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 PA Lyme Resource Network  
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*A 501(c)(3) non-profit organization chartered for charitable and educational purposes dedicated to education, patient advocacy, support and prevention of Lyme and other tick-borne diseases.*

## Common Misunderstandings

### PA SB100 Lyme Disease and Related Tick-Borne Illness Diagnosis & Treatment Act.

*From PA Lyme Resource Network, LymeActionPA Committee:*

This document is a discussion guide designed to clarify some common misconceptions about Senate Bill 100. It shares factual information, with complete references, to help understand the truth facing Pennsylvanians affected by Lyme and other Tickborne Diseases.

### **“WE ARE NOT IN THE BUSINESS OF LEGISLATING MEDICINE”**

This bill is not a mandate, it is a “correction” that is necessary to ensure that insurance companies are providing access, through payment/coverage, of standard treatments supported by evidence-based guidelines. Intervention is required because insurers are improperly intervening in the physician-patient relationship, creating a barrier to viable, and at times, life-saving treatment options. These are safe treatment options readily available for less serious, conditions, such as Acne, or Mycoplasma.

The bill would ensure licensed physicians can carry out their role in helping patients make the best informed treatment decisions, without interference from third-party insurers, and by complying with the physician’s duty to properly inform their patients in an unbiased way, of their options, risks and benefits.

Longer-term antibiotic treatment is a well-established accepted practice in many illnesses. It is specifically recommended as an option for persistent cases in the **ONLY** set of Lyme

Disease Treatment guidelines approved currently by the National Guidelines Clearinghouse (NGC) and meet the stringent SCORE evidence criteria (introduced in 2013). This bill simply ensures that insurers are paying for treatments and patients have access to care that is recommended in the most current Lyme Disease Treatment guidelines (ILADS, 2016).

## **“THERE IS NO AGREEMENT IN THE MEDICAL COMMUNITY”**

**a) Multiple Standards of Care is Common in Medicine:** The vast majority of medicine operates under uncertainty. The Office of Technology Assessment of the U.S. Congress estimates that fewer than 30 percent of procedures currently used in conventional medicine have been rigorously tested (<http://discovermagazine.com/1999/aug/featweil> ).

In emerging diseases, uncertainty is to be expected. In 1970, Lyme disease was first identified in the US. Since then, we’ve learned there are over 100 strains of Lyme, and many coinfections that ticks can transmit, some of them deadly. Knowledge about these tickborne diseases is emerging daily. As new knowledge develops, practices must be updated and evolve – there will always be multiple treatment strategies in such cases. This is how innovation in patient care happens. In many cases, things evolve effectively. But sometimes, things get stuck and patients pay the price. Take breast cancer. Today patients are presented with multiple treatment strategies with their respective evidence, risks and benefits, and the patient chooses based on their circumstances and values. This was not always the case. Breast cancer patients faced much the same issue that Lyme disease patients face today – patients were denied the right to choose lumpectomy, over radical mastectomy. In response to protests, several states passed protective legislation, allowing women to choose lumpectomies, and mandating insurance coverage for that procedure. Lumpectomies are now recognized to be the more appropriate and humane procedure for many women.

**There is a clear precedent for legislative intervention in specific, and rapidly evolving diseases. And Lyme disease is a clear case for such intervention.**

(<http://sd27.senate.ca.gov/news/2012-10-09-all-breast-cancer-patients-deserve-safe-surgeries>)

**b) Long-term Treatment is in FACT the Standard, Yet Insurers are Ignoring these Guidelines and Not Covering Treatment:**

There are two standards of care in Lyme disease today:

- Infectious Disease Society of America (IDSA) are the legacy guidelines (last updated in 2006) and do not recognize chronic/persistent Lyme disease. These guidelines restrict treatment durations to less than 4 weeks, regardless of response to treatment.
- International Lyme and Associated Diseases Society (ILADS) are the most current guidelines available, updated and published in 2016. They recommend extended antibiotic treatment in persistent cases, if the physician considers this medically necessary.

The Lyme disease treatment guidelines developed by the IDSA are often represented as the gold standard. These legacy guidelines are the primary basis for insurance denial of coverage. (3) They have not been updated since 2006 and were removed from the National Guideline Clearinghouse in 2016 because they were considered out of date and didn't conform to the stringent standards for guideline development established by the Institute of Medicine (IOM) using SCORE, in use by the NGC since 2013.

The ILADS guidelines are often represented as “experimental or fringe” and yet these are the only guidelines for Lyme disease currently approved on the NGC website. They were revised in 2014-2016 to reflect recent research, and to conform to the new evidence grading requirement (SCORE). These guidelines recommend the option of extending treatment for persistent cases, when deemed medically necessary by a physician, guiding them to treat according to their clinical judgment. (4)

It is important to understand that the legacy guidelines (IDSA's) have been the subject of considerable criticism:

- They were the target of an investigation by former Connecticut Attorney General Richard Blumenthal, who found significant, undisclosed conflicts of interest among the authors. 5, 6, 7 <http://www.ct.gov/ag/cwp/view.asp?a=2795&q=414284>
- The Institute of Medicine (IOM) cited the IDSA guidelines as an example of the guidelines process gone awry, noting a lack of transparency in the guideline development process (8) <http://nationalacademies.org/hmd/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust/Standards.aspx>

Yet, despite all of these credibility problems, insurance companies continue to rely on the IDSA guidelines in order to deny extended coverage for Lyme disease treatment. They also cite the CDC Surveillance criteria to deny coverage, stating that the patient's clinical records do not meet these criteria, even though it is well known that surveillance criteria are NOT to be used for individual clinical decision making.

**c) Government Studies Found that Longer-term Treatment IS the Standard of Care:**

A Federal study published in 2013 found that the majority of Lyme disease patients are in fact being treated with antibiotics for longer than legacy IDSA guidelines recommend. This federal study also concluded that there are likely more than 300,000 Lyme disease cases annually, a tenfold rise from official reports and an indication of the illness' expansion across America. The study consisted of three public surveys in 2009, 2010, and 2012, and included separate analyses of insurance bills and lab tests.

- Just 39% of Lyme patients reported being treated within the short-term guidelines (for four weeks or less).
- **Fully 56 percent were treated longer (11)** with 36% treated with antibiotics for more than eight weeks — twice the time that the legacy (IDSA) treatment guidelines recommend — and 20 percent treated for five to eight weeks.
- 5 percent said they were not treated at all.

**Children are significantly affected:** the insurance data showed that, among Lyme patients, a significant share were children. The largest group hospitalized for Lyme disease was 5 to 9 years old. Many parents told of children missing long stretches of schooling due to Lyme disease. The average age for chronic Lyme patients surveyed was 30, versus 51 for all respondents. According to the CDC, children are the age group most affected by Lyme (28).

(Doctors bucking Lyme protocols, Mary Beth Pfeiffer , Poughkeepsie Journal Published 12:00 p.m. ET March 28, 2014 | Updated 1:58 p.m. ET Oct. 31, 2014,  
<http://www.poughkeepsiejournal.com/story/news/health/lyme-disease/2014/03/28/lyme-antibiotics-protocols/7008045/>)

Published reports document its negative impact on children's cognitive functioning and academic progress, as well as health-related symptoms (29, 30, 31, 32).

These children lose years of normal childhood, and many continue to struggle with impaired health as young adults. The resulting emotional and physical trauma experienced by these young patients and their families is enormous and must be remedied by providing better access to the most up to date care.

## **The Consequences of These Diseases is Hitting All Demographics:**

- Graphic designer's father, who worked for Caterpillar Corporation, has been on disability since age 37 after he got Lyme disease. He is now in his 50s and has not been able to work since he was 37.
- A mother who cannot work or manage a household because of profound fatigue, muscle and joint pain and weakness prevent her from even lifting a carton of milk without difficulty.
- The 12 year old who cannot attend school or participate in the small joys of growing up because confusion, fatigue, sensitivity to sound and light make attending school or participating in activities impossible.
- A 43 year old father who cannot work because he experiences vertigo, balance problems, confusion, difficulties thinking and weakness in his legs and arms.

Thousands of Pennsylvanians have the same experience. As a result they are supported by payments from disability, worker's comp, unemployment, medicare and medicaid. The costs that should be the responsibility of insurers are being shifted to taxpayers and employers. In the Act 83 Task Force, the Department of Conservation and Natural Resources indicated that the vast majority of their disability cases were related to Lyme disease. Consequences of Lyme disease that is not properly treated costs the medical system itself \$1.3 billion according to a 2015 Johns Hopkins study.

**The medical community is not divided when it comes to recognizing persistent symptoms - some patients do not respond completely to brief treatment. Everyone agrees that this exists, ranging from 10% to 40% are considered "treatment failures".**

We have no interest in a mandate for specific treatments. Instead, this bill will ensure that health care providers can work with their patients to determine the best options for treatment, among options recommended in credible, approved guidelines. This is the standard approach for numerous illnesses and conditions including breast cancer, prostate cancer, high cholesterol, cardiac and arthritic conditions. Patients are given treatment choices. It shouldn't be any different in Lyme/tickborne diseases.

## **“INSURERS ARE ALREADY COVERING TREATMENT FOR LYME DISEASE”**

Insurance companies are routinely denying treatment for Lyme disease for extended oral antibiotics to medically necessary intravenous antibiotics for neurological cases. The IDSA guidelines are relied on by insurers as the basis to determine coverage limits for Lyme disease. Most insurers refuse to pay for long-term treatment, even though this is clearly an accepted treatment option, while sometimes even denying coverage for cases with positive blood tests who do not meet the restrictive CDC Surveillance data. This creates an enormous financial burden because patients must pay out of pocket for necessary, and at times, life-saving treatment.

Because of the insurance quagmire, patients are unable to easily find doctors who will diagnose or treat Lyme disease, particularly when the bacterium has become entrenched. Add to that the denial of persistent infection, and these patients are often forced to seek help outside of traditional medical channels with little or no medical infrastructure in place to help.

Without medical help, patients are left to wander endlessly from one high-priced medical specialty to another or fend for themselves outside of insurance networks just as HIV/AIDS patients did during the early years of the HIV/AIDS crisis. Studies demonstrate significantly higher hospitalizations and healthcare costs for those patients with persistent Lyme disease. To add to the burden of illness, Lyme disease patients are also saddled with financial hardship.

**Insurers are Cherry-Picking Their View of Persistent Lyme Disease:** while insurers deny medical treatment for persistent Lyme disease, they are taking a different view in life insurance. In life insurance, we are seeing coverage rejections on the basis of “a history of tickborne infections” (see example).

## **“LONG-TERM ANTIBIOTIC THERAPY IS DANGEROUS”**

Long-term antibiotic treatment has a long safety record, and is standard in many diseases including Tuberculosis, Q Fever (another tickborne infection), Mycoplasma infections, and even Acne. Proper training and monitoring greatly reduces potential risks associated with these treatments, and must be weighed against the very real and serious risks of under-treated, disseminated, neurological Lyme disease. This is

exactly why medical care is based on informed choice – the patients must be fully informed of their options, and the potential risks and benefits, so they can make the choice that is right for their circumstances.

1) Long-term antibiotic treatment is used in a relatively small percentage of patients with Lyme disease, but has been described as safe (14).

2) In research studies of longer-term treatment, patients that experienced side effects of the treatment were in the placebo group, not the treatment group.

3) IV is prescribed routinely in patients with other serious infectious diseases, such as tuberculosis, in which the full course of antibiotic treatment necessary to eradicate the infection includes up to two years of therapy.

4) It is not unusual for adolescents to receive long-term regimens of oral antibiotics as treatment for the relatively more benign problem of acne, citing the risk of facial scarring and “long-lasting psychological harm” as the rationale for treating (15)

5) Cancer patients are not denied life-saving treatment because of a fear of potential side effects, nor should Lyme patients be denied. There is much data demonstrating the serious potential impact on quality of life of chronic lyme patients, and high morbidity, including death.

## **“THERE IS NO EVIDENCE FOR CHRONIC LYME”**

**The IDSA was found to have ignored credible evidence by the CT Attorney Generals investigation.** This would include more than 21,000 peer-reviewed scientific articles that address the persistence of Lyme.

- In 2012, for example, one such article described the persistence of the Lyme bacterium in primates after having been treated with antibiotics (18).
- More recently, researcher Kim Lewis, Ph.D., of Northeastern University, has reported on viable Lyme persister cells which survive and thrive in the laboratory after antibiotic treatment (19, 20).

- Linden Hu, M.D., of Tufts University/New England Medical Center, presented a recent xenodiagnoses study, which found evidence of infection in humans previously treated with antibiotics. (21)
- The highly respected David Volkman, Ph.D., M.D., Emeritus Professor of Medicine and Pediatrics, SUNY, Stony Brook, NY, a former Senior Investigator at the National Institute of Allergy and Infectious Diseases (NAIAD), a component of the National Institute of Health (NIH), and previous Chairman of both the Internal and External Review Boards of the NIAID, testified at a July, 2009 IDSA guidelines hearing that the IDSA guidelines should be changed, and said that:

“In the face of both animal and human evidence of persistent borreliosis following inadequately treated LD, it is disappointing that Guidelines members continue to dismiss the possibility of persistent borreliosis with unreferenced assertions that it has been “discredited” by “current thinking.” Since mouse models of persistent borrelia infection exist it should be straightforward to design an antibiotic regimen that eliminates this infection. However instead of urging the development of better diagnostic tools to identify individuals with previous infections who may still be infected with chronic symptoms, Guidelines members merely assert the unsupported dogma that chronically infected people are all seropositive. This claim is simply untrue. Some of these committee members have testified as “expert witnesses” for insurance companies attempting to deny health benefits to chronically symptomatic individuals and written articles disputing its existence.”(22)

Here in Pennsylvania, the Act 83 Governor’s Lyme Disease Task Force reviewed this same issue, and developed consensus that it was critical that the various PA agencies represent the broad spectrum of science and views on Lyme and the persistence of Lyme disease to the public, and ensure that these multiple views be communicated in all education programs.

**The PA Department of Health website** now houses a summary of 700 scientific journal articles demonstrating persistence of Lyme disease, as part of the findings of the Act 83 Task Force. There is clear evidence supporting the persistence of the infection cited in the ILADS treatment guidelines, which met even the stringent review of the National Guidelines Clearinghouse.

## **“THERE IS NO EVIDENCE THAT MORE TREATMENT WORKS”**

This is just not true. There are very few studies focused on longer-term treatment. However, of the few done, most showed improvement in some key symptoms. Some showed that improvement wasn't sustained once treatment was removed, and follow-up studies on further treatment were recommended. Several had serious study design issues. Across the 20+ support groups that PA Lyme Disease Resource Network facilitates, we routinely see patients get better once diagnosed and treated effectively. Most patients come to support groups after treatment failure. The explosion of our groups across PA from a handful in 2007 to over 20 groups today, and increasing monthly, are a testimony to the gaps in diagnosis and treatment the patient community faces.

- A critical analysis of at least one retreatment study which failed to find improvement determined that its results were not valid due to flaws in the study design, which lacked statistical power (24)
- In his recent presentation at the 2016 Lyme conference at Massachusetts General Hospital, Dr. Brian Fallon of Columbia University also cited retreatment studies, including his own NIH-sponsored research, in which patients showed improvement (25, 26)
- In her recent testimony at the recent public hearing in Bolton, MA, Dr. Nevena Zebcevek, Co-Director of the Dean Center for Tick Borne Illness, Spaulding Rehabilitation Hospital, cited three antibiotic retreatment studies in which patients demonstrated improved cognition and fatigue (27)

## **CONCLUSION**

This bill is not a mandate, it is a “correction” that is required to ensure that insurance companies are providing access, through payment/coverage, of standard treatments supported by evidence-based guidelines. Intervention is required because insurers are improperly intervening in the physician-patient relationship, creating a barrier to viable, and life-saving treatment options. These are safe treatment options readily available for less serious, conditions, such as Acne, or Mycoplasma.

The number of researchers involved in Lyme research has exploded (Columbia University, Johns Hopkins University, Stanford University, Harvard, Northeastern University, Tulane

University, University of Texas, University of Rhode Island, our own Drexel University College of Medicine, East Stroudsburg University, Edinboro University, Shippensburg University and more). All are being drawn to solving this puzzle of the century. Similar to its cousin, Syphilis, *Borrelia burgdorferi* (Lyme) is seen as potentially holding the key to understanding and solving many chronic conditions (such as Alzheimers), and is already making life-time conditions treatable and reversible (ADD/ADHD, Chronic Fatigue, early Dementia, etc.). Pennsylvania legislators have the opportunity to drive progress in these diseases and significantly improve the quality of care. Given PA's status as #1 in reported cases year after year, and the spread across the entire state, action is absolutely necessary.

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