

# **LymeQuest Support Group and Advocacy Project**

## **New Brunswick, New Jersey**

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#### **COMMENTS SUBMITTED BY 21 ORGANIZATIONS REPRESENTING PATIENTS WITH LYME DISEASE**

SUBMITTED APRIL 24, 2015

On March 9, 2015, the IDSA announced that it will be updating its Lyme disease guidelines. As the first stage of this process, it announced its formation of a review panel and opened a 30-day window for public comment. This period initially closed on April 9, but was extended to April 24.

My name is Jeannine Phillips, President LymeQuest Support Group and Advocacy Project. I am submitting these comments on behalf of the groups indicated below. Please send confirmation that you have received and accepted these comments.

- LymeQuest Support Group and Advocacy Project, NJ is filing these comments on behalf of the itself and the following 21 patient advocacy groups.
- **LymeQuest Support Group & Advocacy Project, NJ**
- Bristol County, MA Lyme Support Group, MA
- LymeCareNow, NY
- Lyme Disease Network of Middle Tennessee, TN
- Portland Lyme Disease Support Group, OR
- Children's Lyme Disease Network, NY
- Bluegrass Lyme Support, KY
- Alabama Lyme Disease Association, AL
- Los Angeles Lyme Group, CA
- TICKED OFF, MA
- Pennsylvania Lyme Group FB, PA
- The Lyme Disease Group, PA
- Indiana Lyme, IN

- Wisconsin Lyme Network, WI
- World Lyme Day, ON
- Cortland County Lyme Disease Support Group, NY
- SF SEAL - San Francisco Support, Education & Advocacy for Lyme, CA
- Lyme Aid-Santa Rosa, CA
- American Lyme Association, CA
- The Mayday Project, VA
- Lyme Nation, NY
- Georgia Lyme Disease Connection, GA

We endorse the comments submitted by LymeDisease.org and the national Lyme Disease Association on behalf of 67 patient groups across the nation on April the 9<sup>th</sup> (April 9<sup>th</sup> Patient Submission). We also submit additional comments as indicated below. These additional comments are endorsed by the original 67 patient groups listed below:

- Lyme Disease.org
- Lyme Disease Association, Inc. NJ
- Indiana Lyme Connect, IN
- WA Lyme Fighters, WA
- Gear Up for Lyme, VT
- The Lyme Association of Greater Kansas City, KS
- Kentuckiana Lyme Disease Support Group, KY
- Greater Manchester Lyme Disease Support Group, NH
- Bedford Lyme Disease Council, NH
- MissouriLyme, MO
- Illinois Lyme Group, IL
- Journey Through Challenge, PA
- Brookfield/Wolfeboro Lyme Support Group, NH
- Greater St Louis Lyme-Masters Disease Support Group, MO
- Mid-Shore Lyme Disease Association, Inc, MD
- Lyme Disease Eugene Oregon, OR
- Military Lyme, CO
- Cfsfml, CO
- Lyme Action Network, NY
- TXLDA, TX
- Hudson Valley Lyme Disease Association, NY
- Lyme Connection/RLDTF, CT

- Lyme Alliance of the Berkshires, NY
- Mid Missouri Lyme Support Group, MO
- United Lyme Action, CA
- New York City Lyme Disease Support Group, NY
- Missouri Lyme, MO
- MN Lyme Association, MN
- Lyme Disease Association of Southeastern Pennsylvania, Inc., PA
- LYME411, NH
- Lyme Disease Seattle WA Organization, WA
- Oregon Lyme Disease Network, OR
- Central Mass Lyme Foundation, MA
- Massachusetts Lyme Legislative Task Force, MA
- Lyme Disease Education & Support Groups of Maryland, MD
- Harford County Lyme Disease Support Group, Inc., MD
- Central Maryland Lyme Disease Support Group, MD
- National Tick-Borne Disease Advocates, TX
- Michigan Lyme Disease Association, MI
- LDA RI Chapter, RI
- Madison Lyme Support Group, WI
- Arizona Lyme Disease Association (AzLDA), AZ
- Bergen Bowmen, NJ
- Iowa Lyme, IA
- Wisconsin Lyme Yahoo, WI
- Newtown Lyme Disease Task Force, CT
- Lyme Disease Support Group of Southwestern Vermont, VT
- Professional Research Center of Naples, FL
- Arklatex Lyme Disease Prevention & Support, TX
- Clarksville Lyme Support, TN
- Lyme Disease Support, WY
- Greater Boston Area Metro West Lyme Disease Support Group, MA
- Ticked Off On Lyme WA, WA
- National Capital Lyme Disease Association, VA
- Greater Danbury Lyme Disease Support Group, CT
- Kentucky Lyme Disease Association (KyLDA), KY
- Sturbridge Lyme Awareness of MA (S.L.A.M.), MA
- Utah Lyme Disease Alliance, UT

- New Hampshire Lyme Alliance, NH
- MaineLyme, ME
- Mid Missouri Lyme support group, MO
- IGeneX, Inc., CA
- PALRN (PA Lyme Resource Network) Delco Region, PA
- Massachusetts Lyme Coalition, MA
- The Charles E. Holman Morgellons Disease Foundation, Nursing Advisory Panel, TN
- Eastern Ct Chapter, Lyme Disease Association, CT
- Florida Lyme Disease Association, FL

Specifically, we endorse and adopt as our own each and every comments and recommendation made in the "April 9<sup>th</sup> Patient Submission" including but not limited to those regarding:

Page 1, lines 6-9: **Organizational Sponsorship**

(Page 2 lines 4-48) and Conflicts of Interest (Pages 8-9, lines 116-126): **Panel Constitution, Lack of Transparency Regarding Panel Selection, Exclusion of Those Affected—Lyme Patients, Exclusion of Those Affected—Physicians who Treat Chronic Lyme Disease, Exclusion of Those affected—Researchers with Divergent Viewpoints, Inclusion of Those with Known Biases and Conflicts of Interest, Key Panel Members--Financial Conflicts of Interest, Key Panel Members—Intellectual Conflicts of Interest, Guidelines Panel Process Distortion; Specific Panel Member Objections**

Page 2, lines 4-11: Guidelines Authors, Panel Leadership.

Page 8-9, lines 116-126: Conflicts of Interest: **Panel Constitution – Authorship and Leadership**

Page 3, lines 16-22: **Background**

Page 5, line 49: **Objectives and Scope**

Page 5, lines 61-65: **Methodology**

Page 8-9, lines 66-90: **Methods of Summarizing**

## **DISTORTION OF PROCESS TO CONFORM TO SPECIFIC OPINIONS AND BIASES OF KEY PANEL MEMBERS**

The panel is supposed to take a systematic, impartial and rigorous look at scientific evidence related to Lyme diagnosis and treatment. Yet that doesn't seem to be the IDSA approach. The 2006 panel ignored studies that didn't support its pre-drawn conclusions. And 40% of its citations were to research studies authored by members of the panel.

The new panel seems poised to go down the same inappropriate road. Before it even starts deliberating, key members appear to be trying to “front load” the evidence. How are they doing this? By rushing to publication a number of biased journal articles, which they can then cite as “evidence” backing their position.

For example, a simple search on either Dr. Wormser or Dr. Lantos during the past year reveals the following published 17 articles that appear to be directly related to this guideline development effort:

1. Agüero-Rosenfeld ME, Wormser GP. Lyme disease: diagnostic issues and controversies. *Expert Rev Mol Diagn.* 2015 Jan;15(1):1-4. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/25482091>.
2. Ajamian M, Cooperstock M, Wormser GP, Vernon SD, Alaedini A. Anti-neural antibody response in patients with post-treatment Lyme disease symptoms versus those with myalgic encephalomyelitis/chronic fatigue syndrome. *Brain Behav Immun.* 2015 Apr 10. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/25866194>.
3. Lantos PM, Shapiro ED, Auwaerter PG, Baker PJ, Halperin JJ, McSweeney E, et al. Unorthodox Alternative Therapies Marketed to Treat Lyme Disease. *Clin Infect Dis.* 2015 Apr 6. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/25852124>.
4. Molins CR, Ashton LV, Wormser GP, Hess AM, Delorey MJ, Mahapatra S, et al. Development of a Metabolic Biosignature for Detection of Early Lyme Disease. *Clin Infect Dis.* 2015 Mar 11. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/25761869>.
5. Wang G, Villafuerte P, Zhuge J, Visintainer P, Wormser GP. Comparison of a quantitative PCR assay with peripheral blood smear examination for detection and quantitation of *Babesia microti* infection in humans. *Diagn Microbiol Infect Dis.* 2015 Mar 18. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/25861873>.
6. Wang G, Wormser GP, Zhuge J, Villafuerte P, Ip D, Zeren C, et al. Utilization of a real-time PCR assay for diagnosis of *Babesia microti* infection in clinical practice. *Ticks Tick Borne Dis.* 2015 Apr;6(3):376-82. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/25819568>.
7. Wormser GP, Weitzner E, McKenna D, Nadelman RB, Scavarda C, Molla I, et al. Long-Term Assessment of Health Related Quality of Life in Patients with Culture-Confirmed Early Lyme Disease. *Clin Infect Dis.* 2015 Apr 17. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/25888674>.
8. Wormser GP, Weitzner E, McKenna D, Nadelman RB, Scavarda C, Nowakowski J. Long-term assessment of fatigue in patients with culture-confirmed Lyme disease. *The American journal of medicine.* 2015 Feb;128(2):181-4. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/25447620>.
9. Wormser GP, Weitzner E, McKenna D, Nadelman RB, Scavarda C, Farber S, et al. Long-Term Assessment of Fibromyalgia in Patients with Culture-Confirmed Lyme Disease. *Arthritis Rheumatol.* 2014 Dec 2. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/25470117>.
12. Pavia CS, Wormser GP. Culture of the entire mouse to determine whether cultivable *Borrelia burgdorferi* persists in infected mice treated with a five-day course of Ceftriaxone. *Antimicrobial agents and chemotherapy.* 2014 Nov;58(11):6701-3. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/25155590>.
13. Bockenstedt LK, Wormser GP. Review: unraveling Lyme disease. *Arthritis Rheumatol.* 2014 Sep;66(9):2313-23. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/24965960>.

14. Krause PJ, Narasimhan S, Wormser GP, Barbour AG, Platonov AE, Brancato J, et al. *Borrelia miyamotoi* sensu lato seroreactivity and seroprevalence in the northeastern United States. *Emerging infectious diseases*. 2014 Jul;20(7):1183-90. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/24960072>.
15. Lantos PM, Wormser GP. Chronic coinfections in patients diagnosed with chronic lyme disease: a systematic review. *The American journal of medicine*. 2014 Nov;127(11):1105-10. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/24929022>.
16. Lantos PM, Auwaerter PG, Wormser GP. A systematic review of *Borrelia burgdorferi* morphologic variants does not support a role in chronic Lyme disease. *Clin Infect Dis*. 2014 Mar;58(5):663-71. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/24336823>.
17. Wormser GP, Tang AT, Schimmoeller NR, Bittker S, Cooper D, Visintainer P, et al. Utility of serodiagnostics designed for use in the United States for detection of Lyme borreliosis acquired in Europe and vice versa. *Med Microbiol Immunol*. 2014 Feb;203(1):65-71. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/24218117>.

This is stacking the deck. It's making sure you have your biased research on the top of the pile, then reviewing it with your own eyes and finding it top rate. Panel members should not be in a position to review and promote their own work while excluding work of their peers. That is not an unbiased review. It makes a mockery of the scientific process. We recommend that both Dr. Wormser and Lantos be removed from the panel and the authorship group.

In addition, the patient survey was completed on April 24th with over 6,100 respondents. The report of the results is here and is incorporated into this document as part of this comments submission. <http://lymedisease.org/activism/idsa-guidelines-survey-results-google.html>

## **WE CONCLUDE WITH THE FOLLOWING RECOMMENDATIONS:**

The current Plan fails to provide the type of process integrity essential to creating trustworthy guidelines. We believe that the Plan to should be revised to achieve the following goals.

1. The IDSA/AAN/ACR panels should be balanced and represent scientists and physicians from both opposing Lyme paradigms.
2. Robust patient representation (2 or more) is important and should not be token. Patients should be empowered and prepared patients who represent the population affected by Lyme disease.
3. Consensus should not be obtained by excluding people who disagree.
4. Controversies and disagreement should be acknowledged. Minority viewpoints should be published with the guidelines.
5. A public docket of all comments should be maintained and be publicly posted on the IDSA website.

6. The IDSA/AAN/ACR guidelines should be reconciled with the guidelines of ILADS.
7. All value judgments by the panel, particularly those pertaining to the patient's role in risk/benefit assessment, should be carefully delineated together with the basis for such judgment.
8. Panel members should not be selecting or reviewing work of their own or their fellow panel members to avoid abusive self-citation that perpetuates their own biased viewpoint in a highly contested area of medicine.
9. Panel members with conflicts of interests, including those related to diagnostic testing, should be eliminated from the panel.
10. Panel members who were subject to investigation by the Connecticut Attorney General for antitrust violations in connection with the 2006 IDSA Lyme disease guidelines development process or the copycat guidelines (e.g. those of the AAN) highlighted in that investigation should also be eliminated from the panel.
11. Guidelines should undergo rigorous external peer review by all interested parties and stakeholders, including patient groups. Responses to comments should be made public.

These comments are submitted by LymeQuest Support Group and Advocacy Project, NJ on behalf of the organizations listed above.

Sincerely,

Jeannine Phillips  
President