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Infectious Diseases Society of America

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IDSA Headquarters

1300 Wilson Boulevard
Suite 300

Arlington, VA 22209

TEL: (703) 299-0200

FAX: (703) 299-0204

EMAIL ADDRESS:

info@idsociety.org

WEBSITE:

www.idsociety.org

June 25, 2009

The Honorable Henry Waxman
Chairman
House Energy & Commerce Committee
United States House of Representatives
Washington, DC 20515

Dear Chairman Waxman:

I write on behalf of the Infectious Diseases Society of America (IDSA) regarding the Lyme and Tick-Borne Disease Prevention, Education, and Research Act (H.R. 1179), which recently was reintroduced in the House of Representatives. IDSA is the largest infectious diseases medical society in the United States, representing more than 8,600 physicians and scientists. Our Society supports many of the goals enumerated by the bill's co-sponsors. However, IDSA must oppose the legislation as currently drafted and urges you not to cosponsor it. IDSA's goal in opposing H.R. 1179 is to ensure the best quality in patient care and to protect the public's health and safety. Instead, we put forth several ideas for Congress to consider in regard to Lyme disease, including the establishment of a Serum Reference Repository that could lead to improved diagnostics tests, increased patient and physician education efforts, and a science-based review of Lyme disease issues by the Institute of Medicine.

Improved Diagnostics

IDSA believes that specific and more sensitive diagnostic tests for Lyme disease are needed. The National Institute for Allergy and Infectious Diseases (NIAID) at the National Institutes of Health (NIH) devotes about 20% of its funding for Lyme disease to research that relates directly or indirectly to diagnosis. Because of enormous advances in bioinformatics and molecular genetics, significant progress has been made in the development of new diagnostic procedures. However, it must be noted that whenever any new diagnostic test is developed, it must be compared to existing diagnostic methods to ensure that it is indeed superior with respect to specificity and sensitivity before it can be widely used and applied.

Studies performed at different institutions may use a variety of experimental methods that make it impossible to compare results in a meaningful way. The establishment of a Serum Reference Repository with a computerized data base would greatly accelerate this decision making process by applying uniform standards to a large number of patient cases. It would enable comparison of results of newly developed and existing diagnostic tests under identical conditions using the same panel of well-characterized reference specimens. At a relatively modest cost (less than \$1 million per year), it can be designed to yield the precise type of information the Food and Drug Administration (FDA) and

Centers for Disease Control (CDC) need to make sound recommendations on the best diagnostic tests to be used routinely as well as to provide pertinent information on a test's strengths and limitations. The establishment of a Serum Reference Repository, which would be funded by the NIH and managed by the CDC, would do a great deal to advance progress on Lyme disease diagnosis.

Controversies Surrounding Lyme Disease Treatment

IDSA recognizes that Lyme disease can be painful and that the disease is not always properly identified or treated. We sympathize with patients who suffer from the wide array of symptoms that have been attributed by some to be due to so-called "chronic" Lyme disease, but we are concerned that most of these patients have been improperly diagnosed and may be receiving a treatment, i.e., long-term antibiotic therapy, that will do them more harm than good.

We believe it is important that Members of Congress who are considering co-sponsorship of H.R. 1179 be fully apprised of IDSA's view, which is aligned with the broader medical and scientific communities' view, that the long-term use of antibiotics for the treatment of Lyme disease is unproven and potentially harmful to the patients being treated and to the public's health (due to the potential creation of drug-resistant organisms). At least four randomized trials do not support the use of long-term antibiotics as an appropriate treatment for Lyme disease. Further, it is IDSA's position that no reliable evidence exists that supports the designation of Lyme disease as a chronic disease. Two recent reviews -- one published in the *New England Journal of Medicine* (*N Engl J Med* 357:14; October 4, 2007) and the other in the *American Journal of Medicine* (2008) 121, 562-564 -- give evidence-based assessments of Lyme disease diagnoses and the recommended treatments which substantiate our position.

Given the broad, nearly unanimous consensus surrounding these issues, IDSA is compelled to raise serious concerns about the proposed composition of the federal advisory committee that H.R. 1179 would establish as it mandates an uneven slate of members tilted toward the viewpoint of a small, financially conflicted minority of physicians who benefit from diagnosing Lyme as a "chronic" disease and by prescribing long-term antibiotic use to treat it. It is unlikely that such an advisory committee could be relied upon to put forth sound, scientifically-based recommendations.

Institute of Medicine Review

IDSA suggests that Congress request the Institute of Medicine (IOM) of the National Academies to conduct a thorough review of all Lyme disease diagnosis, treatment and prevention methods, particularly addressing diagnostic standards, the adequacy of current treatment guidelines, treatment options for post-Lyme disease disorder, effectiveness of current prevention methods, and the controversies surrounding chronic Lyme disease. If at the end of its review, the IOM believes that a federal advisory committee would be beneficial to federal decision-making, IOM should provide Congress with a set of clear and specific mandates and objectives for such a committee, as well as suggestions for the composition of the panel that will assure impartial and scientifically sound deliberations.

In summary, IDSA supports the development of improved diagnostic tests for Lyme disease, increased education about appropriate treatments for this disease as well as IOM's science-

based review of the available evidence in this area. We cannot support the non-evidence based public health policy decision-making and educational efforts that H.R. 1179 would institutionalize. I thank you for taking the time to understand our concerns with this legislation. If you have any questions or need any further information, please feel free to contact Michael Ochs, IDSA Government Relations Associate. Mr. Ochs may be reached at (703) 740-4790 or via e-mail at mochs@idsociety.org.

Sincerely,

A handwritten signature in cursive script that reads "Anne A. Gershon".

Anne A. Gershon, MD, FIDSA
President