

**House Committee on Foreign Affairs,
Subcommittee on Africa, Global Health, & Human Rights
July 17, 2012**

**Patricia V. Smith, President, Lyme Disease Association, Inc. (LDA)
www.LymeDiseaseAssociation.org**



Overview of the Patients and Physicians in the US & Abroad in Managing Lyme Disease: Why Patients Worldwide Can't get Treated

HISTORY: From its murky beginnings 37 years ago to the present day, Lyme disease has presented researchers, clinicians and patients with innumerable challenges medically and politically. Lyme was first thought to be caused by a virus by someone who was later dubbed the "father of Lyme disease," rheumatologist Dr. Allen Steere, and some people thought it was something that did not require treatment. After continued research, he dubbed the condition Lyme arthritis, after the town in Connecticut where the investigation was triggered by a mother, Polly Murray, whose children were diagnosed with rheumatoid arthritis.

In 1982, noted National Institutes of Health (NIH) researcher Dr. Willy Burgdorfer published his studies of isolating the bacterium which causes Lyme disease, *Borrelia burgdorferi* (*Bb*), which now bears his name. Much later, the disease was shown to cause cardiac and neurologic symptoms which required longer term treatment.

By the late 80s, some of the original researchers were postulating that Lyme disease was a persistent infection with considerable degree of complexity, producing varied multi-systemic symptoms which were not always eradicated by a short course of antibiotics.

But as research continued and funding dollars mounted up, researchers began to take sides, and the disease that was thought might be an arthritic disease, then also became a neurologic disease. At first they thought it required short-term antibiotic treatment, then longer-treatment for what they were now considering might be a chronic bacterial infection. In a still unexplained twist, researchers who had been concluding that the disease was a chronic infection seemed suddenly to do an about face in the very late 80s. Their description of Lyme became more narrow, fitting mostly people in the Northeast and portions of the upper Midwest, and patients who had been diagnosed with Lyme were finding they could no longer get treated, their symptoms did not fit a narrow enough criteria. Meanwhile, in spite of that narrowing view, cases in the US began to rise. In Europe, other strains of the bacteria were causing a rise in cases. The controversy which developed has followed the disease wherever it has spread, to now approximately 65 countries.

LYME PARADIGMS: In Lyme disease, there are two distinct disease paradigms, each providing science to support its claims. One paradigm (IDSA) views the disease as "hard to catch and easy to cure" and denies the existence of chronic Lyme disease—persistent infection with *Borrelia burgdorferi*, the spirochete that causes the disease. Under this paradigm, the state of the science for patients with chronic Lyme disease is closed. Any treatment is considered too risky because practitioners are unable to determine the cause or extent of patient symptoms, or they view the subjective symptoms as insignificant and write off the patients' complaints as psychiatric in nature. This leaves seriously ill patients without any viable therapeutic avenues. It also shuts the door on future research necessary to get patients to a state of wellness.¹ Much of mainstream medicine, especially many rheumatologists and the Infectious Diseases Society of America (IDSA) have been taught that viewpoint, although a growing number of these doctors are beginning to recognize that patients continue to be sick or relapse after short courses of treatment for Lyme disease.

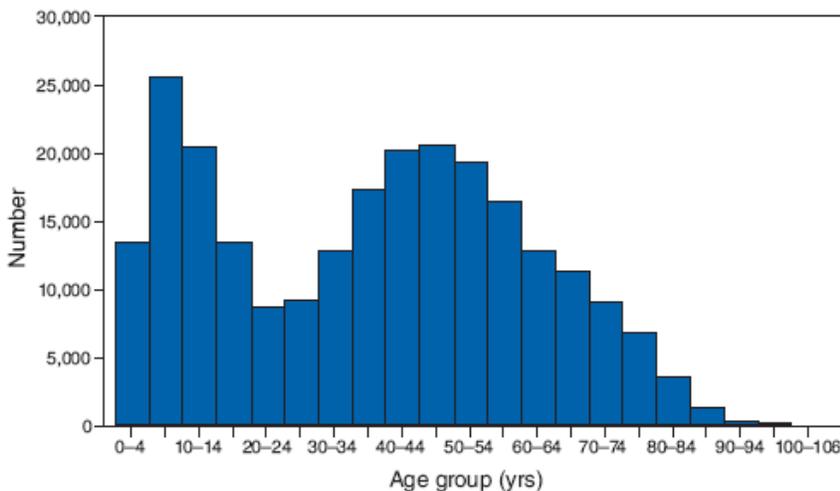
The alternative paradigm (ILADS) says that the science is too unsettled to be definitive, and there can be one or more causes of persistent symptoms after initial treatment in an individual who has been infected with the agent of Lyme disease. These causes include the possibility of persistent infection, or a post-infectious process, or a combination of both, with the Lyme bacterium itself driving the autoimmune process. This paradigm allows doctors the ability to exercise their clinical judgment and

provide therapies that are helping their patients.² This disease paradigm is held by some researchers, the International Lyme & Associated Diseases Society, (ILADS; doctors throughout the world who treat patients with chronic Lyme disease) and most Lyme-related organizations, including the national non-profit Lyme Disease Association, Inc. (LDA), and patients.

US CASE NUMBERS: Lyme disease statistics do not support the “hard to catch and easy to cure” version of Lyme disease. The Centers for Disease Control & Prevention (CDC) numbers themselves are underreported by a factor of ten.³ In 2009, CDC’s Morbidity and Mortality Weekly Report (MMWR) showed Lyme to be the 7th highest reportable disease per 100,000 of population at 12.71, higher than HIV at 12.13. Only sexually transmitted diseases, salmonella, strep, fungal disease, and the flu had higher incident rates.⁴ Children are at the highest risk of acquiring Lyme disease according to CDC (**CDC-Fig.1**) and case numbers continue to rise, with CDC adding a “probable case” category (**CDC Fig. 2**) to count those who do not fall into the limited “confirmed” case definition (1995-2009).⁵

Centers for Disease Control & Prevention, CDC-Fig. 1

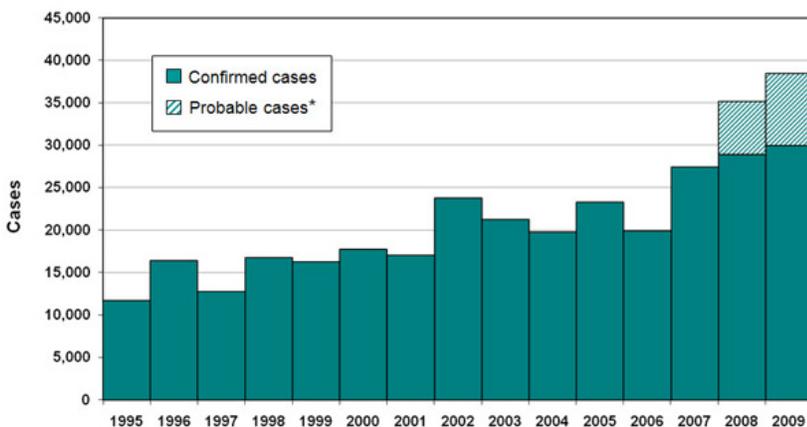
FIGURE 3. Number* of reported Lyme disease cases, by age group — United States, 1992–2006



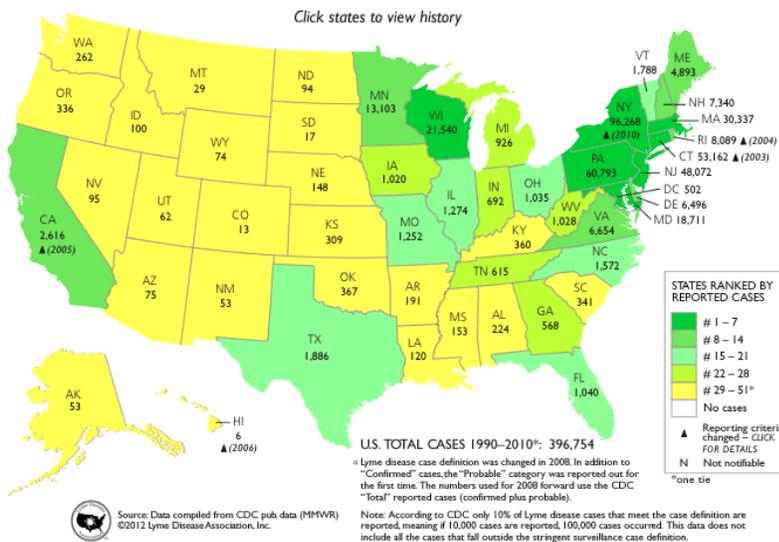
* N = 241,931.

Centers for Disease Control & Prevention CDC-Figure 2

Reported Lyme Cases 1995-2009



TOTAL LYME CASES REPORTED BY CDC 1990–2010*



Lyme Disease Association LDA-Fig. 1

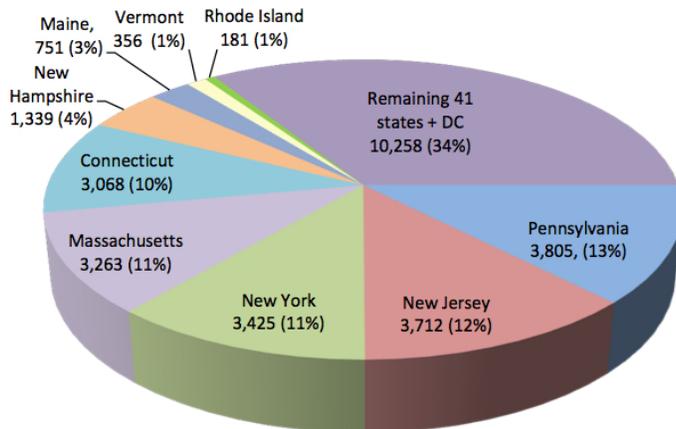
Lyme disease is often considered a problem only in the Northeast, and this perception frequently leads to patients' inability to be diagnosed and treated, as doctors and health officials sometimes deny that Lyme is present in their area, because little or no studies have been done in those areas.

The LDA has compiled case numbers on a US map (LDA-Fig. 1) using CDC reported cases from 1990 through 2010. (A user can click on each state and see a history of the numbers in that state on www.LymeDiseaseAssociation.org).

Additionally, LDA designed a pie graph (LDA-Fig. 2) which shows the percent of Lyme disease CDC-reported case numbers in nine Northeast states (66%) compared to the rest of US (34%) in 2010. Using the same comparisons in 2008, it was Northeastern States (76%), rest of US (24%). Lyme is not just a problem in the Northeast, although patients in other regions are often mistakenly told that when they get a tick bite and try to get diagnosed or treated.

Lyme Disease Association LDA-Fig. 2

2010 Lyme Disease % in Northeast States (66%) Compared to Rest of US (34%)



CHANGES IN REPORTING BY STATES:

Besides the huge under-reporting, the numbers do not reflect the real prevalence of the disease for other reasons. States must use the CDC's surveillance criteria to have a case included for reporting purposes, but they can use various methods to report, which skewer state and national numbers, leading to a paper drop in case numbers which influences public policy, e.g., monies, and diagnostic and treating issues.

Connecticut (CT), which had been generally number 1 or 2 in reported case numbers nationally until 2002 with 4,631 reported cases, removed Lyme as a laboratory reportable disease in 2003, leaving only physicians to report disease cases. That year, CT reported a 70% drop in case numbers compared to the prior year. Over a three year period, 2003–05, without mandatory lab reporting requirements in place, CT's reported cases totaled 4,561—70 cases lower than the single 2002 year total, the last year lab reporting was mandatory.⁶

CT's rationale for changing the reporting was lack of funding to verify the growing numbers of cases that are being reported. The State told concerned residents that it would be restored when electronic

reporting was instituted. In 2007, electronic reporting commenced; however, not all labs have the capability to report electronically, especially the smaller specialty labs which often receive samples from doctors treating Lyme disease patients, so the reported numbers never rose to original levels. According to then CT Attorney General Richard Blumenthal in a CT Lyme hearing in January 2004 (C-p.268), "...This disease now is prevalent, it's off the charts." ... "But we still need the charts to do the counting because we won't know whether we've made a dent, let alone real significant progress in fighting it." Now US Senator Blumenthal continues to pursue the Lyme issue, sponsoring S-1381.

New York State (NYS) has traditionally been #1 in reported cases nationally for many years, and Pennsylvania (PA) now has moved to the top. Are NYS cases declining? No, but in 2010, seventeen New York counties investigated a sample of positive laboratory results, and the number of cases was extrapolated to generate estimates for total case numbers for those counties.⁷ The 2010 number of CDC-reported cases for NYS (including NYC) was 3,425. NYS itself reported 6,316 Lyme cases including those 17 estimated county numbers. Why this dichotomy in case numbers between State and Federal Lyme reporting? The Council of State & Territorial Epidemiologists (CSTE), charged by Congress with surveillance, does not permit inclusion of estimated numbers to be reported in the CDC counts. Thus, NYS reported 6,316 Lyme cases including those 17 county numbers by State count, but CDC only reported a total of 3,425 Lyme cases for NYS.

Several states, including Maryland are moving in the same direction due to the labor intensive Lyme reporting system. They are "exploring alternative data sources, such as billing code datasets to serve as a source of Lyme disease case information."⁸

Last week, Wisconsin (WI), which had moved to #3 nationally in 2010 cases, announced that starting this summer, health officials are no longer required to investigate or report Lyme cases unless the patient has the characteristic bull's-eye rash. The bull's eye has been shown through research studies to be present in less than 50% of cases. Sometimes no rash develops, other times a different type of rash may occur.⁹ WI still requires doctors and laboratories to report all positive test results to local health departments, but departments won't have to pursue cases if there is no rash.¹⁰ WI cited increasing cases of whooping cough (WC; considered cyclical outbreaks in WI) on which they could now concentrate. In 2011, WC reported cases in WI were 1,192, while comparably reported Lyme cases were 3,609.¹¹ Lyme patients there are concerned that loss in Lyme case reporting will cause a further loss of focus on diagnosis and treatment, which many travel out of state for now.

In 2005, the Rhode Island (RI) Department of Health no longer prompted health care providers to report cases in response to positive lab reports.¹² RI numbers were artificially lower in 2005. Although RI had made some internal changes to its reporting system, it quickly understood the negative significance of the changes and promptly rectified its methods.¹³ RI generally ranks at the top in incidence of Lyme in the US.

At the 2012 International Conference on Emerging Infectious Diseases organized by the CDC, CSTE, World Health Organization and others, a study was presented showing that in Maryland (MD), 4,768 Lyme case reports were in the 2009 state database; 2,029 (43%) were "Confirmed" or "Probable." However, local health departments (LHD) in MD did not enter an additional 5,722 Lyme disease reports in the state database that year. Seven (29%) of the LHDs lost Lyme surveillance staff in the past 2 years; one lost all staff and does not currently investigate Lyme. In 2008, 16 (75%) LHDs investigated each Lyme report, while 5 (21%) investigated only if sufficient laboratory evidence of infection.

In California (CA) in September 2005, laboratory reporting of Lyme disease was made mandatory by the Department of Public Health (DPH), because Lyme advocates were seeking legislation to make

changes and DPH did not want that to happen. CA Lyme case numbers went from 32 cases in 2004 to 174 cases in 2006.¹⁴ With the exception of CA, these examples indicate that when states experience high numbers of reported cases, they devise methods which lower case reporting, affecting their own and national numbers.

SURVEILLANCE CRITERIA: Surveillance criteria are narrowly defined to compare “apples to apples” in the field. Clinical treatment criteria are broader to ensure that patients who are sick are able to receive care. CDC surveillance criteria by the current CDC/CSTE definition are as follows:

Confirmed Case: A case of *erythema migrans* (EM) \geq 5cm with a known exposure. A case of EM with laboratory evidence of infection and without a known exposure. A case in a patient with at least one late manifestation that has laboratory evidence of infection.

As mentioned earlier, less than 50% of people who develop Lyme disease get a bull’s eye rash, and those who do may be in an area not considered to have Lyme (non-endemic, no known exposure). One can test negative and still have Lyme disease, and the CDC has tightly regulated what types of tests can be used, thus an antiquated serologic test such as the ELISA is used for the original screening for Lyme even though it is less than 50% sensitive. It may take 4-6 weeks or more for antibodies to build up to a testable level. Even when they do, research has shown that the antibodies often combine with the antigen, the protein on bacterial cell that stimulates antibody production, and the commercial ELISA test can only test for free antibody. Thus, one can test negative and still have Lyme disease.¹⁵ If the test is negative and you do not have an EM rash, doctors will not proceed to the next test, the Western Blot (WB). If they try to proceed with a negative ELISA, some labs refuse to run the test, and often insurance companies will not pay. If the patient does have a positive ELISA, according to the 2-step testing process, the doctor should order a WB for confirmation purposes.

In a Dearborn, MI, 1994 meeting, the CDC decided that only a certain number of bands would be allowed to be used to determine a positive WB test for Lyme. “In a Western blot, the testing laboratory looks for antibodies directed against a wide range of Bb proteins. This is done by first disrupting Bb cells with an electrical current and then “blotting” the separated proteins onto a paper or nylon sheet. The current causes the proteins to separate according to their particle weights, measured in kilodaltons (kDa).”¹⁶ There were researchers present who disagreed with the decision to exclude certain bands they felt were indicative of Lyme, and there was dissension on the floor.¹⁷ According to treating physicians, two of the bands that were not included, the 31KD (OSP A) and 34 KD (OSP B) bands, are often found in chronic Lyme patients and the 31 and 34 are specific for Bb. By scrapping those bands and others, many patients remain undiagnosed and untreated as they may have 5 out of 10 bands, but 2 of the 5 may include the 31 and 34 bands which are not counted in a CDC positive.¹⁸

There are indications that the bands were only scrapped because a vaccine was in the pipeline,¹⁹ and there was concern that tests would not be able to distinguish between a vaccinated and unvaccinated individual, since positive IgG results on Bands 31 or 34 may occur after vaccination in otherwise uninfected people. A person could be asked if he/she had been vaccinated. The only human Lyme vaccine has been off the market for more than 10 years now. Physicians, researchers and advocates have fought to include additional bands in the criteria as so many people are not being counted as positive with current band limitations. Many people are unable to be treated even though they have significant species specific bands.

In 2007, the CDC in Ft. Collins, Colorado (CO) invited me to speak with its Vector-Borne Diseases Division about Lyme problems, and I expressed concerns that a decision on the bands made with then 13 year-old data was condemning patients to a life of debility. CDC assured me they had new data supporting that banding decision. I then requested copies of it, but it has never been provided, and now, to my knowledge, Western Blot test results are based on data that is 18 years old.

Although the CDC criteria are only surveillance criteria, most doctors refuse to diagnose outside these criteria and insurance companies refuse to pay. Thirty-seven years after Lyme was recognized, sick patients cannot get diagnosed and not be treated because of antiquated, unsubstantiated tests which may pick up 50% of cases. HIV was identified as the cause of AIDS in 1984 and the screening test was developed in 1985, and the HIV screening test has a sensitivity of ~ 99%. In 1982, *Bb* was identified as the causative agent of Lyme and the screening test continues to lack sensitivity 30 years later: "...studies conducted by the group responsible for Lyme disease proficiency testing for the College of American Pathologists (CAP) concluded that the currently available ELISA assays for Lyme Disease do not have adequate sensitivity to be part of the two-tiered approach of the CDC/ASPHLD, where only ELISA-positive samples can be tested by Western blotting."²⁰

CHANGES IN REPORTING BY CSTE/CDC: Changes in federal reporting criteria also significantly influence the numbers and the perceptions about the geographic spread of Lyme disease. In 2008, the CSTE who defines the surveillance reporting definitions added new categories of Lyme reporting, "probable" Lyme cases (see CDC-Fig.2) and "suspected" cases. However, despite concerns voiced by LDA and ILADS at the CSTE meeting where definition changes were presented, CSTE adopted a definition that only "confirmed" and "probable" cases are able to be reported out, not the "suspected" case numbers, which may be maintained by the states themselves. New Jersey (NJ), which ranked #2 nationally in total case numbers in 2010, shows the suspected number of cases²¹ in its own reporting: Confirmed 3,320; Probable 392; Total: 3,712; Rate 42.2; Suspected 2,895. How and if these "suspected" numbers are used by anyone is unclear, since they are not factored into the national picture, surprising since the only significant funding for Lyme in most states, federal funds, apparently is number or incident based.

According to an NIH report, "Setting Research Priorities at the National Institutes of Health,"²² disease burden data is given serious consideration during NIH deliberations regarding funding allocations. They indicate that other factors are also considered and that data can be difficult to gather and assess. But the NIH considers the following as it sets its research priorities: the number of people affected, the number of deaths that result, the extent of disability produced, the effect on quality of life and productivity, the economic and social expenses generated, and the importance of halting its spread. Assessing any one of these should begin with mandatory laboratory reporting.

LYME IN THE SOUTH/MIDWEST/CANADA: Other significant changes were made to the surveillance criteria, changes which have significant impact on patient care, especially in specific regions of the US. *Ixodes scapularis*, the black legged tick (deer tick). transmits the Lyme disease bacteria in most of the country, and *Ixodes pacificus*, western black legged tick, transmits the disease on the West Coast. Another tick, *Amblyomma americanum*, the lone star tick, transmits a disease that looks, acts, and is treated the same as Lyme disease, now called Southern Tick-Associated Rash Illness (STARI; which is not confined to the South and does not necessarily include a rash). It is also known as Master's Disease, after a Midwestern doctor/researcher, the late Ed Masters, who did much of the research on it. STARI often does, however, produce a rash virtually indistinguishable from the Lyme EM rash. There is no commercially available test to detect STARI.

Scientific controversy surrounds STARI, which many think is Lyme caused by a different strain of the bacterium, *Borrelia lonestari*, but since its discovery in the mid 90s, the CDC has not confirmed it as the causative agent. Lone star ticks have been shown to have now broadened their range from the deep South to as far North as Maine and Iowa. People are being bitten by this aggressive species of ticks, get sick with the Lyme-like disease STARI, and need treatment. There is no accepted test for STARI, and prior to the Lyme surveillance criteria changes in 2008, patients bitten by a lone star who developed the EM rash were treated with antibiotics just as they were with Lyme disease. Now, many

doctors refuse to treat these patients because they say there is no Lyme in the South and Midwest (No Lyme), and thus they cannot treat an EM.

Originally, reasons used by some doctors, researchers and the CDC for the No Lyme theory were that there are no reservoir hosts (small mammals that carry the bacteria and are fed upon by ticks which then pick up the bacteria and bite people), there are no deer ticks there, there are no infected deer ticks, deer ticks in the South behave differently, deer ticks in the South do not bite people, deer ticks in the South feed upon lizards, which do not transmit *Bb* bacteria to the tick. Research has debunked those assertions, yet the No Lyme mantra has been repeated so often that the doctors in those regions often refuse to diagnose patients, and health department officials continue to deny the obvious or count reported cases.

The same type of scenario took place in Canada, a country which like others throughout the world, often follows CDC guidelines. For many years, the LDA received communications from hundreds of Canadians desperately seeking medical help in the US and also political help to prove that deer ticks were in Canada, were infected with Lyme and other TBDs, were biting people, and were transmitting Lyme disease. In 2008, Lyme problems became so blatant there that the Canadian Public Health Agency and others funded a study creating Canadian risk maps for Lyme disease.²³ The Canadian government has now held conferences on Lyme, some of the speakers have been US CDC officials and US and Canadian Lyme advocates. According to Canadian Lyme patients and advocates, CDC opinions on Lyme disease are often cited by the Canadian government.

According to CDC, “known exposure” to Lyme means one having been (\leq 30 days before onset of EM) in a wooded brushy or grassy area (i.e., potential tick habitats) in a county in which at least two confirmed cases have been acquired or in which established populations of a known tick vector are infected with *Bb*. A history of tick bite is not required. The problem with this surveillance criterion is that it is skewed so that it is almost impossible for a county which has not been declared endemic for Lyme to get that declaration. Few of the areas which are non endemic have the personnel or resources to perform studies to prove the ticks are infected with *Bb*. Additionally, many of those areas are locations where doctors refuse to diagnose cases, so cases are not reported, equaling no endemic county status. Thus the No Lyme in the South and Midwest continues to be perpetuated, and people continue to be sick without getting any medical help in those areas. Besides the patients’ dilemma, go without treatment and let the disease progress, or travel at great expense long distances while sick to see doctors in other areas of the US, this issue also presents a physician dilemma. In endemic areas, the small number of physicians willing to treat are already overwhelmed with patients from their own region, and the influx of patients from non endemic US areas and from international patients strains their practices. Because of the treatment controversy, few new physicians are willing to participate in treating patients.

CDC clearly states that surveillance case definitions establish uniform criteria for disease reporting and are not to be used as the sole criteria for establishing clinical diagnoses, not to be used for determining the standard of care necessary for a particular patient and not to be used for setting guidelines for quality assurance, and not to be used for providing standards for reimbursement. The reality is, doctors are inappropriately requiring CDC surveillance criteria to diagnose patients, doctors are using it to determine the standard of care, and insurance companies are using the criteria to deny reimbursement. Bottom line: due to ‘surveillance only’ criteria, patients cannot get diagnosed, treated or reimbursed for Lyme disease.

IDSA LYME TREATMENT GUIDELINES: A critical aspect of patients’ inability to get treatment is the development of clinical guidelines based on the CDC surveillance criteria by the IDSA. With the apparent blessing of the CDC, IDSA has a set of Lyme treatment guidelines which call for absolute

reliance upon either the presentation of an *Erythema migrans* rash or positive serologic blood tests to diagnose Lyme disease. The Guidelines recommend severely limited courses of antibiotic treatment when either a rash or a positive test are present. They have taken the place of a longstanding policy of deference to the clinical discretion of the treating physician in both diagnosing and treating the disease. The IDSA guidelines fail to explain the scientific justifications for their absolute reliance upon the rash and current blood testing to diagnose the disease in light of the numerous studies and medical opinions concluding that the typical rash is either not discovered by or present in many infected persons and that the serologic testing methods recommended by the IDSA are inherently unreliable because they do not even remotely approach a dispositive level of accuracy. Widespread adoption of these guidelines by practitioners, insurers, and government entities has caused real and egregious harm to many patients by inhibiting physicians who otherwise would be free to clinically diagnose and treat this disease.

The LDA has a petition on its website addressing the IDSA guidelines and currently has about 42,000 signatures opposed to the guidelines: “These guidelines fail to meaningfully address the needs of patients with chronic Lyme disease, who are now relegated to the pile of diseases with unknown etiology, like CFS and FMS, and who are provided with only symptomatic relief, while the underlying infectious disease is allowed to progress unabated. ... Failure to address the underlying infectious disease etiology keeps these patients sick, which is inhumane and immoral. There are no chronic Lyme disease patient studies supporting symptomatic therapies, which presumably would be necessary for life at considerable cost to insurers and society. Moreover, the IDSA rejected out-of-hand the requests by patients and their treating physicians to participate in the guideline development process. No medical society should be able to dictate patient healthcare through exclusionary guidelines that ignore considerable scientific evidence and fail to meet the basic goal of medicine—to improve the quality of life of the patient.”²⁴

Bottom line, the guidelines recommend against any long term treatments, listing numerous specific antibiotic classes not to be given to patients with Lyme, they recommend against alternative treatments (which they list and are many of the treatments patients seek when they cannot get antibiotic treatment) and even recommend against supplements for Lyme patients. Recommendations from the CDC itself encourage patients to speak to their health care providers about treating symptoms of Chronic Fatigue Syndrome (CFS) with vitamins and other nutritional and herbal supplements,²⁵ yet IDSA recommends against the use of the same approaches for Lyme patients. IDSA develops hundreds of guidelines for diseases, and these Lyme guidelines seem to be the only ones that are so anti patient and draconian in nature, consigning patients to an existence with no options and not a life.

IDSA and others like to point out that there are other Lyme treatment guidelines which independently corroborate the IDSA guidelines, referring to the *Practice parameter: treatment of nervous system Lyme disease (an evidence-based review)*, *Report of the Quality Standards Subcommittee of the American Academy of Neurology (2007)*, by the American Academy of Neurology (AAN). These AAN guidelines actually shared several of the same panelists including the lead author of the IDSA guidelines, Gary Wormser, so they really cannot be considered independent corroboration.

The European Federation of Neurological Societies (EFNS) published guidelines on the diagnosis and management of European Lyme neuroborreliosis in 2010 based on an internet search of practice parameters proposed by the American Academy of Neurology (AAN) and the Infectious Diseases Society of America guidelines (IDSA), which formed the basis for the recommendations. As would be expected, European guidelines recommend the same limited treatment as their counterparts (AAN, IDSA), 2 weeks of antibiotics for treatment of all stages of Lyme disease, with the exception of the late stage, peripheral neuropathy and *acrodermatitis chronica atrophicans* (ACA), appearing more often in European Lyme disease. Treatments for these conditions are up to 3 weeks of antibiotics.²⁶

In the Lyme & Tick-Borne Diseases CME scientific conference for physicians jointly sponsored by the Lyme Disease Association and Columbia University, researcher CW Ang, MD, PHD from the Netherlands will discuss *Serologic tests for Lyme disease - how reliable are they?* His recent paper on testing presented to the European Congress of Clinical Microbiology and Infectious Disease on comparing different ELISAs and immunoblots from different labs concluded: “ELISAs and immunoblots for detecting *anti-Borrelia* antibodies have widely divergent sensitivity and specificity, and immunoblots for detecting *anti-Borrelia* antibodies have only limited agreement. Therefore the choice of ELISA-immunoblot combination severely influences the number of positive results, making the exchange of test results between laboratories with different methodologies hazardous. The widespread availability of more specific and sensitive assays for the detection of *anti-Borrelia* antibodies will open the way for reappraisal of 2 tier testing system.”²⁷

The following data was reported in a 2009 survey of Lyme disease patients by LymeDisease.org (previously CALDA) which had over 4,000 respondents. Subsequently, data from the survey was published in HealthCare 2011.²⁸

Only 16% of those responding were <u>diagnosed within 4 months</u> of becoming infected with Lyme. The remainder were diagnosed much later when Lyme disease is much more difficult and expensive to treat. It took more than 6 years for 35% of patients to be properly diagnosed.
Only 13% were <u>diagnosed using the IDSA-recommended two-tiered Lyme testing approach</u> . 20% were diagnosed by western blot using CDC criteria, and 42% were diagnosed clinically with supporting lab tests that did not use CDC surveillance criteria.
90% had <u>difficulty or extremely difficulty obtaining treatment</u> from a knowledgeable physician to treat Lyme disease. 51% had traveled more than 100 miles to obtain treatment and 53% had been forced to travel out of state to obtain care.
54% had been treated and <u>failed treatment under IDSA protocols</u> . A resounding 81% stated that they would not consider being treated under IDSA protocols.
More than 60% of respondents who failed to improve under IDSA protocols <u>improved with additional treatment</u> .
41% of patients were <u>not able to afford the medical care</u> they needed.
88% had to <u>cut back on work, school and household activities</u> . 50% either had to quit work or school due to illness and another 11% went from full time to part time work or school.
65% had to cut back or quit work or school at some point. (Johnson 2011)
28% were unable to work for more than a year. (Johnson 2011)
50% see 7 or more physicians before diagnosis. (Johnson 2011)
30% travel 100 or more miles for treatment. (Johnson 2011)
84% were not diagnosed within 4 months.
Over 40% of patients report substantial improvement with additional therapy and approximately 30% report some improvement with additional antibiotic therapy
65% have had to cut back or quit work or school
25% of those with chronic Lyme disease have been on disability. (Johnson 2011) <ul style="list-style-type: none"> • 75% of those on disability have been for more than 1 year. (Johnson 2011) • 37% of those on disability have been for more than 5 years. (Johnson 2011)

Many doctors across the country and the world have adopted a universal attitude about Lyme patients and Lyme disease based in part upon these guidelines which they espouse in lieu of treating the patient. An example occurred in a meeting in the Northeastern US recently at a forum with federal and state officials. An infectious disease physician who is the director of a Lyme clinic described the patients he

saw in three categories: the first group he described as patients with fatigue and brain fog who were treated for years with antibiotics and not helped. He said they had been diagnosed with chronic Lyme disease, that current research does not support long-term treatment, so they focus only on treating symptoms with these patients and no focus on Lyme disease, but they keep “an open mind.” The second group he described were those who had a “fear” of Lyme disease. They were anxiety ridden. They try to focus those people on protection measures to prevent future tick bites, such as clothing sprays and most go away “at least with information.” The third group he sees have a positive test. This is more difficult, he opined, as the 2-step test for Lyme relies on immune response, there are mis-interpretation of tests and probably cross reactions, so there are a lot of false positives.

Those who heard his remarks were left with the impression that Lyme patients are either anxiety ridden people, people with vague symptoms who are not able to be treated for Lyme, or are those with a positive test who don't really have the disease anyway, and he did not provide anything of substance to back up his remarks. The characterization was very demeaning to patients and contributory to the problems patients face getting diagnosed and treated, and not one official present corrected that perception. Bottom line: the perception is that there is no real Lyme disease problem, just hysteria.

On a daily basis, the LDA and other patient groups across the country hear the same stories repeated, of Lyme patients being sent to psychiatrists rather than treated for Lyme, of parents (usually mothers) being charged with Munchausen by Proxy for having their children treated with antibiotics by a licensed physician for Lyme disease, of people with EM rashes being refused treatment, of people who have positive tests denied treatment, of children being labeled in school systems as fakers when they are out long term due to Lyme symptoms.

LYME IN CHILDREN: Children are at the highest risk acquiring Lyme disease. Just dealing with the usual childhood issues of growing up can be very stressful, now factor in the effects of a chronic disease which can physically, mentally, and emotionally disable that child. Lyme attacks the central nervous system, and there is a study out of Columbia University in New York, showing a drop in IQ of 22 points before a student is treated for Lyme disease and a return to normal after IV treatment for Lyme disease.²⁹

Another study from Columbia on children with Lyme disease showed that they had significantly more cognitive and psychiatric disturbances. Cognitive deficits were still found after controlling for anxiety, depression, and fatigue. Lyme disease in children may be accompanied by long-term neuropsychiatric disturbances, resulting in psychosocial and academic impairments. Parents indicated that 41% of children with LD had suicidal thoughts, 11% had made a suicide gesture.³⁰

Children, as well as adults, experience tremendous brain fog, pain, memory loss and confusion, seizures, and may miss months or years of school. My own daughter was out of school for more than four years, on home instruction. The isolation alone was emotionally hard. Additionally, we had to fight with the school to get her Advanced Placement courses as she was a gifted student, but she and the many other Lyme students like her, were often discriminated against due to the stigma of having Lyme. Fortunately, I was on the Board of Education and understood the laws, and I advocated for her and for students like her throughout the country. Schools did not (and often still do not) believe Lyme could produce such a problem, since their doctors tell them how easy it is to cure.

My daughter was able to go on and graduate from Johns Hopkins and be successful in life, others I worked with have not been that fortunate. Some children with Lyme have been unable to graduate, others did not survive the disease, and quite a few committed suicide. “In one New Jersey case, the child felt no one understood her Lyme disease problems. In another, a young man stopped his medications after a psychiatrist told him he did not have Lyme, it was all in his head. He could not bear

the pain from the disease.”³¹ An NIH-sponsored study found that the impact of Lyme disease on physical health status was at least equal to the disability of patients with congestive heart failure or osteoarthritis, was greater than those observed in type 2 diabetes or a recent myocardial infarction. Chronic pain was an important contributor to the impairment of physical health and was similar to that reported by patients with osteoarthritis.³²

Many advocates have had to help US families deal with charges of Munchausen by Proxy, where a parent is charged with causing a child’s illness— a diagnosis that has largely been disputed by many in the medical community.³³ Often the situation is complicated by split families, where the father is charged with providing funding for care and the mother is charged with custody. These fathers attempt to shirk their financial responsibility by refusing to pay for healthcare and charging the mother with Munchausen by Proxy.

There have been cases where the mother was taking the child to a licensed physician for treatment, and the father called child protective services. In some cases, that child and other children have been taken away from the mother on the basis of the mother getting a child treatment with antibiotics for Lyme disease. Congressman Smith once intervened in NJ to help a mother in such circumstances to keep her children. A surge in the United Kingdom of mothers being charged for the same reason followed a number of US cases.³⁴

Many of the doctors who developed the Guidelines have vested interests in Lyme testing and Lyme vaccines, which was recognized after the then CT Attorney General (AG) Richard Blumenthal took legal action against the IDSA. According to AG Blumenthal’s settlement announcement “My office uncovered undisclosed financial interests held by several of the most powerful IDSA panelists... The IDSA’s guideline panel improperly ignored, or minimized, consideration of alternative medical opinion and evidence regarding chronic Lyme disease, potentially raising serious questions about whether the recommendations reflected all relevant science.... The IDSA’s 2006 Lyme disease guideline panel undercut its credibility by allowing individuals with financial interests — in drug companies, Lyme disease diagnostic tests, patents and consulting arrangements with insurance companies — to exclude divergent medical evidence and opinion.”³⁵

IDSA members and colleagues also sit as reviewers for many of the most significant medical journals. They have authored articles that blame Lyme advocates and patients for “Lyme hysteria,” for being against a vaccine, for giving out faulty scientific information, information published in peer review, (read scientific information with which they do not agree), and for supporting clinical discretion for treating physicians, which is a tenant ostensibly held by CDC. From the CDC website: “No surveillance case definition is 100% accurate. There will always be some patients with Lyme disease whose illness does not meet the national surveillance case definition. For this reason, CDC has stated repeatedly that the surveillance case definition is not a substitute for sound clinical judgment. Given other compelling evidence, a physician may choose to treat a patient for Lyme disease when their condition does not meet the case definition.”³⁶ Despite that statement, CDC only has the IDSA guidelines on their website as diagnostic guidelines, the IDSA guidelines which basically use the CDC surveillance criteria as their basis.³⁷

The IDSA guidelines contain a disclaimer that clinical discretion can be used. However, members of the IDSA have played a role in testifying against doctors who do not subscribe to the IDSA Guidelines viewpoint and who have been brought up on charges by medical boards for treating Lyme patients.

One of the only pediatricians in the country treating and helping children with Lyme disease return to health and to the classroom is in his mid 80’s. He has seen children with Lyme 6 and 7 days a week due to their inability to get care anyplace else. The CT medical board has been actively pursuing 3

cases against him—the State opened by saying the case had nothing to do with Lyme treatment, then proceeded to call several “expert” witnesses in Lyme disease.³⁸ At the end of 2011, the Connecticut Supreme Court agreed to hear his appeal. The doctor has continued to fight the very costly legal battle and still practices, despite having to pay for monitoring charges.

Since 1990, doctors across the US and recently in Canada and Europe have had similar situations where they have been investigated related to treatment of chronic Lyme patients, often in a sham peer review process. Charges range from long term treatment of Lyme, too much testing, not enough testing, not following the standard of care (despite the fact they were following one of the two standards of care), use of alternative therapies. Many time patients did not file any of the complaints, and were very unhappy with their charts being pulled and used in the case. Penalties in the US have ranged from suspending or removal of licenses, continuation of practice but not allowed to treat Lyme, to records keeping fines, and monitoring.

New York has experienced a high number of doctors facing Lyme-related charges over time. Here is an excerpt from testimony from Andy Schlafly, General Counsel, the American Association of Physicians & Surgeons, to the *New York State Assembly, Committees on Health, Higher Education, and Codes. January 31, 2002:*

We have many physician members in New York who feel pressured and intimidated to protect their own licenses by altering their care to patients. They are faced with the choice between avoiding the wrath of insurance companies and delivering the best possible care to their patients. This intimidation interferes with the ethical practice of medicine, and ultimately hurts patients.

Physicians feel threatened because they have fewer rights than almost anyone else in a judicial proceeding. Physicians can lose their license based on very little proof, and inadequate due process. Physicians are vulnerable to manipulation of the process for economic reasons, rather than true concern for patient health. For example, we see unexplained targeting of certain types of physicians for discipline. Physicians who treat Lyme Disease are frequent victims of investigations, but not due to any complaints by their patients. Third-party payers, who find the aggressive treatment of Lyme Disease costly, have too much influence over the disciplining of a physician.

In the mid 90s when areas of particular states starting to see a rise in reported cases, suddenly the doctors who were treating Lyme long term in those areas were targeted by the medical boards and charts were pulled and investigations opened into long-term Lyme treatment. That greatly affected Lyme reporting, doctors were afraid to report, and even today doctors are wary of reporting cases due to investigations.

In some cases doctors with hospital privileges had pressure applied to them by the hospital in relation to treatment of Lyme. Some hospitals became Lyme unfriendly. When my own daughter seized for 3 years, I never took her to a hospital because we knew by then that they were admitting these children to psychiatric facilities, as they said Lyme does not produce seizures, and patients were not permitted Lyme treatment while there. The same thing has happened to adults, and many of those people have become productive with long-term antibiotic Lyme treatment.

Most chronically ill Lyme patients today will not allow themselves to be hospitalized, and if they are for any reason, they often neglect to tell the hospital of their Lyme diagnosis. Patients labeled with Lyme disease are treated as second class citizens, as hysterics, fakers, mentally ill. Hospital personnel themselves are often thirsty for Lyme information. When I took care of my mom with cancer, arthritis,

Lyme, stenosis, other issues, she was hospitalized 8 different times. I would sleep in the hospital in the chair in her room, because she was so fragile. I did my Lyme charity work by phone in her room, and often nurses and aides would suddenly materialize and ask if I were the “Lyme Lady” that they heard was in the hospital. They begged me for info for themselves or family members but would not tell others in hospital they had Lyme. I was careful to indicate I could not provide any medical advice but did provide them access to resources and educational information.

On one of my mom’s stays, I saw an engorged tick hanging from her leg, I rushed to get the oncologist who was just leaving, and he looked at it and told me it was a mole. I said, well then, it is the first mole I have seen with 8 legs. He gathered all staff around and made me remove the tick, said he had no idea how to do it. They brought me all kinds of supplies and gathered around and were amazed when I pulled out the tick remover I always carry and pulled it right off. To his credit, he agreed to give her a course of antibiotics as it was a fully engorged tick.

On another hospital stay, my mom was having upper GI problems. Tests indicated she may have ulcers. For various reasons, the doctor prescribed a biopsy for *H. pylori*, a bacterium which had been finally acknowledged to cause ulcers. I asked her doctor if while they did that, could they biopsy for *Bb*, now shown to be found in lesions in the GI tract.³⁹ He saw no problem, told me to go down with my mom and tell the doctor doing it that he concurred. That doctor at first refused, told me he never saw anyone in his practice who had that, and I opined it is difficult to find something you are not looking for. He did the tests, and a few days later, he came into the hospital room all excited at his good news: no *H. pylori*. I said what about *Bb*? He said well, that takes longer, and they were sending my mom home, and I could get results later.

Days after my mom was at home, I called his office and he refused to speak with me. I finally said I would have my attorney call. Then the office said he told them if I wanted the results, I would have to call the lab myself and get the results! I called the lab and had to beg to just get them to tell me that, yes, a test had been done for her prescribed by Dr. such and such. I said there is some mistake; he is not my mother’s doctor. The lab said, that is who is listed as ordering the test. I called the listed doctor whom I knew—a pediatric doctor who was practicing at the hospital and also doing Lyme research. The first thing he said to me before I said anything is, this is crazy, I just got in a positive Lyme result for an 80 year-old woman I never heard of, and obviously I never prescribed for, since I work with children. I said, that person is my mother. That other doctor used his name on the test, because he was too afraid to put his own there, and here my mother had a positive result, *Bb* in the GI tract, and I would have never known had I not pursued it myself.

Lyme organizations and patients agree that doctors need to adhere to standards and that medical boards have the right to investigate claims, however, in the case of Lyme, there has appeared to be a clear cut pattern of witch hunts. A treating physician was asked to testify before the Senate in the early 90s, which he did. Not long after his testimony, his state medical board began to pull his charts on Lyme disease patients. For years to come, he was continuously harassed by them, as those cases are never really closed, and you cannot confront your accuser. Most of the patients whose records were used were furious, as they had not filed complaints and even held a press conference to indicate that, and felt they were progressing nicely on their treatments regimens. After many years, while he continued to treat and faced staggering legal bills, he was given a slap on the wrist for some trivial charge. He was considered by treating physicians and many researchers, and patients worldwide (many who flew in to avail themselves of his expertise) as one of the most knowledgeable Lyme disease treating physician in the world.

LYME IN THE US MILITARY, HOME & ABROAD: A US Army Centers for Health Promotion & Preventive Medicine (CHPPM; now Public Health Command) report states that ticks are among the

most important of all arthropod vectors of disease. There are over 850 recognized species worldwide. Ticks rank second only to mosquitoes in the number of life-threatening and debilitating diseases they transmit to humans. In the United States, ticks are responsible for more human disease than any other arthropod group. Tick-borne diseases represent potentially serious health threats to troops, their family members, DoD civilian employees, and other residents at military installations in many parts of the world.⁴⁰

According to the Armed Forces Health Surveillance Center report,⁴¹ confirmed cases of Lyme disease in the services were diagnosed at more than 120 locations worldwide. Medical facilities at the following locations accounted for nearly one-half of the total: West Point, NY; Heidelberg, GE; Walter Reed Army Medical Center, Washington; Camp Lejeune, NC; Vilseck, GE; Landstuhl Regional Medical Center, GE; Naval Health Clinic New England (branch clinics in Newport, RI; Groton, CT; Portsmouth, NH; Brunswick, ME; Saratoga Springs, NY); National Naval Medical Center, Bethesda, MD; Fort Knox, KY; Andrews Air Force Base, MD; Fort Meade, MD; and McGuire Air Force Base, NJ. 2008 had nearly 3 times more confirmed cases than 2004.

At a blood products advisory committee meeting on Babesia in the blood supply, Dr. Jesse Goodman, M.D., Director of FDA's Center for Biologics, made the observation, "I will say I just finished a month of clinical attending at the Naval hospital in the summer, and I was actually fairly shocked by the number of cases of disseminated Lyme disease that we are seeing. So I think that the notion that we have control over tick-borne disease...we don't really have a good hand on how many cases of primary infection[Lyme disease] there are."⁴²

The LDA and other advocacy groups including Military Lyme often hear from military personnel who have Lyme disease. Many of them have been unable to get treatment for themselves or their families, despite the fact that military installations were being mapped for Lyme disease risk as far back as the late 80s.

The Lyme Disease Association presented written testimony to the Defense Health Board on a Lyme disease agenda item, September 4-5, 2008. In part, LDA recommended that "the Board should change the Lyme diagnosis and treatment policy to allow treatment under both the IDSA standard of care and the ILADS standard of care for Lyme and for all tick-borne diseases. The use of surveillance criteria to restrict diagnosis/treatment should not be permitted. Military insurance needs to include such provisions.... The military are at high risk for Lyme disease and they require and deserve prompt diagnosis and treatment. If physicians used by the military are not knowledgeable about tick-borne diseases, personnel should be able to avail themselves of knowledgeable treating physicians without penalty to prevent further long-term implications of Lyme disease. Physicians should be encouraged to attend CME conferences on tick-borne diseases."⁴³

Air Force aeromedical concerns may require flyers to receive a waiver to fly if they have Lyme disease. "The symptoms during primary Lyme disease, included arthralgias, fatigue, headache, neck pain and possible fever are obviously not optimal in the flying environment. As with all infectious diseases, if recognized and treated early with full resolution of symptoms, return to flight status is appropriate. However, if untreated, then aeromedical concerns of this disease are its debilitating effects in regards to the neurologic, cardiovascular, and arthritides that may result. Neurocognitive impairment, cardiac arrhythmias and arthritic pain are all manifestations that could impact the safety of the individual and mission."⁴⁴

"LDA has spoken about Lyme disease on several bases and presented a 2002 educational briefing for military officials at a DC meeting arranged by then House Veteran's Committee Chair, Congressman Christopher Smith (NJ). LDA provided noted clinicians who educated military officials from all

branches of the armed services about chronic Lyme disease and the problems faced by Lyme disease patients.... Military doctors indicated they faced the same set of “political” problems in treating their Lyme disease patients.

LDA has been invited twice to US Army Centers for Health Promotion & Preventive Medicine (CHPPM) [*now Public Health Command], Aberdeen Proving Grounds, where...CHPPM has shared its extensive work on identifying tick-borne disease organisms in various ticks found on military installations nationwide. CHPPM discussed its mapping of military installations for risks of Lyme disease and its plan to eventually beam that information to satellites which then will convey it to handheld devices, alerting troops to the presence of ticks. CHPPM shared development of technology which enables it to test ticks in the field for any known disease agent, so that troops can be treated immediately if bitten by infected ticks. CHPPM has been both a speaker and exhibitor at LDA’s annual scientific conference for physicians on tick-borne diseases—conferences jointly sponsored with New York’s Columbia University. The LDA’s 9th annual scientific conference in San Francisco Oct. 17, 2008, has a speaker from the Armed Forces Institute of Pathology who will discuss the pathology of Lyme carditis....[Lyme can also produce palpitations, heart block, and valve prolapse.]”⁴⁵ NOTE: LDA’s 13th international conference is upcoming in Philadelphia in September 2012.

DEATH BY LYME: Although most bacterial diseases can cause death, the establishment has added that to its unending list of things Lyme cannot do, since in their opinion, it is hard to catch and easy to cure. Rocky Mountain spotted fever (RMSF), another tick-borne disease carried by different types of ticks, is considered by experts to be a disease with a relatively high mortality rate. I have never seen that claim disputed. The CDC in their MMWR reported deaths from RMSF and Lyme from 2002 to 2007, and both RMSF and Lyme had the same number of deaths listed, 36.

Even those who die from Lyme disease when listed as a cause of death on death certificates are not left to rest in peace. In 2010, researchers did a study published in *Clinical Infectious Disease* where they reviewed 114 death records from 1999-2003, which listed Lyme disease as an underlying or multiple cause of death. Researchers concluded that only 1 record was consistent with clinical manifestations of Lyme disease and concluded that Lyme disease is rare as a cause of death in the United States.

These conclusions were reached despite the following comments taken from the study "Most importantly, we did not conduct medical chart reviews. Therefore, we were unable to confirm or deny the diagnosis of Lyme disease or the causal sequence leading to death....Most terminal events on death certificates for which Lyme disease was the underlying cause of death were inconsistent with the well-characterized complications of Lyme disease and the rare published case reports of Lyme disease-associated mortality. Additionally, the underlying causes of death when Lyme disease was listed as a multiple cause of death varied widely and also were inconsistent with the well-characterized complications of Lyme disease."⁴⁶

The universal story of Lyme patients: no diagnosis, no treatment, no insurance reimbursement, no compassion, and no dignity even in death.

SOLVING THE PROBLEM: The Lyme surveillance system needs to be revamped so accurate numbers are obtained. More education is needed on Lyme and other tick-borne diseases. A full research agenda needs to be developed with patient and treating physician input. The following comes from the Congressional Record and was submitted by the Lyme Disease Association (LDA), CALDA (now LymeDisease.org) and Time for Lyme (now Lyme Research Alliance). It clearly expresses the need for more practical research which will help Lyme patient get diagnosed and treated in a timely fashion and will lead to physicians finally being able to treat Lyme patients appropriately.

“Patients with Lyme disease need a research agenda that reflects outcomes that matter to patients, namely effective diagnostic tools and effective treatments that restore them to health. The reason there are two disease paradigms in Lyme disease is because central pieces of the puzzle are missing or are inadequate. The first area of concern involves testing.

There are no reliable biomarkers of the disease.¹ Current diagnostic tests commonly used do not detect the spirochete that causes Lyme disease, rather, they detect only whether the patient has developed antibodies to the pathogen. Antibody production, if it registers on the tests at all, takes weeks to appear, thus rendering the current tests ineffective in the earlier and more easily addressed stage. Additionally, the Lyme antibody has been shown to form a “complex” with the bacterium itself--and tests cannot detect “complex” antibodies. Once triggered, antibody reactions may remain long after an infection has been treated, also clouding the diagnostic and treatment picture.

A vast number of strains of *Borrelia burgdorferi* have been identified. Variation in strain may cause differing symptoms or severity of symptoms as well as determine the appropriate antibiotics and duration of treatment needed to clear the infection.³ Different strains may also express different proteins. Preliminary research shows that proteins need to be examined to find the ones most often expressed, then using microarray technology, doctors may be able to diagnose patients using a chip which contains the proteins.

Research is needed concerning the role of mutation on persistence. Some research indicates that bacteria can exchange genetic material, probably contributing to its ability to invade different systems in the body--some may have a proclivity for the heart muscle, others for the brain, and some for muscles and joints. By exchanging genetic material, bacteria may be able to form a symbiotic relationship to avoid detection by the immune response or to further invade the body.

To date, every NIH-funded treatment research study has been designed using the inaccurate diagnostic test results as part of the entry criteria. The entry criterion in these studies excluded the vast majority of Lyme patients and created sample sizes too small (less than 220 patients to date) to detect clinically important treatment effects or generalize to the clinical population. Moreover, Lyme has not attracted industry funding for treatment approaches, which places the disease at a considerable research disadvantage. To detect clinically relevant treatment effects requires much larger treatment trials with sample populations that reflect those seen in clinical practice.⁴

Patients want research which will restore their health. Their voice and the voice of the clinicians must be given the necessary weight to legitimize the research agenda and the research process. Truth in science can be achieved through open debate in an independent process free from bias and conflicts of interest. The scientific process fails when one side of a debate controls the arena and sets the rules to ensure that its viewpoint prevails.⁴⁷

¹ Lyme Disease Association, Time for Lyme, CALDA The Patient Perspectives on the Research Gaps in Tick Borne Diseases. Introduced and read into Record by Congressman Chris Smith (R-NJ), 9-29-10. Congressional Record No.133 Book II Vol. 156 No. 133 E 1872

² *Ibid*

³ Dr. P. Meade, CDC epidemiologist, (NJ) Herald News 5-4-04

⁴ MMWR http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5853a1.htm?s_cid=mm5853a1_w

⁵ CDC http://www.cdc.gov/lyme/resources/brochure/508_LD_Brochure.pdf

⁶ Centers for Disease Control & Prevention Lyme Disease Cases by State 1993-2005

⁷ *NY State Dept of Health*

⁸ Maryland DHMH letter, JUNE 5, 2012

- ⁹ R. Smith et al *Annals of Internal Medicine* 2002;421:421-428, 477-479 ; A. Pachner *Reviews of Infectious Diseases*-Vol. II, supplement 6 - September-October 1989 Neurologic Manifestations of Lyme Disease, the new "Great Imitator"; J.M. Johnson, Ph.D., Chief, Public Health, NPS Ticks and Disease
- ¹⁰ *Beloit Daily News* 7-5-12 (online ed.)
- ¹¹ *Greenfield.Patch.com* July 6, 2012
- ¹² RI DOH Office of Communicable Diseases, Health Advisory 7/20/05
- ¹³ LDA phone conversation with Rhode Island DOH's Dr. Bandy on several occasions including 2-23-07. Note: RI did not end mandatory laboratory reporting at any time according to DOH.
- ¹⁴ Department of Health Services, State of California, *California Summary Monthly Report Selected Reportable Diseases*, <http://www.dhs.ca.gov/ps/dcdc/pdf/cdtables/CM-SEP2006.pdf>, 9-2006, Report Weeks 36-39, 9/3-30/06.
- ¹⁵ *Lancet* 1990, *Journal of Clinical Investigation* 1994 & S. Schutzer et al, *JAMA* Vol 282, No. 20 *Borrelia Burgdorferi: Specific Immune Complexes in Acute Lyme Disease*, Nov. 24, 1999
- ¹⁶ C. Brenner Explanation of the Western Blot <http://www.canlyme.com/wb.html>
- ¹⁷ LDA Conflicts of interest in Lyme Disease: Laboratory Testing, Vaccination, and Treatment Guidelines <http://lymediseaseassociation.org/images/pdf/ConflictReport.pdf> 2001
- ¹⁸ J. Burrascano, MD <http://www.lymenet.org/BurrGuide200810.pdf>
- ¹⁹ LDA Conflicts of interest in Lyme Disease: Laboratory Testing, Vaccination, and Treatment Guidelines <http://lymediseaseassociation.org/images/pdf/ConflictReport.pdf> 2001
- ²⁰ International Lyme & Associated Diseases Society www.ILADS.org
- ²¹ NJ Department of Health & Human Services
- ²² The National Institutes of Health. "Setting Research Priorities at the National Institutes of Health." September 1997. Available at www.nih.gov.
- ²³ N. H. Ogden, et al, *Int J Health Geogr.* 2008; 7: 24. Risk maps for range expansion of the Lyme disease vector, *Ixodes scapularis*, in Canada now and with climate change
- ²⁴ LDA petition against guidelines www.LymeDiseaseAssociation.org
- ²⁵ CDC info on CFS <http://www.cdc.gov/cfs/management/medicines.html>
- ²⁶ A. Mygland, European Federation of Neurological Societies. EFNS guidelines on the diagnosis and management of European Lyme neuroborreliosis. *Eur J Neurol* 2010 Jan;17(1):8-16, e1-4.) <http://guideline.gov/content.aspx?id=25707&search=lyme+disease>
- ²⁷ CW Ang, MD, PHD *Eur J Clin Microbiol Infect Dis* Jan 2011
Serologic tests for Lyme disease - how reliable are they?
- ²⁸ L. Johnson L, et al. Healthcare access and burden of care for patients with Lyme disease: A large United States survey. *HealthPolicy* (2011), doi:10.1016/j.healthpol.2011.05.007)
- ²⁹ B. Fallon et al. The Underdiagnosis of Neuropsychiatric Lyme disease in Children & Adults: The Psychiatric Clinics of North America 1998
- ³⁰ F. Tager et al. A Controlled Study of Cognitive Deficits in Children With Chronic Lyme Disease: *Neuropsychiatry Clin. Neurosci* 2001
- ³¹ P. Smith, The Effects of Lyme Disease on Students, Schools and School Policy. NJ School Boards Association "School Leader" Journal, 2004
- ³² MS Klempner et al. Two controlled trials of antibiotic treatment in patients with persistent symptoms and a history of Lyme disease. *New England Journal of Medicine* vol. 345(2), July 12, 2001.
- ³³ DSM IV term: *Factitious Disorder by Proxy (FDP, FDbP)* (U.S., 2000) American Psychiatric Association, DSM-IV-TR
- ³⁴ UK uses term Fabricated or Induced Illness (FII).
- ³⁵ R. Blumenthal, AG CT IDSA guidelines settlement release <http://www.ct.gov/ag/cwp/view.asp?a=2795&q=414284>
- ³⁶ P. Meade, CDC, Connecticut Lyme Disease Hearing Testimony 1-29-04
- ³⁷ IDSA indicates *Ixodes* species ticks- CSTE does not indicate a tick species. CSTE requires a "physician" diagnosed EM"- IDSA does not mention that. CSTE says- Laboratory confirmation is recommended for persons with no known exposure. IDSA does not say that directly. CSTE includes radiculoneuropathy in its late manifestations. IDSA does not.
- ³⁸ P. Smith was present in the hearing room
- ³⁹ M. Fried, et al. "Confirmation of Chronic Lyme by PCR of Intestinal Biopsies." *Borrelia burgdorferi* Persists in the Gastrointestinal tract of Children and Adolescents with Lyme Disease. *Journal of Spirochetal & Tick-Borne Dis.* V. 9, No.1, 2002.
- ⁴⁰ US Army Centers for Health Promotion and Preventive Medicine (CHPPM) to Congress in 1999 *DoD Research and Surveillance Activities Regarding Lyme Disease and Other Tick-Borne Diseases*,
- ⁴¹ Medical Surveillance Monthly Report Armed Forces Health Surveillance Center July 2009 Lyme disease among U.S. military members, active and reserve component, 2001-2008
- ⁴² Food and Drug Administration Workshop 2008 <http://www.fda.gov/cber/minutes/ttb091208t.pdf>
- ⁴³ http://lymediseaseassociation.org/index.php?option=com_content&view=article&id=480:lyme-disease-and-armed-services-briefing-paper&catid=113:department-of-defense-dod&Itemid=529

⁴⁴ Air Force Aeromedical Corporate Board Meeting Minutes September 2005 *airforcemedicine.afms.mil/waiverguide*
WAIVER GUIDE Updated: Jul 07 By: Lt Col Stephen Hingson (RAM 08) and Dr Karen Fox

⁴⁵ Lyme Disease Association, Inc. testimony, Defense Health Board Meeting, Sept 4-5, 2008 Falls Church, VA

⁴⁶ K. J. Kugeler et al. *Clin Infect Dis.* (2011) 52(3): 364-367. doi: 10.1093/cid/ciq157 First published online: December 28, 2010. A Review of Death Certificates Listing Lyme Disease as a Cause of Death in the United States
47 September 29, 2010 Congressional Record PATIENT PERSPECTIVES ON THE RESEARCH GAPS IN TICK BORNE DISEASES, Submitted by Time for Lyme (Diane Blanchard/Deb Siciliano), the national Lyme Disease Association (Patricia V. Smith), and the California Lyme Disease Association (Lorraine Johnson) on behalf of our patients across the United States, read into the Record by Congressman Christopher Smith