



# *Lyme Disease Association, Inc.*

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April 22, 2009

IDSA Lyme Disease Review Panel

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Dear IDSA Review Panel Members,

I am writing to submit to you the ten page (10) report plus references titled **Challenge to *The Clinical Assessment, Treatment, and Prevention of Lyme Disease, Human Granulocytic Anaplasmosis, and Babesiosis: Clinical Practice Guidelines by the Infectious Diseases Society of America, 2006.***

The report is being submitted on behalf of the Lyme Disease Association, Inc. and the undersigned groups.

Thank you for your consideration of this important issue.

Sincerely,

*Patricia V. Smith*

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## **Challenge to:**

*The Clinical Assessment, Treatment, and Prevention of Lyme Disease, Human Granulocytic Anaplasmosis, and Babesiosis: Clinical Practice Guidelines by the Infectious Diseases Society of America, 2006*

## **Presented to:**

IDSA Lyme Disease Review Panel

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April 21, 2009

## ***Signers (contact info on cover letter)***

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The following report is a challenge to *The Clinical Assessment, Treatment, and Prevention of Lyme Disease, Human Granulocytic Anaplasmosis, and Babesiosis: Clinical Practice Guidelines by the Infectious Diseases Society of America, 2006* (“Guidelines”), the development of which was subsequently reviewed by the Attorney General of Connecticut for process violations. The individual challenges below relate to concerns the undersigned groups have to specific issues in the guidelines pertaining to the ability of patients to obtain medical treatment.

### **I. This section challenges the definition of “post-Lyme syndrome”**

The reclassification of a sub-set of documented Lyme symptoms seen in actively infected patients, to a poorly defined “syndrome,” endangers the welfare of patients who remain symptomatic, relapse, or worsen after following the Guidelines’ protocols. A growing number of patients, including many children, experience persistent symptoms for years, symptoms that interfere with or severely limit their daily activities.

*A history of relapse with major organ involvement had occurred in 28%...Persistent symptoms of arthralgia, arthritis, cardiac or neurologic involvement with or without fatigue were present in 114 (53%) patients. Persistent symptoms correlated with a history of major organ involvement or relapse but not the continued presence of anti-Borrelial antibodies. Thirty-five of the 114 (31%) patients with persistent symptoms had predominantly arthralgia and fatigue.*<sup>1</sup>

Of the 53% of previously treated patients who were originally receiving recommended antimicrobial therapy and continuing to experience persistent symptoms (for an average of 3.2 years), nearly two-thirds reported both fatigue and arthralgia. The IDSA uses those same well-documented symptoms, which originated post-exposure and pre-treatment, to describe a new and seemingly unrelated entity, “post-Lyme syndrome.”

There are no studies concluding that the most common subjective symptoms experienced by Lyme patients during acute infectious stages are not diagnostic, nor are there studies indicating the same remaining, relapsing or continuing symptoms patients experience are post-infectious. In fact, the IDSA’s definition of “post-Lyme syndrome” ignores the fact that three of the most prevalent signs and symptoms reported in patients with early active and treatable Lyme disease – fatigue, arthralgia and a negative *B. burgdorferi* lab test – are identical to those they have chosen to adopt to define “post-Lyme syndrome.” Medical literature does not support the IDSA’s restrictive inclusion or exclusion criteria, which are based on a limited number of specific objective symptoms appearing within a precise time line. According to Pachner, e.g., “Symptoms can be surprisingly variable, so that days of near normality can alternate with days of profound debility.”<sup>2</sup> He also states, “A lengthy latency within the CNS also appears to exist in Lyme disease, with neurologic symptoms not becoming manifest for months or even years.”<sup>3</sup>

Researchers Cooke and Dattwyler agree with Pachner’s conclusion, “...the symptoms may be fulminant, with a sudden onset, or may develop insidiously over many years.”<sup>4</sup>

The same holds true for most of the Guidelines’ “post-Lyme syndrome” exclusion criteria, such as sleep disorders, autoimmune diseases, cardiopulmonary or endocrine disorders, malignant conditions, liver disease, depression, bipolar affective disorders, schizophrenia, delusional disorders, dementia and anorexia nervosa. These conditions have been documented in the scientific literature as occurring due to or in conjunction with Lyme disease. Their presence or absence does not necessarily indicate a patient has or does not have an active Lyme infection, nor does presence or absence indicate or confirm a post-infectious state. As Cooke explains, “The variable clinical manifestations [of Lyme] have led to an awareness of this disorder as a “great imitator” that must be considered in the differential diagnosis of numerous complaints....”<sup>4</sup>

US Army Centers for Health Promotion and Preventive Medicine (USACHPPM) supports this concept and states, “cases presenting with only disseminated stage complications can sometimes be very difficult to diagnose... In advanced disease, treatment failures may occur and retreatment may be necessary.”<sup>6</sup>

In 1986, Steere, one of the Guidelines’ authors, described some of the varied manifestations and presentations of Lyme disease.

*Lyme disease typically begins with a unique skin lesion, erythema chronicum migrans (ECM) (stage 1). Patients with this lesion may also have headache, meningeal irritation, mild encephalopathy, multiple annular secondary lesions, malar or urticarial rash, generalized lymphadenopathy and splenomegaly, migratory musculoskeletal pain, hepatitis, sore throat, non-productive cough, conjunctivitis, periorbital edema, or testicular swelling. After a few weeks to months (stage 2), about 15% of patients develop frank neurologic abnormalities, including meningitis, encephalitis, cranial neuritis (including bilateral facial palsy), motor or sensory radiculoneuritis, mononeuritis multiplex, or myelitis. At this time, about 8% of patients develop cardiac involvement--AV block, acute myopericarditis, cardiomegaly, or pancarditis. Throughout this stage, many patients continue to experience migratory musculoskeletal pain in joints, tendons, bursae, muscle, or bone. Months to years after disease onset (stage 3), about 60% of patients develop frank arthritis, which may be intermittent or chronic. Recently evidence suggests that Lyme disease may also be associated with chronic neurologic or skin involvement. Thus, Lyme disease occurs in stages with different clinical manifestations at each stage, but the course of the illness in each patient is highly variable.*<sup>5</sup>

The US Army Center for Health Promotion and Preventive Medicine (USACHPPM) agrees with the conclusion that the range of symptoms does not follow a specified time line as proposed by the Guidelines. It states “later symptoms of LD can begin to appear shortly after the initial symptoms or not until weeks to months later. These symptoms occur as spirochetes begin to spread via the blood stream and lymph into tissues in other parts of the body. These symptoms may include complications of the joints, the nervous system, and the heart.”<sup>6</sup>

The current criteria listing only a set number of objective symptoms occurring within a specific time frame on which to base scientific studies or treatment protocols, allow for inaccurate conclusions to be drawn and inappropriate treatment to be administered. The author below comments on additional Lyme-related signs and symptoms, more encompassing than the short list currently recognized in the Guidelines for “post-Lyme syndrome.”

*Sigal and Hassett report that many of the patients with post-LB syndrome referred to their centre had positive scores on depression and anxiety scales. Depression and anxiety scales often include symptoms such as fatigue, listlessness, slowed speech, difficulties in working, concentration and memory problems, muscle aches and pain, increased sweating, and weight changes, all of which may be symptoms of post-LB syndrome. And with the distress that often arises from such a chronic illness, it is not surprising if some patients have positive scores on these scales.*<sup>7</sup>

In February 2009, an independent study group that classified persistent symptoms in patients, as TAPOS – “tick associated poly-organic syndrome”– once again debunked the IDSA’s “post-Lyme syndrome” theory. It determined that after patients were prescribed a “codified antibiotic treatment for Lyme,” a significant proportion of them continued to experience “persistent signs and symptoms.” The study concluded that the “pathophysiological mechanisms which underlie this syndrome of post-treatment chronic systemic illness remain unclear.” Rather than recommend against treating these patients, as the IDSA Guidelines do, the researchers concluded, “Patients with post tick-bite symptoms, which often worsens their quality of life, deserve particular attention.”<sup>8</sup>

“Chronic Lyme” and ongoing symptoms have been described in detail and have been documented

multiple times in the literature since 1976 by many of the IDSA Guidelines' authors and their followers. The New England Journal of Medicine published Steere's "Chronic neurologic manifestations of Lyme disease" in 1991, which stated in part:

*...patients had been followed prospectively for 8 to 12 years after the onset of infection....24 (89 percent) had a mild encephalopathy that began 1 month to 14 years after the onset of the disease and was characterized by memory loss, mood changes, or sleep disturbance...14 had memory impairment on neuropsychological tests, and 18 had increased cerebrospinal fluid protein levels, evidence of intrathecal production of antibody to *B. burgdorferi*, or both. Nineteen of the 27 patients (70 percent) had polyneuropathy with radicular pain or distal paresthesias; all but two of these patients also had encephalopathy. In 16 patients electrophysiologic testing showed an axonal polyneuropathy. One patient had leukoencephalitis with asymmetric spastic diplegia, periventricular white-matter lesions, and intrathecal production of antibody to *B. burgdorferi*. Among the 27 patients, associated symptoms included fatigue (74 percent), headache (48 percent), arthritis (37 percent), and hearing loss (15 percent). At the time of examination, chronic neurologic abnormalities had been present from 3 months to 14 years... Months to years after the initial infection with *B. burgdorferi*, patients with Lyme disease may have chronic encephalopathy, polyneuropathy, or less commonly, leukoencephalitis.<sup>9</sup>*

Other published evidence either negating or supporting a post-infectious syndrome continues to build. It is, therefore, a mistake to abandon or eliminate the more plausible and supported theory that Lyme disease symptoms could be the result of active infection.

In 1993, IDSA doctor and Guideline panel member, Krause, reported results from his study on persistence of *B. burgdorferi* in chronic Lyme, which found:

*Despite antibiotic therapy, there was progression to a chronic stage, with multisystem manifestation...Viable spirochetes were identified. Ultramorphologically, the spirochetes were situated between collagen fibers and along fibroblasts, some of which were deeply invaginated by these organisms....tendon tissues serve as a specific site of spirochete residence in human hosts.<sup>10</sup>*

Cairns reports in 2005:

*It then became apparent that Lyme disease is a complex, multisystem disorder. The illness usually begins in summer with erythema chronicum migrans and associated symptoms (stage 1). Weeks to months later, some patients develop neurologic or cardiac abnormalities (stage 2), and weeks to years later, many patients develop intermittent attacks of arthritis (stage 3), which may become chronic, with erosion of cartilage and bone. Patients with severe and prolonged illness have an increased frequency of the B-cell alloantigen, DR2.<sup>7</sup>*

Patients given additional or continuing antimicrobial therapy have shown improvement in some of their Lyme-related symptoms in all studies involving extended treatment, thus patients should be afforded access to all available options by way of their treating physicians.

*In the first study on patients with early LB, 20% of patients had not completely responded 12 months after treatment, and 13% had not completely responded after 30 months. In the second study on patients treated for late LB, the investigators rated 15% of the patients not cured 12 months after treatment. In the third study on Lyme encephalopathy, 61% of the patients stated they had not completely recovered after 12–24 months. However, in all three studies, almost all the patients with persistent symptoms had improved.<sup>7</sup>*

Rigid criteria not only negatively affect the ability of patients to obtain a proper diagnosis and treatment, they also complicate enrollment in clinical trials, results of which are intended to be used to develop improved treatment protocols, and it excludes emerging evidence of the ever-widening clinical presentation and symptoms of Lyme disease experienced by patients. When rigidity in practice overrules or interferes with criteria for entry into studies for a particular disease, accurate conclusions will not be forthcoming and guidelines based on those conclusions will cause human suffering. Feder, et al., noted the difficulty in finding patients to fit the inflexible post-Lyme criteria in their report on chronic Lyme disease, indicating only 11% of patients with Lyme could be admitted into the study:

*The investigators who conducted the controlled treatment trials had great difficulty finding patients who met the criteria for entry, despite intensive efforts that included both the notification and involvement of Lyme disease support groups and associations.<sup>32,33</sup> For two of the three studies, additional sites had to be engaged,<sup>32</sup> and the enrollment period had to be extended for all three studies.<sup>32,33</sup> To enroll 55 patients in one of the studies, investigators had to screen more than 500 people...<sup>11</sup>*

The most ill patients should not be abandoned through creation of a newly described “syndrome” that has no known cause, no known cure, and no treatment options. Allowing a small panel of researchers who had openly admitted prior to and subsequent to the panel formation that they supported the viewpoint that there is no such condition as chronic Lyme disease to recommend that patients who are not cured on their protocol be reclassified to an undocumented, non-existent and non-treatable category is unsafe, unjustified and unethical. Until solid evidence exists that these identical symptoms that patients experience post-exposure and post-treatment are not related to their exposure to *Borrelia burgdorferi*, these patients should not be re-categorized and defined out of the disease, denying treatment and entry into important clinical trials which could help define treatment options.

It may be determined scientifically in the future that post-treatment symptoms are not due to ongoing *Borrelia* infection, or there may be additional evidence to show multiple causes for the continuing symptoms, such as Sigal’s observations on patients examined at a Lyme disease referral center. He stated, “...most symptoms that persist after [Lyme] therapy can be explained by one or more of seven proposed pathogenetic mechanisms, only one of which includes active ongoing infection. Individualization of care and reanalysis of patients’ problems are crucial if misdiagnosis and overtreatment of Lyme disease are to be avoided...”<sup>12</sup> Pending scientific and clinical validation to determine which of mechanisms produce chronic symptoms in Lyme disease, patients who remain ill should not be forced into the abyss, an unrecognized “post-Lyme syndrome” category.

The Guidelines’ authors state they considered in their development of the “post-Lyme” theory, the “inconvenience of prolonged therapies” for the patient. Without just cause or scientific substantiation, they determined no therapy would be an acceptable solution as opposed to risking a presumed “inconvenience” by continuing treatment when necessary. Any inconvenience caused by additional treatment must be weighed against the benefits of patients being able to continue to work, go to school, and have a reduction in their symptoms. In our interactions with tens of thousands of patients, we note that most with chronic Lyme disease prefer to receive treatment and have options, a choice that should be theirs to make.

Until there is solid evidence and sound reasoning why remaining symptoms after treatment should not be considered part of the ongoing disease process, the act of selectively removing a sub-set of Lyme disease patients from the original clinical picture does a disservice to the scientific community, and more importantly, leaves patients without options and the ability to be cured. The only option they have been given to date is to silently suffer at the hands of what has been shown to be highly contested and unsuccessful treatment Guidelines.



## **II. This section challenges the IDSA's list of therapeutic modalities not recommended (p. 1094)**

The inclusion of an extensive “not-recommended” section in the IDSA guidelines advising against individual and entire classes of antibiotics; against alternate dosing schedules or extended duration of therapy; against vitamins and nutritional products recommended by licensed practitioners, diminishes or restricts the ability to base treatment on clinical judgment. It also seriously violates the principles of patient autonomy.

Clinical practice guidelines are intended to improve the quality of life for patients by producing optimal outcomes and minimizing unnecessary risks. The IDSA Guidelines contain no treatment options for those who fail to improve on its recommended protocol. Patients are denied antibiotics on the pretense there is no need for them past the most cost-effective regimens. Alternative treatments are considered taboo.

The policy of advising against all treatment for patients stating there is a “lack of biologic plausibility, lack of efficacy, absence of supporting data, or the potential for harm to the patient” has no foundation and is not accepted practice in the field of medicine.

*A recent article indicates that only 20% of medical practice is confirmed by rigorous scientific research [118]...medical practice is often not based on controlled studies [214]. For example, many well-accepted practices, like cardiopulmonary resuscitation, close observation of suicide risk patients, blood transfusion, surgical treatment of low back pain, and the treatment of meningitis with antibiotics, have no rigorous and little nonrigorous science to support their use [119,214]. Similarly, most advances in surgery result from clinical innovations on the part of the treating physician, and the off-label use of prescription medications is well accepted [109].<sup>13</sup>*

Scientific research has yet to determine the most successful treatment protocols to be used when addressing patients with Lyme and tick borne co-infections. In fact, *B. burgdorferi* has been cultured from patients given intensive antibiotic therapy for twenty-one days to one year. A review of studies found treatment failures ranging from 24 to 50% using the IDSA-recommended protocols.<sup>13</sup> The IDSA's conclusion that there is “eventual recovery in most patients” abandons the 24 to 50% who remain ill due to unsuccessful treatment.

The IDSA Guidelines fail to address the fact there is no ideal route of administering antibiotics successfully and no conclusive data indicating which drugs are superior based on scientific and clinical trials. The appropriate duration of treatment for acute or persistent Lyme disease has never been established. Treatment failures are common. Progression to the later stages of the disease after antibiotic therapy continues to be reported in increasing numbers of patients, delivering a shocking blow to those who must face the reality that they are left with no viable options once their 2-4 weeks of treatment has been completed.

A growing number of health care professionals diagnose and treat patients based on successful clinical treatment experience and a broad range of medical and scientific literature. They have observed through clinical experience that some patients require a different class of antimicrobials to obtain substantial improvement while others respond to alternative plus conventional therapies. Patients with multiple complicating factors may require additional rounds of antibiotics to bring symptom relief; others may thrive while on treatment and relapse when it is discontinued. To discontinue treatment because researchers have not determined the most effective protocols endangers lives and allows many to advance to the more serious, costly and difficult to cure stages of the disease.

Even if persistent infection were eventually ruled-out as a cause for ongoing symptoms, that would not preclude the prescribing of antibiotics for reasons other than their antimicrobial effects, such as for possible anti-inflammatory effects. According to Labro in Clinical Microbial Review,<sup>14</sup> antibiotics are considered a safe and effective agent for the treatment of numerous conditions. Some may be non-

bacterial in origin, others are of unknown origin: Chronic sinusitis, acne, staphylococcal exotoxins, rosacea, inflammatory bowel disease, prostatitis, rheumatoid arthritis, Crohn's disease, lung cancer, neutrophilic dermatoses, asthma, periodontal disease, ulcerative colitis and other inflammatory-based diseases respond well to extended antimicrobials.

Even IDSA states on its web site, "Antibiotics also have anti-inflammatory effects that may help alleviate certain symptoms." The Guidelines' authors also state in the Guidelines, "The fact that some antibiotic classes (e.g., tetracyclines and macrolides) have significant anti-inflammatory effects exclusive of their antimicrobial effects [299, 300] can explain, in part, why uninfected patients with inflammatory conditions might also improve transiently while receiving these drugs." Therefore, antibiotic therapy should not be eliminated as a viable option by way of a "not recommended" section in the Guidelines.

For example, when "bacteria find a spot on the prostate where they can survive" and recommended antibiotic treatment for the acute stages of prostatitis fails, the National Institutes of Health (NIH) recommends continuing long-term antimicrobial therapy for the later developing "chronic" prostatitis, stating patients require "antimicrobials for 6 months to prevent recurrent infection." It concluded health care professionals have difficulty diagnosing prostatitis due to the fact "the symptoms are not the same for every patient, and many of the symptoms...could be signs of another disease." NIH also admits, "no single solution works for everyone with this condition."<sup>15</sup> It certainly does not recommend patients with continuing prostatitis symptoms be afforded no therapies (as the IDSA recommends in its Lyme Guidelines), nor does NIH reclassify the ongoing symptoms or disease process as a post-prostatitis syndrome, deserving of no treatment options.

Doxycycline and tetracycline, in addition to their antimicrobial function, have been shown to exert control over the inflammation specifically elicited by *Borrelia burgdorferi* in Lyme patients. In a recent study in the Journal of Infectious Diseases, both antibiotics "significantly reduced the production of tumor necrosis factor-alpha, interleukin (IL)-6, and (IL)-8 in a dose-dependent manner in all cell types."<sup>16</sup>

A common element in treating Lyme patients is that the best responses are to flexible protocols that take into account their varying clinical pictures. Until optimal treatment regimens have been established, treating on a case-by-case basis often permits patients to function in the real world. Despite overwhelming scientific and clinical evidence pointing to greater success using a variety of treatment options, the IDSA assigned an arbitrary end point for treatment regimens and recommended against practically all treatment options, without scientific or clinical justification. Until a gold standard diagnostic test is designed and developed that is capable of determining that biologic cure has been achieved and that *B. burgdorferi* has been eradicated, the abrupt termination or exclusion of any treatment options for persisting symptoms is not evidenced-based, is inhumane, and engenders a huge cost to society in disability payments.

Offering only non-scientifically based palliative care (i.e. surgical procedures to alleviate pain and suffering), is not a viable option, especially for those whose condition has been shown to clinically improve when treated with antibiotics or other alternative treatments. In addition, the IDSA's recommended use of corticosteroids for a presumed and unsubstantiated "autoimmune condition" affecting patients with documented cases of Lyme disease is contraindicated. "Experimental data is consensual on the deleterious consequences of systemic corticosteroid therapy. Corticosteroids are not indicated in Lyme's disease...."<sup>17</sup>

To abandon symptomatic patients by recommending against antibiotic treatments leaves them with no choice but to seek medical alternatives that may or may not be successful in alleviating their worsening symptoms. Providing unsubstantiated recommendations against all available options, including the use of vitamins and nutritional management or adjunct therapies such as magnesium to reduce painful and often crippling muscle spasms, is apparently without precedent.

Under the medical principle of autonomy, treatment decisions are not to be made based on cost-

effectiveness alone, and the choice of treatment belongs to the patient. Without the ability to access all options, Lyme patients can progress quickly to the late or the chronic stages, become debilitated, and despite denial by some academics, can die from this bacterial infection, which can affect all systems of the body. Research gaps should not equal treatment gaps. Withholding all treatment is not an acceptable option.

The recommendation against treating sick patients due to the IDSA's claim of the "potential impact of the indiscriminate use of antibiotics on the development of antibiotic resistance in the community" has no basis in literature. In fact, if one were to read the guidelines authors' own conclusions in other publications, such as, "*B. burgdorferi* [Lyme disease bacterium] does not acquire resistance to antibiotics,"<sup>18</sup> it would confirm the fact the antibiotic resistance is not relevant in this situation and therefore, this statement should be retracted.

The IDSA recommends against antibiotic treatment due to the possibility of complications developing during treatment, such as septicemia associated with IV therapy. A 2004 study indicates that venous catheters (CVCs) are widely used and cause more than 250,000 bloodstream infections (BSIs) in hospitals each year in the United States.<sup>19</sup> Yet, IDSA is not publishing guidelines that deny hospital patients treatment because the medical procedures they may require have associated risks. Only Lyme patients are being denied based on the assumption there may be complications if IV therapy is required in some circumstances.

The IDSA recommends chronically ill Lyme patients receive no treatment other than palliative care. They fail to mention there is no scientific evidence to support that recommendation. Treatment options should be left open until there is conclusive evidence regarding the cause of the patient symptoms, be it active infection or an identifiable post-infectious cascade, or a combination of both scenarios, which seems to be the direction some current research is highlighting.

Until such time science provides a gold standard test for Lyme that can detect more than 25-50% of the people who are infected, and one that can conclusively prove spirochetes are eradicated with a specific treatment protocol, no options should be excluded.

For all of the reasons discussed in this challenge, the entire "not recommended" section should be removed. Clinical judgment and patient choice should be emphasized throughout the Guidelines.

### **III. This section challenges the IDSA Guidelines disclaimer, which states:**

*These guidelines were developed and issued on behalf of the Infectious Diseases Society of America. It is important to realize that guidelines cannot always account for individual variation among patients. They are not intended to supplant physician judgment with respect to particular patients or special clinical situations. The Infectious Diseases Society of America considers adherence to these guidelines to be voluntary, with the ultimate determination regarding their application to be made by the physician in the light of each patient's individual circumstances. [pg. 1089]*

If it were the authors' intent that the Guidelines not be mandatory or not be perceived as mandatory, they would have included provisions for clinical judgment by the treating physician. Instead, physicians are instructed to diagnose and treat using outdated and questionable standards based on surveillance criteria, including the physician's observation of a rash and the utilization of tests proven to be sub-standard, at best.

The IDSA Guidelines have such a dominating presence in the medical community that in spite of the disclaimer, patients are limited in choice. There are only a few physicians who will brave stepping out of the IDSA box to treat the most ill patients. In fact, doctors and insurance companies alike have zealously pursued physicians who have not followed the "voluntary" IDSA Guidelines. For example, Lawrence Zemel, a professor of pediatrics at the University of Connecticut and Chief of the Rheumatology Division

at the Connecticut Children's Medical Center admits in a letter that he would be "happy"<sup>20</sup> to assist with the investigation and prosecution of a fellow colleague whom he suspects treated chronically ill patients outside the recommendations of the surveillance criteria.

In the letter to the Connecticut Department of Public Health Hearing Office, Zemel states that a fellow Connecticut physician "seems to be over diagnosing Lyme disease, ... is grossly over treating Lyme disease," as well as, "may be profiteering from unnecessary therapies." Zemel also offers not only his advice, but also offers to personally become involved with the Connecticut Department of Public Health to entrap an unsuspecting physician in the act of treating patients who failed to regain their health after following the IDSA Guidelines' protocol. The IDSA disclaimer may state the Guidelines are voluntary, but actions speak louder than words. Zemel stated:

*Have one of your staff investigators pose as a patient, complete with vague symptoms and negative Lyme results but insisting that she have Lyme disease. I would be happy to rehearse that investigator...Examine records of patients treated over the past few years for Lyme disease to see if they truly fulfill established criteria for Lyme disease." Final paragraph: "Good luck with your investigation. I would be happy to assist in any way possible."<sup>20</sup>*

Clearly, the criteria promoted by the Guidelines are not truly voluntary when those who follow the IDSA Guidelines are easily able to disregard the weak disclaimer and persuade licensing boards to force doctors who diagnose and treat Lyme disease clinically to comply with the Guidelines. Even the Centers for Disease Control and Prevention (CDC) maintains a long-standing policy which touts clinical diagnosis for Lyme disease.

Medical guidelines prepared by sub-specialty groups, despite disclaimers, are considered mandatory on many levels, have become "de facto" law and are promoted to the detriment of patients by various health care related for-profit industries. The insurance industry vigorously endorses adherence to medical guidelines, providing incentives to those who follow suit, with no regard to patient's welfare or the individual clinical picture.

*The [Insurance] Department and the Board [Compensation Insurance Rating Board-NYCIRB] ...encourage Insurers to institute voluntary programs that reinforce the use of the treatment guidelines. For example, Insurers could institute an expedited bill payment program for those Health Care Providers that have a track record of successfully using the treatment guidelines. An expedited bill payment program would add a further incentive for Health Care Providers to use the treatment guidelines....<sup>21</sup>*

Cost-reduction concepts are not only strongly encouraged by the insurance industry, they are mirrored at many levels of the appeals' process. For example, those who fail to train medical reviewers on the benefits of strict adherence to guidelines as a means of a cost-saving measure are penalized. According to a NY State Medical Treatment Guidelines Education Plan:

*To ensure that Medical Reviewers attend the educational programs and successfully demonstrate their ability to utilize the treatment guidelines. The Department and the Board should, based on regulation or statute, assess penalties against Insurers for failing to certify that their Medical Reviewers attended and successfully completed the educational programs.<sup>21</sup>*

Requiring health care industries to reduce costs by adhering to medical guidelines is detrimental to patients and is an inhumane practice promoted and sanctioned at the highest levels of state government.

*The Governor's letter directs the Department to provide the Board with a set of medical treatment guidelines to limit unproven, unnecessary, or inappropriate treatment. The combined effect of the networks, fee schedules and medical treatment guidelines will*

*result in significant system savings and improved system quality.*<sup>22</sup>

This egregious policy is especially distasteful and dangerous when the foundation on which the recommendations are based is unstable, unproven, contested, biased or corrupted with conflicts of interest, and the cost of doing business negatively affects the lives of our citizens, especially children, who according to CDC, are at the highest risk of acquiring the disease. Although short-term savings may accrue to insurers, adherence to the Guidelines will spike long-term costs due to increases in long-term care, disability and direct and indirect health care costs.

The superficial savings generated by the IDSA's ineffective Guidelines may appear to show a financial benefit short term for private agencies and increase profits for individual patent holders, but upon closer examination, they transfer the burden of caring for a nation of chronically ill patients to state and local governments. The IDSA, a professional medical society, has members competing for millions of dollars in research funding, and is set up to promote the interests of its members, interests not related to patient autonomy, or in this case, even to clinical judgment. Interests include expanding the Society's sphere of influence, and medical societies as powerful as the IDSA have an obligation not to abuse their power and not to suppress competitive treatment approaches, particularly when these are the only treatment modalities.

Jurisdictions are willing to support superficial guidelines on the premise of saving dollars, with no input from patients or health care providers who suffer from this practice.

*The State of California adopted treatment guidelines in 2004 and it is estimated that these guidelines have produced medical savings of over 45%. New York is unlikely to achieve savings of this magnitude for a variety of reasons, but should nonetheless see a substantial reduction in medical costs once medical treatment guidelines are in place.*<sup>22</sup>

In states where the IDSA Guidelines are strongly promoted by its members, some local pharmacists have refused to fill doctor-prescribed antimicrobials for Lyme disease patients, citing the "voluntary" IDSA Guidelines as their basis. Sometimes this extreme practice causes a patient's condition to decline because symptoms may be exacerbated without treatment. Sick patients are now left to find a pharmacy that will fill the prescription, creating undue anxiety.

The States of California, Maryland, Delaware, New Jersey, Minnesota, Michigan, Iowa, Kansas, Missouri, Pennsylvania, New York, North Carolina, Texas, Wisconsin, Massachusetts, Rhode Island, Connecticut and others actively sought legislative assistance or legal remedies to protect physicians treating Lyme disease patients outside the confines of the IDSA Guidelines or to obtain insurance coverage for Lyme patients refused services based on the "voluntary" IDSA Guidelines. The need for citizens to request assistance from multiple state and federal lawmakers to counter the negative effects IDSA Guidelines have on residents of any state indicates the IDSA Guidelines, even with the disclaimer, are extremely disruptive, rather than productive, to both clinicians and patients.

For all of the reasons discussed in this challenge, the disclaimer should be revised to address the following issues and concerns.

If guidelines are to be offered by the IDSA, they must include strong wording indicating that they are NOT to be used by medical providers to deny treatment or by insurance carriers to deny reimbursement. The Society should take a position that it will not encourage its members to testify against other physicians for non-adherence to its guidelines nor permit members to testify on the Society's behalf against other physicians or patients. The disclaimer should include a statement that the Guidelines were drafted by a Society that supports the theories that continuing illness after treatment is not a significant problem and that it believes "chronic Lyme" does not exist.

Not only should the Guidelines' disclaimer state clinical diagnosis is appropriate, but also the Guidelines themselves should contain that language. Additionally, the disclaimer needs to include that the patient's

health care provider, in agreement with the patient, must be able to freely choose treatment protocols. All patients must be provided with a written copy stating their options, the risks and benefits of all protocols and must sign a consent form stating they were provided that information and agree to the treatment plan. The section is to clearly state that the patient is ultimately responsible for deciding their own standard of care from all available protocols.

If the IDSA Lyme disease Guidelines are reissued after the pending 2009 review, a clear statement should be made that the Guidelines have been reissued after a legal settlement was reached with the Attorney General of Connecticut, who initiated an investigation into the original 2006 Guidelines development process, which found exclusionary conduct and undisclosed conflicts of interest in the original Guidelines' panel.

#### **IV. This section states the summary and conclusion**

Treatment cannot be withheld from patients for Lyme disease when the science remains unsettled. The undersigned groups object to the Guidelines based on the above issues and on the basis of other medical issues that clinicians treating chronic Lyme who are the most knowledgeable and best qualified to address will be presenting to this review board.

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