

October 8, 2010

Lyme and Tick-Borne Diseases Committee
Institute of Medicine of The National Academies
c/o Dr. Christine M. Coussens, Study Director
500 5th Street, N.W.
Washington, DC 20001-2721

LymeDisease@nas.edu

Dear IOM Lyme and Tick-Borne Disease Committee Members:

We hereby submit this letter as testimony for the public record and official IOM Lyme Disease Workshop Report to be presented to Congress.

The Gaps in the Science involving human cases of Lyme and tick-borne disease in the Southeast are tremendous. Thousands of ignored patients report that they have contracted LD and/or Lyme-like illness in the Southeast, where Lyme is reported to be “rare”.

In June, advocates from Virginia, Tennessee, Kentucky, South Carolina, Georgia, and Florida prepared statements and participated on the IOM’s Lyme Disease Workshop Teleconference call. (Copies of some of the statements are attached, and should be recorded as a part of this letter.) We each described the many incidents of Lyme and tick-borne diseases we hear about occurring in southeastern citizens. We explained that these cases are often unrecognized, ignored, dismissed, misdiagnosed, undercounted, unreported, and are even often untreated before permanent damage occurs.

During the call with committee members, we hoped to show that the gaps in science in so-called, “non-endemic” areas are *extremely* wide and require immediate funding for scientific investigation. Thousands of patients in these areas report that they are in desperate need of help. Most must travel far distances to obtain treatment. Many lose the ability to work, play, attend school, and lead normal lives. Some have lost their homes and their families. Our citizens deserve to be protected and our medical providers educated.

We were disturbed to later learn that not a single Lyme advocate from a state considered, “non endemic” was invited to participate in the IOM workshop to describe the problems we outlined in our call. We also understand that our comments during the teleconference were not recorded so that the information we detailed will not be included in the congressional report. We, therefore, again stress that this letter and the written statements following be added to the IOM State of the Science Workshop Report, in its entirety.

We appreciate that the IOM invited Georgia Southern University’s Dr. Jim Oliver to present during the IOM Lyme Disease Workshop. His important work has documented hundreds of

strains of *Borrelia burgdorferi* from the Southeast (reportedly, even more than found in the Northeast). Dr. Oliver's recent discovery of two new *Borrelia burgdorferi* species warrants full and immediate investigation to determine how these may impact public health.

In a Scottish study, when regional Lyme disease (*B. burgdorferi*) isolates were added to a Western Blot assay, it increased the sensitivity of the test. How many people test negative across our region, but are denied crucial treatment because a test is not detecting their strain or species of *Borrelia* infection?

There may be several slightly different *Borellia burgdorferi* strains and/or species, and even other tick-borne disease pathogens, affecting humans in the Southeast that may be undetectable using current testing methods. Some strains or species may only cause mild illness, while others could cause disease far more severe than typically-described Lyme disease. But, make no mistake: human tick-borne disease, often causing severe, debilitating, and permanent damage, *is occurring in humans across the Southeast*.

Public health officials' stance regarding Lyme disease in the Southeast appears to be that they admit the bacterium is in ticks and small animals, but that it is not infecting humans. They often declare that human Lyme disease is either nonexistent or very rare in the Southeast and irresponsibly instruct medical providers to dismiss patients with positive serology as "**false positives**" (even many with history of tick bite, rash (EM), symptoms, and positive test results). While they casually declare that there is some sort of "mild Lyme-like illness" possibly being transmitted by Lone star ticks, long-term studies following large groups of these patients have not been done. Many southern patients report *very severe* symptoms, including heart, neurological, and arthritic involvement, which greatly limit and even halt their daily routines. Patients report suffering permanent damage and ongoing symptoms due to their cases being dismissed by this irresponsible, inadequately proven stance.

Southeastern county-by-county tick flagging studies have never been performed. Studies of tick vectors, hosts, transmission, and reservoirs haven't even scratched the scientific surface. Public health officials have admitted that Lyme disease risk to humans hasn't been assessed here. There is dire need to resolve these issues.

The IOM State of the Science workshop is supposed to determine the gaps in science. If the tremendous flaws in reporting practices are not exposed and addressed, these gaps can hardly be determined. Adequate funding is not awarded to independent scientists to investigate human tick-borne disease cases in areas like ours. Public health officials indicate that Lyme disease research money is allocated according to reported case numbers, but we found that state-by-state Lyme disease reporting practices differ to an extreme. Problematic reporting practices, the myth that Lyme disease is rare in our region, and the notion that patients with positive serology are only *false positives*, prevent the majority of southeastern Lyme cases (even those meeting strict CDC reporting criteria) from being reflected in state and CDC statistics. Statistics are rendered useless when reporting practices differ so greatly.

These problems are curiously not disclosed and referred to by public health officials, who should explain to medical providers, citizens, and the media that Lyme case numbers are

reported differently, are inaccurate, and cannot be compared from one region to the next. Instead, it appears the flawed statistics may be used to justify the failure to fund independent studies necessary to investigate these human cases. If a state must have *cases* to get *funding*, and *funding* to investigate *cases*, how is a disease ever supposed to emerge?

Borrelia burgdorferi has been documented in southeastern ticks, animals, and humans for over 20 years. In 1989, Georgia ranked 4th in the nation with the highest number of CDC-reported Lyme disease cases, and the CDC documented native cases from 27 Georgia counties, as well as counties in Alabama and Florida. In 1993, a scientific conference outlining much of the regional scientific data was held in North Carolina. In the early 1990's, a Georgia State public health official declared that they believed that 10,000 cases of Lyme disease in Georgia are being misdiagnosed and undiagnosed *annually*. Florida has documented hundreds of human cases. Logically, the old adage, "*Where there is smoke...*" comes to mind. To now ignore this evidence (and the CDC's own findings) and dismiss cases as "*false positives*" (which are actually quite rare) without investigation of each, is irrational, irresponsible, and poses a direct threat to public health.

Funding for independent investigations of southeastern human Lyme and tick-borne disease patients is needed immediately. Twenty years is an inexcusable amount of time to wait for public health officials to do something about such a serious health threat.

We call upon the IOM to include this report outlining these significant problems in their IOM Lyme Workshop Report to Congress. In turn, we call upon our political representatives to investigate the reasons many public health officials do not appear to take our cases seriously, leaving thousands of patients very ill, medical providers uninformed and uneducated about tick-borne diseases, and healthy citizens unknowingly at risk.

Sincerely,

Liz Schmitz
President/Cofounder
Georgia Lyme Disease Association

Marilyn Sherlock
Treasurer /Cofounder
Georgia Lyme Disease Association

Windy Blair
Volunteer Advocate
Georgia Lyme Disease Association

Norman and Jackie Morgan, RN
Volunteer Advocates
Georgia Lyme Disease Association

Kim Spach, RN
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Dave Tierney
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Carolina Lyme

Sara Hesley
President and Founder
Kentucky Lyme Disease Awareness

Pamela Waggoner
Kentucky Lyme Disease Association

Lisa Higgins
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Southeastern Tennessee Lyme Support

Norma Engelhardt
Middle Tennessee Lyme Network

Karen Angotti
Co-moderator Tennessee Lyme
Author of *Lyme Disease: A Mother's Perspective*

Angela Allen
Greenville Lyme Advocacy and Support (S.C.)

Ashley Powell
Alabama Lyme

Melissa Slaughter
Founder
Birmingham Lyme Support

Lori Hoerl
Founder/Director
Florida Lyme Advocacy

cc: President Barack Obama

Vice President Joe Biden

Congressman Chris Smith

Congressman Frank R. Wolf

U.S. Federal and State Political Representatives of the Southeast

Dr. Francis S. Collins, Director, National Institutes of Health

Dr. Anthony Fauci, National Institute of Allergy and Infectious Diseases

Dr. Thomas Frieden, CDC

Southeastern State Medical Board Directors

State Health Department Directors - KY, TN, NC, SC, GA, AL, FL

Print and Broadcast News Agencies

***Institute of Medicine Lyme Disease Teleconference
Listening session for Georgia, South Carolina, North Carolina
June 2, 2010 comments
12:00 p.m. – 1:30 p.m.***

Speakers (in order):

- 1. Windy Blair, Georgia Lyme Disease Association**
- 2. Jackie Morgan, RN, Georgia Lyme Disease Association**
- 3. XXXXXXXX, Georgia patient**
- 4. XXXXXXXX, Virginia Beach, VA**
- 5. Sara Hesley, Kentucky Lyme Disease Awareness**
- 6. Liz Schmitz, Georgia Lyme Disease Association**
- 7. Angela Allen, South Carolina, Greenville Lyme Advocacy and Support**
- 8. Lisa Higgins, Southeastern Tennessee Lyme Support**

Windy Blair, MHE, OT/L, Georgia Lyme Disease Association

Lone Star Ticks and STARI

I'm Windy Blair from Georgia.

Lone stars are very aggressive, and are the most commonly found ticks feeding on humans in the South. People here are bitten by them constantly. We strongly suspect that the Lone star tick is a vector of Lyme disease in humans.

Lyme bacteria have been documented in lone star ticks for years. In some areas of the south, scientists have found BB in 17 to 24% of these ticks. But when public health officials assess risk to humans, they seem to only consider the deer tick.

We hear from far too many patients who develop EM's and symptoms, and test positive for Lyme, following Lone star tick bites. Many of these cases are dismissed as "false positives", but we wonder how a test can be so *good* up north, but so *bad* down south? False positives are actually pretty rare. And "*positive predictive value*" cannot be used to dismiss our positives, when we don't have a sensitive test, and can't determine true prevalence.

Research proved Lone star ticks can't transmit Lyme to some *mice*. However, that doesn't mean they can't transmit to *humans*. Some *lizards* can't be infected, either, but eight lizard species here in the South can actually *harbor* Lyme Borrelia. We can't conclude anything yet.

We've heard that Lone star tick saliva kills Borrelia, if true, why did we waste tax dollars looking for *Borrelia* lonestari? And why have *Borrelia* been seen under the microscope in rashes following lone star tick bites?

Lone star ticks may be transmitting other pathogens, but the hallmark of STARI is that patients ***DON'T*** test positive for Lyme. We hear from patients who ***DO*** test positive. A medical College of GA study found that 30% of southern patients with EM's ***did*** have Lyme.

It's reported that STARI is a mild illness. What we are witnessing in the South, is NOT mild. *Where* are the long term human studies documenting this assumption?

The introduction of STARI seemed to stifle any investigation into human Lyme cases in the South. CDC reporting guidelines were never implemented here, partially due to cases being dismissed as STARI. There is no test for STARI, and not even a known agent. But our Lyme cases are still chalked up to STARI.

Recently some doctors and public health officials stated that “STARI probably doesn’t even require treatment”. Lyme disease and STARI rashes are indistinguishable. Not treating early can leave hundreds of Lyme patients permanently damaged with ongoing illness. Until we know more, treating EMs is the only responsible thing to advise.

Independent large-scale human studies in the Southeast should be *immediately* funded by the NIH and CDC. And these should be done by *new* scientists – seeing the same researchers appears to be a little biased.

The scientific evidence is still emerging. It’s the responsibility of every medical professional and public health official *not* to make assumptions, but to consider *all* the evidence, including that in the South. Our citizens are suffering. We need answers *NOW*. *Thank you.*

Jackie Morgan, RN , Georgia Lyme Disease Association

My name is Jackie Morgan. I’m a registered Nurse and a volunteer for the Georgia Lyme Association.

As a medical professional, I want to address my concerns about how the Lyme controversy appears to be affecting the general perception of us in the medical field.

In the South, Lyme disease doesn’t appear to be a differential diagnosis despite the large body of published evidence that should make us look for it in humans. Scientists like Jim Oliver, Lance Durden, Kerry Clark and others have documented the presence of the Lyme bacteria in ticks and nature here for years.

Highly educated, credible people are coming forth with Lyme disease here. These logical people share their disbelief about the denial and lack of response they feel from the medical community. They’re often astonished that many clinicians are unaware of the regional scientific evidence. Patients don’t understand why their human cases are so quickly dismissed.

Patients report there are many assumptions they hear from health care providers, like, “ We don’t have the white footed mouse here” –we do, *and* the cotton mouse, which also harbors the bacteria. “We don’t have that kind of tick here” - Joe Piesman of the CDC documented the deer tick across the Southeast years ago.

Rashes following tick bites are often misdiagnosed as “Fungus” or “ringworm” and are improperly treated. Patients are sometimes told their positive Lyme tests are false, many with compatible history.

Modern day patients are far more educated due to the accessibility of worldwide, peer-reviewed, published research articles online. At the touch of a button, they can read all of the scientific data.

When patients read the conflicting evidence for themselves, they wonder why *we* aren’t familiar with much of it, and why it sometimes directly contradicts what they’ve been told in the doctor’s office. This doesn’t help promote an image of knowledgeable and informed professionals.

When very sick patients seek help and are dismissed, scoffed at, or looked at as if they are crazy, it shakes their faith in the medical community at large.

I was recently frustrated reading comments across the internet by Lyme patients, their family members, and friends who feel they’ve been ignored by the medical community. It’s easy to see that they’re very angry. Some even report they feel they’ve been lied to by the medical community. At the very least, I fear it looks like we’re not keeping up with the science.

I worry about the erosion of the doctor-patient relationship and the reputation of the medical community as a whole. I find it so sad to hear Lyme patients say, “whatever you do, don’t go to an Infectious Disease doctor.”

Citizens are turning to alternative health and away from allopathic medicine in this country. I think we’re missing the mark when we don’t take these issues seriously, don’t acknowledge *all* of the science, and don’t open our minds to the possibilities. Lyme is here and we need to study humans in the South.

Lyme disease has been found across the globe and in many cases of chronic illness. Imagine how far medicine might advance, if we allow ourselves to pursue the “*what if’s?*”

Thank you.

Sara Hesley, Kentucky Lyme Disease Awareness

The Impact of Flawed Reporting Practices

I'm Sara Hesley, Lyme advocate in Kentucky.

When looking at statistics, it's logical to assume that Lyme disease is not in the SE. We were very confused about the few case numbers reflected in southeastern states. We hear from *so* many patients across the region that *have* contracted Lyme here.

The truth is: we can't compare Lyme case numbers across the country. Cases are not counted and reported using the same methodology. Many states claim they adhere to CDC reporting guidelines, but don't and never have.

Up North, where CDC guidelines are used, *rashes* are counted as cases and have been for years in counties, once they are declared "endemic" by having two or more positive LD cases on record. Here across the South, we have *never* counted rashes as cases, even in counties where we have clearly documented two cases.

In Georgia, South Carolina, Alabama, Tennessee, and Kentucky, numerous counties have two or more cases on record that meet CDC reporting criteria. Instead of declaring *counties* endemic as they do up north, many declared their entire states "*non endemic*".

In a single southeastern *neighborhood* alone last spring, there were 9 people with tick bites, rashes, and symptoms in a county that already had two confirmed cases. *Not one* was counted. If we counted rashes, *too*, our numbers would also skyrocket.

Some claim these old cases don't count because they may have been STARI. But the *hallmark* of STARI is that patients *DON'T* test positive for *Lyme*. As of 1994, all these cases on record used the EXACT SAME tests employed to track cases today, both the ELISA and WB. Yet our cases across the south continue to be dismissed as STARI, without any further investigation, even though Bb has clearly been found in nature and the CDC admits there are human cases here.

We can't dismiss cases as STARI, we don't even know what STARI is. We're hearing from patients who *do* test positive for *Lyme disease* after Lone star tick bites. In a medical college of GA study, 30 % of local participants with EMs did, indeed, show evidence of *Borrelia burgdorferi* infection. We need to investigate *each* case and report these.

The flawed statistics further perpetuate the problem, causing doctors to dismiss positive cases as false, so they never report them. Additionally, doctors see the low case numbers, and don't recognize and treat Lyme early, before permanent damage occurs. Many may never be diagnosed and treated.

CDC officials state that only a very small percentage of cases fall outside the Northern United states. But Lyme has been found in humans all over South America. Does it make any sense that Lyme appears in a tiny pocket in the northeastern United States, and then JUMPS across the continent and appears in South America?

PHO need to point out that there is no way to compare statistics from state to state. We can't say Lyme is rare, and we can't determine prevalence until we get a sensitive test.

These flawed statistics cannot be used in positive predictive value formulas, and shouldn't be given to the media, or politicians. Doctors should *never* dismiss Lyme cases based on state statistics. When reporting practices differ so greatly, statistics are meaningless. This is like comparing apples to zebras.

(Sara went on to discuss her case, and how, although she had a classic EM after tick bite, doctors told her she didn't require treatment. She subsequently has chronic symptoms.)

Liz Schmitz, Georgia Lyme Disease Association:

Lyme Disease in Georgia and the Southeast

I'm Liz Schmitz from the Georgia Lyme Disease Association. Thank you for your kind sentiments at the beginning of this call, Dr. King. I absolutely appreciate them and also the opportunity to speak.

In 1989, *Georgia* was 4th highest in the nation in the number of *CDC* reported Lyme cases, with 715 on record. *114 GA counties reported cases*. That year, our legislators funded free blood tests at our health department and found these. The following year, before funding ran out, they documented 161 cases.

Since then, southern scientists have identified *Borrelia burgdorferi* in *thousands* of tick and animal specimens from across our region, including mammals, birds, and wild reptiles. *One* company's lab test confirmed Lyme disease in 600 GA dogs and 600 Florida dogs.

In 1994, Lyme disease made Georgia's *Top 10 Communicable Diseases* list. In 1999, a human study in Georgia found that 30% of EM patients *did* have Lyme disease. Surrounding states have consistently reported cases.

Some now say those 715 Georgia cases were "*False Positives*". But, *where* are the follow up studies to support that assumption?

In 1994, a GA state epidemiologist spoke at our support meeting and was interviewed on TV. He stated -they believed there were *thousands* of Lyme cases being misdiagnosed or undiagnosed across Georgia each year.

We hear from *hundreds* of southeastern patients who have compatible history and positive tests. Many medical professionals don't recognize and treat Lyme disease, and believe it's not here. Positive test results are often not reported. Even public health officials tend to dismiss our positive cases, although Lyme experts have documented that false positives are rare.

At a taped conference in 2007, a CDC official disturbingly advises medical attendees, that if a tick bite patient comes forward in the Southeast, with all symptoms and even positive serology,

there's only a 5% probability it's Lyme. He basically tells them to assume these are false positives.

This is troubling from someone who is employed by our government to protect public health. Why wouldn't medical people be encouraged to report these cases and have them investigated?

We must stop reporting that Bb is rare in the SE when independent, large-scale, human studies haven't been done. Flawed reporting practices, insensitive tests that aren't region specific, dismissed cases, and lack of county-by-county tick flagging studies, all combine to prevent us from assessing true prevalence. To assume all these patients only have a "mild" illness called STARI, is *dangerous*.

I reported 75 local cases directly to CDC and GA state officials last year. I was told we don't have funding to study these. *And* I was told, with so few cases on the books, we aren't likely to *get* funding.

So...we have to have *funding* to find *cases*, but we have to have *cases* to get *funding*?

With reasoning so circular, how is an infection ever supposed to emerge?

We need to investigate of the possibility of other tick vectors, Borrelia reservoirs, various hosts and transmission here. Why hasn't this been done by now?

Untreated Lyme is *serious*. Lack of recognition turns a potentially curable illness into one that can cause permanent damage. Public health officials and medical providers have a responsibility to take each report of Lyme disease *seriously* and to investigate these fully.

Thank you.

Angela Allen, South Carolina

Doctors need to be Educated about Basic Lyme facts

My name is Angela Allen and I'm an advocate from South Carolina.

After nearly 30 years of published research, the number of medical providers uneducated about Lyme disease is **alarming**. We frequently hear from Southeasterners misdiagnosed because many medical professionals do not understand **the most basic Lyme disease facts**. *Everyone* agrees upon the importance of diagnosing and treating this infection **early**, so this should be addressed *immediately*.

Many patients are misdiagnosed at the time they have a rash following a tick bite, because medical providers don't know better than to rely upon negative test results. When the tests come back negative, the doctor declares that they don't have Lyme and send patients away, untreated.

Suffering patients wander from doctor to doctor, while each new medical provider says, "well, you *had* a Lyme test and ruled that out". Patients are often not retested until years later, only to learn that they **do have** Lyme. By this time the infection, that *could* have been effectively treated at the onset, has left permanent damage and ongoing problems. How many people are **never** retested and treated?

The medical literature has long indicated that testing is problematic in the early stages. The majority of patients **will not** test positive for many weeks because antibody levels are not yet high enough. Why do our **doctors not** know this by now?

We even hear from patients who test *fully* "CDC positive", with compatible history, who are being told they cannot possibly have Lyme, and are denied treatment.

We live in a mobile society, people travel and can contract Lyme easily. Even if we only have 25 cases reported in the state this year, a doctor should **never** assume that the patient standing in front of him isn't *the 26th case*.

We hear from an alarming number of citizens who tell us they remove ticks improperly. Doctors should know this **could** play a significant role in transmission, even if the tick hasn't been attached for 24 hours.

Factors that affect test results that many of our doctors don't understand include: use of antibiotics, timing, fluctuating antibodies, and various local Bb strains and species that are not detectible.

Other facts our medical providers need to know include:

- Lyme disease and STARI are indistinguishable at onset so EMs **must** be treated
- Retreatment may be necessary

- In winter months, adult deer ticks do feed on humans in the South.
- Lyme symptoms can appear months to years after a tick bite
- CDC reporting criteria should *not* be used to **diagnose** Lyme
- There is currently **no test** that can rule out Lyme

Most patients will not consult an infectious disease doctor about a tick bite. Therefore, *every single doctor across this country* should know how to recognize, diagnose, and treat Lyme disease EARLY, if we are to protect public health.

Lisa Higgins, Tennessee

Testing needs/CDC's mixed diagnostic message to medical providers

I'm Lisa Higgins, advocate from Tennessee.

We constantly hear from sick people coming forward after tick bites across the South, who test positive for Lyme disease and respond to antibiotic treatment. Some don't have "**CDC reportable**" lab results, but show various bands specific to *Borrelia burgdorferi*, on their Western Blots. Many also have compatible history with tick bites, EMs, and symptoms.

This situation has been ignored for far too long. There is no way to rule out Lyme disease in these patients. They may have traditional Lyme or a strain of *Borrelia burgdorferi* that simply can't be detected with a Western blot that uses a Northern isolate.

Scientists have documented more strains of the Lyme bacteria here in the South, than there are in the North. While some of these strains may not be pathogenic, or could be causing only mild illness, some could be causing symptoms **far** more severe than in cases seen up North. We see

patients debilitated by Lyme all the time, yet no independent human studies have been funded here by the CDC or NIH.

A recent Scottish study proved that adding local *Borrelia* strains in a single mixed antigen significantly improved western blot sensitivity. Another study proved in milder climates, there are more diversified strains. We *desperately* need a regional Western Blot using southern strains and species, so that patients won't go untreated.

We're seeing a disturbing problem on lab reports. Despite the warning on the CDC website, *not* to use reporting criteria to diagnose Lyme, written directives now appear on individual patient lab results that are sent *directly to* our doctors, instructing them to adhere to the very strict CDC *surveillance* criteria to diagnose Lyme. The wording of these interpretations actually indicates that all patients must have CDC reportable test results to be diagnosed. This is dangerous and lets thousands of patients fall thru the cracks. Without early treatment, these patients can become disabled and chronically ill, leaving them personally devastated, as well as a costly burden to our nation.

Dr. David Volkman, Lyme researcher and former Senior Investigator at the NIH, recently wrote:

“In order to reliably track the geographically expanding incidence of Lyme disease, the CDC tried to derive a case definition that would include only definitive cases. Dr. Steere and I were members of the “Committee to Develop a Surveillance Case Definition for Lyme disease”. The CDC explicitly cautioned against using this restrictive case definition for clinical diagnosis and reiterated this proscription with every re-issuing of its “Surveillance Definition.” It has been a source of frustration and confusion that some in the medical community wrongly insist that a Lyme patient must satisfy CDC criteria.”

Ticks bites occur daily and year round in the south. We need to study tick vectors, hosts, various strains and species, and *humans*, immediately.