tibiotic therapy, which is disturbing given the overwhelming evidence showing that such treatment is ineffective, dangerous, and potentially deadly for patients [4–12]. The IDSA has been the author of treatment guidelines for approximately 60 infectious diseases and conditions, none of which has ever been challenged in the way that our guidelines on Lyme disease have been. In fact, no other medical professional society’s guidelines have ever been subjected to this level of political scrutiny. The Review Panel’s report validated the recommendations of the IDSA’s Lyme guidelines, giving physicians and patients additional and impartial assurance that the guidelines are medically sound.

The IDSA’s primary concern is for the health and safety of patients. With all our guidelines, our goal is to ensure that patients are given treatment that is safe, effective, and supported by scientific evidence.

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References


Response of the Infectious Diseases Society of America Lyme Disease Review Panel to Johnson and Stricker

To the Editor—Johnson and Stricker [1] voice several concerns, each of which has been explicitly addressed in our final report [2]. They suggest that the Infectious Diseases Society of America (IDSA) Lyme Disease Review Panel ignored submitted references. On the contrary, we carefully reviewed and discussed all references submitted by Johnson and Stricker—multiple pages of text describing their and their colleagues’ concerns with the 2006 IDSA guidelines, as well as hundreds of other references, including a practice guideline coauthored by Stricker [3]. Many references, even when pertinent to ongoing scientific debate about Lyme disease, did not directly pertain to most recommendations within the 2006 IDSA guidelines [4]; for example, much of the submitted material addressed the biological plausibility of chronic Lyme disease. The guidelines contain only 3 recommendations on the subject of “post-Lyme syndromes,” and only 1 discusses biological plausibility. This recommendation specifically casts doubt on whether there is symptomatic persistent infection after treatment, a conclusion supported by the preponderance of evidence and not countered by Johnson and Stricker’s references.

The efficacy of prolonged antimicrobial therapy has been addressed in 5 studies suitable for evaluation on the basis of the quality of evidence [5–9]. Only 1 primary outcome measure (fatigue) significantly favored the antibiotic treatment arm in 1 study; all other outcome comparisons in this and the other studies revealed no significant difference. Even if the Kлемperner study [7] was underpowered, it was the largest of the prospective trials examining this question; neither it nor any other trial has showed that the benefits of prolonged therapy outweigh the risks.

Adverse events have been observed on numerous occasions among patients receiving prolonged antibiotic therapy for Lyme disease. In arguing that the risk of such events is “extremely low” [1], Johnson and Stricker cite a study of 200 patients in which 7 had allergic reactions, 6 had line sepsis, 4 had catheter-associated thrombosis, and 2 had ceftriaxone-induced toxic effects to the gallbladder, necessitating cholecystectomy [10]. Even though the daily rate of adverse events is low, the cumulative risk per patient is high, particularly given the duration of therapy that Johnson and Stricker defend. In addition to the frequency of adverse events, their potential severity has been well documented in multiple studies, and fatalities are not unknown [11, 12].

The action plan, as agreed on by the IDSA and Attorney General Blumenthal, required review only of recommendations
that were made in the 2006 IDSA guidelines [13]. The statement to which Johnson and Stricker refer, which is in the background section of the executive summary, is not a recommendation; thus, the Review Panel was not required to review this section, and the Review Panel members felt that it was too general to be evaluated on its scientific merits. We voted only on whether it required clarification. The Review Panel was evenly divided on this point. To avoid future ambiguity about whether this statement constitutes a recommendation or not, the Review Panel recommended that a section on diagnostic testing be included in future renditions of the guideline.

Clinical judgment is central to all patient management decisions, including understanding the applicability of a diagnostic test to a particular patient. Compelling evidence suggests that validated serologic tests can help both confirm and exclude Lyme disease and are particularly useful for patients with an intermediate prior probability of infection [14]. When patients have prolonged, nonspecific symptoms, the probability of Lyme disease is so low that this diagnosis is doubtful whether testing is pursued or not. Arguments that reject both the clinical and laboratory descriptions of Lyme disease and invoke “clinical judgment” alone (based only on nonspecific complaints) to diagnose this entity beg the question as to how one could ever prove that a patient has Lyme disease—or for that matter ever exclude it.

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