Newsletter Archive

Animal Studies Show Spirochete Persists After Lyme Treatment

A number of animal studies have shown that the Lyme spirochete has survived antibiotic Lyme treatment. A brief review of these studies can be found in the House Foreign Relations Committee testimony of Stephen Barthold, DVM, PhD, University of California, Davis.

See link: http://archives-republicans-foreignaffairs.house.gov/112/HHRG-112-FA16-WState-BartholdS-20120717.pdf

Congressman Chris Smith (NJ-4), was the Chair of the hearing, in which the Lyme Disease Association President also testified.

Click here for article on the hearing

Click here for Oral Testimony by LDA President, Pat Smith

Click here for Written Testimony by LDA President, Pat Smith

Click here for all LDA Testimonies, Speeches & Positions

registrations

test

Conference Registration

This is the conference registration.

Lyme Comm. Unites: Protect Patient Rights

UPDATE 5-6-15: **Click here for LDA/LDo Press release on IDSA guidelines process**
In a move designed to spotlight concerns about the Infectious Diseases Society of America (IDSA) guidelines' development process, groups in the Lyme community nationwide have come together to make their voices heard. The effort to date consists of three different letters which were signed on by multiple groups representing dozens of states across the U.S. and were then sent to the US House of Representatives Lyme Disease Caucus, the US House of Representatives Energy & Commerce Committee, and the IDSA itself, which requested input into its newly structured guidelines development process.

*2009 LDA file photo depicts Lyme leaders from across the U.S. at an LDA Affiliate Meeting in Maryland.**

Citing concerns about the lack of patient representation– a concept the Institute of Medicine (IOM) has endorsed for guidelines' development in general– and also the lack of clinicians in the trenches who are treating not only Lyme but the often concurrent tick-borne diseases seen in many patients, the groups have requested specific actions to be taken by each letter recipient.

Further actions may be forthcoming by the Lyme Community. As other actions occur, we will post them.

NOTE: The IDSA has just extended its Lyme Guidelines Process Comments until April 24th. Anyone who has not replied to the IDSA directly can go to their website and register their comments. Click here for IDSA website.

VIEW LETTERS RESULTING FROM LYME GROUP LETTERS

Click here for Letter from US House of Representatives Lyme Disease Caucus to the IDSA

VIEW LETTERS FROM THE LYME GROUPS

Click here for Letter to US House of Representatives Lyme Disease Caucus on the proposed new IDSA Guidelines process from 57 Groups

Click here for Letter to US House of Representatives Energy & Commerce Committee asking for a hearing on issues surrounding the IDSA Guidelines process from 57 Groups

Click here for LymeDisease.org and Lyme Disease Association Letter of Comments to IDSA Guidelines process from 67 Groups

Click here for LymeQuest Submission on behalf of 22 groups & 67 groups [#]

[#] NOTE: IDSA extended its filing time but would not permit LDA/LDo to submit additional comments with additional groups signed on. So LymeQuest submitted the additional comments to IDSA on behalf of all the groups, total of 89 (22 + 67).

VIEW LDo's PATIENT SURVEY RESULTS

Click here for LymeDisease.org's IDSA Guidelines Patient Survey Results

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VIEW LETTERS[+] FROM LDA/LDo TO IDSA PARTNER ORGANIZATIONS INVOLVED IN GUIDELINES' DEVELOPMENT PROCESS

Click here for AAFP President
Click here for AAN President
Click here for AAP President
Click here for ACR President
Click here for AMMI-CA President
Click here for CNS President
Click here for ESA President
Click here for ESCMID President
Click here for PIDS President
Click here for ACP President
Click here for IDSA President

[+]NOTE: Each mailing contained the cover letters shown above and copy of the two group submissions to IDSA.

VIEW LETTERS FROM OTHER COUNTRIES

Click here for comment letter to IDSA from the UK

Click here for comment letter to IDSA from Deutsche Borreliose Gesellschaft e.V. (German Society of Lyme Borreliosis)

VIEW HISTORY OF LYME GROUP ACTIONS AND IDSA PROJECT PLAN

Click here for history of Lyme Group actions

Click here for IDSA Project Plan: Guidelines for the Prevention, Diagnosis, and Treatment of Lyme Disease by the Infectious Diseases Society of America, the American Academy of Neurology, and the American College of Rheumatology (Note: By clicking this link, you will leave the LDA website and be on the IDSA website)

*The groups represented in photo above may or may not be signed on to one or more of the letters

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AG's Investigation: Flawed Lyme Guidelines

May 1, 2008, Atty. Gen. Richard Blumenthal today announced that his antitrust investigation has uncovered serious flaws in the Iinfectious Diseases Society of America's (IDSA) process for writing it's 2006 Lyme disease guidelines and the IDSA has agreed to reassess them what the assess assistance of an outside arbiter.

Click here for press release.

IDSA Guidelines Panel Decision 4-22-10

STATEMENT OF THE NATIONAL NON PROFIT LYME DISEASE ASSOCIATION, INC. ON THE IDSA GUIDELINES PANEL DECISION 4-22-10

We are not surprised by the conclusions reached by the IDSA review panel but are certainly disappointed. It is certainly suspect that in considering a disease with numbers on the rise (250% increase from 1993-2008), one which is so highly controversial and with unsettled and "undone" science, that the panel would vote "lockstep" (8-0) except for one dissenting vote to uphold all of the original recommendations. The national Lyme disease Association (LDA) and its 35 associated organizations publicly expressed their concerns about bias in the panel selection throughout the process, including the selection of the chair, who is a former president of the IDSA, and the pronounced lack of community treating physicians.

We note with interest that IDSA separated out the only real area of contention among its panel, a 4-4 vote, and because it did not fit the required voting process, IDSA alleged that this was NOT a recommendation they needed to review, but only a statement in their Guidelines executive summary that the Attorney General asked them to review. It is a crucial statement on testing, the essence of which appears throughout the guidelines and is most often used by doctors and insurers to prevent patients receiving diagnosis and treatment. The panel's apparently improper first vote on this issue was

uncovered by a FOIA, (freedom of information act) on the panel voting process. The vote was 4-4, not meeting the supermajority required to pass it, so they characterized the testing issue as a non recommendation, which they claim, does not require a supermajority.

The IDSA's empty "political" rhetoric, adherence to these guidelines is only voluntary, certainly we support clinical judgment, is belied by their statement "Based on current research for patients with non specific symptoms that may be seen in may illnesses…it would be a deviation from "best fit" [association between illness and likely diagnosis established by medical evidence] to attribute such symptoms to Lyme disease in the absence of more specific clinical features or laboratory results…All Lyme disease clinical findings including erythema migrans can be seen in diseases other than Lyme…It would thus be clinically imprudent to make this diagnosis of Lyme disease using these non specific findings alone."

The IDSA's position at the onset of this investigation and settlement process has been that the Attorney General of Connecticut's investigation was interfering in medical practice rather than the guidelines formation process. To apply logic to their way of thinking, any changes in the Guidelines would admit wrongdoing on their part and set a precedent for future government actions in creation and development of their many guidelines. So instead, the IDSA panel upheld all the recommendations, failed to provide after each recommendation the specific references that were considered and used to justify upholding each recommendation (the resources are lumped at the end of the paper). We consider it striking that they provides lists of items that need to be considered in the "next" upgrade of their guidelines, thereby relieving themselves of responsibility of acknowledging that changes are needed to these current guidelines.

The IDSA admits to receiving a large volume of case reports & case series that attested to “PERCEIVED” clinical improvement with long term treatment. One would assume that in most cases, doctors were perceiving the improvement in patients, and thus their years of clinical judgment would carry significant weight. Yet the IDSA excluded all of that evidence as not justified. IDSA also discounted the controlled studies which did indicate improvement after long term antibiotics

Patients cannot wait for the entrenched medical establishment to address the problems with this disease. They need treatment and relief now. The ratification of these guidelines by IDSA becomes another nail in the coffin for those afflicted with Lyme disease. We call upon the Attorney General of Connecticut to examine the entire process to determine compliance with his stated requirements and to take further action should grounds be found to do so.

Pat Smith Presidentwww.LymeDiseaseAssociation.org

Analysis: Why Klempner Study is Not Useful to Rule Out Benefits of Long-Term Treatment

Analysis: Why Klempner Study is Not Useful to Rule Out Benefits of Long-Term Treatment
Allison DeLong, Brown University

I. The clinical trial by Klempner et al. cannot be used to assess the effectiveness of re-treatment of Lyme disease in

patients with continued symptoms following standard treatment

A. The trial was poorly designed

1. The sample sizes were too small to detect clinically meaningful treatment effects (the study was underpowered).
   a. Determined by examining the ability of Klempner's study to detect levels of improvement that were found to be of value in studies of other chronic illnesses.
2. The (Klempner) presumed treatment effect for sample size calculation was so large for one of the two primary outcomes (mental score) that Lyme patients would have been forced to perform better than the general U.S. population at follow-up.
   a. E.g.– The trial was terminated early because it was unlikely that the presumed treatment effects would be statistically significant.
      1) Since people were not going to achieve Klempner's unreasonable requirement for improvement (see #2), then this poorly designed trial should have been terminated.

3. Lack of statistical significance cannot be used to infer ineffectiveness in a poorly designed study. This is especially true here since Klempner's confidence intervals for the treatment effects contain clinically meaningful values.
   a. Because meaningful values are in the confidence intervals, you can't say treatment is ineffective.

B. The trial data were poorly analyzed (summarized rather than analyzed)

1. The statistical method used was less likely to obtain a statistically significant result than recommended methods for analyzing clinical trials

(e.g. omitted ½ the data, categorized the outcomes leading to loss of information).

a. 30 day, 90 day measures of outcome were not included in the analysis

b. If a longitudinal analysis of uncategorized data was done (all data included), it would have increased the ability to detect a significant treatment effect.

2. Klempner's treatment effects cannot be interpreted for clinical meaning. Patients with Lyme have symptoms that wax and wane. For example, patients classified as "improved" could have unchanged health status, patients classified as "unchanged" could have improved.

a. They categorized people rather than examining individual scores– it is unknown how treatment affected the mean outcomes in the placebo vs. antibiotic groups.

3. The findings are likely biased (i.e. wrong) because the analysis didn't adjust for baseline, and baseline scores differed by arm, and there was an inadequate presentation and analysis of participants lost to follow-up. Klempner does not say how many were lost to follow-up, and they were simply placed in a "worsened" category.

Allison DeLong, MS Biostatistician Brown University Center for Statistical Sciences Providence, RI, provided an in-depth analysis of the Klempner study at the IDSA hearings in Washington, DC on July 30, 2009. A video of that presentation can be found on www.IDSociety.org. The Lyme Disease Association thanks Ms. Delong for working with LDA to provide this shortened simplified analysis.

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2008 Insights Into the Crisis, Key Players and the Future:

Note: Videos can be opened with Windows Media Player. Due to the age of the files, we are not sure that RealPlayer can still open the videos.

NEW VIDEO AVAILABLE!
Footage from the Bergen Community College Event Held Thursday, May 29, 2008
View the videos and read about the event and speakers in the program.

Program: Lyme Disease Forum
Click here to access the printable program from this event.

Part 1: Lyme Disease Forum – Opening Remarks & Personal Insights
From Pat Smith, President, Lyme Disease Assoc., Moderator, and Pamela Weintraub, Author of "CURE UNKNOWN: Inside the Lyme Epidemic." © 2008 Lyme Disease Association, Inc.
View with RealPlayer or Windows Media Player

Part 2: Lyme Disease Forum – Discussion
Joseph J. Burrascano, Jr., MD & Attoney Elliott B. Pollack. © 2008 Lyme Disease Association, Inc.
View with RealPlayer or Windows Media Player.

Part 3: Lyme Disease Forum – Interactive Panel Presentation
© 2008 Lyme Disease Association, Inc.
View with RealPlayer or Windows Media Player

Part 4: Lyme Disease Forum – Questions & Answers with Audience
© 2008 Lyme Disease Association, Inc.
View with RealPlayer or Windows Media Player.

Lyme Organizations: New IDSA Guidelines Panel, Unbalanced & Biased

Lyme Organizations: New IDSA Guidelines Panel, Unbalanced & Biased

Congressman and Patient Groups Voice Concerns

Greenwich, CT, January 28, 2009 – Patient groups voiced concern and disappointment about the new Infectious Diseases Society of America (IDSA) Lyme disease guidelines' panel, which excludes physicians who treat patients with chronic Lyme disease. Last May, the Connecticut Attorney General found the IDSA Lyme disease treatment guidelines' panel had conflicts of interest, engaged in exclusionary conduct, and suppressed scientific evidence. The investigation resulted in a settlement forcing the IDSA to reconstitute a balanced panel free of conflicts of interest under the oversight of an ombudsman to monitor conflicts of interest. No input from patients or treating physicians was permitted in selection.

"This situation is déja vu all over again," said national Lyme Disease Association president Pat Smith about the newly created guidelines' panel. "All Lyme disease treating physicians who applied for a seat were denied, based on having a "conflict" if they made over $10,000 treating Lyme disease. They have confused helping patients get better with 'real' competing conflicts such as interests in testing and vaccines, and relationships with insurers—a profile found in the original panel. Physicians who treat understand what makes patients well."

Attorney Lorraine Johnson of the California Lyme Disease Association points out "The problem is that guidelines conclusions generally reflect panel composition. That is why it is critical that a panel be balanced and include different points of view. Excluding the point of view of physicians who treat chronic Lyme disease makes no sense and biases this panel."

The current IDSA guidelines recommend against treating Lyme disease more than a few weeks, against using specific types of antibiotics, against alternative treatments and even supplements. The guidelines are so restrictive that physicians are not permitted to use clinical judgment in diagnosing or treating Lyme patients. The new panel will review controversial recommendations in the guidelines to determine whether

there is sufficient scientific support for the recommendation.

According to Diane Blanchard, Co-President of Time for Lyme in Connecticut, “Treating physicians must be allowed to make clinical judgments about their patients’ conditions due to the complexity of tick-borne diseases, and there are a number of physicians out there nationwide who are knowledgeable enough to recognize the effects of coinfections on diagnosis and treatment. Some have been treating for over 10-20 years and have tens of thousands of hours of experience seeing patients; yet, these physicians were not selected.”

US Congressman Christopher Smith (NJ) co-chair of the House Lyme Disease Caucus, told the patient groups “The Settlement Agreement of the IDSA requires a balanced panel with a variety of experiences, including clinical experience in treating patients with Lyme disease. I share concerns raised about exclusion of physicians who treat persisting Lyme and the composition of the panel. I know I am joined by colleagues in Congress in the hope and expectation that the reassessment of the Lyme disease guidelines will be conducted with the highest levels of integrity and expertise. Nothing less will protect the rights and welfare of patients. We will continue to monitor this ongoing process.”

The three groups are still hopeful, however, that the panel will take their responsibility seriously, since they have within their grasp the chance to improve the diagnosis and treatment for Lyme patients everywhere. Patients are counting on them to ensure that the weight of the science is evaluated fairly, which would be reflected in new standards that provide help for thousands of children and their families.

The groups feel patients should be provided with treatment options, including the use of long term antibiotics, to fight the disease, which has a disability equivalent to that of congestive heart failure. As in other areas where science is emerging, patients should have choices, and the exercise of clinical judgment by treating physicians should be encouraged. Studies of chronic Lyme disease show a failure rate of 26% to 50%, using the short-term antibiotic approaches currently advocated by IDSA.

ABOUT: The national Lyme Disease Association, (LymeDiseaseAssociation.org), the California Lyme Disease Association (lymedisease.org), and Time for Lyme (timeforlyme.org) are non-profit organizations that were founded by individuals who had personal experience with Lyme disease, in order to address the lack of education and support services available for this newly emerging infection.