

Here is a summary of the presentations given at the IDSA/ILADS review of Lyme practice guidelines

The Evidence Is In: Chronic Lyme Disease Does Exist

Lucy Barnes, July 2009

Not since Chuck Berry sang those famous words, "Roll Over Beethoven", introducing rock and roll to a world previously dominated by classical music, has there been such an upset in the status quo. As lights went out following the presentation in Washington, DC, it was clear that an elite few in the medical world had just been rocked from their ivory towers and rolled over by doctors, researchers and patients presenting evidence that chronic Lyme disease does, indeed, exist. It's a well-documented fact; people can remain ill with Lyme disease even after what was thought to be "adequate treatment". The overwhelming scientific evidence proving this well-known fact was finally put on display for the whole world to see on July 30, 2009, thanks to the continuing efforts of volunteers who are fighting to help their families and others who suffer.

Background- On May 1, 2008, an official press release announced that the Infectious Diseases Society of America (IDSA) was found guilty of multiple wrong-doings in regards to the development of its Lyme disease treatment guidelines. As part of a settlement agreement with the CT Attorney General Richard Blumenthal, the organization was required to host a public hearing which would shine a spot light on all of the available scientific research rather than just the limited, biased view point the IDSA has promoted over the years.

To satisfy the mandates set forth in the agreement, the IDSA, after much delay, finally got around to hosting the hearing on July 30, 2009. As the clock ticked away, and everyone waited anxiously for more than a year for the IDSA to organize the event, approximately 350,000 more innocent people were exposed to Lyme disease. Most will not be adequately treated and may become ill with a disease the IDSA claims, even in letters to Congress, does not exist.

Fortunately, the illumination of the previously buried facts at the hearing finally put to rest the IDSA's theory that chronically ill Lyme patients cannot be sick from persistent infection after receiving a minimal dose of antibiotics. We all know now that is absolutely false and indeed, they can.

Proclamation for a Perfect World- From this day forward, patients shall be treated adequately for their Lyme infections and not be given just a pat on the head and a prescription for antidepressants, as they are gently shoved out the door. Health care professionals should no longer worry about being subjected to punitive actions for following their oath to "first, do no harm" when treating chronically ill Lyme disease patients.

This simple Proclamation, should it be put in effect, would save lives and give patients back the right to choose their treatment from available options. It would also allow doctors to use clinical judgment when making important health care decisions that can affect their patients lives.

For now, those suffering from chronic Lyme disease must continue waiting to see if the IDSA Review Panel does the job they were charged with and if they will make sound recommendations based on all the evidence presented in order to change a long-standing diagnostic and treatment protocol that is not working.

The Evidence- Written testimony challenging the IDSA Guidelines was submitted by 150 individuals and organizations to the IDSA Review Panel prior to their April 2009 deadline. One prominent organization's Working Group, the International Lyme and Associated Diseases Society (ILADS), under the leadership of Lorraine Johnson, submitted close to two thousand pages of scientific evidence, analysis and research studies refuting the recommendations in the IDSA's Guidelines. The all volunteer, non-profit Lyme Disease Association, representing 35 support groups in 23 states and countless individuals across the country, also submitted multiple challenges.

By Invitation Only- Once applications had been submitted to the IDSA Review Panel, a select few were invited to speak at the open hearing. Technically, it wasn't an "open" hearing in the true sense of the word. Patients and the general public, the ones suffering and most concerned, were not allowed to attend. Instead, they were told to watch the event, which was streamed live from the hearing location, on their home computers. According to the IDSA, the final presentations will be posted on the IDSA website (idsasociety.org) and archived for one year.

The Select Few- Two volunteer patient advocates, Lorraine Johnson, JD MBA, and Tina Garcia, were among eighteen speakers selected to present testimony to the Review Panel.

Lorraine Johnson, Chief Executive Officer for the California Lyme Disease Association (CALDA) and a member of the Professional Advisory Boards for both the national Lyme Disease Association (LDA) and the International Lyme and Associated Diseases Society (ILADS), has extensively published on topics such as medical ethics and Lyme disease. Johnson, who has been active for years in creating positive changes in the Lyme community, stated the IDSA Guidelines extend, "well beyond what is known in science" and "gaps in research should not prevent treatment of patients".

According to Johnson, the Guidelines may be promoted as voluntary by the IDSA, but they are often used to deny patients' treatment options and restrict clinicians from using clinical judgment. In addition, Johnson reported, the Guidelines are treated as mandatory by health and disability insurers, medical boards, hospitals, school systems and even by child custody agencies.

Johnson shared results of the 2009 CALDA Patient Survey (3,000 Lyme patients responded), which indicated 73% of the patients had a delayed diagnosis of more than one year. Nearly half the patients (49%) had to see 7 or more doctors before being properly diagnosed. She noted 58% of patients remained ill after being treated by IDSA protocols and 90% found it difficult to find a treating physician.

In addition, more than 60% of chronically ill patients reported improvement with additional courses of antibiotics. Johnson reported 53% had to travel out of state to obtain a proper diagnosis or treatment. Due to their illness, an astounding 88% had to cut down on normal activities, such as work or school, and 50% were unable to attend at all. The survey indicated 41% of the patients responding could not afford to purchase the medications they needed. Her excellent presentation accomplished its goal of representing patient's circumstances accurately, with the added bonus of bringing an array of scientific facts to the Panel that had not been brought to light previously.

Tina Garcia, founder of the Lyme Education Awareness Program (L.E.A.P) in Arizona, used her personal story as an example of how devastating the recommendations in the IDSA Guidelines can be for patients. She told the audience that it took doctors six years to properly diagnose and

treat her illness. In the meantime, she was forced to live with excruciating pain and eventually suffered from dementia, lung infections and paralysis. She lost the ability to drive, to do housework and even to fix herself a meal. Garcia also lost her job and her home before she was treated with a combination of long term antibiotics. The additional treatment, which is not recommended by the IDSA Guidelines, restored much of her functioning and allowed her to be at the hearing to testify. Her tragic experience is similar to many who have been denied adequate treatment. As patients watched the live broadcast on the Internet, they were pleased she was able to present their collective message with such grace, accuracy and strong conviction.

The Medical Experts-

Dan Cameron, MD MPH, who runs an active clinical practice in Mt. Kisco, NY, and serves as President of the International Lyme and Associated Disease Society (ILADS), made it clear to the Review Panel, “patients are being denied treatment based on the IDSA guidelines.” Dr. Cameron headed the sixteen member ILADS Guidelines Working Group, which published evidence-based guidelines in 2004 for the management of Lyme and tick-borne diseases. The ILADS Guidelines provide practitioners with flexible treatment options designed to treat all individuals with Lyme disease, including those with persistent, recurrent and relapsing symptoms of *B. burgdorferi* [Lyme] infection, something the IDSA Guidelines recommend against. Cameron presented data indicating 34-62% of patients entering clinical trials had continuing Lyme symptoms after their initial IDSA recommended treatment failed and they were still sick an average of 4.7 to 9 years later.

Cameron’s well organized and powerful presentation covered a number of important points, including the cost to society of improperly diagnosed and treated Lyme disease. According to conservative studies, chronic Lyme disease has an average cost of \$16,199.00 per year per patient, and an annual economic impact (CDC 10-fold increase) in the US of over \$2 billion.

Benjamin Luft, MD from the State University of New York, Stony Brook, has published extensively on Lyme disease, testing methods, effective and non-effective treatment, and related tick borne disease topics since the late 1980’s. His early studies confirmed the fact that even though *B. burgdorferi* [Lyme] may be sensitive to relatively small concentrations of certain antibiotics such as penicillin and ceftriaxone, the organism is killed slowly, indicating prolonged blood levels of these drugs may be necessary in order to ensure a cure. Research by Luft and others were able to prove two decades ago what the IDSA continues to refuse to acknowledge and what patients and clinicians are experiencing worldwide; chronic Lyme does exist.

Dr. Luft also touched on many critical topics such as *Borrelia* persistence, patient responses, undefined characteristics and treatment success and failures. He described the early and late phases of the disease state, along with a section describing the objective vs. subjective symptoms and how they responded to various treatments. He explained the significance of the mouse studies and how they correlated with persistence of Lyme in humans. Dr. Luft’s contributions to the scientific community have been invaluable in providing front-line clinicians accurate data.

Allison Delong, MS, from Brown University, Center for Statistical Sciences, Department of Public Health, Division of Biology and Medicine presented two challenges to the Guidelines. Delong concluded the clinical trials relied on by the IDSA to deny the existence of chronic Lyme disease, and which are the foundation of their continuing argument to recommend against treating chronically ill patients, have not, as the IDSA claims, proven re-treatment to be ineffective. In fact, trials indicate the benefits of re-treatment among individuals with worsening

fatigue, worsening physical functioning, and those who are in more severe pain. Her conclusions, presented by way of a very impressive and detailed statistical analysis, determined that before IDSA Guideline authors recommend against treatment of patients, more research is needed to support their theories.

David Volkman, a distinguished Ph.D., M.D., Emeritus Professor of Medicine and Pediatrics at SUNY, Stony Brook who is Board certified in Immunology, Diagnostic Laboratory Immunology, and Internal Medicine spoke on numerous relevant issues. As past Senior Investigator at the National Institute of Allergy and Infectious Diseases (NIAID), he was among the first to isolate and clone human antigen-specific T lymphocytes in retroviral investigations. Dr. Volkman has been involved in both clinical and bench research on Lyme disease since 1985. His presentation on persistent/chronic *Borrelia* infection, serology-seronegative infection and the IDSA Guidelines flawed prophylaxis recommendation were all supported by solid scientific evidence. The true meaning and use for the CDC's "surveillance definition" of Lyme disease, along with the optimal diagnostic and therapeutic modalities were covered in his outstanding presentation. Volkman also addressed the 'conflicts of interest policy' in his written testimony, in which he stated, "...committee members should be free of conflicts that may color their treatment recommendations."

Sam Donta, MD, Infectious Diseases Specialist and Professor of Medicine has published multiple studies on chronic Lyme disease and its treatment over the years. His hands-on experience with treating thousands of Lyme patients has been an invaluable tool for himself and those in the position of having to deal with the growing number of chronically ill patients. Dr. Donta kicked off the afternoon session addressing a list of 'guideline issues'. He spoke to the current problems facing clinicians, what should be done with the post treatment issues and about treatment specifics using Chronic Fatigue Syndrome (CFS), Gulf War Syndrome and Fibromyalgia as models to compare the varied symptoms. He asked revisions be made to the Guidelines and felt more funding was needed for further studies.

Until there are more specific markers of disease activity, Donta stated, we should acknowledge that there are patients who are affected by Lyme disease to varying degrees that range from mildly symptomatic to severely debilitating and who depend on the members of the Infectious Diseases Society of America for diagnosis and treatment. Donta feels we should all move forward with plans to better understand the nature of the illness and develop superior ways to diagnose and treat the disease. His exceptional presentation, based on some of his work in the clinical setting, indicated the IDSA Guidelines protocols fail to diagnose many who are infected and leave many more without adequate treatment for their ongoing infections.

Brian Fallon, MD, MPH, from the Columbia University Medical Center, NY, an Associate Professor of Clinical Psychiatry at the Columbia University College of Physicians and Surgeons, is the Director of the Lyme and Tick-borne Diseases Research Center. Dr. Fallon's focus has been on neuropsychiatry as it relates to Lyme and other diseases of the brain. He has published over 100 peer-reviewed articles, papers, and book chapters and has served as a reviewer for many journals.

Fallon, stating clearly that he was not a member of the IDSA or ILADS, addressed the IDSA Guidelines statement that claimed antibiotic therapy has not proven useful and is not recommended for patients with chronic subjective Lyme symptoms. Fallon described the results of his extensive research study as it related to cognition, pain, fatigue and adverse events. He

then looked more closely at other studies and their outcome measures, including unmasking, and provided a revised statistical analysis. He ended his brilliant scientific presentation with suggestions to reword several areas of the Guidelines.

Kenneth Liegner, MD, Internal and Critical Care Medicine, is a distinguished member of ILADS with an active clinical practice specializing in Lyme Borreliosis & Related Disorders, in Armonk, NY. Dr. Liegner began by presenting some background information describing his research and clinical experiences, followed by the simple, yet compelling statement, “Walk a mile in my shoes.”

Dr. Liegner, a highly regarded expert in his field, then proceeded to escort the audience on a virtual tour through his well-documented studies and clinical findings, proving beyond a shadow of a doubt the persistence of and serious consequences associated with chronic Lyme disease. Liegner demonstrated evidence of live spirochetes in patients (including biopsy/autopsy photographs) and the subsequent damage caused to organs, including the brain, when patients were not given adequate treatment. The presence of Lyme spirochetes had been confirmed in studies by using various tests from a number of labs and by numerous related clinical findings.

Dr. Liegner presented additional case histories showing treatment improvement in patients and then relapses when treatment was discontinued. Some of these patients (including children) eventually died from chronic persistent Lyme disease and associated complications, including Martin Eisenhardt, whose wife Mary Lou presented testimony to the NY General Assembly in 2001 in an attempt to draw more attention to the severity of Lyme disease.

Dr. Liegner also shared a 2001 video clip of Vicki Logan in the end stages of her battle with chronic Lyme disease. She was thanking Dr. Liegner for his dedication and caring, two qualities for which he is known for throughout the patient community, and also for giving her a better quality life when no one else would. She stated just prior to her death, “I hope [the story of] what happened to me will benefit others who wind up in the same situation.”

Steven Phillips, MD, Internal Medicine, from Wilton, CT, is the past President of ILADS and a member of the ILADS Guidelines Working Group. He has an active practice in a highly endemic area of the country and has testified as an expert witness in Lyme related hearings across the country. Dr. Phillips presented study after study documenting persistence of Lyme disease after treatment that were not cited by the IDSA during the formulation of their Guidelines. His discussion of independent peer-reviewed literature (both animal and human studies) included some studies by the IDSA guideline authors themselves, indicating persistence of spirochetes and continuing symptoms after treatment and the need for additional treatment.

Phillips concluded his powerful scientific presentation with multiple studies demonstrating re-treatment benefits, leaving no doubt about the need for additional treatment for some patients, something he has demonstrated as beneficial in his own clinical practice. He also proposed new wording for the IDSA Guidelines that reflect the evidence available from 25 studies proving the existence of chronic Lyme disease.

Raphael Stricker, MD, published author and past President of ILADS, from San Francisco, CA, addressed some of the most basic common and damaging myths perpetuated by the IDSA Guidelines. His extensive documentation successfully put to rest several IDSA flawed theories, including some of the most egregious and harmful.

Dr. Stricker provided scientific and clinical studies proving Lyme disease is not “easy to

diagnose” and “easy to treat” and that persistent infection following a short course of antibiotic therapy is not “highly implausible”, which are the IDSA’s unsupported theories that have been responsible for destroying many lives. He addressed a common scare tactic often used by the IDSA concerning the alleged and exaggerated “danger” of prolonged antibiotic therapy for chronically ill patients. Stricker spoke on the limitations of the two-tiered testing system, stealth pathology and treatment considerations relating to early and late stage Lyme disease. Charts, included in his written testimony, brought to light some of the systemic errors and misleading statements in the IDSA Guidelines, including exaggeration, circular reasoning, small sample sizes, data selection exclusion and the author’s reliance on their own so-called expert opinion to the exclusion of all additional evidence.

The IDSA Supporters- Those invited to the hearing in support of the Guidelines (many were the original IDSA Guideline authors) have claimed for years they do not know what causes continuing Lyme symptoms in Lyme patients after their recommended treatment fails, however, they feel it is not caused by active infection and there is no such thing as chronic Lyme disease.

Holding tight to their theory has not helped patients who suffer, but it does please the insurance industry and partially shields the IDSA authors and others from the back lash that would be felt if they were to waver from their floundering and unsubstantiated position.

Some IDSA’s theories presented to explain why so many people remain ill and become disabled or die after receiving their recommended treatment includes:

- a.) People in the community (advocacy groups, media publicity, sympathetic physicians and prominent individuals in society) are able to convince patients they are still sick when they really aren’t (functional somatic syndrome);
- b.) Stress can be the cause of remaining physical symptoms after being bitten by ticks;
- c.) Secondary gain (patient has hidden motive for wanting to remain ill);
- d.) Prior undiagnosed psychiatric disorders (some from as far back as childhood) that don’t appear in individuals until after they have a tick bite;
- e.) Even while living in endemic areas, having a tick bite, EM rash, positive lab work and showing improvement on antibiotic therapy- many of the IDSA supporters claim, without examining patients, that they never actually had Lyme disease in the first place so they can’t possibly have chronic Lyme disease;
- f.) They feel patients experience improvement due to the placebo effect, so those with continuing symptoms are just easily influenced into believing they are still sick when they aren’t;
- g.) If tests don’t support the IDSA’s position, they are being labeled as producing too many false-positives by the IDSA and therefore, the Lyme symptoms remaining must be discounted because the lab tests are inaccurate and the patient can’t have Lyme disease;
- h.) Patients that are well-documented, even those house-bound or in the hospital, must have had another tick bite at some point that is causing the continuing symptoms;
- i.) A pre-infection emotional state that was never detected or diagnosed is suddenly discovered after getting Lyme disease;
- j.) The “no one else had these symptoms before you did, so you can’t have Lyme” theory;
- k.) IDSA feels other doctors are not as versed as they happen to be and are part of the problem because they are telling patients they have Lyme disease and they treat them for

it when they don't actually have it;

- l.) Patients often decide on their own they have chronic Lyme disease because they don't like the stigma attached to having unexplained chronic symptoms after having a tick bite and contracting Lyme disease;
- m.) There is not enough research being done on how to explain to patients that they aren't suffering from Lyme (when they really are) and more research (\$\$) is needed by the IDSA so they can figure out how to explain that to patients so they believe what they are being told;
- n.) Patients have symptoms but they aren't the same symptoms the IDSA authors have listed in their Guidelines, so it can't be Lyme disease;
- o.) You are a female or you are getting older and the symptoms you have just became noticeable to you since you got Lyme disease;
- p.) Your symptoms aren't bad enough to be Lyme disease, or the opposite, the symptoms are too severe to be Lyme disease;
- q.) People in the general population can have those symptoms, so they can't be Lyme related;
- r.) Doctors treating children in endemic areas don't know the difference between mosquito bites and tick bites and falsely label patients who are experiencing Lyme symptoms with having Lyme;
- s.) Anxiety about the illness, derived from reading information on the Internet, causes patients to remain ill and think they have chronic Lyme disease;
- t.) The authoritative "you are not sick because I said so" theory;
- u.) Patients develop an unexplained personality disorder, or fibromyalgia, or depression, but only after having a bite from a tick infected with Lyme disease, so it is a coincidence and is unrelated.

The IDSA supporters also state there are no studies proving chronic Lyme disease exists, which as we know is completely false. Some believe if patients are to be diagnosed with the condition, they must first have studies on chronic Lyme showing it exists before they can actually have chronic Lyme. This circular logic was actually reported by Phil Baker, who controlled the distribution of NIH Lyme research funding for years and who, after retiring, immediately started working with those supporting the IDSA theories, the same ones who received many lucrative Lyme research grants from the NIH.

One IDSA supporter, a pediatrician on Long Island, stated that the Guidelines should be changed to reflect the theory that ticks need to be attached for 60-72 hours before patients should be given the infamous, cost-effective, one pill of Doxycycline to 'cure' their Lyme disease, instead of the currently recommended tick attachment time of 36 hours. He cited potential problems surrounding the indiscriminate use of antibiotics as the reason to deny patients the one dose of an antibiotic and stated if it takes 60-72 hours to increase the risk of deer being infected from a tick bite in the wild (deer hide that resists briars and limbs), that it must be the same for children (soft skin tissue).

The Big Picture- Other than palliative care, the IDSA Guidelines have recommended against using any and all treatment options (from vitamins to different classes of antibiotics) for chronically ill Lyme patients. This dogma has been spread far and wide, negatively affecting patients across the globe.

The IDSA Guidelines have been responsible for the decline in patient's health and their advancement into the later, more difficult and costly to treat stages of Lyme disease. The Guidelines have also put a chain around the neck of professionals who desire to treat patients appropriately, but who refuse to do so due to the potential consequences experienced by those who have stepped out of the IDSA "box" to help the growing number of people who suffer.

The IDSA Guidelines Fate- The IDSA Review Panel (consisting mainly of IDSA members and supporters) will now consider the oral arguments, the mounds of written testimony and the overwhelming scientific evidence presented before making their recommendations on how to improve their highly contested Guidelines. They have the option to discard them, or, if they dare, continue to ignore the scientific evidence and make no changes. The option to keep them "as is" is not acceptable. Their decision is expected to be released by the end of the year.

Bottom Line- There has never been any convincing evidence presented for supporting the current recommendations in the IDSA Guidelines.

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