



## International Lyme and Associated Diseases Society

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### Statement regarding revising the IDSA Guidelines

Connecticut Attorney General Richard Blumenthal announced on Thursday, May 1, 2008 that his antitrust investigation has “uncovered serious flaws in the Infectious Diseases Society of America’s (IDSA) process for writing its 2006 Lyme disease guidelines”. Blumenthal’s office reached an agreement with IDSA calling for creation of a review panel “to thoroughly scrutinize the 2006 Lyme disease guidelines and update or revise them if necessary”. ILADS appreciates the commitment by AG Blumenthal and ombudsman Dr. Howard Brody to ensure that the review panel members are free from conflicts of interest. Dr. Brody is a recognized expert and author on medical ethics and conflicts of interest and is director of the Institute for Medical Humanities at the University of Texas Medical Branch in Galveston.

The settlement with the Attorney General sets the stage for improving the outcome for all Lyme disease patients—especially those who remain ill under the IDSA protocols. Three government sponsored trials have documented that Lyme disease patients continue to suffer for years after diagnosis, and have a quality of life poorer than that of patients with diabetes or heart conditions. Yet under the IDSA guidelines, Lyme disease patients who remain ill after the designated treatment period are denied further treatment. ILADS believes that patients need the option of continued treatment when they remain ill.

The Attorney General found that IDSA suppressed scientific evidence and blocked participation by physicians holding different viewpoints on treating Lyme disease. IDSA relied on trials of fewer than 350 patients who had been ill for 5 to 9 years. The small selected sample sizes used in the studies preclude generalization of the results to actual practice. The 2006 IDSA guidelines never addressed the following generalizability concern: “Applying the findings to target populations with characteristics that differ from those included in these trials is inappropriate and may limit options for chronic Lyme disease patients who might benefit from antibiotic treatment [1].” Other studies supporting longer term treatment were excluded from consideration. The experience of clinicians who treat patients who remain ill was also excluded.

ILADS is concerned that initial statements made by the IDSA President, Donald Poretz, demonstrate a continued unwillingness to support a guideline development process that reflects divergent points of view. Dr. Poretz stated in an IDSA press release that “We are confident that our guidelines for the diagnosis and treatment of Lyme disease represent the best advice that medicine currently has to offer, as is the case with all of the medical guidelines issued by the Society, and we look forward to the opportunity to put to rest any questions about them.” We trust that this complacent attitude will not find its way into the IDSA's conduct going forward, and we expect the IDSA to fulfill its obligations in good faith under the settlement agreement.

The published ILADS evidence-based guidelines have already demonstrated how two panels reviewing the same body of scientific literature can reach differing conclusions. ILADS would like to see a new set of guidelines that better reflect the view that Lyme disease is a complex illness that is difficult to treat, and that take into account the breadth of research and clinical experience in treating it.

It is ILADS' view that chronic Lyme disease can be considered "another example of a 'clinical equipoise'-- absence of consensus within the clinical community". When clinical equipoise exists, it is even more critical for the medical community to be able to evaluate conflicting positions, the basis for the medical evidence cited, study criteria, professional agendas and conflicts of interests that may exist. "Only by airing different points of view will the medical and scientific community reach a better understanding of controversial topics such as chronic Lyme disease [2]".



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1. Cameron DJ: **Generalizability in two clinical trials of Lyme disease**. *Epidemiol Perspect Innov* 2006, **3**(1):12.
2. Cameron DJ: **An appraisal of "chronic Lyme disease"**. *N Engl J Med* 2008, **358**(4):429-430; author reply 430-1.

Attorney General's Press release: <http://www.ct.gov/ag/cwp/view.asp?A=2795&Q=414284>

IDSA's press release: <http://www.idsociety.org/PrintFriendly.aspx?id=11182>