

# NY– Assembly Health Committee Lyme Hearing

**Pat Smith's, President of the Lyme Disease Association, testimony to the New York Assembly Health Committee, November 27, 2001, in Albany, New York**

Thank you. I am former chair of the NJ Governor's Lyme Disease Advisory Council, former president of the Wall Township Board of Education and I sit on the board of directors of the International Lyme and Associated Diseases Society, a professional, medical society. The LDA is an all-volunteer national organization providing Lyme disease education and research dollars. Along with an affiliate, The Greenwich Lyme Disease Task Force, the LDA is opening an endowed Lyme disease research center at Columbia.

Lyme is the fastest-growing vector-borne disease in the U.S., yet it is rarely given the weight it deserves. The situation facing patients and physicians in New York is not unique; it mirrors the nation. Patients frequently cannot obtain diagnosis, treatment, insurance reimbursement, disability, education or even understanding from their families and peers. Treating physicians have faced a variety of licensure sanctions including being supervised, fined, not allowed to treat Lyme patients, and license suspension and revocation.

In one of the earliest responses to Lyme problems, New Jersey enacted the first Governor's Lyme Disease Advisory Council in 1991. California and Rhode Island are following suit. Minnesota, Connecticut, New Jersey, New York (Tick-borne Disease Institute), and Pennsylvania have enacted or introduced legislation, addressing issues ranging from treatment and tick control to mandatory teacher in-service for educators.

At the federal level, several pieces of legislation are before congress. Additionally, in 1993, Senator Edward Kennedy heard a prominent New York physician testify in DC Senate hearing concerning the problems facing treating physicians: "...a few state health departments have now begun to investigate in a very threatening way, physicians who have more liberal views on Lyme disease diagnosis and treatment than they do... And indeed, I have to confess that today I feel I am taking a personal risk, a large one, because I am stating these views publicly."<sup>[1]</sup> The doctor was later charged by the New York OPMC .

The US Army Centers for Health Promotion and Preventive Medicine has developed a pocket-sized lab to test ticks in the field. Soldiers may receive immediate treatment if bitten by ticks that test positive for Lyme. Babesiosis and Ehrlichiosis are also being studied. Tick populations are being mapped. Satellites are beaming the data to special prototype helmets worn by field soldiers, allowing armies to maneuver around heavy tick concentrations. NASA and the NIH have a joint culturing project for Lyme disease bacteria using microgravity chambers, which mimic conditions in space and in the human body. <sup>[2]</sup>

New York, with its highest reported Lyme disease cases, joins its contiguous states Connecticut, Pennsylvania, and New Jersey constituting a block of the top four states in the nation in reported cases. Reported cases must meet the CDC (Centers

for Disease Control & Prevention) surveillance criteria: **a physician diagnosed EM (bullseye) rash, or positive bloodwork and other system involvement.** The actual number of Lyme cases is estimated to be 10 times higher than reported cases.[3] The CDC reports 3,626 Lyme disease cases in New York for the year 2000, which equals 36,260 actual cases for that one year alone. Nationally in 2000, the reported number is 15,328, which equals 153,280 actual cases.[4]

According to the CDC, the surveillance criteria is NOT to be used for diagnosis, since patients often do not meet the strict surveillance definition. Despite CDC warnings, many physicians use the surveillance criteria to diagnose cases, and many insurance companies deny treatment to anyone not meeting those criteria. Excerpts from two Lyme protocols used by insurance companies seem to base coverage on the surveillance criteria, requiring symptoms supported by positive antibody response tests. [5]

Insurance companies use graphs depicting antibiotic prescribing patterns and often do not accept doctor-prescribed testing such as PCR, which shows the presence of the DNA of the infecting organism, although PCR is accepted for other diseases such as HIV, hepatitis, TB, even anthrax. They limit treatment to 28 days, substitute orals for IV, and use the surveillance criteria for reimbursement determination. Therefore, doctors have a dilemma: treating sick patients who do not meet the criteria. Privately, several doctors have revealed that their insurance carriers strongly suggested they either leave the plan or stop treating Lyme patients long term. A few continue to treat, some refer their patients to long-term treating physicians, while others, fearing reprisals or facing economic hardship, stop seeing Lyme patients.

An insurance company letter to a New Jersey patient states: "Unfortunately, a number of unscrupulous practitioners in this and neighboring states have held themselves out as experts in the treatment of Lyme disease. These individuals have subjected patients to improper diagnoses, excessive treatments, inordinately long courses of intravenous therapy, and other activities not supported by science or generally accepted standards of medical practice. Because our organization has been appropriately vigilant and aggressive in dealing with certain practitioners, they have chosen to leave our network." [6]

At issue nationally to patients and doctors is the volume of complaints by medical boards against these treating physicians who already constitute a very small number overall. To address the situation in New Jersey, in 1993, Congressman Christopher Smith held a public Congressional Lyme forum. Last year, the NJ State Board of Medical Examiners met with Smith's office, followed by a meeting with the LDA and a Lyme literate physician. The LDA had other meetings on the controversy with state health commissioners in Connecticut, Rhode Island and New Jersey, and we addressed the Pennsylvania House of Representatives majority caucus.

Today's hearings are not without precedent. Besides Attorney General Blumenthal's Connecticut hearings, Texas recently held state senate hearings on harassment of physicians who treat Lyme. A recommendation from that hearing committee "Direct[ed] the Texas Board of Medical Examiners (BME) to develop review guidelines for doctors who provide medical care related to tick-borne illnesses." [7]

In New York, we met with representatives of the OPMC, health department, and the Governor's office, motivated by the fact that almost 60% of doctors who treat chronic Lyme disease in NY State have faced OPMC scrutiny the past year. At a

meeting this year OPMC reps said that "some of our best tips come from insurance companies." NY law prevents doctors from ever knowing the original complaint or complainant, thus treating doctors run the risk of spending tens of thousands of dollars defending their right to treat a patient even when the patient has improved, the patient is not complaining, and the patient objects to his/her records being used against the doctor. (See Sowell letter in packet).

In a letter from Congressman Christopher Smith, House of Representatives Veterans' Affairs Committee Chairman, to the NY Assembly Health Committee he states: "While it is the job of state boards of medical examiners to review complaints logged against doctors and to take action when needed, a concern that was expressed in my state was that some of the complaints were filed not by patients, but by insurance companies (and entities associated with them) who did not want to pay for the costs associated with treating Lyme patients under an aggressive antibiotic regimen. Using a state panel that is supposed to investigate malpractice to help achieve financial gain is simply wrong." [8]

Additional concerns arose from the NY meetings when officials repeatedly assured us that none of the charges against the NY physicians was related to Lyme disease. We subsequently discovered the word "Lyme" appears a total of 41 times in the factual allegations against two of the doctors. A New York Assemblyman who viewed the charges, confirmed at the meeting with the Governor's chief counsel that the charges were Lyme-related.

The Department of Health indicated that it was not actively soliciting complaints against treating doctors. A patient letter suggesting otherwise details her call to the NYDOH and two subsequent calls from them. Only seeking information on Lyme and other tick-borne diseases, she was subject to her diagnosis being questioned, told to see another physician other than her own, received an unsolicited complaint form in the mail from the DOH, and was pressured to file a complaint against her treating doctor. The DOH doctor told her that he and the DOH could obtain anyone's record that they chose, including hers. She never filed a complaint; however, her medical records were pulled soon after the call, and she never heard from that doctor again. [9] Her treating physician eventually faced charges.

Lyme disease is so complicated that physicians whose publications are often quoted to deny persisting infection have been shown to make statements that appear to be conflicting. Witness a 1990 response letter from a prominent rheumatologist to the Connecticut Department of Health. He refers to a specific doctor "treating these people with prolonged courses of antibiotic therapy. ...patients have usually not required the prolonged courses of antibiotics suggested in his handout....I think it is unfortunate that the Lyme Borreliosis Foundation and the doctors often associated with them have become major spokesmen for Lyme disease. I believe they are the principal force leading to the overdiagnosis and overtreatment of this illness. Do you have any ideas regarding what to do about this?" [10] Coincidentally, the two physicians named in the letter by the rheumatologist were subsequently charged in their respective states.

In 1994, that same rheumatologist wrote to patients: "I would like to invite you to participate in long-term follow-up studies of our patients who have had Lyme disease. It has become increasingly apparent that the Lyme disease spirochete, ... may persist in some patients for years. Of particular concern, recent studies have shown that the spirochete may persist in the nervous system in a small percentage of patients and may cause chronic neurologic involvement." [11]

(Present book with persistence of infection documentation). Add that the committee is free to review or not review these articles which give peer-review weight to persistence; contrast this with our doctors in New York, who have not been permitted to enter into evidence in their OPMC hearings, many peer-reviewed articles supporting their treatment regimens so that the validity of their treatments could be more adequately assessed.

Also at this time ask hypothetical question: How would the committee feel if I announced at this time that I am a CEO of a major pharmaceutical company? Would you be upset that I am testifying and you would have called another witness if you had known in advance, since I could benefit significantly from testimony? Would you look back on my testimony and assess it a different weight because of my position, give it less credibility perhaps? This is how our doctors feel, because as I found out in directly questioning OPMC officials, they have no disclosure policy or procedure for either selecting or during proceedings disclosure from witnesses testifying against our doctors, and although it may be exposed during lawyer cross-examination, this exposure may come later in process or not at all. For the record, please let it be known I am not now nor never have been a CEO for a major pharmaceutical.

Lyme is an enigma. While the debate rages over proper diagnostic and treatment procedures, patients get sicker and some even die. [12] The rational answer to this medical and moral dilemma lies in a quote from Ansel Marks, MD, JD, Executive Secretary for the Board of Professional Misconduct. In a letter to a Lyme patient who filed a complaint against a doctor opposed to long term treatment, Dr Marks states: "As defined by law, a difference of medical opinion, in and of itself, is not medical misconduct." [13]

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[1] *Lyme disease: A Diagnostic and Treatment Dilemma* Hearing of the Committee on Labor and Human Resources United State Senate, August 5, 1993

[2] *Lyme & Other Tick-borne Diseases: A 21<sup>st</sup> Century View*, LDA Princeton medical conference brochure, November 10, 2001

[3] Roberts, David M., et.al., "The bdr Gene Families of the Lyme Disease and Relapsing Fever Spirochetes," *Emerging infectious Diseases*, 6(2), 2000. Centers for Disease Control

- [4] Centers for Disease Control & Prevention, ed., *Morbidity & Mortality Weekly Report*, November 17, 2001
- [5] Aetna guidelines <http://www.aetnaushc.com/cpb/data/CPBA0215.html>, Prudential Guidelines, March 1995
- [6] Horizon Blue Cross Blue Shield letter to patient, August 24, 1999
- [7] [Texas] Senate Committee on Administration, *The Prevalence of Tick-Borne Illnesses in Texas*, Interim report, 77<sup>th</sup> legislature, November 2000
- [8] Congressman Christopher H. Smith letter to Chairman Richard Gottfried, November 27, 2001
- [9] K.M. letter To Whom It May Concern, about experiences calling NY Department of Health July 2, 1998
- [10] M.D. letter to George Kraus, Director of Health, DOH, Milford, Connecticut, July 30, 1990
- [11] M.D. letter to physicians, August 11, 1994
- [12] Death certificate
- [13] Ansel Marks, MD, JD letter to Joseph Burke, December 29, 1999