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 Lymie 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 9th (April 9th 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
• Cfisfmld, 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 9th 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:


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/ida-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