by one or more microbes, the systemic inflammation leads to multiple other sensitivities that contribute to even more inflammation. Brad likely did not acquire food sensitivities until after the infections flared. Then he also became more sensitive to mold.

These kids are suffering a great deal; some of them are suicidal. If we do careful detective work and treat the sources of their inflammation as well as the inflammation itself, we can help them get their lives back. Moleculera Labs, which performs the Cunningham Panel, offers a host of information on PANS.

Dr. Daniel Kinderlehrer is an internal medicine physician with a private practice in Denver, Colorado, devoted to treating patients with tick-borne illness. He is the author of the forthcoming book Recovery From Lyme: The Integrative Medicine Guide to the Diagnosis and Treatment of Tick-Borne Illness, which will be released next year.

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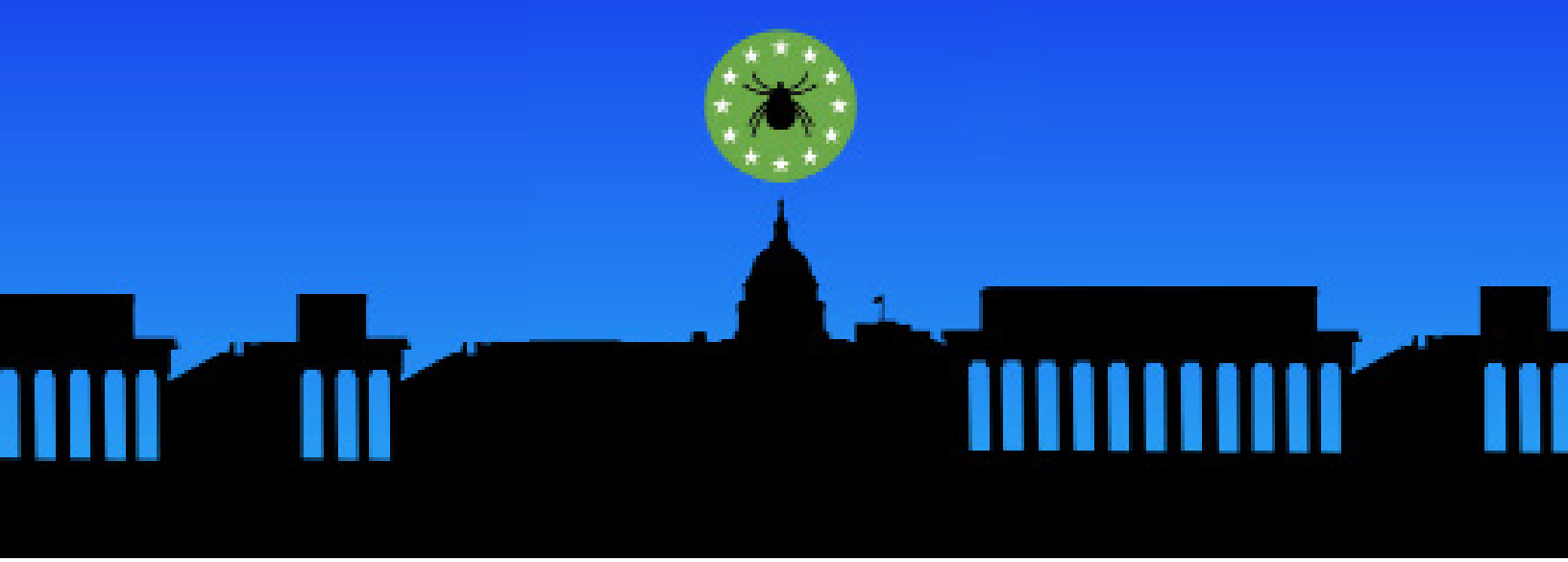


Flying in to Washington to Lobby for Increased Lyme Disease Funding

The Center for Lyme Action held its first Lyme Action Fly-in in February 2020

By Dorothy Kupcha Leland

They call it a fly-in. Advocates from throughout the country converge on the U.S. Capitol to talk with their senators and Congressional representatives. (Of course, not everybody arrives by airplane … but they do come from all over!)

I was pleased and proud to join the Center for Lyme Action (CLA)'s first Lyme Action Fly-in, which took place February 11–12, 2020.

The Center for Lyme Action was founded last fall by three people who want to increase the level of federal funding for Lyme and other tick-borne diseases. With charter member funding from Alexandra Cohen of the Bay Area Lyme Foundation and Project Lyme, the CLA jumped right into helping get the Kay Hagan Tick Act passed.

That measure became law in December 2019. But that's only the beginning. Now it needs to be funded. And there are some other Lyme-related projects that need funding as well. That's what advocates worked on during the fly-in.

February 11

Events on the first day brought us all up to speed. We heard from the CLA and from retired Air Force Colonel Nicole Malachowski. (She was the first female Thunderbird pilot, later forced to medically retire due to tick-borne illness. Now she's a dynamite inspirational speaker and warrior for the Lyme cause.)

A dinner and reception that evening honored members of Congress and administration officials who "have demonstrated extraordinary support in the push to cure Lyme disease."

Among those honored were Senator Susan Collins (R-ME), who received the CLA Champion Award, and Department of Health and Human Services Deputy Secretary Eric Hargan, who was the dinner's keynote speaker and recipient of the Bay Area Lyme Foundation Lyme Innovation Award.

"Lyme is a frustrating and debilitating disease, but it's a problem we can solve," said Bonnie Crater, co-founder of the CLA. "Our award recipients have demonstrated extraordinary leadership in finding a cure and we are honored to have them as long-term partners in this important fight."

Also receiving the CLA Lyme Champion Award were Senator Tina Smith (D-MN), Representative Collin Peterson (D-MN), Representative Anna Eshoo (D-CA), and Representative Chris Smith (R-NJ).

Getting ready to walk the halls of Congress.

Dorothy Leland and Bonnie Crater

Senator Susan Collins

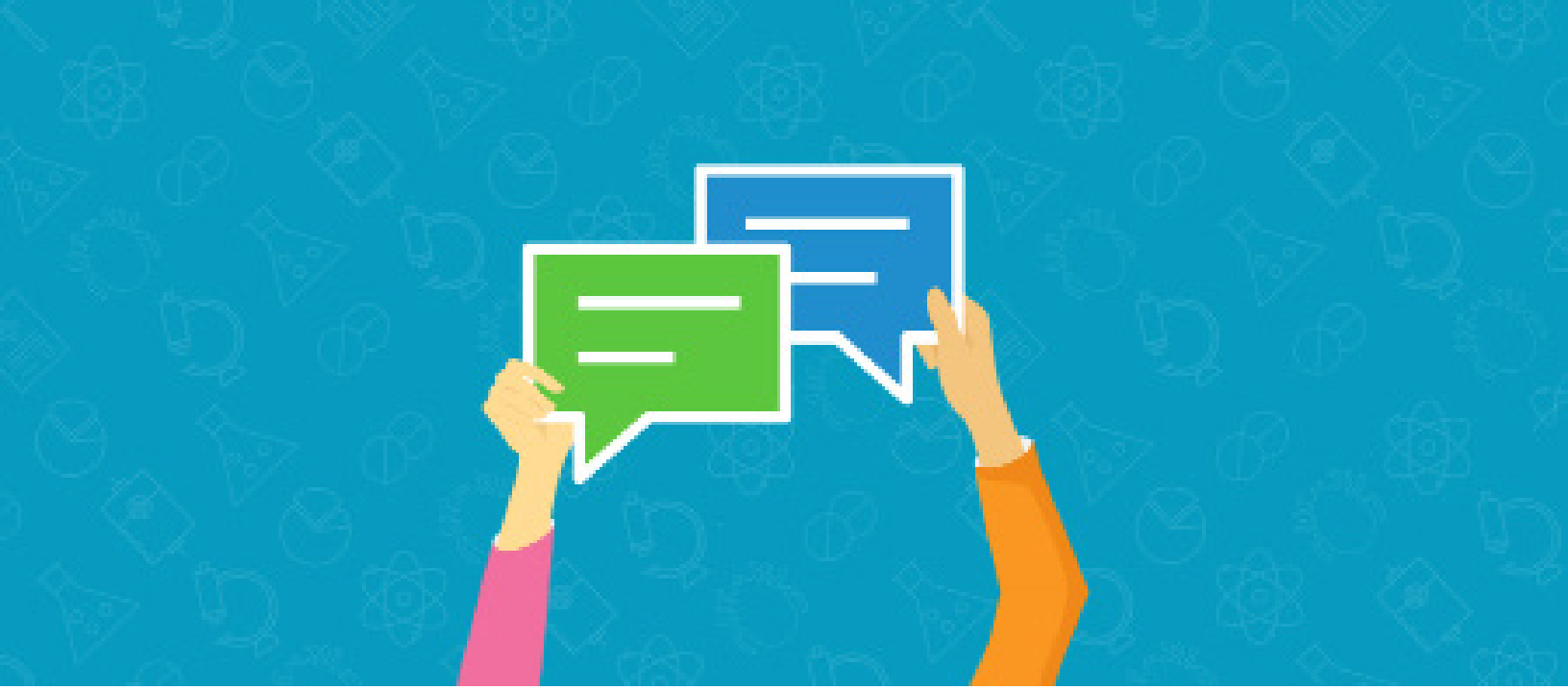
Rep. Chris Smith, flanked by Bonnie and Jeff Crater

February 12

The next day, advocates fanned out to meet with their senators and Congressional representatives (or, more often, with key staff members). Armed with talking points and packets of information to distribute, we walked the halls in our bright green neck scarfs. (Such identifiers have become a "thing" in grassroots lobbying efforts these days. I found my scarf was a real conversation starter when standing in the security screening lines!)

About 60 advocates took part in this first Lyme Action Fly-in. It's an important initial step toward educating our elected officials about what's needed. Stay tuned for future developments.

Written by Dorothy Kupcha Leland, LymeDisease.org's vice president and director of communications. She is co-author of When Your Child Has Lyme Disease: A Parent's Survival Guide. Contact her at dleland@lymedisease.org.



Tick-Bourne Disease Working Group Comments

Lyme disease community members shared both written and spoken remarks with TBDWG.

By Dorothy Kupcha Leland

The Tick-Borne Disease Working Group is organized under the auspices of the United States Department of Health and Human Services. Panelists include seven public members and seven members who represent federal agencies. There are also subcommittee members, who help the Working Group by doing research and making recommendations regarding the panel's upcoming Report to Congress, due in December 2020.

Other important forms of input for the Working Group include written and spoken public comments. The following remarks were delivered in person or by phone at the March 4, 2020, meeting in Philadelphia.

Condemned to a Life of Debilitating Illness? There's a Better Way.

By Phyllis Mervine

The single most important thing the Working Group can do right now for the Lyme community and all the patients suffering with Lyme disease is to ask Congress to instruct the CDC to educate the medical community about the two standards of care.

For years, the CDC promoted and linked to the Lyme diagnostic and treatment guidelines of the Infectious Diseases Society of America (IDSA). This violated its own ethics rules about not taking sides in a scientific debate when the evidence is uncertain, undermining public trust in government.

They persisted even after new International Lyme and Associated Diseases Society (ILADS) guidelines were published by the National Guideline Clearinghouse, while the IDSA guidelines were delisted for being out of date.

Phyllis Mervine

Today, inexplicably, the CDC does not mention anywhere on its website the only peer-reviewed guidelines that adhere to the rigorous Grading of Recommendations Assessment, Development, and Evaluation (GRADE) evidence assessment standards recommended by the National Academy of Sciences.

GRADE recommendations take into account not only the quality of the evidence but also the balance between benefits and harms and patient values and preferences.

The CDC no longer recommends the IDSA guidelines explicitly. Instead, it promotes IDSA diagnosis and treatment recommendations, chapter and verse. It completely fails to mention the ILADS perspective or even that there are different guidelines.

There are two big problems with this. First, the IDSA guidelines recommend the use of the restrictive surveillance case definition for clinical diagnosis.

As Paul Mead of the CDC has noted in the past, neither research definitions nor surveillance definitions are developed to guide clinical diagnosis and care, nor should they be.

Such definitions leave out the vast majority of patients diagnosed in clinical practice. As a result, people are not being diagnosed and are condemned to a life of debilitating sickness. Acknowledging the two standards of care would allow more patients to be diagnosed early and saved from years of suffering.

Second, the standard IDSA diagnosis and treatment recommendations leave many patients chronically ill—applying a one-size-fits-all approach to a complex problem. The ILADS standard of care solves this problem by providing individualized treatment that takes into account the patient's disease risk, severity, and treatment response.

It is time for the CDC to inform the medical community that there are two standards of care. By taking this simple step, the CDC could save lives. Please ask Congress to make this happen.

Phyllis Mervine is founder and president of LymeDisease.org.

MyLymeData Helps Build a Collaborative Research Engine for Lyme Disease

By Melissa Potter

I am here on behalf of LymeDisease.org.

LymeDisease.org is one of the oldest Lyme disease nonprofits in the nation. We have played an instrumental role in patient- and science-based advocacy both in connection with Lyme disease and more broadly in national healthcare policy.

Members of LymeDisease.org have served on advisory panels and presented on patient engagement in government-funded organizations, such as the Patient-Centered Outcomes Research Institute, the National Institutes of Health (NIH) Collaboratory, the White House's Precision Medicine Initiative, as patient partners for the Society to Improve Diagnosis in Medicine, and as subcommittee members for this Working Group.

Melissa Potter

We advise researchers at the University of Chicago, and we have authored two academic textbook chapters on patient engagement and patient registries.

Modern medicine knows a lot about how to treat early Lyme disease, but even so, treatment failure rates remain unacceptably high (10 to 20 percent). Yet, little is known about what works—what is effective—for treating late or persistent Lyme disease.

NIH-funded trials in persistent Lyme disease have been very small (37–129 people). By their nature, they do not observe real-world patients responding to the variety of clinical treatments used to improve patient quality of life.

This is an area in which patient registries excel. At the last Tick-Borne Disease Working Group meeting, Dennis Dixon noted that patient registries are one way to advance the knowledge of Lyme disease. However, neither he nor this group seemed to be aware that a large patient registry for Lyme disease presently exists.

MyLymeData is a patient registry developed by LymeDisease.org that enables patients to pool longitudinal healthcare data. Since its launch in November 2015, over 12,000 patients have enrolled.

It is modeled after many of the rare disease registries and adheres to the patient registry recommendations of the Agency for Healthcare Research and Quality. Like most patient registries, entry criteria are intentionally broad—patients must be U.S. residents who are clinically diagnosed with Lyme disease.

The registry has gathered over three million data points on Lyme disease demographics, tick bites, diagnosis, symptoms, lab tests, co-infections, treatments, and quality of life.

Last year, we published our first peer-reviewed study analyzing data from the registry. We also released our MyLymeData Chart Book, highlighting results from Phase 1 of the study.

We are collaborating on a tissue bio-repository with the National Disease Research Interchange and the Bay Area Lyme Foundation. We also work with academic researchers at UCLA and the University of Washington. The National Science Foundation has funded UCLA researchers to explore big-data analytics using data from MyLymeData.

This has been an essential step in building a collaborative research engine designed to realize the promise of big data in Lyme disease.

Melissa Potter is LymeDisease.org's director of patient engagement and outreach.

Accelerating Pace and Increasing the Depth and Breadth of Lyme Disease Research

By Mira Shapiro

I am here today on behalf of LymeDisease.org. I am also a chronic Lyme disease patient and a biostatistician.

My colleague Melissa Potter just spoke about our organization's history, our MyLymeData patient registry, and our collaborations and how they are driving our efforts to build a Lyme disease research engine.

I would like to share information about some of our Institutional Review Board (IRB)-approved research. We use data from over 12,000 enrolled patients and over three million associated data points to better characterize the Lyme patient population, for whom previously there was very little information.

Mira Shapiro

All of these patients expressly consented to this use of their data. We act as a data steward on behalf of the community to ensure that their data is used solely for the benefit of patients.

As you probably are aware, Lyme disease is a research-disadvantaged disease. There are few clinical trials on patients who remain ill after a short course of treatment. Those trials have been hampered by very small sample sizes that do not allow the type of subgroup analysis essential to tease out differences among patient groups in terms of symptom severity, diagnostic delays, and treatment response.

In the fall of 2018, we published our first peer-reviewed article using data from over 3,900 registry patients to distinguish between subgroups of patients who respond more favorably to antibiotic treatment and those who do not.

Using a widely validated global rating of change scale, we identified a subgroup of 35 percent of patients who were high treatment responders, versus groups of low treatment responders and non-responders.

Why do these patients respond so differently to treatment? Do some of them have co-infections? Were there diagnostic delays? Different treatments or treatment durations? We don't know yet, but examining real-world data from patient registries may provide the path to more individualized care.

Subgroup analysis of large samples allows us to uncover information that otherwise may not be available using small randomized controlled trials.

We have several more research studies in the pipeline. We collaborate with research partners to conduct big-data research studies. We can also assist with clinical trial recruitment, augment clinical trial research findings, and generate hypotheses for further clinical studies.

We view the patient registry as a vital part of a research engine that can accelerate the pace, and increase the depth and breadth of Lyme patient research.

Mira Shapiro, MSc, is a biostatistician/data scientist. Her work with LymeDisease.org's MyLymeData Patient Registry has been presented at the International Lyme and Associated Diseases Conference (ILADS) , in peer-reviewed publications, and at the LymeMind 2019 conference.

Proxy Votes Violate Spirit of Tick-Borne Disease Working Group

By Dorothy Leland

I am vice president of LymeDisease.org.

I have two points regarding yesterday's meeting. The first speaks to process integrity—how this Working Group should operate.

Why in the world did David Walker cast proxy votes for Eugene Shapiro?

The point of the Working Group is for people from diverse scientific viewpoints to listen to each other, discuss the issues, and then decide how to vote. Dr. Shapiro wasn't in the room and didn't take part by phone. Yet, Dr. Walker cast votes on Dr. Shapiro's behalf.

Why is this even allowed? If it doesn't technically violate a rule, it certainly violates the spirit of the Working Group.

It mocks the concept of the healthy exchange of ideas. Here, somebody doesn't have to participate at all … and still has a vote.

When Dr. Shapiro was first named to this group, LymeDisease.org protested vociferously—because of his flagrant financial conflicts of interest. More than 37,000 members of the Lyme community signed our petition to remove him from this panel. It fell on deaf ears.

My second point about yesterday's meeting concerns Ben Beard's defense of the CDC website—and his dismissal of questions about the validity of Lyme disease testing.

Beard stated—and I quote—"The vast majority of Lyme disease patients are served quite well by the guidance we have on our website. The diagnostic test is reliable in terms of it telling you what you expect to hear."

Here's my response: It's true that some people get Lyme disease, get treated, and get well—in short order. But many people don't get well. They stay desperately sick for years, often losing their jobs, their homes, their marriages, their families. Children lose their childhoods, often too impaired to go to school.

The CDC acknowledges that 10 to 20 percent of Lyme patients remain ill after treatment. Over 20 years, that could mean up to three million people with persistent symptoms of Lyme disease—using the CDC's own figures.

And that doesn't count people who remain undiagnosed and untreated. They are the ones most ill served by the CDC's "guidance"—and a lousy lab test.

Beard's comment highlighted another process irregularity with the Working Group: 2018's group had three representatives of the Lyme patient community; this 2020 group has only one—Pat Smith.

Dorothy Leland

Meaningful patient representation requires more than a single voice crying in the wilderness.

When Smith raised questions about patients with persistent Lyme disease, the CDC spokesman dismissed those concerns—and there was nobody else willing to support the patient point of view.

This Working Group was created due to the efforts of patients with persistent Lyme disease—not people who got well quickly.

Those folks don't need a Working Group. I urge you not to forget your core constituency.

Dorothy Kupcha Leland is vice president and communications director for LymeDisease.org.

CDC's Recommendations for Lyme Epitomize Institutional Bias

By Elizabeth Maloney, MD

Good morning, committee members. I'm Dr. Elizabeth Maloney. I spoke with you at the January meeting and appreciate the opportunity to speak with you again.

I want to address statements made regarding the independence and neutrality of the CDC's in-house treatment guidelines made yesterday.

I am concerned about the CDC's in-house treat-

ment guidelines because they epitomize the institutional bias patients, advocates, and providers face in regard to Lyme disease.


Elizabeth Maloney, MD

Despite claims to the contrary, the CDC treatment recommendations are merely a synopsis of the IDSA guidelines. The CDC recommendations cite only four references. One of the four states that its treatment recommendations come from the IDSA, while another review ignores ILADS 2014 treatment guidelines entirely.

The sole author of the first review paper was one of four authors of the second. And that latter group included the lead author of the 2006 IDSA guidelines. This suggests that the CDC did not do its own, independent assessment of the evidence.

It was said that the CDC treatment recommendations work well for most patients with erythema migrans (EM) rashes. I've reviewed the comparative trial evidence and concluded that reported outcomes cannot be taken at face value.

My review identified significant design and execution problems as well as unsupported conclusions. Failing to discuss these obvious shortcomings suggests to me that the CDC treatment recommendations were a foregone conclusion, and that the group simply worked backward to pick a few supporting references.

Perhaps that explains why a 2013 study of 74 EM patients by Aucott and colleagues wasn't cited. That carefully designed study demonstrated that 21 days of doxycycline failed to return 40 percent of study participants to their pre-Lyme baseline at six months post-treatment, including 11 percent who had ongoing symptoms and functional decline and 25 percent who had ongoing symptoms alone. If this represents "works well for most," we've set the outcome bar much too low.

The CDC suggests that U.S. EM patients can be treated with 14 days of cefuroxime or amoxicillin, yet none of the U.S. trials used these agents for fewer than 20 days. It is said that 10 days of doxycycline is sufficient, but of the two trials of that duration, one had a noncompletion rate of 50 percent, and in the other, 36 percent of the patients were retreated.

Given the poor quality of the CDC's process for generating recommendations, I now think it's imperative that the curriculum development team include members who understand the limitations of the current evidence and who include a broader diversity of scientific viewpoints to avoid group think and bias. Otherwise, clinicians will get the same old, same old, and patients who might be helped won't be.

Dr. Elizabeth Maloney is president of Partnership for Tick-borne Diseases Education, a 501(c) that provides educational resources to medical professionals and the public. She lives in a high-Lyme area of Minnesota.

NIH's COVID-19 guidelines offer useful advice for Lyme disease, too

By Phyllis Mervine

Phyllis Mervine prepared the following remarks as public comment to the federal Tick-Borne Disease Working Group. Due to phone connectivity problems, however, she was unable to deliver them herself. Therefore, at April 27's online meeting, they were read to the panel by LymeDisease.org's Dorothy Leland.

It's been hard in recent weeks to even think about Lyme disease. The coronavirus has infected close to a million Americans and killed over 50,000 so far.

But this pandemic will not stop the nymphal tick season. It's already underway here in northern California and many other parts of the country.

And there's every reason to believe that at least 300,000 new cases of Lyme disease will occur in the US this year—per the CDC's estimate.

Last week, the NIH announced its COVID-19 treatment guidelines.

This was a surprise to us—because at one of these Working Group meetings, Dennis Dixon, who represents the NIH on this panel, told us that his agency does not DO guidelines.

That's apparently changed. Now, since NIH DOES do guidelines, we could use some for Lyme disease.

NIH guidelines for Lyme disease could help us bridge the divide between treatment recommendations from ILADS and the IDSA.

Furthermore, here are three significant points in the NIH's COVID-19 guidelines:

They point out that there are "insufficient clinical

data" to recommend either for or against using certain drugs for the treatment of this disease.

They say, "at present, no drug has been proven to be safe and effective."

Therefore, they also state—quote—"Treatment decisions ultimately reside with the patient and their health care provider."

All three of those statements about COVID-19 absolutely should be applied to Lyme disease—but currently are not.

NIH Guidelines could also remind the medical boards—those that hover over Lyme doctors' every move, scrutinize their practices and threaten their licenses—that just as for COVID-19, "treatment recommendations in these Guidelines should not be considered mandates."

Like COVID-19 patients, people with Lyme need treatments now. Clinical trials are expensive and take too long, and our last one was 20 years ago. Also, Lyme disease research receives less federal funding than leprosy, which has 200 cases per year.

With limited treatment options, patients with persistent Lyme disease, like people with COVID-19, may be willing to accept more risk—depending upon how sick they are.

Ultimately the choice of what to do for an individual patient should be decided by the patient and their treating physician.

That's what the NIH's COVID-19 Guidelines say. Shouldn't we offer the same for people with Lyme disease?

TBD Working Group Squares Off Over Issue of Persistent Lyme Disease

TBDWG votes on including guidelines on persistent Lyme disease in CDC treatment guidelines.

By Dorothy Kupcha Leland

On April 27, 2020, the rubber hit the road for the Tick-Borne Disease Working Group (TBDWG). What seemed like a routine vote quite unexpectedly turned out to be highly significant—because of what it showed us about many members of the Working Group.

This clarifying moment materialized around the issue of persistent Lyme disease, always a controversial issue in the medical world.

But first, some background.

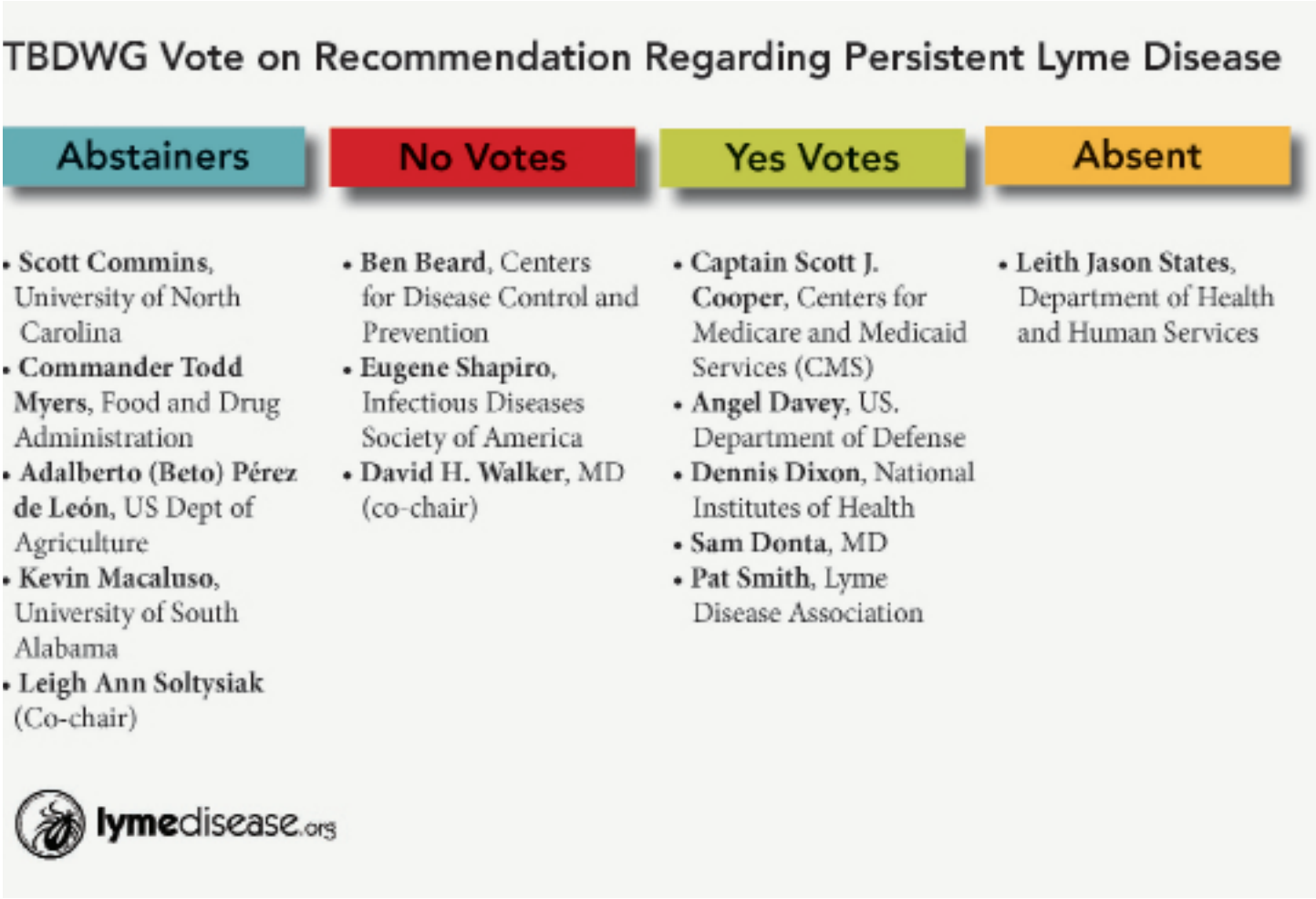
The TBDWG is a federal panel under the auspices of the US Department of Health and Human Services.

Over the past year, it has held meetings, received and voted on recommendations from its various subcommittees, and started the process of compiling a report to Congress that is due in November 2020.

In March, the panel dealt with most subcommittee recommendations during two days of in-person meetings in Philadelphia.

A few remaining issues filled the agenda of the April 27 online meeting. These included recommendations from the Federal Inventory Subcommittee.

(Sounds eye-glazing, I know. Who knew we were in for such a show of fireworks?)



The TBDWG had previously asked pertinent federal agencies to provide an inventory of any programs that relate to tick-borne diseases. The goal was to figure out what's already happening and what still needs to happen.

Based on this research, this subcommittee offered several recommendations that sailed through without a problem. Then things hit a snag with the following proposal:

Recommend that IF the CDC posts any Lyme treatment guidelines, that they include guidelines on persistent Lyme disease.

It is important to know that the CDC website currently only provides information about early Lyme disease. It offers nothing for people with persistent Lyme, those still sick and suffering long after the acute phase has passed. Non-recognition of persistent infection is a central concern of the Lyme disease community. It is why we fought to have the TBDWG formed in the first place, and why we've continued to fight for adequate representation of chronic Lyme patients. (The first incarnation of the Working Group, which prepared the 2018 Report to Congress, had three representatives of the Lyme patient community. This panel has only one, the Lyme Disease Association's Pat Smith.)

It's also important to know that for many years, the CDC openly endorsed the IDSA's Lyme treatment guidelines—which do not acknowledge persistent Lyme. Currently, while the CDC does not list any Lyme guidelines on its website, the Lyme information it posts is consistent with the IDSA guidelines. Thus, to recommend that the CDC include guidelines about persistent Lyme was a big deal—one sure to draw a strong reaction.

As I listened to the online meeting via my computer, I couldn't always tell who was speaking—or even, sometimes, what they said. Here's what happened next, as near as I could tell:

The recommendation regarding persistent Lyme disease was moved and seconded. Then, for unstated

reasons, five panel members abstained from voting. The vote was announced as five abstaining, five yes votes and three no votes.

Remarks made after the vote made it clear that the abstainers felt they had defeated the measure, because "yes" votes didn't comprise a majority of panel members. But, OOPS, guess what? Abstentions don't count one way or the other. So, the recommendation passed, 5-3.

As that reality sank in, pandemonium broke out. Panelist Scott Commins stoutly announced that he wanted to change his abstaining vote to "no." He was told that Robert's Rules of Order doesn't allow you to change your vote after the fact.

Things then got very bizarre very fast, with many people talking at once. Some wanted to vote on the original question again. Others didn't. Some wanted to re-open discussion, others didn't. It was very confusing to the listener at home.

However, the five abstainers sure gave the impression they had been trying to game the system—to gain a "no" vote without having to publicly own up to it. When that ploy didn't work, they scrambled to recoup their original objective— to deep-six the proposal regarding persistent Lyme disease.

That's what this whole kabuki dance has been about since the inception of this 2019-2020 panel of the Working Group. There's been a concerted effort to minimize Lyme disease as much as possible. It started by choosing only one representative of the Lyme community to serve on the panel. Then, at its first meeting, Co-chair Walker announced that the previous panel had spent enough time on Lyme disease, and he didn't want the group to devote any more time on it. And it's why, even though Lyme disease makes up 80% of the cases of tick-borne disease in this country, it will get only 25% of the TBDWG's upcoming report. (Two chapters out of eight.)

However, despite the strenuous complaints of the "anti-persistent Lyme camp," ultimately, there was no re-discussion nor re-vote on this original recommendation:

> **Recommend that IF the CDC posts any Lyme treatment guidelines, that they include guidelines on persistent Lyme disease.**

For now, the motion stands. But the flash of true colors displayed in this episode clarifies who is and who is not working in our best interests. This panel will disband after its November 2020 Report to Congress. But there will be a third panel of the Working Group, serving from 2021-2022. Meaningful representation of the Lyme patient community is crucially important. Without it, we'll be stymied in our efforts to bring about the change we need.