

Oral testimony presented to the New York Senate Task Force on Lyme & Tick Borne Disease and the Senate Standing Committee on Health, August 29, 2017

Good morning, my name is Dr. Sunil Sood and I am here today representing the Infectious Diseases Society of America, or IDSA. I would like to begin by thanking Senator Hannon and Senator Serino and the rest of the Senate Task Force on Lyme and Tick Borne Diseases and the Senate Health Committee for extending the invitation to speak as a part of the hearing today. IDSA is the largest infectious diseases medical society in the United States, representing more than 11,000 physicians and scientists. The Society's members focus on the epidemiology, diagnosis, investigation, prevention, and treatment of infectious diseases in the U.S. and abroad. Our members care for patients of all ages with serious infections including tick-borne infections such as Lyme disease. IDSA is committed to ensuring that patients receive the highest quality care for infectious diseases, including Lyme disease. We have great sympathy for patients who are suffering from persisting symptoms after treatment for Lyme disease or other conditions, and want all of these patients to achieve the best possible outcomes.

I am a practicing infectious disease physician, and I developed a research interest in tick-borne diseases when I moved to Long Island in 1990. I have published several papers in peer-reviewed journals, edited a book on Lyme disease and actively teach as professor at the Hofstra Northwell medical school. I currently serve on the joint IDSA-American College of Rheumatology-American Academy of Neurology panel that is revising our guideline for diagnosis and treatment of Lyme disease.

Lyme disease is caused by the bacterium *Borrelia burgdorferi*. There is little doubt that the number of cases of Lyme disease is increasing, because of a geographic expansion of the deer tick, which is moving west and south from its customary mid-Atlantic and New England locations. In the majority of patients, Lyme disease causes a skin lesion (erythema migrans), often accompanied by muscle and joint aches. Infection can spread to the joints, the heart, and the nervous system.

Lyme disease is diagnosed on the basis of a combination of factors:

- potential exposure in an area where there are deer ticks
- the medical history as well as physical exam for characteristic signs of the infection
- a confirmatory blood test , although for patients who are newly infected with the rash , diagnosis is made on clinical grounds with no need to obtain blood testing

Lyme disease has well-characterized clinical presentations. However, there is a public perception that Lyme disease can routinely present in a myriad of ways. That is incorrect and may lead to over-testing and over-diagnosis for symptoms such as fatigue or pain due to other conditions. This practice can lead to individuals who do not have Lyme disease receiving dangerous treatments including long-term antibiotic therapy as well as delay in reaching an accurate diagnosis. For patients with persisting symptoms beyond initial treatment for confirmed Lyme disease, additional antibiotics have not proven helpful compared to a placebo, in 5 randomized controlled trials. In fact, the CDC released a report

describing 5 patients who had been put on long-term antibiotics that caused serious and in some cases life threatening infections, but were found not to have Lyme disease. (Serious Bacterial Infections Acquired During Treatment of Patients Given a Diagnosis of Chronic Lyme Disease — United States, MMWR Weekly / June 16, 2017 / 66(23);607–609)

Clinically validated, FDA-approved tests are the best currently available tests for diagnosis of Lyme disease. While in early Lyme disease the test may be negative, because antibodies have not yet been produced by the body, this does not mean that these tests are bad, but is an inherent limitation of ALL antibody-based testing of infections. In fact, for patients with symptoms for more than two to three weeks, serology tests are positive in 70-100% of patients and are highly specific, >95% accurate.

Important progress has been made to facilitate the development of even better diagnostic methods. The NIH and CDC initiated a Serum Reference repository in 2008. In 2011, this repository became available using well-characterized Lyme disease serum samples available to the scientific and manufacturing communities, for the testing and comparison of new and current diagnostic tests. CDC is also developing next generation diagnostic tests (e.g., biomarkers) to improve upon current serological tests. However, the development, validation and commercial distribution of new tests can take many years and millions of dollars. IDSA is advocating for greater federal support to advance research and development of such new diagnostics.

IDSA has done much work to educate policymakers, health care providers and the public about Lyme disease in an attempt to advance prevention strategies, improve testing and diagnosis, prevent unnecessary and potentially harmful antibiotic use, and ensure all patients receive the best care based on available evidence. IDSA strongly supports increased funding for the National Institutes of Health for Lyme disease related research, and for the CDC to improve surveillance and epidemiology of Lyme and other tick-borne illnesses.

The best strategy to prevent tick-borne illnesses is personal protection with the use of approved insect repellents. There is considerable lack of awareness and practice of this strategy. More public service advertisements on how to reduce tick bites would go a long way in reducing these illnesses.

I would like to thank you all again for the opportunity to discuss this important issue with the Task Force and Health Committee, and I will be more than happy to answer any questions you may have.

Respectfully submitted,
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Lyme disease and State Policy Primer for State Legislators

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What is Lyme disease? Lyme disease is a tick-transmitted bacterial infection caused by *Borrelia burgdorferi* that in many patients can cause a skin lesion (erythema migrans, classically causing the familiar “bull’s-eye” rash), often accompanied by muscle and joint aches. If left untreated, infection can spread to the joints, the heart, and the nervous system.

How is Lyme disease diagnosed? Lyme disease is diagnosed by medical history, physical exam, and sometimes a blood test. The blood test works best for patients who have had symptoms for more than four to six weeks because that’s how long it typically takes for the human immune system to make antibodies against the Lyme bacterium. In patients who are newly infected, diagnosis is usually made clinically. Scientific advances may well lead to improved testing strategies for the diagnosis of Lyme disease. IDSA continues to advocate for progress in this area.

Except in very rare cases, Lyme disease causes well-characterized presentations. There is a public perception that Lyme disease can present in a myriad of ways routinely, which is incorrect and may lead to over-testing and over-diagnosis. This practice can lead to individuals who do not have Lyme disease receiving dangerous treatments, including long-term antibiotic therapy as well as delay in reaching an accurate diagnosis.

Can Lyme disease cause a chronic infection after antibiotic treatment? There is not sufficient evidence to support this. It’s important to distinguish between having an active, chronic infection versus having lingering symptoms from a previous infection. Scientific evidence indicates that a 10-28 day course of antibiotics, depending on the stage of Lyme disease, will kill the Lyme disease bacterium in humans. Some patients may continue to experience symptoms such as fatigue, pain, or joint and muscle aches even after the infection has been cleared. While prolonged courses of antibiotics have been proven ineffective in speeding relief of these lingering problems, doctors can talk to patients about other ways to relieve these symptoms, which normally get better over time.

Some people use the term “chronic Lyme disease” for these symptoms. However, this lacks a precise definition. Some people do not quickly recover fully after Lyme disease and have persisting symptoms; however, as there is no evidence of active infection nor evidence to support the effectiveness of additional antibiotic therapy, post-treatment Lyme disease syndrome (PTLDS) is a better term for these symptoms.

Is long-term antibiotic therapy appropriate for Lyme disease? No. The potential benefit of long-term use of antibiotics for the treatment of Lyme disease has been examined and found ineffective in multiple well-done clinical trials, and is potentially harmful both to treated patients and to the public’s health (due to the creation of antibiotic-resistant bacteria). Long-term antibiotic therapy can cause many serious health consequences for patients, including protracted and intractable diarrhea, severe colitis, antibiotic resistance, allergic reactions, bloodstream infections and clots from intravenous catheters, and even death, without any scientifically-founded prospect of benefit.

IDSA's 2006 practice guidelines for the clinical assessment, treatment, and prevention of Lyme disease are widely recognized and referenced by physicians across the country. A special Review Panel in 2010 unanimously supported all of the recommendations in the IDSA guidelines, including the conclusion that long-term antibiotic treatment is unwarranted for Lyme disease and potentially dangerous.

To provide an update to these previous guidelines, 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 with input from eight other major medical and scientific organizations whose members care for patients with Lyme disease. Experts representing the fields of cardiology, pathology, microbiology and entomology (though ticks are not insects but arachnids) are also included among the panel's membership. Finally a healthcare consumer, three patients and a parent of a patient with confirmed Lyme disease are represented. IDSA, AAN and ACR are also providing multiple opportunities for public comment throughout the development process for the new guidelines.

Approximately 20 clinical and scientific organizations in North America and Europe, and numerous scientific and public health bodies agree with IDSA's perspective. Multiple randomized trials fail to support the use of long-term antibiotics as an appropriate treatment for Lyme disease including most recently a large trial comparing two different antibiotic regimens (*New England Journal of Medicine* 2016; 374:1209-1220 March 31, 2016). Three reviews -- one published in the *New England Journal of Medicine* (*N Engl J Med* 357:14; October 4, 2007), one in the *American Journal of Medicine* (2008) 121, 562-564, and a more recent report in *Expert Reviews in Anti-Infective Therapy* (*Expert Rev. Anti Infect. Ther.* 9(7), 787-797 (2011)) -- give evidence-based assessments of Lyme disease diagnoses and the recommended treatments that substantiate IDSA's position. Numerous studies have found that long-term therapy neither ameliorates nor prevents symptoms attributable to Lyme disease.

Lyme diseases state policy issues: There have been and continue to be legislative efforts in several states, many of which are well-intentioned but therapeutically dangerous, that would sanction prolonged courses of antibiotics for patients with Lyme disease, as promoted by a very small group of doctors, despite the lack of evidence for efficacy and with serious concern for adverse events. Such legislation can take many forms, including:

- Requiring health insurers to cover Lyme disease treatments that are not supported by scientific evidence, including long-term antibiotic use and experimental drugs;
- Restricting state boards of medicine (which are charged with protecting the public from harmful medical practices) from disciplining physicians who prescribe dangerous therapy for Lyme disease and other suspected tick-borne infections;
- Mandating specific communications between doctors and patients regarding Lyme disease testing and/or treatment;
- Making it easier for patients who do not have Lyme disease to access inappropriate and dangerous treatments by calling into question negative diagnoses;
- Requiring state health agencies to provide misinformation about Lyme disease diagnosis and treatment.

For more information on Lyme disease, please visit <http://www.idsociety.org/Lyme/>, <http://www.cdc.gov/lyme/>, or <http://www.niaid.nih.gov/topics/lymedisease/Pages/LymeDisease.aspx>.

IDSA has developed a free, online CME program to help physicians recognize, diagnose, and treat Lyme disease. For more information, see <http://lymecourse.idsociety.org/>.