



Lyme Disease Association, Inc.

PO Box 1438, Jackson, New Jersey 08527

888-366-6611 Lymeliter@aol.com 732-938-7215 (Fax)

April 6, 2015

US House of Representatives Lyme Disease Caucus
Attn: Co-Chairman Congressman Christopher H. Smith
Washington, DC
By Email

Dear Congressman Smith and Congressman Peterson,

I am writing on behalf of the Lyme Disease Association (LDA) and the undersigned organizations concerning an issue of importance to Lyme patients across the US and the world.

The Infectious Diseases Society of America (IDSA), a 501(c)(6) organization (business leagues, etc.) represents infectious disease experts who produce disease treatment guidelines, including those for Lyme and other tick-borne diseases. Currently, IDSA is in the process of reviewing their Lyme guidelines to update them. While the IDSA is utilizing a structured methodology – Grading of Recommendations Assessment, Development and Evaluation (GRADE), what is more important than the choice of a methodology is the degree of bias of those who composed the guidelines project plan, the bias of guidelines development panel members and the commitment of those individuals to the spirit of a fair and honest process. A prerequisite, but not a guarantor, for a successful outcome from the perspective of patient welfare is a high level of transparency throughout the entire process from development of the project plan to finalization of the guidelines.

As briefly discussed below, an examination of the Project Plan for new guidelines indicates that certain members of the IDSA will continue their history of bias and ensuring pre-determined outcomes in a process lacking meaningful transparency.

History of IDSA Guidelines. The 2006 guidelines that IDSA generated became a standard of care, one so restrictive that patients were often unable to receive treatment, and physicians who treated were disciplined for treating patients for Lyme disease longer term than the guidelines indicated. The LDA had an online petition opposing the Guidelines which generated 45,000+ signatures. In 2006, then Attorney General now Senator from Connecticut, Richard Blumenthal, opened an investigation into the IDSA Guidelines, filing a Civil Investigative Demand, to look into possible anti-trust violations in the Guidelines' development process and found that the panel who developed the Guidelines had undisclosed conflicts of interest in testing, vaccines, and as consultants to insurance companies. As a result, the IDSA had to appoint another panel to evaluate the guidelines' formation in relationship to those conflicts. Although a process was set up and a new panel selected, the results of the new panel again came into question, as the newly constituted panel did register a concern about one of the indicators, the testing indicator, but IDSA construed the decision-making on that indicator in such a way to imply that the particular indicator results were not really challenged by the new panel.

The IDSA has held itself out as the Lyme experts despite its refusal to address patients with chronic Lyme symptoms, and the IDSA Lyme Guidelines panel has always precluded input from another group of physicians, the International Lyme & Associated Diseases Society (ILADS). ILADS physicians are in the trenches treating patients who suffer from chronic Lyme symptoms. ILADS' published Guidelines address the treatment of chronic Lyme disease, which is generally longer-term antibiotic treatment.

As a private entity, the IDSA has always seemed to be above accountability for its Guidelines' formation process. However, since its Lyme disease Guidelines are accepted almost universally as the standard of care and those in violation of its terms

often find themselves investigated and sanctioned, it is akin to a monopoly, whereby IDSA exercises almost total control over Lyme disease. It has the power to define Lyme, restrict testing and treating practices, exclude those with differing opinions, and control to a large extent the peer review process, since its representatives sit on the review boards of many major journals which are recognized by mainstream medicine and even has a chilling effect on meaningful Lyme disease research.

Testimony from a highly respected Lyme researcher (then soon to retire) to the 2012 House Foreign Affairs Health Subcommittee hearing, *Global Challenges in Diagnosing and Managing Lyme Disease – Closing Knowledge Gaps*, demonstrates the ramifications of the Guidelines: “Because of firmly entrenched opinion within the medical scientific community, evidence of persisting viable but non-cultivable spirochetes is slow to be accepted, and research proposals submitted to NIH that feature persistence following treatment are likely to receive prejudicial peer review in the contentious environment of Lyme disease.* Negative comments by peer reviewers of grant applications in the current financially austere NIH climate result in unfundable scores, if they are scored at all (triaged).” [Barthold Foreign Affairs Testimony](#) . It should be noted that the IDSA was asked to appear and testify in person at the hearing and did not do so.

Project Plan for New Guidelines. On March 9, 2015, the IDSA posted its intent to revamp its treatment guidelines. IDSA has brought to the process sponsorships from 3 medical organizations and other official representation from 9 organizations, 8 medical and one scientific. The development of the Project Plan and the selection of panel members lacked transparency. The panel selected to do the process excludes physicians who treat chronic Lyme disease, specifically ILADS, doctors in the trenches treating patients who do not recover with a short course of antibiotics recommended by existent IDSA Guidelines.

The panel is also composed of many of the same individuals who have produced a tremendous amount of peer review publications opposed to chronic Lyme and whose resultant intellectual conflicts are not listed. According to [Gordon Guyatt](#), a Professor in the Faculty of Medicine at McMaster University, “ ‘intellectual conflicts of interest are completely ubiquitous’ and have generally been ignored. Intellectual conflicts occur when clinicians or researchers may be too deeply embedded in their own area of expertise to objectively look at a research question with an open mind....even when money is not involved ... we [scientists] get very attached to our ideas.’ This is compounded by university culture, which rewards researchers if their work is highly referenced by others and is perceived to be influential. This environment creates an incentive for those participating in guideline development to highlight their own research in clinical practice guidelines.”

Lyme disease diagnostics plays a large role in the Lyme controversy and many who disavow chronic Lyme have conflicts in that area. The new Guidelines’ panel contains 6 individuals with significant diagnostic backgrounds, including 4 with ties to Immunetics –a lab with the C6 peptide test– a test which will undoubtedly be considered for Lyme to replace the existent 2-step process under the new Guidelines when the panel debates Question 76.

Contrary to recommendations of the Institute of Medicine (IOM) and the World Health Organization (WHO), IDSA has also excluded patient representation on its panel. Both IOM and the WHO emphasize the critical importance of patient representation in the process of developing clinical guidelines. IDSA includes a single “consumer” who, the Lyme community learned after calling her, has no knowledge of Lyme and does not even know anyone with Lyme, but rather she is a cancer advocate from Nebraska– a state whose 2013 Lyme reported case numbers were 10.

IDSA has allowed input from the public in a cumbersome process announced March 9 and ending April 9, which will most likely preclude too many from responding. A 30 day comment period, encompassing both Easter and Passover, is not a sufficient period for obtaining input from the public. The last two weeks of the 30-day comment period are during a district work period, disadvantaging members of Congress who have a personal interest in Lyme or who wish to have the opportunity to consider the views of their constituents.

Therefore, at this time, we ask the Lyme Caucus to consider our concerns such as the need for real transparency throughout the process, for IDSA to make public the results of a literature search for each question, for an extension of the comment period to 60 days and for all comments to be made readily available to the public as is done through public dockets in federal, and to inform the IDSA of the problematic implications to Lyme patients and treating physicians and to express the Caucus' intent to continue to follow the process which is of such importance to its constituents. While the IDSA would not be required to grant these requests, we would question why they would not want to be transparent in the development of

clinical guidelines which affect the health of millions of people worldwide and their ability to keep their jobs, attend school, keep their homes and maintain the integrity of their families.

Thank you for your attention to this matter.

Sincerely,

Patricia V. Smith



President for LDA and signing for undersigned groups

Lyme Illuminati	DC	Ginger Savely
Gear Up for Lyme	VT	Rhiannon Woolwich-Holzman
The Lyme Disease Group	PA	Katrina Wrabel
Pennsylvania Chapter LDA	PA	Leslie Giardiello
Brookfield/Wolfeboro Lyme Support Group	NH	Jeffrey Dugas
LIFELYME	FL	Sandi Lanford
Mid Missouri Lyme Support Group	MO	Naoma Coffman
Lyme Association of Greater Kansas City	KS	Ila Utley
MissouriLyme	MO	Gary Vaught
Oregon Lyme Disease Network	OR	Theresa Denham
WA Lyme Fighters	WA	Anna Willo Hart
Family Connections Center for Counseling	CT	Sandra K. Berenbaum,LCSW,BCD
Military Lyme Support	CO	Colleen Nicholson
CFSFMLD	CO	Colleen Nicholson
PA Lyme Resource Network, a 501c3	PA	Julia Wagner
LDA RI Chapter	RI	Julie Merolla
Greater St. Louis Lyme/Masters Disease Support Group	MO	Gary Carmichael
New York City Lyme Disease Support Group	NY	ellenluba@yahoo.com
Lyme Alliance of the Berkshires	NY	Karla Lehtonen
Madison Lyme Support Group	WI	Alicia Cashman
Greater Manchester Lyme Disease Support Group	NH	David Hunter
Bedford Lyme Disease Council	NH	David Hunter
Lancaster County, PA - Lyme Support Group	PA	Rita Rhoads
VT Lyme Support Group	VT	Bern Rose
Lyme Treatment Initiative	PA	Sherrill Franklin
Minnesota Lyme Association - Maple Grove Support Group	MN	Lorrie Link
Illinois Lyme Group	IL	Joan Sullivan
Lyme Disease Support Group of Southwestern Vermont	VT	revclairenorth@mac.com
Calling for a Congressional Investigation of CDC, IDSA & ALDF	NH	Carl Tuttle
MaineLyme	ME	Constance Dickey RN
Harrisburg Area Lyme Disease Support Group	PA	Linda Olley, R.N.

MN Lyme Association	MN	Mark Thompson
Lyme Aid- Santa Rosa	CA	Karen Miller
Florida Lyme Advocacy	FL	Lori Hoerl
Lyme Action Network	NY	Christina Fisk
Tennessee Lyme Support Network of the Midsouth	TN	Shelley Brown
Lyme Disease Eugene Oregon	OR	Deb Elder
SF SEAL-San Francisco Support, Education & Advocacy for Lyme	CA	Robin Krop
Cortland County Lyme Disease Support Group	NY	Laurie Tebbe
Hudson Valley Lyme Disease Association	NY	Jill Auerbach
Central Maryland Lyme Disease Support Group	MD	Robin Wolfenden
Lyme Disease Education & Support Groups of Maryland	MD	Lucy Barnes
Harford County Lyme Disease Support Group, Inc.	MD	Jean Galbreath
Florida Lyme	MD	Lucy Barnes
Delaware, Maryland, Virginia- Del-Mar-Va Lyme	MD	Lucy Barnes
Washington DC Lyme	MD	Lucy Barnes
Indiana Lyme Connect	IN	Susan Coleman Morse
Mid-Shore Lyme Disease Association, Inc.	MD	Linda C. Reilly
A Hope 4 Lyme, Inc.	NY	Linda Wales
Journey Through Challenge	PA	David R Thomas
Lyme Connection	CT	Karen Gaudian
Texas Lyme Disease Association	CA	Patricia Ricks
United Lyme Action	CA	Jessica Bernstein
LymeDisease.org	CA	Lorraine Johnson
Kentuckiana Lyme Support Group	KY	Tondia Burrows
St. Cloud Lyme Support Group	MN	Nicole Koll