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

Statistical Review Refutes Studies Used as Basis of IDSA Guidelines

Allison DeLongA just published statistical review in Contemporary Clinical Trials, August 19, 2012, has cast doubt on the NIH funded studies which have been used as a basis for Lyme disease guidelines most often used by treating physicians for diagnosis and treatment and by insurers to determine reimbursement, i.e. Infectious Diseases Society of America (IDSA) and American Academy of Neurology (AAN) guidelines. The review by Brown statistician, Allison DeLong, and co-authors has reported “flaws in design, analysis, and interpretation that call into question the strength of the evidence against retreatment.” (see Brown release) The most detrimental of those studies to patients has been Klempner et al, which has been shown in this review to have significant statistical issues.

Ms. DeLong is an LDA Scientific and Professional Advisory Board Member. Other authors are statistics graduate Barbara Blossom, Dr. Elizabeth Maloney, and Dr. Steven Phillips.

Visit below link for Brown Press Release on the study:

http://news.brown.edu/pressreleases/2012/08/lyme

Click here for abstract

Click here for short analysis done by Ms. DeLong in 2009 for LDA Analysis: Why

Klempner Study is Not Useful to Rule Out Benefits of Long-Term Treatment.

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.

Congress Calls for Removal of Outdated Lyme Disease Guidelines / Sign Petition Here!

January 21, 2012- Congressman Christopher Smith (NJ) with co-signers Congressmen Gibson (NY), and Wolf (VA) recently sent a letter to the National Guideline Clearing House (NGC), Agency for Healthcare Review &

Quality (AHRQ) requesting the removal of the highly controversial Infectious Diseases Society of America's (IDSA) Lyme Disease Treatment Guidelines from the NGC website, since NGC policy mandates removal after 5 years of "stale" guidelines unless a specific review process is followed.

For treatment guidelines to remain on the NGC site more than five years, they must be reviewed and updated to reflect current science, with a designated review panel responsible for that duty. IDSA failed to convene such a panel, indicating that its current Lyme guidelines were reviewed already, thus do not require another review, and are then eligible to remain on the NGC until 2015.

IDSA claims are based on a review convened as a one-time legal remedy to comply with an anti-trust settlement IDSA reached with then CT Attorney General, now US Senator, Richard Blumenthal. He initiated an investigation after input from CALDA, TFL, and LDA, Lyme organizations, which have been working to ensure patients can obtain treatment for chronic Lyme disease, demonstrated to Blumenthal how the Guidelines were hurting patients.

After the antitrust settlement review was completed, recommended changes to future IDSA Lyme guidelines made by the IDSA's own settlement review panel members were not incorporated anywhere.

The NGC uses the definition of clinical practice guidelines developed by the Institute of Medicine (IOM) in 1990: clinical practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.

IDSA Lyme disease treatment guidelines, instead of being used to assist practitioners and help patients, have been used as a weapon to prosecute physicians who refuse to follow the guidelines "recommendations" and to give insurers carte blanch in denying reimbursement for treatment beyond a few weeks.

Thanks to Congressman Christopher Smith for spearheading the congressional communication to National Guidelines Clearing House and to

the Congressional co-signers, Congressmen Wolfe and Gibson. In addition, thanks to LymeDisease.org, an LDA affiliate, for doing the coordination and leg work on this issue.

The NGC's response will determine the fate of hundreds of thousands of patients. Go to http://www.lymedisease.org/news/lymepolicywonk/898.html for further details. You can also register your opinion on how the guidelines are preventing your Lyme treatment with your Congressman.

Sign Petition To Remove Outdated IDSA Guidelines From NGC!!

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click for pdf of below letter

January 18, 2012

Vivian H. Coates, MBA
Vice President, Information Services and Health Technology Assessment
ECRI Institute
5200 Butler Pike
Plymouth Meeting, PA 19462-1298

Dear Ms. Coates:

As your organization is currently contracted by the U.S. Department of Health and Human Services' Agency for Healthcare Research and Quality (AHRQ) to maintain the National Guidelines Clearinghouse (NGC), we write to you as representatives of areas that have a large and growing Lyme disease problem. Our constituents have again contacted us about an issue that needs immediate attention to protect their welfare.

As you no doubt know, the Lyme disease guidelines of the Infectious Diseases Society of America (IDS A) have been highly controversial and have been responsible for insurance

company denials of Lyme disease treatments. We have recently been informed that these guidelines have been re-instated on the NGC Web site, notwithstanding the fact that they are more than 5 years old and, hence, are no longer current. Our constituents are concerned that these guidelines have not been subject to a complete review for currency and that the methodology of any review has not been disclosed as required by the NGC's guidelines.

Our understanding is that the recently re-submitted guidelines are based on the July 2010
Final Report of the Lyme Disease Review Panel of the Infectious Diseases Society of America, which specifically was "not charged with updating or rewriting the 2006 Lyme disease guidelines. "This aforementioned review panel was convened pursuant to an agreement between the Connecticut Attorney General and the IDS A to end the Attorney General's antitrust investigation into the IDSA's 2006 Lyme disease guidelines. The 2010 panel recommended more than 25 revisions to the guidelines, which have not been addressed. We have been presented with considerable evidence that the NGC process, which requires that guidelines be reviewed for currency and disclosure of the methodology for the process, was not complied with before reinstating the guidelines until 2015.

We urge you to follow NGC currency compliance procedure and remove the guidelines until they have been fully reviewed and revised. The mission of the NGC is "to provide physicians and other health professionals, health care providers, health plans, integrated delivery systems, purchasers, and others an accessible mechanism for obtaining objective, detailed information on clinical practice guidelines and to further their dissemination, implementation, and use." Only a careful and transparent procedure will remove the cloud that has hung over these guidelines.

Thank you for your serious consideration. We look forward to your reply.

CHRISTOPHER H. SMITH, Member of Congress
FRANK WOLF, Member of Congress
CHRIS GIBSON, Member of Congress

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.

PO Box 1438

Jackson, NJ 08527 www.LymeDiseaseAssociation.org

IDSA Violates Lyme Antitrust Settlement Agreement with Connecticut Attorney General

IDSA Violates Lyme Antitrust Settlement Agreement with Connecticut Attorney General

Greenwich, CT, February 4, 2010 – On Monday, February 1, 2010, the Connecticut Attorney General Richard Blumenthal sent a letter to the IDSA expressing "concern" over "improper voting procedures" used by the IDSA in the Lyme guidelines review voting process. The IDSA may soon approve hearing determinations based on this improper voting procedure. The Attorney General requested that the IDSA redo the vote to comply with the Settlement Agreement.

"First, the IDSA stacked the panel by excluding our physicians and now they're stacking the ballot box. The IDSA needs to comply with the settlement agreement and place the interest of patients' paramount," commented Attorney Lorraine Johnson, Executive Director of the California Lyme Disease Association.

The four-page Attorney General letter was released in response to a Freedom of Information Request made on behalf of patient groups for information regarding the IDSA's compliance with the Settlement Agreement.

"Attorney General Blumenthal continues his fine work ensuring that agencies such as the IDSA take the legal settlement process seriously. If not for his oversight, the IDSA would once again violate a process that could medically impact hundreds of thousands of patients," said Debbie Siciliano, Co-President of Time for Lyme.

What happened? The IDSA used an "improper voting procedure," based on a process of its own design, which blatantly violates the Settlement Agreement and undermines the integrity of the voting process. The IDSA consented to the voting procedure in the Settlement Agreement and confirmed its understanding of

the required voting procedure in an internal memo from the IDSA to the panel before the panel met. The Attorney General's letter and the IDSA internal memo to the panel are attached to this release.

What voting process was required and how was it violated? The Settlement Agreement requires a two step voting procedure, with each step requiring a supermajority vote (6 of 8 panelists). The first vote asks the question whether each of the contested guideline recommendations is "medically/ scientifically justified in light of all of the evidence and information provided." This vote requires a supermajority of the panel (6 of 8) in order for a guideline recommendation to stand. In essence, it asks "did the panel that adopted the 2006 guidelines get it right"? The second vote, also by supermajority, determines whether the guidelines require no changes, partial revision or complete revision.

The IDSA's flawed voting procedure combined the two voting steps into one. First, the panel failed to conduct the vote to determine whether the science was sufficient to support the guideline recommendations. Next, the panel substituted its own procedure for the second step in the voting and required a supermajority for any change. This process effectively flipped the supermajority requirement to favor no change to the guidelines.

From the get-go, two significant points stand out:

The IDSA failed to voluntarily comply with the Settlement Agreement in good faith.

Absent oversight by the AG pursuant to the Settlement Agreement, the IDSA would have carried out a corrupted process that blatantly violates the agreement—and it might never have been discovered.

Patient groups are appalled that so far the IDSA, which should conduct an honest review and assessment of the evidence supporting the IDSA recommendations, has chosen to manipulate the voting requirement to influence the outcome, in clear violation of the Settlement Agreement and the scientifically based review and voting process which it provides. This turns evidence-based medicine on its head.

"It is unconscionable that IDSA professionals would so little value patient health. By manipulating the vote, they continue to subvert the scientific truths about the devastating effects

of Lyme and refuse to allow patients to be diagnosed and treated. They can't face the truth," adds Pat Smith, President of the national Lyme Disease Association.

Can the process be saved? Patient groups, along with the public at large, expected that the IDSA would comply with the Settlement Agreement in good faith. It is, after all, a settlement agreement with the Attorney General of the State of Connecticut. When the IDSA panel so deliberately violates the voting procedures, as expressly confirmed by the words of the IDSA's own internal memo, and refuses to comply with the Attorney General's request, there can be only one conclusion: The ability of the IDSA to run this process with integrity is extremely suspect and any outcome must be viewed critically.

Other examples of abuse by IDSA of settlement process: This is not the first time legitimate questions have been raised regarding the IDSA's willingness and reliability in performing its obligations with integrity under the settlement process. For instance, the IDSA was charged with selecting the panel and chose to exclude divergent viewpoints (including physicians who treat chronic Lyme disease). One panelist was removed by the panel after patients complained because he had served on another Lyme guidelines' panel– a direct violation of the settlement agreement. Another panelist had also served on a previous Lyme guidelines' panel, but despite patient complaints, was not removed.

Patient organizations call upon the IDSA to hold an individual vote on whether each of the guidelines' recommendations is medically/scientifically justified in light of all the evidence as requested by the Attorney General. If IDSA fails to do so in good faith, patients continue to rely upon the Attorney General to continue to enforce the Settlement Agreement.

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

[An example of the IDSA manipulation of the voting procedure.

The guidelines mandate that Lyme cannot be diagnosed without a confirming diagnostic test. The tests are known to be insensitive and flawed. Requiring a positive test means that many patients with Lyme disease will fail to be diagnosed. One panel vote described in the AG's letter was whether this recommendation should be revised. Four of the eight panel members voted for change, without the panel first having voted to determine whether the recommendation was supported by the science. As the AG's letter points out, this clearly means that had the panel voted in accordance with the Settlement Agreement, this recommendation would have failed as not properly supported by the medical/scientific evidence. Why? A vote to uphold this recommendation would have required 6 votes; however, the 4 votes calling for revision (even though predicated on a flawed procedure) plainly indicates insufficient evidence to support the recommendation. Thus, (a) the IDSA failed to vote to determine whether the science supported the recommendation, (b) substituted its own procedure regarding revision (requiring a supermajority vote to revise), and (c) thereby manipulated the voting requirements to achieve a result in its favor.]

Settlement Announced in Landmark Investigation of

Lyme Disease Diagnosis and Treatment Guidelines

FOR IMMEDIATE RELEASE
CONTACT: Melissa Chefec, 203-968-6625 or Nicole Rodgers, 202-822-5200, ext. 249/226

Settlement Announced in Landmark Investigation of Lyme Disease Diagnosis and Treatment Guidelines
Patients' Rights Groups Applaud Connecticut Attorney General Blumenthal's Settlement in Anti-trust Case Against Powerful Medical Society

Hartford, CT, May 1, 2008 – Patients' rights groups today hailed Connecticut Attorney General Blumenthal's announcement of a settlement in a landmark antitrust investigation into the Lyme treatment guidelines of the Infectious Diseases Society of America (IDSA).

"My office uncovered undisclosed financial interests held by several of the most powerful IDSA panelists," said Blumenthal. "The IDSA's guideline panel improperly ignored, or minimized, consideration of alternative medical opinion and evidence regarding chronic Lyme disease, potentially raising serious questions about whether the recommendations reflected all relevant science."

The groundbreaking settlement announced today forces a complete review of the IDSA guidelines by a new panel free from conflicts of interest, specifically excluding previous panel members. This panel will consider a range of scientific evidence in a public forum broadcast live over the internet and will be overseen by a specialist in financial conflicts of interest in medicine.

“This settlement makes it clear that the IDSA guideline development process was corrupted by a commercially driven panel that excluded evidence supporting longer term treatment of Lyme disease,” said attorney Lorraine Johnson, Executive Director of the California Lyme Disease Association (CALDA). “This settlement allows suppressed scientific viewpoints and evidence to be heard, and it is promising news for patients.”

This is the first-ever antitrust investigation against a medical society’s guidelines development process.

“We congratulate Attorney General Blumenthal for exposing the IDSA’s conflicts of interest and helping reduce the suffering of Lyme patients everywhere,” said Pat Smith, president of the national Lyme Disease Association (LDA). Diane Blanchard, co-president of Time for Lyme adds, “The IDSA guidelines are dangerous for patients who suffer longer-term Lyme symptoms that do not fall within the IDSA’s narrow disease definition.”

The IDSA guidelines are treated as mandatory within the medical community. More than 50 physicians who use longer-term treatment approaches have been investigated or sanctioned by state medical boards. The guidelines can also result in financial problems for patients, since insurance companies refuse to reimburse for longer-term treatment and pharmacies may refuse to fill prescriptions.

The majority of individuals involved in the IDSA guidelines development process held direct or indirect commercial interests related to Lyme vaccines, patents, and/or test kits, and did not take the opinions or experiences of the competing Lyme groups into account.
While the announcement of a settlement comes as a huge relief to suffering Lyme patients, the case has much broader implications for a health care system that often contends with conflicts-of-interest in guideline processes – guidelines which are often used by insurance companies to limit diagnosis and treatment options.

“Today’s settlement marks an important victory for all patients who suffer Lyme disease, but it is also a victory for anyone concerned about health care,” said Johnson. “Commercially driven guidelines that limit patient treatment options are a major issue today in healthcare, and this decision marks an important step towards addressing it.”

The national Lyme Disease Association, (LDA), CALDA, and Time for Lyme 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.

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.

Lyme Disease Physicians and Patients Expose Research Group's Ploy to Silence Them

FOR IMMEDIATE RELEASE CONTACT:

April 9, 2008 Nicole Rodgers or Eliza Brinkmeyer 202-822-5200, ext. 249/226

Lyme Disease Physicians and Patients Expose Research Group's Ploy to Silence Them

Already caught up in an anti-trust investigation, IDSA opposes research bill in order to maintain monopoly over Lyme diagnosis and treatment options

Washington, DC – Physicians specializing in treating chronic Lyme disease and a national coalition of Lyme disease patients and their families today accused a medical research group of trying to exercise monopoly control over research on Lyme and tick-borne diseases.

"We're very disappointed," said Pat Smith, president of the national Lyme Disease Association (LDA), responding to a letter to Congress by the Infectious Diseases Society of America (IDSA) that seeks to deny patients a voice regarding the research needed to better understand the disease.

Lyme disease is a serious bacterial infection that develops from the bite of an infected tick. The disease is often misdiagnosed or goes untreated, causing many patients to suffer persistent health problems, including neurological disorders, crippling muscle and joint pain, disabling fatigue, psychological disorders, and even death. Even when Lyme disease is caught early and treated with a short course of antibiotics, the debilitating symptoms can persist and require additional longer-term treatment.

In March, IDSA wrote Congress attacking the Lyme and Tick-Borne Disease Prevention, Education and Research Act of 2007, introduced by Chris Smith (R-NJ) and Bart Stupak (D-MI) in the House, and Christopher Dodd (D-CT), Charles Schumer (D-NY) and Chuck Hagel (R-NE) in the Senate. The broadly supported bipartisan bill calls for acceleration of Lyme disease research and creates a new federal advisory committee made up of the full range of scientific viewpoints on Lyme, including a seat for patient advocacy groups.

The IDSA is currently under investigation by the Connecticut Attorney General for abuse of monopoly power and exclusionary conduct in formulating its Lyme disease guidelines, which were developed by a panel that held significant commercial interests in diagnostic tests, vaccines, and consulting arrangements. In its letter to Congress opposing the Lyme Bill, the IDSA failed to mention this ongoing investigation.

IDSA researchers have virtually controlled Lyme disease research for the past 30 years amidst ongoing controversy surrounding its guidelines, which deny patients the right to treatment options and undermine the ability of physicians to use their clinical discretion in treating patients. IDSA provides private health insurance companies with the basis for denying long-term treatment for chronic Lyme disease.

The California Lyme Disease Association (CALDA), national Lyme Disease Association (LDA) and Time for Lyme (TFL) are non-

profit organizations that were founded by individuals who had personal experience with Lyme disease, in order to address the lack of research, education and support services available for this newly emerging infection.