New Lyme Vaccine in Clinical Trials: Update!

An article on a new vaccine for Lyme disease, "New Effort for Lyme Disease Vaccine Draws Early Fire," by Sumathi Reddy, appeared in the Wall Street Journal on July 9, 2018. The article, which includes a quote by LDA President, Pat Smith, reports that a European company, Valneva SE, is in clinical trials for a vaccine for Lyme disease, which has been fast tracked by the FDA. **(see 4/28/19 update at end of article)**

A company official estimates it will take at least five years before it becomes commercially available. The vaccine is similar to Lymerix, by Smith Klein Beecham (SKB), now GlaxoSmithKline, which was approved by the Food and Drug Administration (FDA) in December 1998 but was withdrawn from the market in 2002 due to low demand.

"We don't feel that there has been enough research done to answer the questions as to what occurred with the prior vaccine," says Patricia Smith, president of the Lyme Disease Association Inc., a New Jersey-based national nonprofit group, which raises money for Lyme research, education and patient support. "The vaccine that is now in development is something with the same base. There were a lot of patients that thought they were harmed from that vaccine. It's very problematic."

Check out the history of Lymerix and efforts by the LDA and others to get the facts behind the vaccine and its withdrawal—individuals who took the vaccine who spoke at the FDA on the problems they felt were related to the vaccine; class-action lawsuits that alleged it caused serious side effects; and a

meeting requested by LDA at the FDA where LDA brought in a vaccine expert and physicians who were seeing patients with problems they felt were connected to receiving the vaccine.

Update on Lyme vaccine 4-28-19 On July 2017, Valneva received from the Food & Drug Administration (FDA) a Fast Track Designation for VLA15. On April 4, 2018, Valneva presented Phase 1 interim results of the vaccine at the World Vaccine Congress in DC. In December of 2018, Valneva announced the initiation of Phase 2 Clinical Trial Development to determine the optimal dosage level and schedule for use in Phase 3 field efficacy studies, based on immunogenicity & safety data.

Click here for a history of the LDA's involvement with the FDA and the Lymerix vaccine

Click here to read full Wall Street Journal article

Lyme Vaccine Meeting: FDA Vaccines & Related Biologics Products Advisory Committee

Food And Drug Administration Center For Biologics Evaluation And Research. Open meeting of: The Vaccines & Related Biologics Products Advisory Committee, June 7, 1994, Silver Spring, MD. **Click Here for Lyme Vaccine Meeting**

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Class Action Suit Filed Against Smithkline Beecham For Vaccine

On December 14, 1999, a lawsuit was filed in the Chester County Court of Common Pleas, alleging that SKB manufacturer of Lymerix, the Lyme vaccine, failed to warn doctors and the public at large that about 30% of the general public could possibly be predisposed to a degenerative autoimmune arthritis that can be triggered by the vaccine. According to the complaint, the autoimmune reaction, once triggered, is unstoppable, and the victim can only be treated for symptoms thereafter.

Read whole article here – Reprinted with permission from the Lyme Disease Association's *Tiny Tick Tales*, Volume III Fall 1999

Vaccine Remarks

Remarks of Pat Smith, President, Lyme Disease Association, Inc. before the Vaccines and Related Biological Products Advisory Committee, January 31, 2001, Bethesda, Maryland.

Mr. Chairman and Committee members:

The Lyme Disease Association's mission is Lyme disease education, prevention, and research funding, so one might automatically assume we're favorable to a safe and effective vaccine for Lyme disease. That's certainly a valid assumption. The Association's board consists of patients and families of patients—all of whose lives have been personally touched by this disease, and all who are dedicated to preventing others from experiencing the physical, mental, and emotional devastation Lyme disease can produce. To that end, we fund research projects, sponsor medical conferences and continue to work with Members of Congress developing federal legislation providing $125 million for Lyme disease research, physician education, and prevention.

I am here today because we do favor a safe and effective vaccine, but we are unsure whether an OSP A based vaccine can meet those criteria. Since the inception of OSP A vaccine trials, we heard from individuals experiencing difficulties after immunization. The information was startling, not only because of the problems described, but also because of doctors' apparent incomprehension of the problem. At a vaccine meeting sponsored by the LDF where pharmaceuticals reps were discussing how well the trials were going, I questioned, without satisfaction, the issue of these trial-patient complaints.

After vaccine approval, LDA received inquiries about the vaccine, many from individuals who had received all or some of the vaccination series. Most proceeded to talk about symptoms they developed subsequent to receiving the vaccine. When asked if they had reported this to the administering doctor, and if the doctor had reported the adverse event, the usual response was that the doctor did not take the complaint seriously or did not think the symptoms were related.

Sadly, none were aware of the HLADR4 situation, and several

were in the midst of the immunization series and did not know whether to continue taking the shots. Some called to ask if they should get the shots if they had had Lyme in the past, a question which appears to have no clear answer—particularly in light of the unreliable antibody response tests used to determine who has or had Lyme disease. A few insisted they had gotten

"full blown Lyme" from the shots, and after further discussion, indicated they had had Lyme disease in the past.

I want to share an email I received Monday. "I live in Wisconsin. I received your name from person X who told me you may be able to give me some direction. I received two vaccines in the spring of 2000. Couple days within the first shot my neck and higher back stiffened up severely. In a month I went back for the second shot and asked the nurse and doc to check for side effects before I took the second. They informed me there were none. I took the second dose and the problem with my neck and back worsened within a couple of days. My family doctor gave me anti-inflammatories but they did nothing. I've tried a chiropractor but the only relief was for a couple of hours. Never tried one before but am getting desperate. Then I went to a orthopedic and am now on anti inflammatories again but not helping. He told me that I have a disc that is somewhat smaller than the others in my neck and maybe the vaccine somehow aggravated it. Prior to the vaccine I have had 0 neck or back problems. I am looking for treatment somehow someway." I called him. He is 39 years old. He asked me to help him. He wants treatment for what he has.

Today you are hearing about how this vaccine has physically impacted human lives. It appears that little can be done to stop whatever process triggers some of these reactions, or if something can be done, it remains as yet undiscovered. I listen to the despair and bewilderment of those adversely impacted: How can this happen from a medicine to keep me from getting sick? Who can help me get better? I can only comfort

them as I do not have any answers, and I do not know who does.

This committee has the authority to formulate recommendations that may prevent others from potentially suffering the same fate. You can revisit the original data and research which appears to show a link between OSP A and adverse reactions and view it in light of the adverse events you have now heard about. You can recommend further studies. You can find out why many doctors who treat chronic Lyme disease are not giving the vaccine.

The Advisory Committee on Immunization Practices recommends under future considerations in their report on the Lyme disease vaccine, June 4, 1999 MMWR, "establish post licensure epidemiological studies of safety, efficacy, prevention effectiveness, cost effectiveness, and patterns of use." We concur with that recommendation and would like to see a moratorium on vaccine administration until those studies are completed and the results critically analyzed.

Thank you for your time.

Conflicts of Interest in Lyme Disease: Treatment, Laboratory Testing, and Vaccination

Conflicts of Interest in Lyme Disease: Treatment, Laboratory Testing, and Vaccination. Lyme Disease Association, Inc. April

2001. The Lyme vaccine is discussed on p.40-70.

Click here to read report

LDA Remarks Before Vaccines & Related Biological Products Advisory Committee

REMARKS OF PAT SMITH, PRESIDENT, LYME DISEASE ASSOCIATION, INC. BEFORE THE VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE, MAY 21, 2002.

DISCLOSURE: No money from SKB.

The Lyme Disease Association, LDA, an all-volunteer organization with five nationwide affiliates, consists of patients and families of patients. The LDA has provded funding for research coast to coast, some published in peer review journals including *JAMA*. Along with our Greenwich affiliate, we were recently honored at a luncheon by Columbia University for partnering with them in the establishment of an endowed chronic Lyme disease research center at Columbia, and we also co-sponsored a fully accredited medical conference for physicians with Columbia. Working with legislators, we developed a bill in Congress, HR 1254, which will provide $125 million for Lyme disease research, prevention, and physician education.

The Lyme Disease Association provided testimony to this committee in January 2001, seeking a moratorium on the vaccine, but felt no action was taken by the FDA, and to that end, in January 2002, the LDA had a private meeting with the FDA's Center for Biologics Evaluation and Research (CBER) and brought several experts to discuss the vaccine issue with FDA

officials including Karen Midthun, Susan Ellenberg, Peter Beckerman, Norman Baylor, Miles Braun, and Robert Ball.

Donald H. Marks, MD, PhD, former lab director for Cannaught, fourteen years of clinical research and regulatory affairs experience in the pharmaceutical industry including Director of Clinical Research, in charge of the Lyme disease vaccine program at Aventis Pasteur, presented to the FDA. Dr. Marks was the leader of the competttitive effort to manufacturer a virtually identical vaccine.

Currently, his focus is diagnosis of adverse events from medications, vaccines, biologicals, and medical devices. Lymerix associated cases he reviewed included athralgias and arthritis as well as complicated neurological problems and include adverse events that are long-lasting. A summary of Dr. Mark's power point presentation follows.

WHY MORE ADVERSE EVENTS WERE SEEN AFTER THE VACCINE REACHED THE MARKET:

- People receiving Lymerix after product launch lived in Lyme-endemic areas.
- Many people may have had prior exposure and clinical or subclinical infection. In these cases, Lymerix could be triggering or reactivating the damage caused by old and presumably cured Lyme disease.
- Pattern of symptoms experienced after Lymerix mimicked pattern of prior infections in many individuals. In these patients, Lymerix-related symptoms seemed to respond to antibiotics, as did the initial infection, bolstering the theory of disease reactivation.

ISSUES WHICH CONFUSED THE VACCINE PICTURE

- As proof of safety, the company inoculated arthritis-prone mice with Osp-A. But since the mice did not possess the HLA marker known to interact with Osp-A in humans, rendering the experiment meaningless.
- The company masked serious causally-related adverse events behind qualifiers, such as "…and which may have no causal relationship with the vaccine" and "…cannot be distinguished from the natural history of the underlying disease."

- The company says that “the possibility of a severe rheumatologic, neurologic, autoimmune adverse event is inherent in Lyme disease,” attempting to shift the blame onto the patient and their illness, and does not inform physicians that the same adverse events can be separately caused by the vaccine, in addition to the symptoms of an underlying disease
- As a result of these actions, GPs in the US were kept in the dark about the life-threatening side effects of Lymerix, severe rheumatologic, neurologic, autoimmune adverse events.

SOME BASIC PROBLEMS.

- Non-specific hyper-activation of the immune system, often evidenced through swollen hands or arthritis, is an adverse event associated with Lymerix. This may be due to the presence of adjuvant.
- This hyper-activation creates “dirty” Western blots in which multiple Lyme disease bands appear, whether the individual has Lyme disease or not.
- The dirty banding makes it impossible for physicians to differentiate between Lymerix vaccination, new infection with Borrelia burgdorferi, or reactivation of infection.
- The net result is that cases of Lyme disease will go undiagnosed and untreated. Adverse reactions to Lymerix will be misdiagnosed as Lyme disease and people will be unnecessarily treated with antibiotics.
- The vaccine manufacture provides no warnings as to these possibilities.
- Physicians unaware of the spectrum of problems cannot appropriately treat these patients.
- The intention of FDA regulations is to provide a vaccine that is safe and effective. The intention of prescribing regulations is to provide sufficient information to prescribing physicians to enable safe and effective use of the vaccine. In both regards, SKB’s actions appear to be contrary to FDA regulations and intentions, and contrary to accepted standards within the vaccine industry.

Dr. Marks provided some case assessments based on stringent parameters and his extensive experience in the field. “The adverse events I have examine from Lymerix are similar to those I am familiar with from another

vaccine." In the cases Marks examined –in his opinion, the adverse events were not anecdotal but a medical certainty.

- 4 of 4 neurological adverse events were related to Lymerix with presentations including transverse myelitis, inflammatory polyneuropathy, radiculopathy and cervical throacic myelopathy with multiple neurologic, including CNS, symptoms, memory loss and difficulty concentrating with immune-related complex of joint pain and fatigue.
- 15 of 17 rheumatologic adverse events were related, including inflammatory seronegative spondyloarthropathy, polyarthropathy, arthralgias, and arthritis.
- 2 of 2 miscellaneous reports were unrelated. These included chest pain and myofacial pain.

Based on his research, Marks said, "SKB should have devised and conducted clinical trials, epidemiological studies, or after-the-fact investigations to study the causal relationship between severe rheumatologic, neurologic, autoimmune and other adverse events and the use of Lymerix….there is sufficient evidence that Lymerix is causally related to severe rheumatologic, neurologic, autoimmune, and other adverse events in some individuals. This evidence is such as to warrant a significantly heightened degree of warnings and possible limitations or removal from marketing of Lymerix."

Andrea Gaito, MD, a rheumatologist seeing 35 patients with vaccine problems described three categories (**bold)** of problems to FDA. The first case, no history of Lyme, presented with acute synovitis, tests showed negative rheumatoid factor, Western Blot suggestive of active Lyme disease, with eight IgM and three IgG bands. Patient had minimal response to doxycycline, was prescribed and continues on anti-inflammatory medication. Conclusion: **autoimmune disease.**

The second case, **asymptomatic at time of innoculation, with a history of IV treated Lyme** meningitis. After Lymerix, patient experienced the onset of Obsessive Compulsive Disorder, headache, and fatigue. Upon testing, he had a positive ELISA and a Western Blot with every band positive. Retreatment with IV was not effective. Patient remains sick.
The third case, three shots of Lymerix, then bitten by a tick. **She went on to develop symptoms of Lyme disease**, including night sweats and

fatigue. Tests showed: a Western Blot with every band positive; positive for the HLA markers that have been associated with Lyme-related autoimmune disease. Two courses of antibiotics produced no response. This patient now has Lyme disease but does not respond to treatment.

Dr Gaito is concerned about the efficacy of this vaccine and boosters. Will vaccinated individuals with prior Lyme who ultimately present with symptoms respond to retreatment? Is the vaccine itself retriggering an autoimmune response? She felt it is possible that the difference between the pre- and post-marketing results of Lymerix relates to the fact that those using it post-marketing lived in endemic areas for Lyme disease.

The LDA is concerned that despite presentations to the contrary by individuals at both the Vaccine Advisory Committee hearing in January 2001, the private meeting above, VAERS data, and other communications from the public, the FDA has not seemed to find any problems with this vaccine. LDA’s concern stems from the fact that although the approved vaccine is not on the market currently, since it was a unilateral decision by the company to remove the product, this same or a similar product may be remarketed without the full implications of the safety and efficacy of the current vaccine having been fully assessed or integrated into the Lyme vaccine picture. The LDA asks this committee to advise the FDA that significant arguments have been raised about safety and efficacy of this vaccine and that objective studies should continue on safety and efficacy of this vaccine or any other future vaccine that may seek FDA approval. Thank you for your time.

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.

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.]

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

Statistical Review Refutes Studies Used as Basis of

IDSA Guidelines

Allison DeLong

A 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.