



May 22, 2015

The Honorable Christopher H. Smith
2373 Rayburn House Office Building
Washington, DC 20515

The Honorable Collin Peterson
2204 Rayburn House Office Building
Washington, DC 20515

The Honorable Barbara Comstock
226 Cannon House Office Building
Washington, DC 20515

The Honorable Chris Gibson
1708 Longworth House Office Building
Washington, DC 20515

The Honorable Sean Patrick Maloney
1529 Longworth House Office Building
Washington, DC 20515

Dear Representatives Smith, Peterson, Comstock, Gibson and Maloney:

As the leading medical authorities on the diagnosis and treatment of Lyme disease, we empathize with patients who are suffering and we are committed to providing the highest-quality patient-centered care. It is within this spirit that the Infectious Diseases Society of America (IDSA), the American Academy of Neurology (AAN), and the American College of Rheumatology (ACR) are jointly developing new guidelines for the diagnosis and treatment of Lyme disease. We are pleased to report how: (1) our guideline author panel includes diverse and expert representation of a methodologist and physicians who care for Lyme disease patients, as well as a consumer representative; (2) our organizations will add a current or former patient and a parent of a patient who has had Lyme disease; and (3) we extended the public comment period on the Lyme Disease Guideline Project Plan by 15 days for a total of 45 days.

An effort unlike any other Lyme disease guideline carried out to date, our current project brings together medical specialty societies that represent the authorities in the care of the multiple manifestations of Lyme disease. We appreciate your view that members of this panel must be fully familiar with the complexities of Lyme disease. In addition to representatives from IDSA, AAN, and ACR, representatives from eight other major medical and scientific organizations (Attachment 1) whose members care for patients with this disease are included on the panel. Three additional panelists have been added for their expertise in cardiology, pathology and microbiology. The panel is comprised of expert individuals who are “in the trenches” treating all manifestations of Lyme disease.

We also recognize the Institute of Medicine's (IOM) emphasis in its 2011 report on *Standards for Developing Trustworthy Clinical Practice Guidelines*¹ on inclusion of methodological experts in guideline development, which you noted, and we have included an expert in guideline methodology and member of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) Working Group on the panel as a co-chair. GRADE is a widely accepted methodology that all three of our lead organizations, and several of the other collaborating organizations, have adopted for their guideline development. Consistent with the process in GRADE, two experienced medical librarians will conduct the systematic review of the literature, and the summary of findings tables will be published with the guideline.

We have also been responsive to the IOM's recommendation regarding consumer representation on the panel and have included an individual who represents the healthcare consumer perspective, a perspective that is critical to this process. This individual has experience in the review process and discussion of medical and scientific information and decision-making, and was specifically chosen because she had never been affected by Lyme disease and therefore would be able to approach this topic objectively.

We appreciate your request that we include a patient who has or previously has had Lyme disease on the panel. Since the initiation of this project, we have very seriously considered how best to involve a patient (or patients) in a manner that maximizes participation, benefits the development of the guideline, and protects the patient from criticism. As above, we will add at least one current or former patient and a parent of a patient treated for confirmed Lyme disease to the panel. The patient(s) will be involved as we're finalizing the clinical question formulation, and throughout the development of the guideline. We're presently working on identifying these individuals.

Another recommendation from the IOM is that panel members with a conflict of interest (COI) not represent a majority of the panel members. All members of the guideline panel were required to submit a COI disclosure form and copies of their curriculum vitae (CV). In order to provide thorough transparency, the full disclosure of all relationships, regardless of relevancy to the guideline topic, was required. A six-person COI review group representative of the three sponsoring organizations was established to review COI forms and CVs for financial and intellectual COI. The six-person COI review group was free from intellectual and financial conflicts. The COI review group determined which members of the guideline panel were deemed to have COI vs. those without COI. The COI review group ensured that the majority of the panel members and each co-chair were without potential conflicts, and the panel was approved.

We are working very hard to ensure ample opportunity for public input. In fact, there will be two periods for public input, both at critical points in the development of the guideline. The first was a 45-day public input period on the Project Plan, which took place from March 9 to April 9 and was extended an additional 15 days (and ended on April 24). The second opportunity for

¹ Institute of Medicine of the National Academies. Clinical Practice Guidelines We Can Trust: Standards for Developing Trustworthy Clinical Practice Guidelines (CPGs). <http://www.iom.edu/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust.aspx>. Released March 23, 2011.

public input will be established once a draft of the new guideline is available. Please note the comments obtained as part of the first public comment period will not be made publicly available for several reasons. First, we did not inform submitters that their comments would be made public. In addition, some public comments include individual medical information, despite our request that they not include this type of information. Lastly, some of the comments include profanities. As a result, we will review, group, and summarize comments into broad categories and provide an official response from the panel.

Lastly, the 2006 IDSA guidelines and the new IDSA/AAN/ACR guidelines are assessments of current scientific and clinical information provided as an educational service and do not mandate any particular course of medical care. Guidelines should not be considered inclusive of all proper treatments, methods of care, or as a statement of the standard of care. In all cases, the selected course of action should be considered by the treating provider in the context of treating the individual patient. Use of the guidelines is voluntary.

Once again, we thank you for giving us the opportunity to respond to your concerns on this important matter. We share your commitment to ensuring that all patients with Lyme disease have access to the highest quality evidence-based care, which is why we are devoting significant resources to this highly robust project. Please contact us at any time with any additional questions.

Sincerely,



Stephen B. Calderwood, MD, FIDSA
President, Infectious Diseases Society of America (IDSA)



Terrence L. Cascino, MD, FAAN
President, American Academy of Neurology (AAN)



E. William St. Clair, MD
President, American College of Rheumatology (ACR)

Attachment 1

American Academy of Family Physicians (AAFP)

American Academy of Pediatrics

 Committee on Infectious Diseases (AAP-COID)

 Section on Emergency Medicine (AAP-EM)

American College of Physicians (ACP)

Association of Medical Microbiology and Infectious Diseases – Canada (AMMI-CA)

Child Neurology Society (CNS)

Pediatric Infectious Diseases Society (PIDS)

Entomological Society of America (ESA)

European Society of Clinical Microbiology and Infectious Diseases (ESCMID)