

Dr. Daniel Cameron, MD, MPH

Testimony in support of PA Senate Bill #1199

June 22, 2010

Chairman, members of the committee, I appreciate the opportunity to speak on behalf of the International Lyme and Associated Diseases Society (ILADS) in support of Pennsylvania S.B. 1199, "Lyme and Related Tick-Borne Disease Education, Prevention and Treatment Act". I am an Internist with a practice in New York, an epidemiologist, the immediate past president of ILADS, and member of the Infectious Diseases Society of America (IDSA) and the Council of State and Territorial Epidemiologists (CSTE).

I will review how the PA Senate Bill #1199 will address the burden of Lyme disease (LD) in Pennsylvania. The number of new LD cases has reached 8,087 in 2009. The actual numbers of cases of LD in Pennsylvania in 2009 has been estimated to be ten times higher or 80,000.

All four National Institutes of Health (NIH) sponsored clinical trials validate the burden of LD as measured by severity and duration of illness, diagnostic delays, and treatment failures.[1-3] Fallon et al. described pain reported by patients with LD encephalopathy as being "... similar to those of post surgery patients", fatigue as "similar to that of patients with multiple sclerosis," and limitations in physical functioning on a SF-36 measure of quality of life (QOL) scale as "comparable with those of patients with congestive heart failure." [2] Klempner described the QOL as "more than 0.5 SD greater than the impairment observed in patients with type 2 diabetes or a recent myocardial infarction." [3]

The average duration of illness was 4.7 years for individuals with CLD in two Klempner trials and 9 years for individuals with CLD in the Fallon trial.[2, 3] The average diagnostic delay was two years in the Fallon trial.[2] Thirty-six to sixty percent of chronic Lyme disease (CLD) patients failed antibiotic treatment.[1-3]

IDSA and ILADS evidence based guidelines reached differing conclusions regarding the burden of Lyme disease. IDSA concluded that CLD does not exist and that symptoms are nothing more than the aches and pains of daily living.[4] ILADS concluded that CLD exists and that symptoms can be severe. Thirty-four to sixty-two percent of Lyme disease patients were chronically ill years after antibiotic treatment in studies in Massachusetts [5] and New York.[6]. Ten to sixteen percent of patients treated at the time of an erythema migrans rash remained symptomatic a mean of 30 months after treatment.[7] The four NIH retreatment trials validated the severity of symptoms on 22 standardized measures of fatigue, pain, role function, psychopathology, cognition, and quality of life (QOL).[8]

The economic burden of Lyme disease can be estimated based on a collaboration of Zhang and Meltzer from the Centers for Disease Control and Prevention (CDC), Peña and Hopkins, from the University of Maryland, and Wroth and Fix from Care First-Easton Branch (previously Delmarva Health Plan), Easton, Maryland, USA.[9] The average annual cost of acute LD was \$1,310 in 2002 dollars. The average annual cost of CLD was \$16,199, a cost 12 times higher than cost for early Lyme disease. Eighty-eight percent of the average annual cost was indirect medical costs, nonmedical costs, and productivity.

The economic burden of Lyme disease in Pennsylvania is high using either the IDSA or ILADS conclusion. The annual cost of acute Lyme disease in Pennsylvania under the IDSA conclusion would be \$105 million based on the 80,000 estimated in the state.\* The IDSA conclusion assumes there are no cost associated with chronic manifestations of Lyme disease.

The annual cost of acute Lyme disease in Pennsylvania under the ILADS conclusion reflects the additional cost for CLD. The annual cost of Lyme disease in Pennsylvania would be an additional \$130 million if ten percent of the 80,000 cases of Lyme disease would become chronic.\*\* The annual cost of CLD in Pennsylvania would be \$609 million to \$1.2 billion if individuals with CLD remained ill for the 4.7 and 9 years respectively as described in the NIH clinical trials.[2, 10]\*\*\*

IDSA and ILADS evidence based guidelines reached differing conclusion regarding the treatment of Lyme disease. IDSA advised against antibiotic treatment after considering the following risks and benefit assumptions: 1) the risk of adverse events, 2) the risk of emerging infections, 3) the absence of risk of CLD, and 4) and the absence of benefits of antibiotics in the NIH trials.

ILADS concluded that the risk to society of overuse of antibiotics and emergence of multi-resistant infectious disease organisms has received considerable attention. The risk to society of the emerging population of CLD has received little attention. ILADS advised antibiotic treatment after considering the following risks and benefit assumptions: 1) the risk of adverse events, 2) risk of emerging infections, 3) the risk of CLD, and 4) the benefits treating CLD in the Krupp trial and previous studies. ILADS has also encouraged professionals “to examine whether “innovative treatments for early LD might prevent CLD, (2) early diagnosis of CLD might result in better treatment outcomes, and (3) more effective regimens can be developed for CLD patients who have had prolonged illness and an associated poor quality of life.”[11]

If PA Senate Bill #1199 does not pass its citizens may not be informed of differing conclusions regarding the burden of CLD. Health insurers can continue to deny coverage for CLD. The state could interfere with the practice of medicine by investigating and potentially revoking the license of physicians who treat CLD.

If PA Senate Bill #1199 passes, Pennsylvania citizens will hear differing conclusions regarding the burden of CLD. Health insurers will be encouraged to provide coverage for treatment prescribed by licensed physician. Its physicians will be more likely to look for Lyme disease in its early and more treatable stages, and will be able to apply individualized strategies, that might include the appropriate use of longer-term antibiotics for CLD.

Respectively,

Daniel Cameron, MD, MPH

Immediate past president, ILADS

Addendum:

\* 80,000 acute cases x \$1,310 per case = \$104,800,000

\*\* 8,000 new chronic cases x \$16,199 per case = \$129,592,000

\*\*\* \$129,592,000 x 4.7 years = \$609,082,400

\*\*\* \$129,592,000 x 9 years = \$1,166,328,000

Attachments:

1. Zhang X, Meltzer MI, Pena CA, Hopkins AB, Wroth L, Fix AD: Economic impact of Lyme disease. *Emerg Infect Dis* 2006, 12(4):653-660.
2. Cameron, D., et al., *Evidence-based guidelines for the management of Lyme disease*. Expert Rev Anti Infect Ther, 2004. 2(1 Suppl): p. S1-13.
3. Cameron, D.J., *Generalizability in two clinical trials of Lyme disease*. Epidemiol Perspect Innov, 2006. 3: p. 12.
4. Cameron, D.J., *Consequences of treatment delay in Lyme disease*. J Eval Clin Pract, 2007. 13(3): p. 470-2.
5. Cameron, D., *Severity of Lyme disease with persistent symptoms. Insights from a double-blind placebo-controlled clinical trial*. Minerva Med, 2008. 99(5): p. 489-96.
6. Cameron, D.J., *Clinical trials validate the severity of persistent Lyme disease symptoms*. Med Hypotheses, 2008. 72: p. 153-156.
7. Cameron, D.J., *An appraisal of "chronic Lyme disease"*. N Engl J Med, 2008. 358(4): p. 429-30; author reply 430-1.
8. Cameron, D.J., *Insufficient evidence to deny antibiotic coverage to chronic Lyme disease patients*. Med Hypotheses, 2009. 72: p. 688-691.

9. Cameron, D., *Obstacles to trials of chronic Lyme disease in actual practice*. *Minerva Med*, 2009. **100**(5): p. 435-6.
10. Cameron, D.J., *Proof that chronic lyme disease exists*. *Interdiscip Perspect Infect Dis*, 2010. Article ID 876450, 4 pages, doi:10.1155/2010/876450.

## References

1. Krupp, L.B., et al., *Study and treatment of post Lyme disease (STOP-LD): a randomized double masked clinical trial*. *Neurology*, 2003. **60**(12): p. 1923-30.
2. Fallon, B.A., et al., *A randomized, placebo-controlled trial of repeated IV antibiotic therapy for Lyme encephalopathy*. *Neurology*, 2008. **70**(13): p. 992-1003.
3. Klemmner, M.S., et al., *Two controlled trials of antibiotic treatment in patients with persistent symptoms and a history of Lyme disease*. *N Engl J Med*, 2001. **345**(2): p. 85-92.
4. Wormser, G.P., 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*. *Clin Infect Dis*, 2006. **43**(9): p. 1089-134.
5. Shadick, N.A., et al., *The long-term clinical outcomes of Lyme disease. A population-based retrospective cohort study*. *Ann Intern Med*, 1994. **121**(8): p. 560-7.
6. Asch, E.S., et al., *Lyme disease: an infectious and postinfectious syndrome*. *J Rheumatol*, 1994. **21**(3): p. 454-61.
7. Wormser, G.P., et al., *Duration of antibiotic therapy for early Lyme disease. A randomized, double-blind, placebo-controlled trial*. *Ann Intern Med*, 2003. **138**(9): p. 697-704.
8. Cameron, D.J., *Clinical trials validate the severity of persistent Lyme disease symptoms*. *Med Hypotheses*, 2008. **72**: p. 153-156.
9. Zhang, X., et al., *Economic impact of Lyme disease*. *Emerg Infect Dis*, 2006. **12**(4): p. 653-60.
10. Klemmner, M.S., *Controlled trials of antibiotic treatment in patients with post-treatment chronic Lyme disease*. *Vector Borne Zoonotic Dis*, 2002. **2**(4): p. 255-63.
11. Cameron, D.J., *Proof that chronic lyme disease exists*. *Interdiscip Perspect Infect Dis*, 2010. **Article ID 876450, 4 pages, doi:10.1155/2010/876450**.