

October 15, 2017

TO: Senate Committees of Health & Human Services and Aging and Youth

FROM: Doug Fearn, Chairman/President, Lyme Disease Association of Southeastern Pennsylvania, Inc. (LDASEPA)

Our organization is an all-volunteer 501(c) (3) corporation founded in 2003. We provide support and education to our community in Chester County and surrounding areas, although our reach is national in scope through our web site/Facebook page and our publications (Ref 1). I have been involved in Lyme disease advocacy and education since 1994. I have Lyme disease; so does all my family.

I attend at least one medical conference on Lyme and other tick-borne diseases annually. I am an associate member of the International Lyme and Associated Diseases Society (ILADS), a professional medical organization. (Ref 2) I have no formal medical background, but I have learned a lot about medicine over the years of dealing with Lyme and I use that knowledge to educate others. I do not give medical advice.

I give about 50 talks a year on the topic, and the booklet I wrote, "Lyme Disease: The Basics," has been requested by over 400,000 people, including many doctors. LDASEPA participates in about 30 public outreach events each year, including health fairs organized by PA legislators. All of the information we provide is based on high-quality, peer-reviewed published research.

Over the years I have interacted with thousands of Lyme disease patients, listened to their stories, and helped them to find the medical professionals who can help them regain their health. LDASEPA provides this no-cost, personalized service to about 1500 individuals a year in this way.

Pennsylvania has the greatest number of Lyme disease cases in the U.S. for most of the past ten years. Recent years' data reveal that one-third of all Lyme cases in the country are in PA. (Ref 3) In recent years, the number of PA reported cases has been about 10,000 annually. The CDC's own research indicates that the actual number of PA cases is 100,000 to 120,000 per year. In our area, it is difficult to find an individual who has not been touched by this disease.

Often we encounter people who have been undiagnosed, or misdiagnosed, for years, even decades. This failure is due to four main problems:

1. The lack of an accurate test for Lyme disease. The currently available tests miss 20-50% of infected patients, according to the published research. (A meta-analysis of research statistics is in Ref 4.) Although new tests are in development, there does not appear to be a test that accurately diagnoses Lyme at all stages of the disease. It is also noteworthy that the commonly used tests will always be negative during the first 4-6 weeks of infection. At present, proper diagnosis requires the clinical expertise and experience of the physician.

Developing a reliable test is likely beyond the scope of any state. Research funding should come from federal government agencies or private foundations. The former seem reluctant to provide grants for this research, and the latter, although dedicated and well-supported by the Lyme community, cannot provide the millions of dollars annually to fund this type of research and development.

2. Lack of Physicians/Physician Training. Although PA has the greatest number of Lyme cases in the country, we have very few physicians who have expertise in this disease. In Chester County, for example, we have only 4-5 doctors who have specialized in diagnosing and treating Lyme. (Chester County

traditionally has the greatest number of cases in PA, and is second in the U.S. for reported cases.) Throughout the Commonwealth, there are fewer than 20 Lyme specialists.

The reasons for the lack of physician knowledge are many, but I believe the majority of doctors shy away from getting involved in treating Lyme patients because the patients are complex and take far more than the typical 15 minutes appointment time to properly diagnose them and devise a treatment plan.

ILADS, the medical organization devoted to tick-borne diseases, has been educating doctors over the past fifteen years through mentorship programs that pair an interested physician with an established Lyme disease expert in a clinical setting. ILADS also offers physician training courses at their annual conferences in the U.S. and in Europe. They have trained hundreds of doctors, most of whom subsequently devote their practice to Lyme patients. While helpful, this alone is inadequate to address the epidemic.

Although the ILADS program has been very successful, it rarely reaches the average family practice doctors who are on the front line of Lyme disease diagnosis and treatment. Although many family practice doctors have become quite knowledgeable about Lyme disease fundamentals, they usually will not treat complicated patients (many of whom are severely debilitated). However, if PA doctors in general had a better fundamental knowledge of Lyme disease, there would be far fewer patients who go undiagnosed and untreated. The path for these patients is towards a decreasing quality of life and increasing disability.

The bacterium, *Borrelia burgdorferi* (Bb) that causes Lyme disease has been studied for over 35 years, and has been characterized as the most complex of any bacterium ever studied. It has the ability to evade the patient's immune system, and to protect itself from attack by antibiotics. Lyme disease is a huge challenge to the medical profession. Each patient tends to have a customized set of symptoms and response to treatment. Treating this disease requires a lot of expertise.

Further complicating the diagnosis and treatment is the fact that the ticks that spread Lyme disease also carry additional diseases. Some of these diseases are bacterial, like Lyme, but may require different antibiotics than those used to treat Lyme. Other diseases are caused by a virus, and some, like Powassan fever, can be fatal. Another common co-infection is Babesiosis, caused by a blood parasite, which requires a totally different class of drugs than those used to treat Lyme disease.

Lyme specialists find that their patients are invariably infected with multiple tick-borne diseases. To date, about 20 such diseases have been identified, with more being added each year.

Treating only Lyme disease when the patient has multiple infections causes many patients to never get well. An expert with full knowledge of these diseases is required for the patient to regain full health.

We do not have a "silver bullet" treatment for Lyme disease. No truly new antibiotics have emerged in many years. Hopefully a pharmaceutical company is working on a new antibiotic to target Lyme bacteria. In the meantime, doctors use the best antibiotics they have found to have some effect on Lyme. Treatment is often lengthy for chronic Lyme patients because of the stealthy nature of the bacteria and the lack of better antibiotics.

Over the years, two distinctly different schools of thought have emerged on Lyme disease. This is not unusual in many diseases, particularly emerging ones, but in this instance the dichotomy is astounding. Unfortunately, one position states that Lyme disease is "hard to catch and easy to cure" and "vastly overdiagnosed" has been adopted by many health insurers, possibly because it minimizes the money they have to provide to physicians and for prescriptions. This advice, from the Infectious Diseases Society of

America (IDSA), also states that a short course of treatment (10-21 days) will cure every case of Lyme disease. Most doctors follow these guidelines, even when that treatment fails to cure the patient. Our experience in the real world of Lyme patients shows that this approach is inadequate for many patients. ILADS, on the other hand, suggests in their government-approved guidelines that it is prudent to treat the patient until they are well. (Ref 5)

In general, I find that the general public is reasonably knowledgeable about Lyme disease. There has been a lot of national news coverage of Lyme in 2017, and several high-profile celebrities have discussed their disease in books and in the media. However, public knowledge of the other tick-borne diseases is minimal. And, most discouragingly, many people are resigned to a lifetime of diminished health because they believe that there is no way for them to get better.

Inappropriate treatment by minimally trained doctors is likely to fail, especially in patients with multiple tick-borne diseases.. This is caused by inadequate treatment (too short, wrong medication), failure to treat all the tick-borne diseases, and patient non-compliance. Public education would certainly help, along with better physician education.

3. Lack of adequate health insurance coverage. Lyme disease treatment coverage appears to be limited by most health insurance companies, and most Lyme expert physicians do not accept any health insurance. The doctors are forced into this situation because the health insurers may drop a physician from their network if the doctor prescribes treatment beyond that the insurer considers “adequate.” Also, the payment for an office visit is insufficient for the doctor to spend the necessary time to examine, question, and discuss the plan with the patient.

Consequently, patients have to pay out-of-pocket for their Lyme treatment. From talking with many patients (and my personal experience), I learned that the cost for treatment can easily exceed \$20,000 per year. As a result, it appears that only those with above average financial means can get better. The rest are left to struggle to pay as they can, usually losing their job due to illness, and then losing their home. Many get divorced when a spouse is no longer supportive of the financial burden of the treatment. And a surprising number of people, even in affluent Chester County, become homeless. There is minimal help available to these patients and they will often become a burden on the government. Tragically, some commit suicide.

4. Prevention Education. Ideally, no one would get a tick bite in the first place. Preventing tick bites not only avoids Lyme disease, but also all the other tick-borne diseases. My experience has been that many people understand what they need to do to avoid tick bites (repellents, treated clothing, avoidance of tick habitat), but few people follow the advice. More education in this area would be helpful, if you presume you can change human nature. Also, controlling the deer population would minimize the tick numbers.

This is a very complicated issue and I see no easy fix. However, development of an accurate test, teaching all physicians about tick-borne disease, and making sure all Lyme patients are covered by adequate health insurance are the key issues. The two-schools-of-thought on Lyme disease ensures that progress will not be easy. But we have to start the process. The lives on many in our community are at risk.

Ref 1: www.lymepa.org

<https://www.facebook.com/Lyme-Disease-Association-of-Southeastern-Pennsylvania-632796186838098/>

http://www.lymepa.org/Basics_7th_Edition_2017.pdf

http://www.lymepa.org/Prevention_Tips_2015rev2.pdf

Ref 2: www.ilads.org

Ref 3: https://www.cdc.gov/mmwr/volumes/65/wr/mm6519md.htm?s_cid=mm6519md_w#table-3

Ref 4:

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Table: Sensitivity/Specificity of Commercial Two-Tier Testing for Lyme Disease

Study	Year	Sensitivity	Specificity
Schmitz et al	1993	66%	100%
Engstrom et al	1995	55%	96%
Ledue et al	1996	50%	100%
Trevejo et al	1999	29%	100%
Nowakowski et al	2001	66%	99%
Bacon et al	2003	68%	99%
Wormser et al	2008	14.1%	---
MEAN TOTAL		49.7%	99%

1. Schmitz et al. Eur J Clin Microbiol Infect Dis. 1993;12:419-24
2. Engstrom et al. J Clin Microbiol. 1995;33:419-27.
3. Ledue et al. J Clin Microbiol. 1996;34:2343-50.
4. Trevejo et al. J Infect Dis. 1999;179:931-8.
5. Nowakowski et al. Clin Infect Dis. 2001;33:2023-7.
6. Bacon et al. J Infect Dis. 2003;187:1187-99.
7. Wormser et al. Clin Vaccine Immunol. 2008;(10):1519-22.

Ref 5: <https://www.guideline.gov/summaries/summary/49320/evidence-assessments-and-guideline-recommendations-in-lyme-disease-the-clinical-management-of-known-tick-bites-erythema-migrans-rashes-and-persistent-disease?q=lyme>