

Congress of the United States
Washington, DC 20515

April 7, 2014

Stephen B. Calderwood, MD, FIDSA, President
Infectious Disease Society of America
1300 Wilson Boulevard, Suite 300
Arlington, VA 22209

Dr. Calderwood:

It has come to our attention that the Infectious Disease Society of America (IDSA) is currently seeking public comment on their recently proposed Lyme Disease Guideline Project Plan, in order to lay the groundwork for updating the 2006 guidelines. While we encourage revision of current guidelines which have created unnecessary hurdles to care for many patients with Lyme disease and should be updated appropriately, we have concerns regarding the process used by IDSA to do so.

Our constituents and others in the patient advocacy community continue to have strong objections to the standard of care originally formed by IDSA in 2006, which has been unduly restrictive and negatively impacted the health of thousands of Lyme patients.

As members of the House Lyme Disease Caucus and representatives of many constituents who have been gravely affected by Lyme disease, it is of great importance to us that IDSA ensures transparency and accountability as they evaluate and update these guidelines that are sometimes the only source for treatment protocols, especially by Lyme doctors who may not be fully familiar with the complexities of Lyme. By way of background, our caucus works to educate Members of Congress and staff about Lyme and other tick-borne diseases, and advances initiatives—especially and including treatment options—designed to help the estimated 300,000 Americans diagnosed with Lyme disease each year.

Accordingly, we are hopeful that you will work to avoid the legitimate and ongoing concerns raised in response to the 2006 guidelines, and adopt processes that give the public greater insight into the IDSA's decision-making and encourage the full consideration of all comments raised by external stakeholders.

Specifically, we request as a matter of good practice that you adhere to the IOM's standard for developing trustworthy clinical practice guidelines to ensure patient and public involvement by: (a) including at least one current or former patient, and at least one patient advocate or patient/consumer organization representative of the populations expected to be affected by the guidelines; (b) provide a 30 day extension of the public comment period—now scheduled to close on April 9th—to increase effective participation by patients and consumer representatives, many of whom are concerned that the current time frame does not afford the public adequate time to respond.

IOM also stresses the need not only for a variety of disciplines but also for the panel to be “comprise[d] of a variety of methodological experts and clinicians and populations expected to be affected by the CPG.” A lack of inclusion of physicians treating the chronic manifestations of Lyme disease may undermine the ability of the panel to represent the many patients who experience chronic manifestations.

We further request that IDSA make public the results of a literature search for each clinical question screened by IDSA reviewers, and that this and other information collected, including all submitted comments, be made available through public docket, as is done in the federal rulemaking process.

For your review, we have enclosed a letter we received from advocates for patients with Lyme disease, which provides their concerns regarding the guideline process. We urge you to contact them directly if you need any additional information regarding their insights.

Thank you for your prompt attention to this matter.

Sincerely,



Christopher H. Smith
Co-Chair
Lyme Disease Caucus



Collin Peterson
Co-Chair
Lyme Disease Caucus


Barbara Comstock
Member of Congress
Chris Gibson
Member of Congress

Sean Patrick Maloney
Member of Congress