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Lyme Disease: A Biting Conflict

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I. INTRODUCTION

Lyme disease, the most common tick-borne illness, is a serious public health problem.¹ Lyme disease has existed in the United States since the 1940s.² It takes its name from the town Lyme in Connecticut, where it was recognized as a cluster of cases in the mid 1970s.³ From 1992 to 2006, a total of 248,074 Lyme disease cases were reported to the Centers for Disease Control and Prevention.⁴ The overall trend indicates a steady increase in the number of reported cases each year.⁵ Ecological changes are one of the direct causes of the spread of Lyme disease.⁶ Avoidance of exposure to the deer tick, the primary source of Lyme disease in the United States, is a fundamental solution.⁷

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¹ Henry M. Feder, Jr. et al., *A Critical Appraisal of "Chronic Lyme Disease,"* 357 NEW ENG. J. MED. 1422, 1422 (2007).

² Alfred DeMaria, Jr., *Globalization of Infectious Diseases: Questions Posed by the Behavioral, Social, Economic and Environmental Context of Emerging Infections,* 11 NEW ENG. J. INT'L & COMP. L. 37, 43 (2004).

³ *See id.*

⁴ Rendi Murphree Bacon, Kiersten J. Kugeler & Paul S. Mead, MORBIDITY & MORTALITY WKLY. REP. SURVEILLANCE SUMMARIES (Ctrs. for Disease Control & Prevention, Atlanta, Ga.), Oct. 3, 2008, at 1, 1, *available at* <http://www.cdc.gov/mmwr/PDF/ss/ss5710.pdf>.

⁵ *Id.* ("During 1992-2006, the number of reported cases more than doubled.")

⁶ DeMaria, *supra* note 2, at 44.

⁷ *See* CTRS. for Disease Control & Prevention, Learn About Lyme Disease, <http://www.cdc.gov/ncidod/dvbid/lyme> (last visited Mar. 28, 2009).

Lyme disease presents itself with diverse clinical signs and symptoms and with several variations in the progression of the unmitigated disease course.⁸ This uncertain progression led to contrasting opinions in the medical community about the existence and treatment of long-term symptoms of the disease.⁹ In 2006, the Infectious Diseases Society of America (IDSA) released guidelines recommending that patients infected with Lyme disease should receive only one treatment of antibiotics, but the International Lyme and Associated Diseases Society (ILADS) called for a retraction of these guidelines.¹⁰ Additionally, in 2007, both the Senate and the House of Representatives presented bills designed to combat Lyme disease, but neither has been implemented.¹¹

This article will first discuss the signs and symptoms of Lyme disease. This article will then discuss the implications of the conflicting points of view surrounding chronic Lyme disease and how they affect the clinical care of patients stricken with Lyme disease. Finally, this article will briefly explore Lyme disease legislation.

II. SIGNS AND SYMPTOMS OF LYME DISEASE

Lyme disease is transmitted by a deer tick infected with borrelia, highly invasive bacteria that can localize in selected tissues.¹² A complete presentation of the untreated disease is a very unusual observation; a tick bite leading to a skin lesion, followed by involvement of the heart and nervous system, and then arthritis.¹³ The only physical sign that enables a reliable clinical diagnosis in everyday medical practice is a typical skin lesion called erythema migrans.¹⁴ At

⁸ Feder et al., *supra* note 1, at 1422.

⁹ *Id.*

¹⁰ Press Release, Int'l Lyme & Associated Diseases Soc'y, Lyme Wars: Lyme Disease Expert Critical of New Treatment Guidelines (Nov. 27, 2006), available at http://www.ilads.org/publications_cameron_11_2006.pdf [hereinafter Lyme Wars].

¹¹ Lyme and Tick-Borne Disease Prevention, Education, and Research Act of 2007, H.R. 741, 110th Cong. (1st Sess. 2007); S. 1708, 110th Cong. (1st Sess. 2007).

¹² Gerold Stanek & Franc Strle, *Lyme Borreliosis*, 362 LANCET 1639, 1640 (2003).

¹³ Feder et al., *supra* note 1, at 1422.

¹⁴ *Id.* Laboratory tests can also confirm the presence of the bacteria early in the illness. Allen C. Steere, *Lyme Disease*, 345 NEW ENG. J. MED. 115, 116, 120 (2001).

this first sign, conventional antibiotics, such as doxycycline and amoxicillin, are normally prescribed.¹⁵ Most other signs and symptoms are of low or even no diagnostic value because they can be attributed to other causes.¹⁶

Erythema migrans, commonly referred to as a bulls-eye rash, is the most valuable clinical sign of Lyme disease.¹⁷ After being bitten by an infected tick, “a small red macula or papule appears on the skin, usually at the site of the bite.”¹⁸ A ring-like lesion becomes visible as the red patch slowly enlarges and the middle of the lesion begins to clear.¹⁹ If left untreated, the lesion will persist and expand.²⁰ The lesion’s diameter may range from a few centimeters to more than a meter and can often go undetected depending on what area of the body the lesion is located.²¹ In adult patients, the lesion is more often located on the lower half of the body; in children, the upper part of the body is more frequently affected.²² Symptoms accompanying the bite include mild itching, burning, or pain.²³ A smaller proportion of people have systemic flu-like symptoms such as fatigue and malaise, headache, and muscle or joint pain.²⁴ Without treatment, the disease can affect the nervous system, heart, and the joints.²⁵ These symptoms are intermittent and differ in intensity and position.²⁶ Antibiotic therapy is effective

¹⁵ Steere, *supra* note 14, at 121.

¹⁶ See JONATHAN A. EDLOW, TICK-BORNE DISEASES, LYME, EMEDICINE, Dec. 12, 2008, <http://emedicine.medscape.com/article/786767-overview> (last visited Mar. 28, 2009); see also Feder et al., *supra* note 1, at 1422.

¹⁷ Stanek & Strle, *supra* note 12, at 1640.

¹⁸ *Id.*; see American Lyme Disease Foundation, Pictures of Erythema Migrans, <http://www.aldf.com/EMPoster.shtml> (last visited Mar. 28, 2009) (showing pictures of the ring-like lesion).

¹⁹ Stanek & Strle, *supra* note 12, at 1640.

²⁰ *Id.*

²¹ *Id.*

²² *Id.* Children and adults have similar manifestations of Lyme disease. Kristina A. Bryant & Gary S. Marshall, *Clinical Manifestations of Tick-Borne Infections in Children*, 7 CLINICAL & DIAGNOSTIC LABORATORY IMMUNOLOGY, 523, 523 (2000).

²³ Stanek & Strle, *supra* note 12, at 1640.

²⁴ *Id.*

²⁵ Steere, *supra* note 14, at 117-18.

²⁶ *Id.*

for patients with objective manifestations of Lyme disease, especially when given early in the course of the illness.²⁷

III. THE MEDICAL CONFLICT SURROUNDING CHRONIC LYME DISEASE

A minority of patients progress to a chronic course of Lyme disease, where patients continue to have “fatigue, musculoskeletal pain, difficulties with concentration or short-term memory, or all of these symptoms” even after antibiotic treatment and resolution of the objective signs of Lyme disease.²⁸ The diagnosis of chronic Lyme disease is based on clinical judgment and surveillance rather than clinical criteria or laboratory studies.²⁹ As such, the progressed disease often remains unchecked and undiagnosed.

A medical conflict arises for patients who suffer from a chronic state of Lyme disease. In 2006, the IDSA released guidelines stating that Lyme disease must be diagnosed by a visible rash and common blood tests and should be treated with a standard course of antibiotics for ten to twenty-one days.³⁰ While the IDSA questions the existence of chronic Lyme disease,³¹ ILADS recognizes chronic Lyme disease and the ILADS guidelines call for long-term antibiotic treatment for persistent Lyme disease or infection complications.³²

The IDSA uses the term “chronic Lyme disease” to refer to patients who have well-documented Lyme disease and remain symptomatic for months to years after receipt of appropriate antibiotics.³³ Often these patients complain only of

²⁷ *Id.* at 121.

²⁸ Feder et al. *supra* note 1, at 1422.

²⁹ *Id.* at 1423.

³⁰ Gary P. Wormser, et al., *The Clinical Assessment, Treatment, and Prevention of Lyme Disease, Human Granulocytic Anaplasmosis, and Babesiosis: Clinical Practice Guidelines by the Infectious Diseases Society of America*, 43 *CLINICAL INFECTIOUS DISEASES* 1089, 1089-90, 1091 (2006).

³¹ *Id.* at 1094.

³² Int'l Lyme & Associated Diseases Soc'y, *Evidence-Based Guidelines for the Management of Lyme Disease*, 2 *EXPERT REV. ANTI-INFECTIVE THERAPY* S1, at S9 (2004) [hereinafter ILADS] (responding to the 2000 IDSA guidelines that also denied the existence of chronic Lyme disease).

³³ Wormser et al., *supra* note 30, at 1116.

subjective symptoms such as musculoskeletal pain, cognitive issues, and fatigue.³⁴ The IDSA claims that the unoriginality of these complaints is suspect because many people without Lyme disease also report having these symptoms.³⁵ Citing two controlled treatment studies, the IDSA concluded that there is no convincing evidence for the existence of symptomatic chronic Lyme disease infection among patients after receiving appropriate treatment.³⁶ They concluded that antibiotic therapy has not proven successful and is not recommended for patients who experience more than six months of subjective symptoms after receiving the recommended treatment for Lyme disease.³⁷ The IDSA also stated that there are inherent risks from long-term antibiotic treatment such as infection at intravenous sites and the creation of antibiotic resistant bacteria.³⁸

Alternatively, ILADS claims that IDSA's symptomatic approaches to Lyme disease are limited and exclude many individuals with persisting clinical and laboratory evidence of active Lyme infection.³⁹ In addition, physicians treating patients with Lyme disease recognize the need for new treatment protocols to better serve the population.⁴⁰ ILADS recognizes that some patients respond poorly to the initial antibiotic treatment and may need further interventions.⁴¹ The organization criticized the accuracy of the studies embraced by IDSA for enrolling patients with chronic Lyme disease who were sick for an average of about five years despite three courses of antibiotics, and for relying only on one treatment protocol.⁴² In view of this unreliable research, ILADS recommends that physicians base their treatment on the patient's clinical response

³⁴ *Id.*

³⁵ *Id.* at 1115.

³⁶ *Id.* at 1119-21.

³⁷ *Id.* at 1121.

³⁸ Ronni Berke, *10-Year Battle with Pain Highlights Lyme Disease Debate*, CNN, <http://www.cnn.com/2008/HEALTH/conditions/07/06/lymedisease.treatment/index.html> (last visited Mar. 28, 2009).

³⁹ ILADS, *supra* note 32, at S4.

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² *Id.* at S6.

and notes that several months of antibiotic therapy may be required to accomplish noticeable improvement.⁴³

IV. REPERCUSSIONS FOR PATIENTS

The medical community and insurers generally respect guidelines published by medical organizations.⁴⁴ However, there is a real contradiction between two Lyme disease societies about chronic Lyme disease.⁴⁵ Patients who believe they suffer from chronic Lyme disease want antibiotic treatment, and the IDSA guidelines potentially deny them access to that treatment.⁴⁶ The attorney general's office in Connecticut, the state with the country's highest incidence of Lyme disease, launched an anti-trust investigation into the IDSA panel.⁴⁷ Connecticut Attorney General Richard Blumenthal inquired into whether IDSA ignored any studies supporting long-term antibiotic treatment and if there were any conflicts of interests.⁴⁸ There was a concern that insurance companies might use these new guidelines to deny payment for Lyme treatment.⁴⁹ Blumenthal also claimed that some members of the IDSA panel who wrote the guidelines consulted for insurance companies and one member had a patent for a Lyme disease treatment.⁵⁰ Both issues represent conflicts of interest that could arguably lead to unfair guidelines in respect to chronic Lyme disease.

On April 30, 2008, the IDSA reached a settlement with Blumenthal; the IDSA was required to implement a plan in which a review panel will determine whether the 2006 guidelines should be revised or updated.⁵¹ This review panel

⁴³ *Id.* at S6, S9.

⁴⁴ Lyme Wars, *supra* note 10.

⁴⁵ *E.g.*, Mary Carmichael, *The Great Lyme Debate*, NEWSWEEK, Aug. 6, 2007, at 42, available at <http://www.newsweek.com/id/32657>.

⁴⁶ *See* Lyme Wars, *supra* note 10.

⁴⁷ Berke, *supra* note 38; Bacon, Kugeler & Mead, *supra* note 4, at 4.

⁴⁸ Berke, *supra* note 38.

⁴⁹ *Id.*

⁵⁰ *Id.*

⁵¹ Agreement Between Conn. Att'y Gen. & Infectious Diseases Soc'y of Am. 1, 5 (April 30, 2008), available at <http://www.ct.gov/ag/lib/ag/health/idsaagreement.pdf>.

was selected on January 26, 2009.⁵² On February 2, 2009, the panel initiated a sixty day input period to allow the public to submit information to ensure that all points of view are taken into consideration.⁵³ The outcomes of the investigation by the review panel remain to be seen.

V. CONCLUSION

The prevalence of Lyme disease is on the rise in the United States.⁵⁴ With the possibility that Lyme disease can be a chronic infection and that early treatment is most effective, prevention of this disease is essential. In response to this concern, on January 31, 2007, Rep. Christopher Smith from New Jersey introduced the Lyme and Tick-Borne Disease Prevention, Education, and Research Act of 2007.⁵⁵ This bill would “provide for the expansion of Federal efforts concerning the prevention, education, treatment, and research activities related to Lyme [disease].”⁵⁶ The bill also called for the establishment of a Tick-Borne Diseases Advisory Committee.⁵⁷ Unfortunately, the bill was referred to the Subcommittee on Health.⁵⁸ The authors of the bill recognized that Lyme disease can lead to serious problems, and patients reporting persistent symptoms without reliable testing make treatment more difficult.⁵⁹ The fact that the efficacy and treatment of chronic Lyme disease remains in dispute complicates the dilemma and clinical treatment of patients.

⁵² Statement from IDSA on Selection of Panelists for Review, <http://www.idsociety.org/PrintFriendly.aspx?id=13310> (last visited Mar. 28, 2009).

⁵³ IDSA Lyme Disease Review Panel Announces Public Input Period and Hearing Date, <http://www.idsociety.org/PrintFriendly.aspx?id=13352> (last visited Feb. 15, 2009).

⁵⁴ See Bacon, Kugeler & Mead, *supra* note 4 (“During 1992-2006, the number of cases more than doubled.”).

⁵⁵ See Lyme and Tick-Borne Disease Prevention, Education, and Research Act of 2007, H.R. 741, 110th Cong. (2007). The Senate version of the bill was introduced by Sen. Christopher Dodd on June 27, 2007. S. 1708, 110th Cong. (2007). It was read twice and then referred to the Committee on Health, Education, Labor, and Pensions. 153 CONG. REC. S8610 (2007).

⁵⁶ H.R. 741.

⁵⁷ *Id.* § 3.

⁵⁸ Library of Congress, THOMAS, <http://thomas.loc.gov/cgi-bin/bdquery/z?d110:h.r.00741>: (last visited Mar. 28, 2009).

⁵⁹ H.R. 741 § 2.

Although the IDSA does not currently recognize chronic Lyme disease, many physicians agree that there are a large number of patients who have chronic symptoms of Lyme disease.⁶⁰ Both the IDSA and ILADS provide guidelines for clinicians in deciding the appropriate treatment of Lyme disease.⁶¹ These societies should be cautious to rule out long-term treatments for Lyme disease without thorough research, especially due to the fact that insurers rely on these guidelines and are looking for means to avoid costs in these times of coverage crisis. In the case of Lyme disease, anything less than expert medical analysis of effective treatment does a disservice to those stricken with the disease.

⁶⁰ See Carmichael, *supra* note 45. However, “the doctors who made the new IDSA guidelines on treatment say there’s no such thing as chronic Lyme.” *Id.*

⁶¹ See *supra* Part III.