

5. POLITICAL ISSUES IN LYME DISEASE

LYME DISEASE IS FRAUGHT WITH POLITICAL DIVISION AND CONTROVERSY, perhaps more so than any other disease. While this largely stems from within the United States, it unfortunately spills over into other nations and greatly shapes the recognition and acceptance of Lyme, as well as the policies and standards of care that are enforced.

CDC Surveillance Criteria

What has become clear is that being “notifiable” and being “accurately assessed” are two different things. The CDC’s surveillance criteria, adopted in 1994, pose a great problem for the accurate assessment of Lyme disease, firstly because these criteria are so narrowly defined (for the purpose of having a high degree of specificity and confidence in the diagnosis); and secondly, because those criteria were simply never designed to be used for clinical diagnosis.

Even the CDC acknowledges, “This surveillance case definition was developed for the national reporting of Lyme disease: it is NOT appropriate for clinical diagnosis.” Yet, the definition is repeatedly misused as a standard of care for healthcare reimbursement, product development, medical licensing hearings, and other legal cases.

Prior to 1994, Lyme disease was diagnosed based on certain clinical findings along with certain general laboratory findings. The criteria were as follows:

The Beginner's Guide to LYME DISEASE

Clinical Criteria:

1. Erythema migrans rash.
2. At least one late manifestation of musculoskeletal, nervous or cardiovascular system disorders; and laboratory confirmation.

Laboratory Criteria:

1. Isolation of *B. burgdorferi* from clinical specimens; *or*
2. Demonstration of diagnostic levels of IgG and IgM antibodies to the spirochete in serum or CSF (could be by ELISA, Western Blot or IFA);
or
3. Significant changes in IgG and IgM antibody response to *B. burgdorferi* in paired acute- and convalescent phase samples.

While this criteria did have limitations—mainly that there was a strong emphasis placed on the EM rash which only a small subset of patients actually exhibited—it did have broad enough parameters to catch a wider range of cases, and it had more emphasis on clinical criteria. The lab criteria was *either* the first *or* the second *or* the third option, not necessarily all three.

The new CDC surveillance criteria are more oriented to the detection of early Lyme, and rheumatologic manifestations of Lyme, whereas we know that in reality Lyme has many diverse systemic manifestations, and that the guidelines leave out a host of other symptoms indicative of Lyme. One example is the cognitive dysfunction and neuropsychiatric manifestations associated with Lyme disease. If a patient has a positive Lyme test with symptoms of late neurological Lyme such as memory loss, difficulty concentrating and “brain fog”, they would not be diagnosed as a Lyme disease case by the CDC. Why? Because cognitive dysfunction is not part of the CDC’s “surveillance criteria” even though they recognize that these symptoms may be attributable to Lyme disease. Their criteria are centered more on the erythema migrans rash, arthritis, Bell’s palsy, or early neurological Lyme symptoms involving meningitis or encephalitis (inflammation of the brain and surrounding tissues). The criteria that supposedly aim to achieve accurate assessment and tracking of Lyme disease may actually be preventing many people from getting the

diagnosis and treatment they need—and in cases of early Lyme, this may ironically turn a treatable, acute disease into a much more difficult to treat, chronic one.

The CDC surveillance criteria also impact the laboratory testing for Lyme disease by dictating which tests are to be ordered, and what constitutes a positive test result, both to receive a positive diagnosis of Lyme disease, and to meet the criteria to be reportable to health authorities (hence influencing how many cases of Lyme disease are actually recorded).

A two-tiered approach to testing was adopted. The requirement dictated that a positive sensitive ELISA or IFA must be followed by a positive Western Blot with a defined number of approved antibody bands to be considered positive. This created a much more stringent set of criteria, and while those criteria were not intended to be adopted for clinical diagnostics, they were. In particular, they became the standard for insurance companies, for whom a stricter diagnostic criterion means fewer official diagnoses and consequently, less money paid out for patients' medical care.

While the CDC was encouraged to correct the misuse of the surveillance criteria, to date, not much has been done to rectify the problem. Even the passing of Public Law 107-116 in 2002, signed by President Bush, who himself has his own experiences with Lyme disease, has not had a major impact. That law clearly states that the CDC case surveillance definition is unacceptable as a diagnostic tool. Unfortunately it continues to be used and this, combined with the unreliability of laboratory testing for Lyme, has led to misdiagnosis and delayed therapy for many individuals. Yet 99% of practicing physicians are completely unaware of the law and still misuse the surveillance case definition.¹ Part of the necessary education for physicians is to learn the clinical presentations of Lyme disease and make diagnostic decisions based on those, as opposed to following the strict and unrealistic CDC surveillance case definition.

IDSA Treatment Guidelines

Another major barrier to adequate treatment of Lyme disease and a

The Beginner's Guide to LYME DISEASE

hugely divisive, political phenomenon is the Infectious Disease Society of America (IDSA) stance on acute versus chronic Lyme disease. Where the CDC surveillance criteria are more involved with the diagnosis of Lyme disease, the IDSA guidelines, published in 2006, provide information on the treatment of Lyme disease, including medication dosages and duration of treatment. Those guidelines recognize acute Lyme disease but more or less deny the existence of a chronic Lyme infection, speaking only of “post-Lyme syndrome”. According to the IDSA, it is not possible to have the actual infection beyond the acute stage. Any symptoms that exist beyond this stage are just residual symptoms (known as post-Lyme syndrome) that, according to them, are not caused by persistent infection and will resolve by themselves over time.

Not only have these guidelines severely restricted the care available to Lyme patients, they have also been used to prosecute doctors who prescribe outside the limits of their recommendations.

Given the IDSA's thinking that Lyme disease (per their standards) is only an acute and short-term infection, their treatment protocol entails only a short course of antibiotics—between 14 and 21 days. This becomes a significant issue in the world of chronic Lyme disease treatment. If the IDSA publishes guidelines limiting the treatment of Lyme to a maximum of 21 days, then that is what doctors learn and assume to be correct. Furthermore, any doctor who treats outside of those guidelines or standards of care is subjecting him- or herself to scrutiny, censure, and even disciplinary action by the medical boards.

Following are some of the treatment recommendations given by the IDSA, according to the stage of illness:

For early Lyme disease (which by IDSA standards is necessarily associated with erythema migrans “bull’s eye” rash, even though in 50% or more of Lyme disease cases this rash never occurs or is not memorable by the patient):

- Simple erythema migrans—doxycycline, amoxicillin or cefuroxime taken orally for 10-21 days.

- For Lyme meningitis and early neurological Lyme disease—ceftriaxone given intravenously for 14 days (up to maximum 21 days).
- For Lyme carditis—oral or parenteral (via intravenous route or intramuscular injection) antibiotic therapy for 14 days (up to maximum 21 days).

For late Lyme disease (which they do not consider to be “chronic” Lyme disease):

- Lyme arthritis without neurological involvement—doxycycline, amoxicillin or cefuroxime for 28 days.
- Neurological Lyme disease—ceftriaxone via IV for 2-4 weeks.

It is clear that none of the recommendations go beyond a maximum one-month course of antibiotics, with most of them suggesting 14 days only. Yet, according to extensive clinical experience by physicians who have treated thousands of cases of chronic Lyme disease, a four-week course of antibiotics will barely even scratch the surface. Most patients require several months up to a couple of years of treatment to get significant improvements in symptoms. These faulty IDSA recommendations are the key to the disparity between treatment that is needed, and treatment that is being provided.

Furthermore, IDSA guidelines also restrict other treatment approaches that might be attempted, outside of the four or five antibiotics they support.

“Because of a lack of biologic plausibility, lack of efficacy, absence of supporting data, or the potential for harm to the patient, the following are not recommended for treatment of patients with any manifestation of Lyme disease: first-generation cephalosporins, fluoroquinolones, carbapenems, vancomycin, metronidazole, tinidazole, amantadine, ketolides, isoniazid, trimethoprim-sulfamethoxazole, fluconazole, benzathine penicillin G, combinations of antimicrobials, pulsed-dosing (i.e., dosing on some days but not others), long-term antibiotic therapy, anti-Bartonella therapies, hyperbaric oxygen, ozone, fever therapy, intravenous immunoglobulin, cholestyramine, intravenous hydrogen peroxide, specific nutritional supplements, and others.” (p.1094)

The Beginner's Guide to LYME DISEASE

That's really quite a list of things *not* to do. How can the IDSA possibly verify the “lack of efficacy” for this huge, all-inclusive list of treatments, which even includes “specific nutritional supplements”? It does not seem reasonable that they can categorically dismiss such a range of modalities that have not been individually studied, and yet this broad list was included in their treatment guidelines, which became the medical standard of care.



Let us look now at the IDSA view on acute Lyme, post-Lyme syndrome and chronic Lyme disease.

The IDSA talks about post-Lyme syndrome, but there is no recognition of chronic Lyme disease in their treatment guidelines. In fact, they vehemently oppose the possibility of it (page numbers below are in reference to the IDSA guidelines publication, available through their website www.idsociety.org/lyme):

“There is no convincing biologic evidence for the existence of symptomatic chronic *B. burgdorferi* infection among patients after receipt of recommended treatment regimens for Lyme disease. Antibiotic therapy has not proven to be useful and is not recommended for patients with chronic (> 6 months) subjective symptoms after recommended treatment regimens for Lyme disease.” (p.1094).

So to clarify—the guidelines recognize a continuation of symptoms beyond the treatment regimen, which they term post-Lyme syndrome. They just deny that the symptoms are due to the presence of continued infection in the body.

“The response to treatment of late manifestations may be slow, and weeks to months may be required for improvement or resolution of symptoms after treatment. However, appropriate treatment [their 14 day protocols] leads to recovery in most patients.” (p. 1110). They claim that “more indolent forms of neurological Lyme disease are actually quite rare” (p.1110). The reasons given for the persistence of symptoms include ongoing inflammatory

processes, residual/irreversible neurological damage or co-infection with other agents such as Babesia (p.1115). At one point, where a tiny window seems to have been opened to the suggestion of persistent infection, somehow those particular microbes seem to be harmless:

“Even if a few residual *B. burgdorferi* spirochetes or their DNA debris persist after antibiotic treatment in animal systems, they no longer appear to be capable of causing disease” (p.1119).

My favorites, though, are the implications that ongoing symptomatology is related to the emotional state of the patient, or that the symptoms are in line with what other healthy people experience.

“In many patients, post-treatment symptoms appear to be more related to the aches and pains of daily living rather than to either Lyme disease or a tick-borne co-infection. Put simply, there is a relatively high frequency of the same kinds of symptoms in “healthy” people” (p.1115).

“Previous studies of various infectious diseases have suggested that delayed convalescence can be related to the emotional state of the patient before onset of the illness. In those studies, fatigue was often a persistent symptom. Consistent with these observations, one study of patients with Lyme disease found that poor outcome was associated with prior traumatic psychological events and/or past treatment with psychotropic medications” (p.1116). So ongoing Lyme symptoms correlate with emotional instability prior to the onset of illness? Does this also mean that emotionally unstable people are more likely to attract, and get bitten by, a tick? While I do believe that psycho-emotional elements can contribute to illness, and impact recovery, it is somewhat ridiculous to postulate that the people who are reporting ongoing Lyme symptoms beyond standard 21-day courses of antibiotics are simply manifesting emotional imbalances and prior traumas rather than true infectious processes.

“To summarize, it can be expected that a minority of patients with Lyme disease will be symptomatic following a recommended course of antibiotic treatment as a result of the slow resolution of symptoms over the course of weeks to months or as a result of a variety of other factors, such

The Beginner's Guide to LYME DISEASE

as the high frequency of identical complaints in the general population” (p.1116). This argument completely fails to acknowledge the thousands of Lyme patients who were completely healthy, or at least asymptomatic, before their tick bite, and now have ongoing and continuous debilitating symptoms despite “appropriate” antibiotic therapy.

Clearly the IDSA is very specific in their diagnostic parameters and treatment protocols and very definite about the acute nature of *Borrelia burgdorferi*. Their position is happily enforced by medical insurance providers in the United States, who resist covering the costs of long-term medications and care needed for patients.

Of course, the elephant in the room is the thousands of people who have positive lab results for Lyme and/or co-infections and experience health issues following a tick bite; those who have been treated with short courses of antibiotics and still experience symptoms; as well as the thousands who may not necessarily have (for reasons discussed later) positive test results but have the history and symptomatology indicative of chronic Lyme/tick-borne illness.

How can we possibly explain the suffering that is caused by these infectious agents, disabling many, robbing people of quality of life, taking away their feelings of being smart, productive, happy, healthy individuals—saying that the very thing that is becoming a global epidemic does not exist beyond an acute phase, and is “cured” with 14 days of a single antibiotic?

Unfortunately, the misinformation produced by the IDSA guidelines was driven even deeper into traditional medical circles by way of a journal article published in the *New England Journal of Medicine* (NEJM), one of the most well-respected and credible medical publications in the world.

The article entitled *A Critical Appraisal of “Chronic Lyme Disease”*², written by a group of doctors and researchers affiliated with the Infectious Disease Society of America, acknowledges that Lyme disease is the most common tick-borne illness in the Northern Hemisphere, and that it is a serious public health problem. But its grounding in reality stops there.

The authors recognize that "...after antibiotic treatment, a minority of patients have fatigue, musculoskeletal pain, difficulties with concentration or short-term memory, or all of these symptoms." But, instead of attributing these symptoms to an active bacterial infection, the article states: "Data from controlled trials have shown that there is substantial risk, with little or no benefit, associated with additional antibiotic treatment for patients who have long-standing subjective symptoms after appropriate initial treatment for an episode of Lyme disease." Furthermore, the article dismisses the improvements attained by patients who have received benefit from long-term antibiotic treatment: "Although anecdotal evidence and findings from uncontrolled studies have been used to provide support for long-term treatment of chronic Lyme disease, a response to treatment alone is neither a reliable indicator that the diagnosis is accurate nor proof of an antimicrobial effect of treatment."

Finally, the article concludes by stating that "It is highly unlikely that post-Lyme disease syndrome is a consequence of occult infection of the central nervous system." The following advice is offered to clinicians who see patients claiming to have chronic Lyme disease:

"How should clinicians handle the referral of symptomatic patients who are purported to have chronic Lyme disease? The scientific evidence against the concept of chronic Lyme disease should be discussed and the patient should be advised about the risks of unnecessary antibiotic therapy. The patient should be thoroughly evaluated for medical conditions that could explain the symptoms. If a diagnosis for which there is a specific treatment cannot be made, the goal should be to provide emotional support and management of pain, fatigue, or other symptoms as required. Explaining that there is no medication, such as an antibiotic, to cure the condition is one of the most difficult aspects of caring for such patients. Nevertheless, failure to do so in clear and empathetic language leaves the patient susceptible to those who would offer unproven and potentially dangerous therapies."

It is not difficult to imagine the damaging and completely counterproductive effects this published article had on sufferers of chronic Lyme

disease. This report raised the stakes considerably and rendered an already red-hot, hostile environment, even more perilous.

It is not true and it is not fair, but the big kids in the playground have set the rules, and now hundreds of thousands, or even more, people suffer—through denial of treatment, ridicule, rejection within the medical community, and even rejection by their friends and family members who do not understand the depth and complexity of the illness.



Scientific Studies Proving the Existence of Chronic Lyme Disease

In examining the science, it becomes crystal clear that chronic Lyme disease is a true and valid condition. Although much of the research comes from other countries, especially Europe, the following studies show that standard, short courses of antibiotics lead to many treatment failures and relapses, reflecting the chronic nature of the illness.

Some of the following information was excerpted from Bryan Rosner's *Lyme Disease Annual Report*.³

Studies Outside the United States

The Institute of Rheumatology, in Prague, Czech Republic reported a case of a female patient suffering from Lyme disease. Her case was confirmed by detection of *Borrelia garinii* DNA present in her blood and synovial fluid. After treatment with antibiotics, symptoms persisted and six months later, *Borrelia garinii* DNA was "repeatedly detected in the synovial fluid and the tissue of the patient." Additionally, even after antibiotic therapy, antigens and parts of spirochetes were detected by electron microscopy in the synovial fluid, tissue, and blood.

A similar discovery was made in Germany at the University Hospital of Frankfurt. Researchers described Lyme disease as a "disorder of potentially chronic proportions." They also noted that "therapeutic failures have been reported for almost every suitable antimicrobial agent currently available

and resistance to treatment...continues to pose problems for clinicians in the management of patients suffering from chronic Lyme disease."

Another University in Germany, Ludwig-Maximilians-University, located in Munich, reported that "failures in the antibiotic therapy of Lyme disease have repeatedly been demonstrated by post-treatment isolations of the infecting *Borrelia*."

One of the most interesting German studies, completed at Ludwig-Maximilians-Universität Munich, attributed the clinical persistence of Lyme disease after antibiotic therapy to the presence of variants and atypical forms of *B. burgdorferi*. German researchers concluded that "*B. burgdorferi* produce spheroplast-L-form variants...these forms without cell walls can be a possible reason why *Borrelia* survive in the organism for a long time."

Researchers at the University of Dermatologische Privatpraxis, Munich, Germany, agreed with their German peers in a 1996 study, which noted that patients with erythema migrans failed to respond to antibiotic therapy. "Persistent or recurrent erythema migrans, major sequelae such as meningitis and arthritis, survival of *Borrelia burgdorferi* and significant and persistent increase of antibody titers against *B. burgdorferi* after antibiotic therapy are strong indications of a treatment failure."

In Austria, in 2001, the Lainz Municipal Hospital in Vienna admitted a 64-year-old woman who presented with various systemic symptoms hinting of Lyme disease. When spirochetes were detected in samples of her skin lesions, a diagnosis of Lyme disease was made. According to doctors, "Despite treatment with four courses of intravenous ceftriaxone for up to 20 days, progression of [Lyme symptoms] was only stopped for a maximum of one year."

Researchers at the Turku University Central Hospital, Finland, conducted a study in which 165 patients with disseminated Lyme disease were followed after antibiotic treatment. Approximately 10% of the patients experienced a clinical relapse with positive PCR tests and spirochetes successfully cultured from the blood of the patients. In this case, the Lyme disease relapse was evidenced not only by continuing symptoms,

The Beginner's Guide to LYME DISEASE

but also by two independent testing methods: both PCR testing and blood culture. This single study, even without aid from the numerous other studies presented in this chapter, should be enough to call into question the IDSA's staunch and dogmatic stance on chronic Lyme disease.

Italy also has experience with chronic Lyme disease. In 1992, the Università di Genova, located in Genoa, Italy, reported on two patients with "chronic Lyme arthritis resistant to the recommended antibiotic regimens." These patients were eventually cured by long-term treatment with benzathine penicillin. The Italian researchers who conducted this study offered two possible reasons why antibiotic therapy finally worked, and both of these reasons involve active, persistent infection: "The sustained therapeutic levels of penicillin were effective either by the inhibition of germ replication or by lysis of the spirochetes when they were leaving their sanctuaries."

Moving across the globe to Thailand, scientists at KhonKaen University wrote that "Electron microscopy adds further evidence for persistence of spirochetal antigens in the joint in chronic Lyme disease. Locations of spirochetes or spirochetal antigens both intracellularly and extracellularly in deep synovial connective tissue as reported here suggest sites at which spirochetes may elude host immune response and antibiotic treatment."

In France, a study was published in the *Journal of Antimicrobial Agents and Chemotherapy* in 1996, conducted by the University of Marseille. The study notes that "despite appropriate antibiotic treatment, Lyme disease patients may develop chronic manifestations."



Studies Within The United States

It would be understandable for the IDSA to neglect, or at least take less seriously, research conducted outside the borders of the United States, since the IDSA is an organization that operates inside, and is accountable to, U.S. citizens and the U.S. government. However, when we examine studies conducted in the United States, you will see that a significant

portion of the evidence in favor of chronic Lyme disease actually originated on American soil.

In 1996, the Fox Chase Cancer Centre in Philadelphia, Pennsylvania, conducted a study in which it was discovered that urine samples from 97 patients clinically diagnosed with chronic Lyme disease contained *Borrelia burgdorferi* DNA. The interesting aspect of this finding is that most of these patients had previously been treated with extended courses of antibiotics, the implications of which are simply that antibiotic therapy (even an extended course) does not always eradicate the infection. The study concluded that "a sizeable group of patients diagnosed on clinical grounds as having chronic Lyme disease may still excrete *Borrelia* DNA, and may do so in spite of intensive antibiotic treatment."

While the IDSA was releasing their guidelines in which it concluded that chronic Lyme disease was not a medical condition that justified extended antibiotic therapy, researchers at the New York State Psychiatric Institute were discovering just the opposite. The authors of a report produced at that institution described a case of fatal neuropsychiatric Lyme disease that was "expressed clinically by progressive frontal lobe dementia and pathologically by severe subcortical degeneration." Doctors noted that "antibiotic treatment resulted in transient improvement, but the patient relapsed after the antibiotics were discontinued...prolonged antibiotic therapy may be necessary [in some cases]."

In Boston, Massachusetts, researchers at Tufts University School of Medicine conducted a study to investigate neurological abnormalities found in chronic Lyme disease sufferers; 27 patients were followed. Six months after a two-week course of intravenous ceftriaxone (2 g daily), 17 patients showed improvement, 6 had improvement but then relapsed, and 4 had no change in their condition. Researchers concluded that "months to years after the initial infection with *B. burgdorferi*, patients with Lyme disease may have chronic encephalopathy, polyneuropathy, or less commonly, leukoencephalitis." With regard to the cause of chronic Lyme disease, Tufts University in their closing statement in the study implies a bacterial origin: "These chronic neurologic abnormalities usually improve with antibiotic therapy."

The Beginner's Guide to LYME DISEASE

At Thomas Jefferson University, Philadelphia, Pennsylvania, urologists who treated seven patients with Lyme disease found that "neurological and urological symptoms in all patients were slow to resolve and convalescence was protracted...relapses of active Lyme disease and residual neurological deficits were common."

In direct opposition to IDSA statements, researchers at the Department of Pathology, Southampton Hospital, New York, noted that active cases of Lyme disease may show clinical relapse following antibiotic therapy. It is noted that "the latency and relapse phenomena suggest that the Lyme disease spirochete is capable of survival in the host for prolonged periods of time." In their studies of 63 patients with Lyme disease, the researchers concluded that "some patients with Lyme Borreliosis may require more than the currently recommended two to three week course of antibiotic therapy..."

Also in the State of New York, the New York University School of Medicine conducted a study, which evaluated antibiotic treatment of 215 patients between the years 1981 and 1987. Of those with "major" Lyme disease manifestations, a relapse rate of over 20% was observed.

This next study is even more interesting for several reasons, as we will see. The Albert Einstein College of Medicine, New York, reported in 1995 an "unusual" case of Lyme disease in which the patient experienced repeated neurologic relapses despite aggressive antibiotic therapy. What makes this study interesting is that each subsequent course of antibiotics given after the relapses was followed by Jarisch-Herxheimer reactions, which are known to occur only when active bacteria are dying. This implies that active bacteria were still present in the body after multiple courses of antibiotics. Additionally, subsequent to the various courses of antibiotics, the patient's cerebral spinal fluid tested positive "on multiple occasions" for not only complex anti-Borrelia antibodies, but also Borrelia nucleic acids and free antigen proteins. This study demonstrates persistent infection via two separate indicators: repeated Jarisch-Herxheimer reactions, and repeated observation of antibodies and antigens. Both indicators were found after not just one, but multiple courses of "adequate antibiotic therapy" had been administered!

Another similar case observed in Bethesda, Maryland, further calls into question the statement that chronic, persistent Lyme disease infection is "unusual." Doctors in Maryland working with the National Institute of Arthritis and Musculoskeletal and Skin Diseases, a part of the National Institutes of Health (NIH), reported that a 40-year-old Caucasian man who developed clinical Lyme disease after being bitten by a tick was treated with oral tetracycline, after which his symptoms resolved. However, at a later date, the man was re-tested and *Borrelia* was detected by PCR in his peripheral blood leukocytes. After being re-treated with a longer course of ampicillin, probenecid, and concurrent cytotoxic therapy, symptoms improved significantly. This individual's case of Lyme disease illustrates two important points: First, ongoing symptoms that occurred after antibiotic therapy were confirmed by PCR testing to be caused by active bacteria. Second, re-treatment with antibiotics resulted in significant clinical improvement.

A study published in 2012 demonstrated persistence of *Borrelia* in monkeys despite antibiotic therapy. Rhesus macaques were infected with *B. burgdorferi* and a subset of them received aggressive antibiotic therapy four to six months later (antibiotic regimens being doxycycline and/or ceftriaxone). Note that this study was done four to six months post-infection, not immediately, so the infection would have been more disseminated by that point. Subsequent studies via PCR and several other means of testing demonstrated persistence of infection despite antibiotic therapy. This implication of this is recognition that the standard antibiotic protocols suggested by the IDSA are inadequate to eradicate *Borreliosis* especially once disseminated, and that persistence of infection is possible despite antibiotic therapy.

The other finding of this study is that C6 peptides went down in all treated animals (C6 peptide is an immune marker sometimes used in Lyme disease diagnostics), even though the spirochetes persisted. This demonstrates that chronic infection can be present even with negative antibody tests.⁴

What does the literature tell us? If you take the time to read it and think about its implications, you'll find that the existence of chronic Lyme disease (as caused by an active bacterial infection) is quite obvious and

The Beginner's Guide to LYME DISEASE

established. Numerous scientific studies conducted across the globe by interdisciplinary scientists have plainly shown this to be the case. The controversy is one of political and dogmatic origin, not of scientific origin. The IDSA denies an active bacterial infection as the cause of chronic Lyme disease not as a result of scientific observation, but instead, because of various inefficiencies and shortcomings inherent in the bureaucratic procedures through which the IDSA operates. The process by which bureaucratic entities accept new truths and grow in knowledge has always been painfully slow and inefficient—and such is the case with the IDSA. Because chronic Lyme disease is in fact real, I am confident that it will be recognized as such sooner or later. Unfortunately, in the meantime, patients are left to dangle in the gap between two sides of an ideological debate.



Another falsity that originates from the IDSA guidelines is the limited routes by which *Borrelia burgdorferi* (and its friends, the co-infections) can be transmitted. The guidelines state that “there is little evidence that a congenital Lyme syndrome occurs” (p.1098) so that rules out mother-to-baby transmission. Also, “unengorged nymphal or adult *Ixodes* ticks also pose little or no risk of transmission of *B. burgdorferi*” (p.1098), so that rules out ticks that have been attached less than 36 hours. “Many different tick species bite humans, and some “ticks” removed from humans are actually spiders, scabs, lice, or dirt, and, thus, pose no risk of Lyme disease” (p.1099), so that rules out a high likelihood of transmission based on confusion between a tick and a piece of dirt, and also rules out the possibility of transmission by other bugs such as lice or spiders. The guidelines cite the only route of transmission in fact, of any type of *Borrelia*, is *Ixodes* species ticks—*Ixodes scapularis* and *Ixodes pacificus*. All other ticks are supposedly safe and irrelevant to the conversation. In section two we will examine the evidence that clearly disproves these claims.

The IDSA's slow-turning wheels and "selective filtering of information" are not the only hindrances to its production of accurate and relevant information. In 2006, its entire legitimacy was called into question when an antitrust investigation was launched to investigate its political and ethical motivations.

Former Connecticut Attorney General (now Connecticut State Senator), Richard Blumenthal, announced an antitrust investigation into the IDSA writing of the 2006 Lyme disease guidelines, which are considered the authoritative guidelines on the diagnosis and treatment of Lyme disease. He recognized that the guidelines had sweeping and significant impacts on Lyme disease medical care; that they were commonly applied by insurance companies in restricting coverage for long-term antibiotic treatment or other medical care; and that they strongly influenced physicians' treatment decisions. He also recognized that there were serious flaws in the production of the guidelines:

"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."

Blumenthal's findings, as cited on the official State of Connecticut Office of the Attorney General website⁵, include the following:

- The IDSA failed to conduct a conflicts of interest review for any of the panelists prior to their appointment to the 2006 Lyme disease guideline panel.
- Subsequent disclosures demonstrate that several of the 2006 Lyme disease panelists had conflicts of interest.
- The IDSA failed to follow its own procedures for appointing the 2006 panel chairman and members, enabling the chairman, who held a bias regarding the existence of chronic Lyme, to handpick a like-minded panel without scrutiny by, or formal approval of, the IDSA's oversight committee.

The Beginner's Guide to LYME DISEASE

- The IDSA's 2000 and 2006 Lyme disease panels refused to accept or meaningfully consider information regarding the existence of chronic Lyme disease, once removing a panelist from the 2000 panel who dissented from the group's position on chronic Lyme disease to achieve "consensus."
- The IDSA blocked appointment of scientists and physicians with divergent views on chronic Lyme who sought to serve on the 2006 guidelines panel by informing them that the panel was fully staffed, even though it was later expanded.
- The IDSA portrayed another medical association's Lyme disease guidelines as corroborating its own when it knew that the two panels shared several authors, including the chairmen of both groups, and were working on guidelines at the same time. In allowing its panelists to serve on both groups at the same time, IDSA violated its own conflicts of interest policy.

Blumenthal added, "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. In today's healthcare system, clinical practice guidelines have tremendous influence on the marketing of medical services and products, insurance reimbursements and treatment decisions."

It is clear that the very guidelines that drive decisions affecting thousands of people and their day-to-day lives were created by a group that had conflicts of interest, excluded significant medical opinion that did not support its agenda, and were driven by commercial and financial interests.



As much as this kind of ignorance seems like a problem that might relate only to the United States, there is a trickle-down effect that impacts other countries and the opinions of the medical professions there. After all, shouldn't the Infectious Disease Society of America know everything there is to know about an infectious illness like Lyme disease? And shouldn't they be right about it? One would think so; subsequently many

doctors look to them for information, read their guidelines, and simply assume that they are accurate and appropriate.

This highlights one of the fundamental issues we face—trying to get chronic Lyme disease recognized in a world where denial by the medical establishment of the very problem that so many people are living with everyday has become the status quo.

On a happier note, the International Lyme and Associated Disease Society (ILADS, www.ilads.org) is a body of clinicians and researchers who have actually studied the science and recognize that chronic Lyme disease is a valid medical problem. ILADS is a non-profit, multinational, interdisciplinary medical society aimed at increasing awareness of tick-borne illness; educating within and outside of the medical community; training physicians and other health care professionals; and sharing guidelines of its own as to testing and treatment protocols for Lyme disease. ILADS is one of the most important resources available for patients and practitioners dealing with chronic Lyme disease, and this organization is growing exponentially as dozens of physicians abandon their old ways of thinking to join ILADS and take their place in the ranks of the growing number of doctors who know how to help people with chronic Lyme disease.

Lyme disease is possibly the greatest medical controversy in history. The political debate between the two sides—the IDSA on one and ILADS on the other, continues. But ILADS is working hard to present the scientific facts of the case—it has published treatment guidelines of its own, and its membership increases every year as more doctors get on board with the reality of chronic Lyme disease.

Interestingly, one of the founding members of the IDSA, Dr. Burton Waisbren, has adapted his stance on the existence of chronic Lyme disease in response to his clinical experience, where he treated many chronically ill patients with Lyme disease. Dr. Waisbren has great influence in the medical community due to his current membership in IDSA and his status as one of its Founding Members. In early 2012, Dr. Waisbren published a book entitled, *Treatment of Chronic Lyme Disease: 51 Case Reports and Essays in Their Regard*.⁶ In this book, Dr. Waisbren describes how he

The Beginner's Guide to LYME DISEASE

now believes that chronic Lyme disease is in fact a real medical condition, and he presents 51 case reports of Lyme disease which he himself has treated, as well as the therapies he used to help these patients. Dr. Waisbren's abandonment of the IDSA Lyme disease treatment guidelines might be seen as a foreshadowing of what is to come, as more and more physicians follow suit in choosing science over entrenched dogma.

Lyme disease has always been controversial, and it has always been misunderstood. I will end this chapter with an excerpt from the book *Bull's-Eye*, on the history of Lyme disease. The author, Dr. Jonathon Edlow, Professor of Medicine at Harvard Medical School, quotes the late Ed Masters, who discovered STARI, a Lyme-like illness:

Masters points out that the "track record" of the "conventional wisdom" regarding Lyme disease is not very good: "First off, they said it was a new disease, which it wasn't. Then it was thought to be viral, but it isn't. Then it was thought that sero-negativity didn't exist, which it does. They thought it was easily treated by short courses of antibiotics, which sometimes it isn't. Then it was only the *Ixodes dammini* tick, which we now know is not even a separate valid tick species. If you look throughout the history, almost every time a major dogmatic statement has been made about what we 'know' about this disease, it was subsequently proven wrong or underwent major modifications."¹⁷

REFERENCES

1. Unknown. Federal Law and a disconnect. In: Lyme MD Blog [Internet]. Montgomery: Montgomery County, MD. 2008 May – [cited 2008 Jun 18]. Available from: <http://lymemd.blogspot.com/2008/06/federal-law-and-disconnect.html>.
2. Feder Jr HM, Johnson B, O'Connell S, Shapiro ED, Steere AC, Wormser GP; Ad Hoc International Lyme disease Group. A critical appraisal of chronic Lyme disease. *N Engl J Med*. 2007 Oct 4;357:1422-30.
3. Rosner B, et al. 2008 Lyme disease annual report. South Lake Tahoe (CA): BioMed Publishing Group; 2008 [cited 2012 Apr]. Available from: <http://www.lymebook.com/lyme-annual-report>.
4. Embers ME, Barthold SW, Borda JT, Bowers L, Doyle L, Hodzic E, Jacobs MB, Hasenkampf NR, Martin DS, Narasimhan S, Phillippi-Falkenstein KM, Purcell JE, Ratterree MS, Philipp MT. Persistence of *Borrelia burgdorferi* in rhesus macaques following antibiotic treatment of disseminated infection. *PLoS One*. 2012;7(1):e29914. Epub 2012 Jan 11. Erratum in: *PLoS One*. 2012;7(4):10.1371/annotation/4cafed66-fb84-4589-a001-131d9c50aea6
5. Blumenthal R. Attorney General's investigation reveals flawed Lyme disease guideline process, IDSA agrees to reassess guidelines, install independent arbiter [Internet]. Hartford (CT): Connecticut Attorney General's Office; 2002 [released 2008 May 1; cited 2012 Jun 5]. Available from: <http://www.ct.gov/AG/cwp/view.asp?a=2795&q=414284>
6. Waisbren, Burton, Treatment of Chronic Lyme Disease. South Lake Tahoe (CA): BioMed Publishing Group; 2012. Available from: <http://www.lymebook.com/>
7. Edlow JA. *Bull's-Eye: Unraveling the medical mystery of Lyme disease*. 2nd rev. ed. New Haven: Yale University Press; 2003. 304 p.