

**Testimony before US House of Representatives Energy & Commerce Health Subcommittee**

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Chairman Pitts and Committee Members,

Thank you for allowing me to testify on the need to establish an advisory committee on Lyme disease to ensure that government resources are being appropriately used to move forward the field of science and treatment in an area that is fraught with political, scientific, and medical obstacles, yet is dominating discussion on the worldwide stage. In 2009, the Centers for Disease Control & Prevention (CDC) indicated that Lyme surpassed HIV in incidence followed by a 2013 announcement confirming a 10-fold under-reporting of Lyme cases, estimating 300,000 Lyme cases annually. A 2001 National Institutes of Health (NIH) sponsored study found that the impact of Lyme disease on physical health status was at least equal to the disability of patients with congestive heart failure or osteoarthritis, was greater than those observed in type II diabetes or in recent myocardial infarction, and chronic pain contributing to impairment was similar to that reported by patients with osteoarthritis.<sup>i[1]</sup> Couple those facts with Lyme spreading worldwide to 80 countries and the discovery of many newly emerging tick-borne pathogens being carried by many different ticks, then the passage of HR 610 is long overdue.

The LDA just revised its comprehensive education and prevention brochure, LymeR Primer, which went from featuring 7 tick-borne diseases (TBD) in 2009 to 15 diseases. Besides Lyme disease, there are at least 15 other TBD of concern in the US: anaplasmosis; babesiosis, bartonellosis; ehrlichiosis; Rocky Mountain Spotted fever; Colorado tick fever; Q fever; tick paralysis; tularemia; Powassan encephalitis; STARI, a Lyme-like disease often with the same rash, transmitted by a lone star tick bite, pathogen cause unknown, but may be a bacteria similar to the Lyme bacteria; *Rickettsia parkeri* *Rickettsiosis* found increasingly along the Gulf Coast and

in the South; *Borrelia miyamotoi*, a tick-borne bacteria which had been producing disease outside the US, now found in the US; newly found *Rickettsia* species 364D in the Pacific Region; and a newly discovered tick-borne virus in Missouri, Heartland, carried by the lone star tick.<sup>ii</sup>[2]

One tick-bite can give someone more than one disease.

My education on Lyme began almost 30 years ago as a NJ Board of Education member whose district had a large number of students and staff out with Lyme disease. Then, only a few US ticks were recognized as major health threats to humans. Now, many ticks in the US are causing more human diseases, ticks including *Ixodes scapularis* (deer, black legged), *Amblyomma americanum* (lone star), *Dermacentor variabilis* (American dog), *Dermacentor andersoni* (Rocky Mt. wood), *Ixodes pacificus* (western black legged), *Amblyomma maculatum* (Gulf Coast), and *Dermacentor occidentalis* (Pacific Coast).

My Lyme work, including 17+ as president of the national volunteer-run non-profit Lyme Disease Association (LDA), has kept me in close contact with patients nationwide. The complicated nature of Lyme disease, the difficulty in diagnosis, and lack of recognition by some in the medical community have exacerbated the plight of patients and their families, many of which contain more than one Lyme victim. Medical bills rise; jobs are lost; education is interrupted. Divorce is not an uncommon result in these families, further complicating the picture. Often, the families are forced to seek government help, government which is already burdened with more debt than it is able to handle.

Children have always been at the highest risk of acquiring Lyme disease. Based on CDC's Lyme reported cases numbers from 2001-2010 by age, LDA estimated that 37% of reported cases were

children. Using 1990-2011 CDC reported numbers adjusted for 10-fold underreporting, LDA found that 1,590,449 children have developed Lyme disease over that period. Many more children were probably clinically diagnosed but not included in the CDC surveillance figure, which uses a strict reporting definition not meant for clinical diagnosis. These are children who often go on to develop chronic Lyme disease— who often miss months/years of school and have their childhood destroyed. Showering, walking, talking, thinking can be a problem, and serious pain is a daily challenge. A 1998 Columbia University study documents improvement in IQ of 22 points in a 16 year-old after IV treatment for Lyme disease.iii[3]

A 1992 CDC/NJ Department of Health study in NJ of 64 school children with Lyme showed that the median duration of Lyme at time of interview was 363 days; the median number of days the illness was said to have significantly affected normal activities was 293; the mean number of total school days lost was 140; the mean duration of home instruction, 153 days. Only 26% of children under study were said to have fully recovered.iv[4]

The direct medical costs per case incurred by 54 case-patients totaled \$5.2 million, \$8.7 million in CPI adjusted 2013 dollars.v[5] The mean estimate was \$96,569 (\$274,412-2013); and costs of \$100,000 (\$166,891-2013) or greater were incurred by more than 1/5 of children. Some indirect costs were assessed totaling about \$15,000 (\$ 25,034- 2013) due to lost time caring for patient and parents' lost time transporting children to medical treatment.

A 2001 Columbia study showed children with Lyme disease had significantly more cognitive and psychiatric disturbances. Cognitive deficits were still found after controlling for anxiety, depression, and fatigue. Lyme disease in children may be accompanied by long-term

neuropsychiatric disturbances, resulting in psychosocial and academic impairments. Regarding depression, parents indicated that 41% of children with LD had suicidal thoughts, 11% had made a suicide gesture.vi[6]

Early intervention and appropriate treatment are the answers for patients with Lyme to prevent the development of chronic Lyme disease, aka, Post Treatment Lyme Disease, late disseminated Lyme, persistent Lyme, Post Lyme Disease Syndrome, etc. While discussions continue on the justifications for the various terms used for chronic Lyme disease, we cannot allow the semantics to eclipse the need for research on chronic Lyme, the area producing the most human suffering and receiving the least research funding. According to a new Columbia University Lyme study, based upon 10-fold underreporting and on 10% of newly infected and treated patients developing symptoms that persist for more than 6 months, “the actual incidence of new chronic cases (PTLS) is...30,000.” vii[7]

Currently, many major health threats including chronic fatigue have an advisory committee. Lyme disease does not, placing its patients and advocates at a great disadvantage. We have lobbied for a research agenda which includes more effective treatments for Lyme and other TBD and better diagnostics, including detection of active infection. *B. burgdorferi* was recognized in 1981 to cause Lyme, almost 33 years ago, yet the two-tier testing system endorsed by CDC is very specific for Lyme disease (99%), so it gives few false positives, but according to some sources, the tests have a uniformly low sensitivity (56%)— missing 88 of every 200 patients with Lyme disease.viii[8] Yet HIV was identified as the cause of AIDS in 1984, and tests were developed within a few years after and are 99% sensitive and specific.ix[9] Moreover, Lyme has not attracted industry funding for treatment approaches, which has allowed patients to develop

severe mental and physical disabilities from the disease without help from science. There is also a need for educating doctors and the public about the state of the science regarding these diseases.

The above agenda requires the establishment of a venue where government agencies working on diverse aspects of tick-borne diseases (e.g., CDC surveillance, testing; NIH research funding-clinical trials, as well as basic and translational research; FDA drug, vaccine and device approvals; USDA research into natural tick prevention strategies; EPA tick prevention strategies) can present their activities, submit their proposed TBD agenda, and receive input from committee members who represent a wide variety of stakeholders with diverse scientific viewpoints on development of new diagnostics, treatment methods, and prevention strategies. Utilizing this format, government would ensure its agencies were providing the most judicious use of human and financial resources for Lyme and TBD. Using an already established federal advisory committee format ensures that the committee is only advisory in nature – committee members would not control nor dictate agency agendas, a concern that has been expressed by an outside group in the past. However, those agencies should not be insulated from the public input and diverse scientific viewpoints this committee would provide in shaping an agenda and ensuring the wise use of tight federal dollars, which are provided by taxpayers. Another concern might be whether an advisory committee is worth the costs, including time, to support the operation of the committee. In the case of Lyme disease, the history of the past decades should lead to an easy yes.

One does not have to be a scientist to realize that it is premature and unwise to preclude further clinical trials studying a broader range of treatment regimens when there are numerous major and

significant aspects of the bacteria's known pathophysiology which have not been accounted for in studies conducted to date, when there are still many unknowns in that pathophysiology, and when we are learning more every day. While our knowledge of the pathophysiology of the bacteria continues to evolve, we must be open to additional clinical trials to document and establish better treatment regimens. There is preliminary evidence for more effective regimens, and a specific forum for open dialogue can help ensure we move forward and don't get waylaid.

An open dialogue also could only improve the process of utilizing the pool of competent researchers- not in any manner that would interfere with established fair and open processes for grant-making, but only to increase awareness. It's a fact that a small number -a handful- of Lyme researchers have individually received many millions of federal research dollars, many of whom shared the same set of biases and perspectives. Common biases and perspectives are not objectionable if they are based upon the best scientific evidence; open dialogue, information sharing, and transparency can help safeguard the process and the taxpayers' money.

Patients want research which will restore their health. Their voice and the voice of the clinicians must be given the necessary weight to legitimize the research agenda and the research process.

Truth in science can be achieved through open discussion with diverse viewpoints in an independent process free from bias and conflicts of interest. The scientific process fails when one side of a debate controls the arena and sets the rules to ensure that its viewpoint prevails.

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i[1] *NEJM*, 7/2001, Mark S. Klempner MD. et al, "Two Controlled Trials of Antibiotic Treatment in Patients with Persistent Symptoms and a History of Lyme Disease"

ii[2] *American Journal of Tropical Medicine and Hygiene*, 7/22/13, Harry M. Savage, PhD et al, "First Detection of Heartland Virus (Bunyaviridae: Phlebovirus) from Field Collected Arthropods"

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- iii[3] *Psychiatric Clinics of North America*, 1998, Brian Fallon, MD, “The Underdiagnosis of Neuropsychiatric Lyme Disease in Children & Adults”
- iv[4] “Economic & Social Costs of Illness Diagnosed as Lyme Disease in NJ,” Presented by Centers for Disease Control & Prevention, David Dennis, at Congressman C. Smith’s Lyme Forum, Wall Township, NJ, Oct. 1992
- v[5] Department of Labor & Statistics CPI calculator
- vi[6] *J Neuropsychiatry Clin Neurosci* 2001, Tager,F, Fallon BA, “Controlled Study of Cognitive Deficits in Children With Chronic Lyme Disease”
- vii[7] *The Journal of Neuropsychiatry & Clinical Neurosciences*, 2013, Batheja S., “Post Treatment Lyme Syndrome & Central Sensitization”
- viii[8] *BMJ* 2007; 335:1008, Stricker RB, Johnson L. “Lyme wars: let's tackle the testing.”
- ix[9] <http://www.uspreventiveservicestaskforce.org/uspstf05/hiv/hivrs.htm>

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## **Patricia V. Smith Lyme Disease Association**

### **MAJOR POINTS SUMMARY**

1. Lyme disease is increasing in numbers and range worldwide, with CDC announcing U.S. cases are 300,000 annually. It is found in about 80 countries worldwide.
2. A government study has indicated the impact of Lyme disease on patients is as severe as disability of patients with congestive heart failure or osteoarthritis, is greater than those observed in type II diabetes or in recent myocardial infarction, and chronic pain contributing to impairment is similar to that reported by patients with osteoarthritis.
3. Other tick-borne diseases are being discovered with greater frequency and people are becoming co-infected with a number of diseases.
4. More ticks are spreading different diseases to humans.
5. My work with the Lyme Disease Association has put me in close contact with patients who are sick and have other family members with the disease, which is costly to them financially and also impacts education and family structure.
6. Children are at the highest risk of acquiring Lyme disease. They often miss long periods of school and experience cognitive difficulties, severe pain, and may attempt suicide related to their Lyme disease.
7. There is a need for HR 610 creating an advisory committee which will permit all stakeholder input, including treating physicians, patients, and advocates, to be presented to government agencies. Currently patients have no voice.
8. The Committee would ensure that all sides of the science would be factored into the decision making process.
9. Government agencies need to interact with other government agencies, each bringing different perspectives and priorities to the table.
10. Having diverse stakeholders at the table ensures all perspectives are heard to develop a comprehensive coordinated approach to tick-borne diseases, helping ensure that government funding is used widely.
11. Truth in science can be achieved through open discussion with diverse viewpoints in an independent process free from bias and conflicts of interest.