

Kenneth B. Liegner, M.D., P.C.
592 Route 22 - Suite 1B
Pawling, New York 12564
Phone: 845 493-0274
FAX: 845 493-0279
February 17, 2012

Congressman Chris Gibson
Lyme Forum Committee
Congressional Office
513 Broadway
Saratoga Springs, NY 12866

Dear Congressman Gibson:

Thank you for organizing and planning "**A Forum on Tick-Borne Diseases - What's NEXT**" this upcoming Spring and seeking input from patients, physicians and others concerned with the problems posed by Lyme disease and other tick-borne diseases.

Introduction

Circumstance over the past 25 years has provided me opportunity to study with care and in depth, patients with Lyme disease, their illnesses a consequence of the emerging epidemic of Lyme disease in New York State. I presented at the 2001 New York State Assembly Committee on Health hearings on Lyme disease, presided over by committee Chair, Hon. Richard Gottfried, during which the problems faced by persons with Lyme disease as well as their physicians was explored. Accompanying find the text of my testimony before that committee, with all cited references) (**1- see binder**).

Daunting enough are challenges of a strictly medical nature surrounding diagnosis and treatment of Lyme disease and other tick-borne disorders. Equally challenging - if not more so - however, are those of a medical socioeconomic and political nature. Circumstance has also made me privy to certain information, not widely known, but having important bearing on the controversy over chronic Lyme disease.

Insurers and government seek to define algorithms of care by which to reimburse patients and reward (or sanction) physicians whose practice patterns may deviate from accepted patterns. Such "guideline-based" algorithms may function reasonably well in areas of medicine for which there exists true consensus but poorly when a minority of physicians interprets the science differently from the majority. It is worth pointing out that it took medical science some 500 years to attain a good understanding of syphilis. We are but 40 years into Lyme disease. We definitely do not have all the answers!

It may be desirable to put in place a process that protects the rights of patients and physicians when paradigm change results in a choice between opposing and competing disease conceptualizations, as is currently the case with Lyme disease. Such process would likely be applicable to other disease entities undergoing paradigm change. Patient autonomy, an important tenet of medical ethics, is vital when science is unsettled, two schools of thought exist in an area of medicine and the standard of care is evolving (2 Johnson L, Stricker, RB. **The Infectious Diseases Society of America Lyme guidelines: a cautionary tale about the development of clinical practice guidelines. Philosophy, Ethics, and Humanities in Medicine 2010,5:9 [see binder] & 3 Bernat J. Ethical Issues in Neurology. Boston:Butterworth-Heinmann;2002).**

I would like to relate to you insights borne of my experiences and supported with factual documentation which demonstrate why legislative remedy is required to assure that the medical interests of persons with Lyme disease, especially *chronic* Lyme disease, are protected. Persons with chronic Lyme disease are subject to **severe** discrimination and are treated in a way by many physicians, insurers (health, life and disability) and some governmental entities somewhat analogous to the crimes of bias committed against other minority groups which have required special protection under the law.

My Early Experience with Lyme Disease

I entered practice in Westchester County in 1985 knowing virtually nothing about Lyme disease. Unwittingly, I had plunked myself down smack dab in the middle of an epicenter of the emerging Lyme disease epidemic. I began to see patients with the illness, as would any internist in Westchester County at the time. It soon became apparent patients' illnesses did not behave the way the "textbooks" said they should. Patients' symptoms would respond to application of antibiotics but the same symptoms would often rebound when treatment was discontinued. I found it necessary to lengthen durations of therapy. Many patients including some with unequivocal histories of tick bite and an erythema migrans rash which proved the diagnosis, tested negative on standard tests for Lyme disease both early and late in the illness. Standard testing for Lyme disease, evidently, was not *always* reliable.

Perhaps as a consequence of my post-graduate training in critical care medicine, I began to see many of the sickest patients with Lyme disease including those with very serious central nervous system involvement. Training in anatomic pathology equipped me to study my patients in depth. Such patients often required *exhaustive* evaluation using all available standard and research methods to correctly determine diagnosis. Some required maximally intensive treatment including intravenous antibiotics for extended periods of time especially those evidencing serious central nervous system involvement.

Troubled by the problems posed by Lyme disease, I conceived of and received the first United States Patent for a device targeting deer with acaricide as a means of controlling the tick vector of Lyme disease over broad geographic areas. The device has been dubbed by some the "Deer Gazebo" (**4 United States Patent # 5,050,539. Liegner Kenneth B. Acaricide dispenser. Filed Jul. 30, 1990. Issued Sept.24, 1991 - see binder**).

**CDC Case-surveillance Definition of Lyme Disease
And "Two-tiered" Testing**

The Centers for Disease Control and Prevention (CDC) has maintained from its earliest involvement in Lyme disease that physicians need to exercise clinical judgment to diagnose the disease (e.g. that a diagnosis of Lyme disease was necessarily a "clinical" diagnosis, with support from the laboratory). However, for *epidemiologic purposes* stringent case and laboratory definitions were developed in order to track case numbers from locale to locale and over time. CDC made clear failure to satisfy the epidemiologic case definition did not negate a *clinical* diagnosis of Lyme disease.

In October of 1994 the 2nd National Conference on Lyme Disease Testing, held in Dearborn, Michigan (**5 Proceedings of the Second National Conference on Serologic Diagnosis of Lyme Disease, 1994 Oct 27-29. Dearborn MI. 106 pages. Sponsors: Assoc. of State and Territorial Public Health Laboratory Directors, US CDC and Prevention, MI Dept. of Health. Co-sponsors US FDA, NIH, Council of State and Territorial Epidemiologists and National Committee for Clinical Laboratory Standards**) set official *laboratory criteria* for diagnosis of Lyme disease for *epidemiologic case surveillance purposes*. A two-tiered methodology was recommended with a screening test (Lyme serology or Lyme E.L.I.S.A. [acronym for **Enzyme Linked Immunosorbent Assay**]) followed by IgM and IgG Lyme Western blot. A positive IgM Western blot result requires presence of 2 out of 3 particular bands and a positive IgG Western blot requires 5 out of 10 particular bands.

Such an algorithm consisting of a screening test followed by a confirmatory Western blot is suitable in H.I.V./A.I.D.S. because the ELISA for that disease is 95% sensitive. In Lyme disease, however, the screening test has been estimated to be only 50% sensitive making the two-tier approach inappropriate (**6 Coulter P et. al. Two-Year Evaluation of *Borrelia burgdorferi* Culture and Supplemental Tests for Definitive Diagnosis of Lyme Disease. J Clin Microbiol 2005 October, 43(10):5080-5084.**). Even so, CDC never intended *failure* to satisfy the stringent case surveillance laboratory criteria to rule out a diagnosis of Lyme disease.

Two extremely important bands were excluded from the Lyme Western blot criteria at the Dearborn meeting: the 31 kiloDalton (kDa) band and the 34 kDa band. One of these bands was the basis of a Lyme disease vaccine developed by SmithKline Beecham (the 31 kDa band). As it happened, the SmithKline Beecham vaccine, LymeRix, was withdrawn from the market. Perhaps it was thought it would be too confusing to include the 31 kDa band in the Western blot criteria when it was thought large numbers of persons might have been vaccinated. Omission of these two highly specific bands has needlessly diminished the sensitivity of the Lyme Western blot as a diagnostic tool since most labs do not test for or report antibodies to the 31 and 34 kiloDalton bands.

Relevance of IgM reactivity has been arbitrarily dismissed by academicians, CDC and insurers in late disease with the untrue claim that late disease is invariably characterized by fully diagnostic IgG bands on Western blot **(7 Wormser GP 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, 43:1089-1134)**. Development of IgG antibodies is characteristic of old or healed infection for many illnesses which are rapidly vanquished by patients' immune systems. No doubt, a subset of patients with Lyme disease does show fully diagnostic IgG Western blots. However, another subset of patients, some of whom exhibit signs and symptoms of chronic Lyme disease demonstrate a preponderance of IgM reactivity, often with an expanded pattern of highly relevant bands. This implies long exposure of the immune system to the organism and ongoing antigen-presentation as would occur with a chronic persistent infection. Some authors have noted IgM reactivity late in active disease **(8 Craft JE et. al. Antigens of Borrelia burgdorferi recognized during Lyme disease. Appearance of a new immunoglobulin M response and expansion of the immunoglobulin G response late in the illness. J Clin Invest 1986 Oct 78(4):934-9)**. This argues against ignoring IgM findings after the first month or two of illness. Recent work in a mouse model of infection has demonstrated that persisting IgM reactivity may signify persistent intracellular infection **(9 Racine R et. al. IgM Production by Bone Marrow Plasmablasts Contributes to Long-Term Protection against Intracellular Bacterial Infection. J Immunol 2011:186;1011-1021)**. The Lyme organism has been

demonstrated to invade and persist in a variety of human cells: fibroblasts, neurons and glial cells, and synovial cells among others (10 Livengood JA, Gilmore RD Jr. Invasion of human neuronal and glial cells by an infectious strain of *Borrelia burgdorferi*. *Microbes and Infection* 2006;8(14-15):2832-40 & 11 Georgilis K, Peacocke M, Klempner MS. Fibroblasts Protect the Lyme Disease Spirochete, *Borrelia burgdorferi*, from Ceftriaxone In Vitro. *J Infect Dis* 1992;166:440-4 & 12 Girschick HJ et.al. Intracellular persistence of *Borrelia burgdorferi* in human synovial cells. *Rheumatol Int* 1996;16:125-132) & 13 Chary-Valckenaere I, Jaulhac B, Champigneulle J et al. Ultrastructural Demonstration of Intracellular Localization of *Borrelia burgdorferi* in Lyme Arthritis. (Letter). *Br J Rheumatol* (1998) 37:468-470).

A patient who came under my care within the past two years gave a clear history of a tick attachment and erythema migrans rash about the tick-bite site and serious multi-system symptoms to all 17 physicians whom she consulted over a three year period. The physicians insisted she could not have Lyme disease because her screening test for Lyme disease was negative. She received no antibiotic treatment and has evolved abnormalities on brain MRI which most likely are due to untreated central nervous system Lyme disease. I diagnosed her with Lyme disease based on her history. Screening Lyme ELISA at the well-regarded Laboratory for the Diagnosis of Lyme Disease at the State University of New York at Stony Brook was *still* negative but her IgG and IgM Lyme Western blots were fully diagnostic. When the Frederick County, Maryland Department of Health contacted me seeking information on the case, I decided to include a cover letter copying CDC Director (and former NYC Health Commissioner) Thomas Frieden since her case was a clear-cut example of the glaring deficiencies of the currently recommended two-tier schema of testing for Lyme disease. A series of correspondences culminated with a letter from CDC Associate Director for Science Ron Rosenberg, Sc.D., who indicated that CDC was collaborating on the development of improved tests for Lyme disease that would allow early and accurate diagnosis and was in the process of developing improved educational materials for physicians. In response, I wished Dr. Rosenberg "Godspeed" in accomplishing the stated objectives, but also entreated him to incorporate consideration of the *bona fide* problems of seronegativity and chronic persistent infection in

diagnostics tests and in physician education. Copies of correspondence accompany preceded by the patient's consent for information disclosure **(14 - see binder)**.

Research Collaborations Reveal Disease Complexity

Opportunity to collaborate with first-rank researchers who have studied specimens from my patients with Lyme disease has revealed a complex illness not adequately characterized by simplistic formulations nor detected with standard antibody tests.

In the late 1980s and early 1990s scientists at the CDC, Fort Collins, Colorado requested that I forward to them specimens of blood, urine and spinal fluid from patients I was evaluating for possible Lyme disease.

The Lyme disease organism was grown in culture at CDC from the spinal fluid from one of my patients previously treated empirically for the possibility of Lyme disease with intravenous and oral antibiotics thought more than adequate to cure the illness if she had it **(15 - copy of actual report of culture isolation at CDC - see binder)**. The patient had been ill for several years with unexplained chronic meningitis and gait disturbance. She had tested negative for Lyme disease on standard antibody tests during the first several years of illness. Her case was reported with colleagues from CDC as an abstract at the V International Conference on Lyme Borreliosis in Arlington, VA in 1992 **(16 Liegner KB, Rosenkilde CE, Campbell GL, Quan TJ, Dennis DT. Culture-confirmed treatment failure of cefotaxime and minocycline in a case of Lyme meningoencephalomyelitis in the United States [abstract]. Programs and abstracts of the Fifth International Conference on Lyme Borreliosis, Arlington, VA, May 30-June 2, 1992. Bethesda, MD: Federation of American Societies for Experimental Biology; 1992:A11. - see binder)**.

CDC had also forwarded specimens of frozen urine from my patients to scientists Claude Garon, Ph.D. and David Dorward, Ph.D. at the National Institutes of Allergy and Infectious Diseases' Rocky Mountain Laboratory in Hamilton, Montana. Garon & Dorward subjected these specimens to testing with their experimental direct antigen-capture

assay. This method used electron microscopy to detect immunogold-labeled blebs shed by the Lyme organism (17 Garon CF et. al. **Structural features of *Borrelia burgdorferi* - the Lyme disease spirochete: silver staining for nucleic acids.** *Scanning Microsc Suppl.* 1989;3109-15 & 18 Dorward DW et. al. **Immune capture and detection of *Borrelia burgdorferi* antigens in urine, blood, or tissues from infected ticks, mice, dogs and humans.** *J Clin Microbiol* 1991 Jun;29(6)1162-70 & 19 **More Accurate Way to Detect Lyme Disease May Be Near.** *New York Times. Health Section C.* June 17, 1992. p. C12 - see binder). Thirty-seven out of fifty-one patients who tested negative on standard antibody testing tested positive for direct detection of Lyme-specific blebs using their research assay (20 - see binder). Their findings suggested many persons actually suffering from Lyme disease might test negative with standard methods of antibody testing. Many of the patients testing positive had already received lengthy courses of antibiotic treatment findings implying ongoing infection despite application of antibiotic treatment. We reported these findings in an abstract for the V International Conference on Lyme Borreliosis in Arlington, VA. In 1992 (21 **Liegner KB, Garon C, Dorward D. Lyme borreliosis (LB) studied with the Rocky Mountain Laboratory (RML) antigen capture assay in urine [abstract 18].** Program and abstracts of the Fifth International Conference on Lyme Borreliosis, Arlington, VA, May 30-June 2, 1992. Bethesda, MD: Federation of American Societies for Experimental Biology, 1992 - see binder).

In the year 2000 I had the opportunity to send more than 140 frozen spinal fluid specimens from my patients to the research laboratory of Dr. Raymond Dattwyler at SUNY Stony Brook, for experimental research assays. This testing, performed by laboratory supervisor Priscilla Munoz, included antigen capture assays (for OspA & OspC [Outer surface protein A and Outer surface protein C]) and borrelia-specific IgM and IgG antibodies. These were compared to standard antibody tests in spinal fluid. Whereas only 2% of spinal fluids tested positive on standard antibody assays, 62% were positive on one or more of the research assays (22 **Print-out of results of research assays versus standard assays on 129 frozen CSF specimens from 108 patients from Dr. Liegner's practice performed 2002 in the research laboratory of Dr. Raymond Dattwyler at SUNY Stony Brook by Priscilla Munoz, Laboratory Supervisor, Research Coordinator and Administrator. Names of all patients except Vicki Logan are redacted. All positive results are highlighted in yellow - see binder).** These research assays were developed by well-respected scientists with methods published in peer-reviewed journals (23 **Coyle PK, Deng Z, Schutzer SE, Belman AL, Benach J, Krupp L, Luft B. Detection of *Borrelia burgdorferi* antigens in**

cerebrospinal fluid. *Neurology* 1993;43:1093-1097. & 24 Coyle PK, Schutzer SE, Deng Z, Krupp LB, Belman AL, Benach JL, Luft BJ. Detection of *Borrelia burgdorferi*-specific antigen in antibody-negative cerebrospinal fluid in neurologic Lyme disease. *Neurology* 1995;45:2010-5 & 25 Schutzer SE et. al. Sequestration of antibody to *Borrelia burgdorferi* in immune complexes in seronegative Lyme disease. *Lancet* 1990 Feb 10;335(8685):312-5). Ms. Munoz advised me that three cooperating laboratories engaged in CDC-funded research using these methods previously had demonstrated good reproducibility on split aliquots.

Access to advanced research methodologies provided a glimpse into the hidden complexity of Lyme disease, inadequacy of clinically-available test methods and resilient nature of the infectious agent.

Incidentally, CDC and their collaborators have **never** reported their results on the patients being tested by the three research groups using the direct detections methods at the time which, fortuitously, I had access to for my patients' CSF specimens.

Impact of Managed Care

Lyme disease is the first disease of truly epidemic proportions that emerged hand in hand with another new phenomenon affecting the health of Americans: the penetration of managed care into the health care insurance marketplace. Whereas, initially, there was a spirit of conviviality and excitement shared amongst physicians and scientists laboring in this field, severe polarization soon developed in the early 1990s as many academicians consulted heavily for the insurance industry.

The Infectious Diseases Society of America (IDSA) Lyme Disease Treatment Guidelines of 2000 (26 Wormser GP et. al. **Practice Guidelines for the treatment of Lyme disease. The Infectious Diseases Society of America. Clin Infect Dis. 2000 Jul;31 Suppl 1:1-14**) and 2006 (7) promoted use of CDC case-surveillance criteria and the Dearborn laboratory criteria as the sine qua non for a diagnosis of Lyme disease. This set a very high bar which many patients actually suffering from Lyme disease have been unable to surmount. Virtually no mention is made about the problems posed by seronegative Lyme disease in the IDSA 2000 and 2006 Lyme Disease Guidelines, despite one of the co-authors

of these having written an important paper describing this phenomenon (27 Dattwyler RJ et.al. **Seronegative Lyme Disease. Dissociation of Specific T- and B-Lymphocyte Responses to *Borrelia burgdorferi*. N Engl J Med: 1988;319:1441-6.**) The last paragraph of the abstract of that article states:

"We conclude that the presence of chronic Lyme disease cannot be excluded by the absence of antibodies against *B. burgdorferi* and that a specific T-cell blastogenic response to *B. burgdorferi* is evidence of infection in seronegative patients with clinical indications of chronic Lyme disease."

It is notable that many of the culture-proven cases of Lyme disease reported in the worldwide peer-reviewed scientific literature occurred in seronegative cases (28 Schmidli J et. al. **Cultivation of *Borrelia burgdorferi* from joint fluid three months after treatment of facial palsy due to Lyme borreliosis. J Infect Dis 1988;158:905-6** & 29 Preac-Mursic V et. al. **Survival of *Borrelia burgdorferi* in antibiotically treated patients with Lyme borreliosis. Infection 1989;17:355-9** & 30 Hassler D et. al. **Pulsed high-dose cefotaxime therapy in refractory Lyme borreliosis (letter) Lancet 1991;338:193** & 31 Preac-Mursic V et. al. **First isolation of *Borrelia burgdorferi* from an iris biopsy. J Clin Neuro-ophthalmol 1993;13:155-161** & 32 Haupl T et. al. **Persistence of *Borrelia burgdorferi* in ligamentous tissue from a patient with chronic Lyme borreliosis. Arth Rheum 1993;36:1621-6** & 33 Preac-Mursic V et. al. **Kill kinetics of *Borrelia burgdorferi* and bacterial findings in relation to the treatment of Lyme borreliosis. Infection 1996;24:9-16 [compilation thanks to Carl Brenner]).**

Additionally, IDSA Guideline authors took the *extreme* position that chronic Lyme disease due to chronic persistent infection did not exist (7).

Connecticut Attorney General Richard Blumenthal undertook an investigation of the process by which the 2006 IDSA Lyme Disease Guidelines were developed. He discovered significant undisclosed conflicts of interest by some guidelines authors as well as irregularities of the process by which the 2006 IDSA Lyme Disease Guidelines were developed **(34 Johnson L Stricker RB. Attorney General forces Infectious Diseases Society of America to redo Lyme guidelines due to flawed development process. J Med Ethics 2009;35:283-288 - see binder).**

As a result of Attorney General Blumenthal's investigation a settlement agreement required the IDSA to undertake reassessment of the its 2006 Lyme Guidelines. Accordingly, presentations were given before an IDSA-selected Lyme Disease Review Panel, Hemisphere Suite A, Ronald Reagan Building, Washington, D.C., July 30, 2009.

Very substantial evidence from the worldwide published peer-reviewed scientific literature was presented to the panel, demonstrating the reality of seronegative and serovariable Lyme disease and chronic persistent infection in humans and animals despite application of antibiotic therapy **(35 IDSA Hearings, Part I and Part II. Lyme Times #56, Summer 2009 and # 59 & 60, Spring/Summer 2010: Presentations to the Lyme disease Review Panel of the Infectious Diseases Society of America).**

Regrettably, the IDSA Lyme Disease Review Panel opted to ignore the evidence presented, maintaining no significant modifications to the 2006 IDSA Lyme Disease Guidelines were necessary.

Notably, all panel members were selected by the IDSA, most panelists were IDSA members and physicians who earned more than \$10,000/year caring for persons with Lyme disease were excluded from the panel. As a result, physicians most experienced with treating persons with Lyme disease, including chronic Lyme disease, were *not* represented on the panel.

The insurance industry has utilized the 2000 & 2006 IDSA Lyme Disease Guidelines as an economic tool to minimize expenditures caring for persons who have (or *might* have) Lyme disease. Girded by IDSA Lyme Guidelines, insurers systematically *misuse* the CDC epidemiologic case definition and Dearborn meeting-based laboratory standards,

requiring satisfaction of these stringent criteria (intended for epidemiologic surveillance purposes) as *prerequisite* for reimbursement for treatment for Lyme disease. This ***sleight of hand*** has greatly redounded to the financial benefit of the insurance industry and its consultants but deprives many patients who actually *have* Lyme disease from reimbursement for needed care by *defining them out of existence*. Insurers' positions have hardened noticeably after the IDSA Lyme Review Panel upheld the IDSA 2006 Lyme Disease Guidelines.

Institute of Medicine Lyme and Tick-borne Disease State of the Science Review

October 2010 a Lyme and Tick-borne Diseases State of the Science Review was held in Washington, D.C. by the Institute of Medicine (IOM). Panelists responsible for drafting the final report represented diverse disciplines. Invited presenters expressed a range of views. Active participation of audience attendees (which included patients and some Lyme-treating physicians) was encouraged with questions being directed to the panel as well as expression of brief personal statements. There was guarded optimism the IOM report might break the log-jam of denial and stone-walling by the IDSA and CDC concerning the existence of chronic Lyme disease. However, in view of the intransigence of the IDSA Lyme Disease Review Panel and that many members of the IDSA are represented in the composition of the IOM, concern also existed the IOM report might whitewash the IDSA Lyme Disease Guidelines, serving to maintain the *status quo* (**36 Liegner KB letter to IOM Committee on Lyme Disease and Other Tick-Borne Diseases, Chair & Panelists - see binder**). The IOM report, issued Spring 2011, acknowledges the complexity of Lyme disease and the many unanswered questions and research needs that obtain in this area (**37 Critical Needs and Gaps in Understanding Prevention, Amelioration, and Resolution of Lyme And Other Tick-Borne Diseases. The Short-Term and Long-Term Outcomes. Workshop Report. Committee on Lyme Disease and Other Tick-borne Diseases: The State of the Science. Board on Population Health and Public Health Practice. Institute of Medicine. The National Academies Press 2011**).

Favoritism of CDC for IDSA Guidelines

The International Lyme and Associated Diseases Society (**ILADS**) developed its own set of Lyme Disease Treatment Guidelines published in Expert Review of Infectious Disease 2004 (**38 Cameron D et. al. Evidence-based guidelines for the management of Lyme disease. Expert Rev Anti Infect Ther.2004;2(1 Suppl):S1-13**) and listed on the National Guidelines Clearinghouse Web-site. These contrast markedly with IDSA Lyme Disease Treatment Guidelines, emphasizing the importance of clinical judgment in diagnosis of Lyme disease and individualization of treatment regimens in view of uncertain eradication of the infectious agent and imperfect testing methods. Despite existence of two sets of Lyme guidelines, CDC has had links **only** to the IDSA Lyme disease guidelines.

Recently, on behalf of the Health Protection Authority (**HPA**) of Great Britain (charged with establishing policies for the British National Health Service) a panel chaired by microbiologist Brian Duerden issued a highly critical assessment of the ILADS guidelines. The report reinforced restrictive policies in Great Britain concerning diagnosis and treatment of Lyme disease echoing the IDSA Lyme guidelines by confining diagnosis to the seropositive subset and denying the existence of *chronic* Lyme disease. While emphasizing the risks of intensive treatment the report ignores the potentially devastating consequences of failure to diagnose Lyme disease or treat it adequately. In Great Britain, where the government IS the insurer, an atmosphere of fear and intimidation exists amongst physicians who might wish to treat patients having Lyme disease. British subjects with Lyme disease, especially *chronic* Lyme disease, are desperate.

**(39 Independent Appraisal and Review of ILADS 2004
'Evidence-based guidelines for the management of Lyme disease' 8 December 2010
www.hpa.uk/web/HPAweb_C/1294739293177)**

**Boards of Medical Practice Used as Tools to
"Break the Knees" of "non-conforming" Practitioners**

There have been a number of instances where practitioners who do not agree with the IDSA view of Lyme disease have been targeted for disciplinary actions by various state boards of medical practice. Often, actions are not instigated by patient complaints, but rather insurers seeking to "rein in cost outliers" or by physicians seeking to hamstring their direct economic competitors. Other physicians may lodge complaints, righteously indignant at those who flout IDSA guidelines. Finally, complaints may be motivated by sheer malice.

Dr. Joseph Burrascano, Jr. a leading innovative clinician caring for patients with Lyme disease, defended himself against thirty-nine charges brought against him by the New York State Department of Health, including allegations of fraud. The State Board for Professional Medical Conduct Hearing Committee, upon examination of all facts of the case, issued a decision November 6, 2001 finding all but two charges not sustained. One sustained charge determined Burrascano had not exercised appropriate judgment in prescribing doxycycline for a patient who tested positive for antibodies to ehrlichiosis but who lacked a clear clinical picture of the illness. The second sustained charge determined that he exercised poor judgment in using Bicillin-LA (a long-acting depot preparation of intramuscular penicillin) in a person with a seizure disorder, where the Bicillin-LA may have exacerbated the patient's seizures.

In evaluating the credibility of the Department of Health's expert witness against Dr. Burrascano, infectious diseases specialist Peter Welch, M.D., the Committee stated **(38 NYS BMPC #01-265)**:

"The Committee found him to be an arrogant witness, who appeared to be on a crusade, constantly lecturing, rather than answering, after questions were posed to him. He answered every question emphatically, without equivocation, determined to get across his view that the Respondent (Dr. Burrascano) had acted improperly. On those occasions when he was confronted on cross examination with conclusive evidence, for example, that he had overlooked some portion of the medical record, or that the entire editorial staff of a

particular journal shared the Respondent's approach, he was reluctant to acknowledge his error. On other occasions when challenged he answered in a flip manner. For example, when asked what he would do if faced with a patient who did not improve after extensive treatment, he replied "when it happens you write an article about it in a journal and get it published" (T.863). Had Dr. Welch even appeared to consider other viewpoints than his own, as well as the documented chart evidence before drawing conclusions in his testimony, it would have added to his credibility."

The Hearing Committee's report also stated:

"The Hearing Committee recognizes the existence of the current debate within the medical community over issues concerning management of patients with recurrent or long term Lyme disease. This appears to be a highly polarized and politicized conflict, as was demonstrated to this Committee by expert testimony from both sides, each supported by numerous medical journal articles, and each emphatic that the opposite position was clearly incorrect. In fact, it often appeared that the testimony was framed to espouse specific viewpoints, rather than directly answer questions posed. What clearly did emerge, however, was that the Respondent's approach, while certainly a minority viewpoint, is one that is shared by many other physicians. We recognize that the practice of medicine may not always be an exact science, "issued guidelines" are not regulatory, and patient care is frequently individualized.

We are also acutely aware that it was not this Committee's role to resolve this medical debate, but rather to answer the questions raised in the Statement of Charges:.."

Despite the relatively minor findings which were upheld in Dr. Burrascano's case, the Hearing Committee ordered a stayed suspension of Dr. Burrascano's license with a 6 month period of probationary practice of medicine with supervision by an infectious diseases physician as a practice monitor at Dr. Burrascano's expense.

Even if a physician prevails in an encounter with a state medical board or exits with minimal sanctions, traversing this tortuous and often prolonged administrative process can be an emotionally and financially draining ordeal and distracts the physician from patient care.

Dr. Burrascano opted to close his practice November 2006 to pursue other avenues of medicine, citing the unfavorable practice environment for physicians caring for persons with Lyme disease **(41 movie, Under Our Skin)**.

Charles Ray Jones, M.D., who has virtually single-handedly cared for this nation's children ill with chronic Lyme disease, is another example. He attended Yale Divinity School, friend and classmate of Martin Luther King, Jr. with whom he marched in Alabama during the struggle for desegregation. Jones has been hounded by the Connecticut State Medical Board for years. His patients and colleagues have helped to defray the costs of his legal defense, which has exceeded one million dollars. His alleged crime: allegedly diagnosing a child over the telephone - a charge which he denies.

Jones, an altruist, has acted in what he has perceived to be the best medical interests of his child patients. Doing so has sometimes placed him in the middle of nasty divorce cases, where parents disagreed on diagnosis and management. A father unwilling to pay costs of medical care instigated the Connecticut Department of Health's investigation of Jones, who has only helped and never harmed a child **(42 Stephenson T. Amid medical controversy, children saved. Yale Daily News. April 5, 2011 - see binder)**.

On the other hand, a physician's failure to treat for an engorged deer-tick bite despite the mother's plea and an insurance company physician reviewer's refusal to authorize reimbursement for continuation of intravenous antibiotic treatment to which the child was responding favorably eventuated in the child's death **(43 Liegner KB & Jones CR. Fatal progressive encephalitis following an untreated deer tick attachment in a 7 year-old Fairfield County, Connecticut child. [Abstract] VIII International Conference on Lyme Disease and other Emerging Tick-borne Diseases, Munich, Germany, June 1999 - see binder & 44 Liegner letter to the review physician of CIGNA's Intracorp - see binder)**.

Dr. Charles Ray Jones and I reported the case to the public health official charged with overseeing Lyme disease cases in Connecticut. Our motive was not punishment of the physicians involved but the opportunity for medical science to learn from the case. The official declined to investigate stating to me: "well, what evidence was there, really, that this child had Lyme disease?" (the child had 4 out of 5 CDC-specific IgG bands on Lyme Western blot at SUNY Stony Brook but tested negative by Lyme ELISA).

Such nonfeasance exposes the hypocrisy of Connecticut State health officials, refusing to investigate a fatal case of chronic Lyme disease in a child occasioned by **failure** to treat but hounding a physician who diagnoses and **treats** chronic Lyme disease. The Connecticut Board of Medical Practice insists Lyme disease has *nothing* to do with its dogged pursuit of Dr. Jones.

Therapeutic Nihilism/Minimalism

Steere suspected a viral cause for what he called Lyme arthritis. He studied the natural history of the illness, untreated, prospectively (**45 Grant number: 1R01AM020358-01 Project Title: LYME ARTHRITIS: A NEW EPIDEMIC DISEASES 1977 CRISP**).

In 1982, scientist Willy Burgdorfer discovered the cause of Lyme disease, the borrelial spirochete, later named *Borrelia burgdorferi* in his honor. (**46 Burgdorfer W et. al. Lyme Disease - a tick-borne spirochetosis? Science 1982 Jun 18;216(4552)1317-1319**). Steere then averred that antibiotics were effective in treating Lyme disease. Conventional doses of antibiotics were chosen for the treatment of Lyme disease, not unreasonable at the time. However, it later became apparent that the Lyme organism was capable of spreading to the central nervous system very early in the course of the illness (**47 Luft BJ et. al. Invasion of the central nervous system by Borrelia burgdorferi in acute disseminated infection. JAMA 1992 Mar 11;267(10):1364-7 & 48 Garcia-Monco JC et. al. Borrelia burgdorferi in the central nervous system: experimental and clinical evidence for early invasion. J Infect Dis 1990 Jun;161(6):1187-93**). Virtually all of the regimens recommended at that time for early Lyme disease are likely insufficient for treatment of or protection from central nervous system infection. Nonetheless, dosages originally used have remained the recommended regimens, "carved in stone", reinforced by the

2000 & 2006 IDSA Lyme Guidelines. Such dosages are irrational, virtually assuring a subset of patients treated for early disease will progress to late central nervous system complications of the illness.

There has been controversy about almost everything surrounding Lyme disease. One controversy has been whether or not to treat a deer-tick bite preventively with antibiotics (**49 Magid D et. al. Prevention of Lyme Disease after tick bites. A cost-effectiveness analysis. N Engl J Med 1992 Aug20;327(8);534-41 & 50 Liegner KB N Engl J Med 1993 May 13;328(19)1419-20**). Lead author of IDSA Guidelines Gary Wormser and colleagues reported a study preventively treating deer tick bites with but a single dose of doxycycline, 200 mgs (**51 Nadelman RB et. al. Prophylaxis with single-dose doxycycline for the prevention of Lyme disease after an ixodes scapularis tick bite. N Engl J Med 2001 Jul 12;345(2):79-84**). They did find a diminution in incidence of erythema migrans in the single-dose doxycycline-treated cohort, but some patients failed the regimen and went on to develop Lyme disease. Furthermore, the study only followed patients for some 6 weeks and thus it could not be determined whether the treated and untreated study groups progressed to develop later complications of the disease, including chronic Lyme disease. Regrettably, I have heard reports of ignorant physicians misconstruing Nadelman's group's study and prescribing but a single 200 milligram dose of doxycycline for patients having erythema migrans.

The Case of Vicki Logan

(52, 53 Consents by Vicki Logan & her next of kin, Robert Reitman authorizing me to discuss her case publicly - see binder).

Vicki Logan consulted me in 1989. This pediatric ICU nurse had suffered for several years prior to seeing me, with an undiagnosed illness characterized by gait disturbance and chronic meningitis. She had grown up in Golden's Bridge in northern Westchester County, New York but gave no history of ever having had a tick bite or any rash that would have been suspicious for Lyme disease. I studied her case in great depth for more than one year but I was unable to make a definite diagnosis that would explain her illness. Since she had been at risk for Lyme disease and since negative tests did not necessarily rule

out the diagnosis, I decided to treat her empirically for the possibility that she *might* have Lyme disease. She had a spinal tap before and after 21 days of an intravenous antibiotic thought to be curative for the illness. Spinal tap after treatment did not show any changes and her condition also did not improve. I treated her with 4 months of an oral antibiotic appropriate if she had Lyme disease (minocycline, a tetracycline) just for good measure, again with no impact. At that point without a definite diagnosis and without clear response to a trial of treatment, further treatment was deferred. Vicki contacted me again about a year later and begged to have another spinal tap. At that point I was collaborating with scientists at the Centers for Disease Control in Fort Collins, Colorado who had supplied me with culture media to try to grow the Lyme spirochete. When I tapped Vicki, December 1991, I placed a small amount of spinal fluid in the culture media (Barbour-Stoenner-Kelly II media) and a few weeks later I received a phone call from an excited David Dennis at CDC Fort Collins reporting spirochetes were growing from Vicki's spinal fluid. These later proved to be *Borrelia burgdorferi*, the Lyme disease agent **(15 copy of original report of culture isolation from CSF by CDC - see binder)**. Vicki was the first American patient from whom the Lyme organism had been isolated in culture after application of putatively curative antibiotic treatment. CDC requested and received a unit donation of blood for their Lyme disease serum reference bank **(54 - Copy of receipt for Unit Donation to CDC - see binder)**.

Colleagues from CDC reported this with me as an abstract at the V International Conference on Lyme Borreliosis held in Arlington, Virginia in 1992 **(16 - see binder)** and I authored a Guest Commentary published in the Journal of Clinical Microbiology, prompted by the circumstances of her case **(55 Liegner KB Lyme Disease: The Sensible Pursuit of Answers. (Guest Commentary). J Clin Microbiol 1993;31:1961-1963 - see binder)**.

Now knowing that Vicki had neurologic Lyme disease, I reinstated treatment with intravenous antibiotics for 13 weeks and meningitis that had been present for years resolved completely and she experienced modest improvement in her status. When treatment was discontinued her condition began to worsen. She was seen at the Mayo Clinic where she received steroids which worsened her condition. Upon return to New York she was desperately ill and needed

hospitalization. She was severely encephalopathic, unable to remember conversations held minutes earlier, could not walk, turn over in bed or hold a cup.

She had developed an accumulation of fluid around her heart and needed to have a hole created in the sac surrounding her heart (pericardium) to allow fluid to drain so her heart's pumping would not be prevented. I treated her in the hospital for 109 continuous days of intravenous antibiotics and her condition dramatically improved. I published her case along with cases of three other patients believed to have chronic neurologic Lyme disease in the *Journal of Spirochetal and Tick-borne Diseases* (**56 Liegner KB et. al. Lyme Disease and the Clinical Spectrum of Antibiotic-responsive Meningoencephalomyelitides. J Spirochetal and Tick-borne Dis 1997;4:61-73 - see binder**).

Many patients who acquire Lyme disease, especially when diagnosed early, do well following a short course of antibiotic treatment. Others, particularly when diagnosis and application of treatment is delayed, experience more difficulty. Some require lengthy and/or repeated courses of oral antibiotics because antibiotics may not invariably eradicate the infectious agent. A smaller subset requires use of intravenous antibiotics to recover. A still smaller subset seems to require repeated or very prolonged intravenous antibiotic treatment. In rare cases (such as Vicki's) a somewhat "open-ended" approach to intravenous antibiotics is necessary because without such treatment the patient experiences progressive neurological deterioration.

Initially, Vicki's health insurer, Empire Blue Cross & Blue Shield, was helpful to her. I dealt early on with Sherwood Miller, M.D., Empire Assistant Medical Director, Medical Policy and Research. Whenever I could demonstrate the need for treatment in objectively measurable ways, Dr. Miller would agree to resumption of intravenous antibiotic therapy often in periods of 12-16 weeks. Such durations invariably led to objective clinical improvement which is very well documented in her clinical record both as in-patient and out-patient.

Changes in personnel at the executive level occurred at Empire Blue Cross & Blue Shield and policies were put into effect in relation to Lyme disease which made it increasingly difficult and finally impossible for Vicki to receive reimbursement for further intravenous antibiotic treatment.

I admitted Vicki to Northern Westchester Hospital in order for her to receive physical therapy services and intravenous antibiotic treatment. The latter could not be undertaken as an outpatient due to Empire's changes in policy. Empire denied reimbursement to the hospital for the entire hospitalization claiming her care was "medically unnecessary", leaving the hospital with some \$175,000 in un-reimbursed charges. Empire Blue Cross & Blue Shield Senior Vice President Richard Sanchez, M.D. notified me by letter that reimbursement for Vicki's hospitalization was denied **(57 - see binder)**. I wrote a letter in response **(58 - see binder)**. Thereafter, a succession of Empire medical reviewers continued to obstruct care for Vicki over the succeeding years 1996 to 2002 terming intravenous antibiotic therapy, the only treatment well-documented to improve her condition or avert her deterioration, either "not medically necessary" or "experimental" and thus not eligible for reimbursement.

Vicki's condition deteriorated. Copies of correspondence between me and Empire Blue Cross & Blue Shield medical review physicians and Medical Directors between 1993 and 2002 accompany **(59 - see binder)**. One can note the dramatic change in position after the *exitus* of Sherwood Miller and the arrival of Richard Sanchez. Extensive correspondence other than with Empire BlueCross BlueShield, consultations, various items from her medical record and a representative sampling of her labs accompany for inspection **(60 - see binder)**.

Logan Lawsuit against Empire Blue Cross Blue Shield

In 1996 Logan and five other patients with Lyme disease sued Empire Blue Cross and Blue Shield for their refusal to reimburse for needed treatment **(61 SUPREME COURT OF THE STATE OF NEW YORK COUNTY OF WESTCHESTER Index No. 96/20517)**. The suit was ultimately settled out of court, the terms of which were sealed. Whatever the settlement was, it did not include any acknowledgement of Vicki's right to be reimbursed for costs of treatment.

During litigation, Empire Blue Cross & Blue Shield Senior Vice President, Richard Sanchez, M.D., the same physician who had denied reimbursement to Northern Westchester Hospital for Vicki's hospitalization, gave important testimony in a deposition. I've separated out and enlarged to 8 ½ X 11 inch pages the most relevant portions of his deposition testimony **(62 - see binder)** but I am providing you with a copy of the entire deposition should you wish to inspect it in order to be able to interpret his testimony in its full context **(63 - see binder)**.

Dr. Sanchez revealed that, upon advice of their accountants, Deloitte & Touche, Empire Blue Cross and Blue Shield targeted costly illnesses, including Lyme disease, raising the bar in order to make it harder for patients to qualify for reimbursement with the goal of boosting corporate profits. At the time, Empire Blue Cross & Blue Shield was positioning to transition from "not for profit" to "for profit" status **(64 Robinson JC. The Curious Conversion of Empire Blue Cross. Health Affairs 2003;22(4):100-118 - see binder)**.

Dr. Sanchez acknowledged that there might be some patients with Lyme disease who really had the illness but who would not satisfy Empire Blue Cross and Blue Shield's high hurdle of satisfying CDC epidemiologic case surveillance definition and case surveillance laboratory criteria. He admitted these patients might deteriorate as a result of their denial of care. He acknowledged awareness seronegative patients might exist, making reference to Dr. Raymond Dattwyler's work demonstrating that phenomenon. He states that he and his colleagues were "able to sleep at night" by rationalizing that patients who were initially denied would eventually wend their way through Empire Blue Cross & Blue Shield's tortuous appeals process and perhaps get treated at a later date.

He acknowledges that some patients would not be able to successfully negotiate the appeals process and might "fall by the wayside" with unfortunate consequences. Vicki Logan was such a case.

When Vicki inadvertently lost her insurance through Empire Blue Cross and Blue Shield 2002, I encouraged her not to seek reinstatement of the policy because having insurance with Empire Blue Cross & Blue Shield was an impediment to her treatment not a means to it. I believed she would be more likely to get the treatment she needed if Medicaid were her sole medical insurer.

Spring 2002, after she obtained Medicaid, I admitted Vicki to Northern Westchester Hospital Center. I arranged for her to have a PORT placed to facilitate a long course of intravenous antibiotics. I was mindful of the burden of un-reimbursed care that had fallen on the hospital during a prior admission when Empire Blue Cross & Blue Shield had been her insurer and I requested a meeting of the Medical Ethics/Quality Improvement Committees to discuss her case **(65 - see binder)**. About two years earlier, the IDSA 2000 Lyme Disease Guidelines had been published. Like the 2006 IDSA Lyme Disease Guidelines, these asserted a discrete entity of chronic Lyme disease didn't exist. The meeting occurred with a medical ethicist participating by phone with the other members of the committee. I was quite taken aback when the medical ethicist opined the care I proposed for Vicki was "not a wise use of scarce resources". I was forced to discharge her from the hospital.

Eventually I was able to locate a nursing home, Tree Tops in Mohegan Lake, NY, that was equipped and willing to provide intravenous antibiotic treatment to Vicki. In order to do this, I secured privileges in the nursing home. We began treatment, but after three weeks of therapy I was requested by the administrator of the nursing home to desist further treatment until and unless New York State Office of Medicaid Management would permit a "carve out" of additional funds to make it financially feasible for the nursing home to stay in the black while providing the treatment to Vicki. It seems the amount of reimbursement for patients in nursing homes under Medicaid does not make extended intravenous antibiotic therapy financially feasible.

I had met previously, May 3, 2002, in Albany with Thomas Fanning, Ph.D. of the Office of Medicaid Management, Foster Gesten, M.D., Medical Director NYS DOH Office of Managed Care and DOH Attorney Glen Lefebvre. Assemblyman Joel Miller and Brian Fallon, M.D., M.P.H. (a research psychiatrist with extensive experience and publications on

Lyme disease who had seen Vicki in consultation) participated by phone. Science journalist Pamela Weintraub and Lyme advocate Jill Auerbach were present. I was seeking assistance from NY Medicaid to pre-authorize added reimbursement to a nursing home such that Vicki could receive the treatment she needed in that setting. The position taken by Mr. Fanning was that services had to be rendered first and only then could a request for a "carve out" be considered **(66, 67, 68 correspondence from me to Kathy Kuhmerker, Mr. Fanning's superior and between me and Mr. Fanning - see binder)**.

Thus, at the three week mark of intravenous antibiotics, with further treatment on hold, I endeavored to seek a "carve out" for Vicki to enable continued treatment for her. This proved to be no easy task as I was shunted from one bureaucrat to another requiring numerous phone calls and delays with no decision and not even a clear path to pursue **(69 - see binder of hand notes of telephone conversations with Medicaid personnel while seeking a "carve out")**.

While I was trying to navigate this morass of bureaucracy, Vicki sustained a series of three *grand mal* seizures and was taken to Hudson Valley Hospital in Peekskill, NY. Vicki had developed a seizure disorder as a part of her illness and was on anti-seizure medication with therapeutic levels at the time the seizure occurred. I did not hold privileges at Hudson Valley Hospital. I expected that Vicki would get her anti-seizure medication adjusted and would soon return to Tree Tops, but that was not the case.

At Hudson Valley Hospital Vicki had become hypotensive. Her condition appeared grave and after consultation between the physician caring for her and her brother a decision was made to make her status "DNR" (do not resuscitate) and medical support was withdrawn. She died a few days later. I know that she was *compos mentis* because her close friend Rosalind was with her shortly before she died. Rosalind reported to me that Vicki mouthed to her "I love you" at Rosalind's last visit. Although some might have felt that Vicki's quality of life was poor, a relatively young woman consigned to a nursing home, she loved life despite her circumstances and very much wanted to live.

Consent for an autopsy had been obtained in the event of Vicki's death. When I spoke with the pathologist at Hudson Valley Hospital, he adamantly refused to perform an autopsy. Furthermore, he advised he would not even allow an outside pathologist to perform an autopsy on the premises of Hudson Valley Hospital, citing danger of infection to himself or his staff in performance of the autopsy (**70 - see binder of hand notes of my conversations with the Hudson Valley Hospital pathologist**). I was incredulous of his position and challenged it; he ran it by the Hudson Valley Hospital administration which, according to him, backed his position.

Fortunately, I was able to contact my colleague, Dr. Fallon at Columbia Presbyterian and was put in touch with the Chief of Neuropathology at that institution, James Goldman, M.D. who readily accepted Vicki's case for autopsy. The main finding of the autopsy was chronic neuroborreliosis however acute myocardial infarction was revealed to be the proximate cause of death (**71 - see binder**).

Myocardial infarction was, evidently, neither diagnosed nor treated at Hudson Valley Hospital. In retrospect her hypotension was most likely due to an acute myocardial infarction resulting from her series of seizures.

The actions of the pathologist and the Hudson Valley Hospital administration, had they been successful in preventing an autopsy, would not only have impeded medical knowledge of chronic and neurologic Lyme disease but would have served to conceal the cause of her hypotension, a missed diagnosis of myocardial infarction. Whereas a work-up to rule out myocardial infarction as a treatable cause of unexplained hypotension would be routine for most patients, it appears not to have been undertaken in Vicki's case. Had a heart attack been diagnosed and treated she might have been enabled to survive instead of having "crepe laid" with issuance of a DNR order, assuring her premature death.

Events at Hudson Valley Hospital demonstrate medical professionals' fear, ignorance and superstition when it comes to Lyme disease and exemplifies the discrimination and medical neglect to which patients with chronic Lyme disease are subject, not only in life but even after death.

Vicki's brain showed chronic meningoencephalitis with inflammation of brain blood vessels with prominence of plasma cells, a cell type often found in the vicinity of spirochetes, including in syphilis and Lyme disease. Immunohistochemical study of the brain performed by Austrian dermatologist Klaus Eisendle, M.D., Ph.D using methods he developed for study of Lyme spirochetes in skin **(72 Eisendle K et. al. Focus Floating Microscopy "Gold Standard" for cutaneous Borreliosis? Am J Clin Pathol. 2007;127:213-222)** showed up-take in the vicinity of blood vessels where inflammation and plasma cells were seen. Further studies of Vicki's tissues can be undertaken because they are preserved both in formalin and in liquid nitrogen in the Brain Bank of Columbia Presbyterian's Department of Neuropathology.

Vicki's case of severe chronic and neurologic Lyme disease is not unique. I reported on three other similar cases in my article in the Journal of Spirochetal and Tick-borne Diseases **(56 - see binder)**.

One of those cases, Martin Eisenhardt, an outdoorsman and resort owner from Cairo, New York became seriously neurologically ill following an eruption historically consistent with erythema migrans, Fall of 1985. He was cared for at Albany Medical College and Massachusetts General Hospital. His devoted wife, Mary Lou, kept asking the doctors if he could have Lyme disease. Because tests for Lyme were negative she was told it could not be Lyme disease. He was treated with immunosuppressive drugs for vasculitis with progressive neurologic deterioration, suffering horribly. He came under my care late in his illness. He improved modestly with an extended course of intravenous antibiotic treatment, succumbing to his disease after intravenous antibiotics were discontinued. His brain showed evidence of spirochetes on electron microscopy and DNA of the Lyme organism was detected by PCR methodology by Dagmar Hulinska, Ph.D., Director of the Borrelia Reference Laboratory of the Czech Republic. His wife's heartfelt letter and a photograph of Martin when he was well accompany **(73 - see binder)**.

**Evidence of Apparent Duplicity on the part of IDSA Lyme
Guideline Authors**

IDSA Lyme disease guidelines have had a profound effect on persons with Lyme disease, making it difficult for them to receive care which they require whether such care is rendered on an out-patient basis or in the hospital. Evidence indicates the positions taken by some guideline authors as signatories to the IDSA Guidelines is diametrically opposite what they declare in their published scientific work, private communications and patents.

Guideline signatory Raymond Dattwyler endorses the categorical assertion that chronic Lyme disease does not exist yet his patent for novel chimeric nucleic acids and protein antigens which could serve as a basis for a vaccine or for improved immunodiagnostic reagents for Lyme disease, issuing almost contemporaneously with the 2006 IDSA Lyme Disease Guidelines seems to say exactly the opposite:

"Currently, Lyme Disease is treated with a range of antibiotics, e.g. tetracycline, penicillin and cephalosporins. However, such treatment is not always successful in clearing the infection. Treatment is often delayed due to improper diagnosis with the deleterious effect that the infection proceeds to a chronic condition, where treatment with antibiotics is often not useful. One of the factors contributing to delayed treatment is the lack of effective diagnostic tools." **(74 Dattwyler, et.al. United States Patent 7,179,448) .**

The 2000 and 2006 IDSA Lyme Disease Guidelines do not disclose that Dr. Dattwyler had served as a consultant to Empire Blue Cross & Blue Shield in its defense of the Logan suit, where patients with chronic Lyme disease were seeking damages for Empire's refusal to reimburse them for costs of their care.

Ironically, Vicki Logan's previously frozen cerebrospinal fluid samples were tested using experimental research assays in Dr. Dattwyler's research lab at SUNY Stony Brook unbeknownst to him. All three samples from different dates tested were positive. The latest specimen tested positive on all four components of the research assays, with direct detection of Outer surface protein A antigen at a level more than seven times greater than the positive cut-off **(75 - Reports of results of research**

assays from Dr. Dattwyler's Research Laboratory on Vicki Logan's CSF samples from 7/6/99, 9/18/2000 and 6/20/2001 - see binder).

In a personal letter to me dated June 14, 1990, after I had provided him with a copy of a landmark article from Europe by Dr. Vera Preac-Mursic isolating the Lyme disease agent in culture from a series of patients previously treated with antibiotics for Lyme disease, including intravenous antibiotics **(29)**, Dr. Allen C. Steere stated:

"..because they isolated the organism they proved that *B. burgdorferi* can survive antibiotic treatment and can occur in seronegative individuals.." **(76 - see binder).**

Steere signs on to the IDSA 2000 and 2006 Lyme Guidelines which admit of no possibility of the existence of chronic Lyme disease due to chronic persistent infection but stated *exactly* the opposite in his article on chronic neurologic manifestations of Lyme disease published in the New England Journal of Medicine in 1990 which ends with the following paragraph:

"The typical response of our patients to antibiotic therapy supports the role of spirochetal infection in the pathogenesis of each of the syndromes described here. However, our results were not as good as those in previous reports.^{6,7} Six months after treatment, more than one third of the patients had either relapsed or were no better. In addition, more than half had previously received antibiotic therapy thought to be appropriate for their stage of disease and still had progression of the illness. The likely reason for relapse is failure to eradicate the spirochete completely with a two-week course of intravenous ceftriaxone therapy. On the other hand, the patients whose condition did not improve may have had irreversible damage to the nervous system, particularly since the response tended to be worse in patients with longer durations of disease. This is reminiscent of far-advanced neurosyphilis, in which the response to penicillin may be minimal.³⁶" **(77 Logigian EL, Kaplan RF, Steere AC. CHRONIC NEUROLOGIC MANIFESTATIONS OF LYME DISEASE. N Engl J Med 1990;323:1438-1444).**

Steere is co-author of a paper with Nancy Shadick as first author, which described a patient with Lyme disease eventuating in death with documentation of persistent infection in the brain despite intravenous antibiotic treatment and despite negative cerebrospinal fluid antibody tests:

"Patient 12 had had high fever, meningeal symptoms, and subsequent arthritis in 1982. She was noted to have a positive serologic test result for Lyme disease 4 years later and was treated with 2 weeks of parenteral penicillin. She later developed a progressive speech disorder, bradykinesia, and abnormal oculomotor function. Magnetic resonance imaging of the brain showed scattered white matter lesions in the hemispheres and pons, and she was diagnosed with supranuclear palsy. Lumbar puncture showed no selective concentration of antibody in the spinal fluid. Nevertheless, she was re-treated with 2 weeks of parenteral ceftriaxone in 1989 that had no effect on her neurologic symptoms. During the time of observation, this patient died. At autopsy, lymphoid mononuclear cells were observed surrounding the intracerebral vessels in one section. Using Dieterle silver stain, a spirochete was present in the cortex and another was exterior to a leptomenigeal vessel." (78 Shadick NA, Phillips CB, Logigian EL, Steere AC et.al. **The Long-Term Clinical Outcomes of Lyme Disease. Ann Int Med 1994;121:560-567**).

When Vicki Logan's case was described in a **New York Times Science Times** feature article, Dr. Steere wrote to the Times seeking two corrections. They had erroneously identified him as "Robert" Steere. He informed the Times his opinion had been reported incompletely and the Times issued the following additional correction: "...; he says that the small percentage of Lyme patients who have inflammation of the brain or nerves despite standard antibiotic treatment do have persistent infection." (79 - **Rosenthal E. Lyme Disease: Does It Really Linger? Correction Appended. New York Times Science Times. August 24, 1993 - see binder**).

In a letter to his former patients dated August 11, 1994 soliciting their cooperation in his further research Steere states: "...It has become increasingly apparent that the Lyme disease spirochete, *Borrelia burgdorferi*, may persist in the nervous system of a small percentage of patients and may cause chronic neurologic involvement. The purpose of our long-term follow-up studies is to determine whether past patients may still have evidence of Lyme disease and, if so, to offer appropriate treatment. These studies are being funded by the National Institutes of Health and the Centers for Disease Control..." (80 - see binder) .

Again, Steere's statements in his published scientific work, private letters and a correction by the **New York Times** at his request stand, apparently, in direct and seemingly irreconcilable contradiction to the 2000 and 2006 IDSA Lyme Disease Guidelines of which he is co-author and signatory which assert with absolute certainty no such thing as chronic Lyme disease exists.

Gary Wormser, lead author of the 2000 & 2006 IDSA Lyme Disease Guidelines, published an article in the New England Journal of Medicine in 1994 that demonstrated persistence of the syphilis spirochete in a patient with HIV/AIDS who died despite treatment with a standard course of intravenous penicillin. He and co-workers used PCR (polymerase chain reaction) methodology to detect the DNA of the syphilis spirochete in the brain and visualized the syphilis spirochete in the brain post-mortem using special stains (81 Horowitz HW, Valsamis MP, Wicher V, Abbruscato F, Larsen SA, Wormser GP, Wicher K. Brief Report: Cerebral Syphilitic Gumma Confirmed by the Polymerase Chain Reaction in a Man with Human Immunodeficiency Virus Infection. N Engl J Med 1994;331:1488-91) .

Whereas his own work demonstrated the persistence of one type of spirochete (the syphilis organism) despite intravenous antibiotics, he admits of no possibility whatsoever that such an eventuality might occur in Lyme disease.

Yet the Lyme spirochete has a much more complex genome than even the wily the syphilis organism **(82 Fraser CM et. al. Genomic sequence of a Lyme disease spirochaete, *Borrelia burgdorferi*. Nature 1997 Dec11;390(6660):580-6)**. Although Wormser might argue that his case represented an immunocompromised host, it is well accepted that Lyme disease and other tick-borne co-infections can compromise the immune integrity of human and animal hosts **(83 Diterich I et. al. *Borrelia burgdorferi*-induced tolerance as a model of persistence via immunosuppression. Infect Immunol 2003 Jul;71(7):3979-87)**.

Suppression of Opposing Views by the Infectious Diseases Society of America

One of the findings of Attorney General Blumenthal's investigation was the elimination of opposing viewpoints from consideration in the drafting of the 2000 IDSA Lyme Disease Guidelines. Sam Donta, an infectious diseases expert originally participating in the drafting of the 2000 IDSA Lyme Disease Guidelines withdrew from participation after it became apparent to him that Dr. Wormser was unilaterally and arbitrarily excluding information concerning chronic Lyme disease **(41)**.

The substance of what eventually became my published article on chronic meningoencephalomyelitis in Lyme disease **(56)** was initially presented in the form of a talk given in Boston in 1996 at the 9th Annual International Conference on Lyme and other Tick-borne Disorders held under the auspices of the Lyme Disease Foundation. I and other presenters were invited to submit articles based on our talks for consideration for inclusion in a supplement to **Clinical Infectious Diseases (Clin Infect Dis)**, the official journal of the IDSA.

My article included the Logan case, the first well-documented American case of treatment failure in Lyme disease with culture isolation at the Centers for Disease Control, no less. The manuscript received a somewhat mixed reception but included one very favorable review **(84 - correspondence from Sidney M. Finegold, M.D., Editor of Clinical Infectious Diseases concerning submission of manuscript "Lyme Disease and the Clinical Spectrum of Antibiotic Responsive Meningoencephalo-myelitides" with copy of reviews by initial reviewers; see also my correspondence to Dr. Finegold conveying the revised**

manuscript - see binder). The editor encouraged revision and resubmission of the manuscript. The editor claimed the revised manuscript was reviewed by the original reviewers but it appears the favorable reviewer was purged and instead a highly critical reviewer was proffered as justification for rejection of the manuscript **(85 - correspondence from Sidney M. Finegold, M.D with copies of reviews by subsequent reviewers; the strongly favorable reviewer is inexplicably dropped from the review process - see binder).** It would appear rejection the manuscript was a political decision rather than one based upon scientific or literary merits. The article was eventually published, instead, in the **Journal of Spirochetel and Tick-borne Diseases (56)**, a peer-reviewed journal with a tiny circulation not indexed on National Library of Medicine's PubMed. By quashing publication of the article in **Clinical Infectious Diseases**, the editor effectively blocked dissemination of information about chronic Lyme disease in American patients to a wide audience including members of the IDSA itself. This has been the *modus operandi* of the IDSA regarding the issue of chronic Lyme disease ever since: **suppress** the evidence and then declare there **is** no evidence.

In 2002 an international conference on Lyme disease was held at the Hyatt Hotel in New York City. Gary Wormser was the chairman of the conference which was hosted by New York Medical College. Many clinicians and researchers had submitted abstracts concerning chronic Lyme disease. All abstracts dealing with chronic Lyme disease were rejected. I telephoned Dr. Wormser discussing this situation and seeking the reasons for across the board rejection of abstracts dealing with chronic Lyme disease, which included two which I had submitted. Dr. Wormser tried to assuage my concerns by pointing out that some of his own abstracts were not accepted. He argued the rejected abstracts lacked required scientific rigor. He also admitted, ultimately, he was the final arbiter of what was accepted and what was rejected. I also directly asked him whether or not the conference was sponsored and supported by CDC. He was **emphatic** in stating that it was not.

This was an important point because during the Fifth International Conference on Lyme Borreliosis held in Arlington, Virginia in 1992, numerous abstracts had also been arbitrarily rejected by the conference organizers. As a recognized government-funded conference, patients complained to their legislators about the closed process of

abstract selection. Organizers of the conference were forced to back down and accept previously rejected abstracts (**86 Barinaga M. Furor at Lyme Disease Conference. Science 5 June 1992;256:1384-1385 - see binder**).

One of the abstracts which had been rejected at the Fifth International Conference was my case report of global cerebellar atrophy in a case of Lyme disease (**87 Liegner KB et. al. Global Cerebellar Atrophy in Lyme Borreliosis (LB).[Abstract 55B] In: Program and abstracts of the Fifth International Conference on Lyme Borreliosis, Arlington, Va., May 30-June 2, 1992. Bethesda, Md.:Federation of American Societies for Experimental Biology, 1992:A11**). This was subsequently accepted into the program due to patient complaints and legislator intervention. My abstract, to the best of my knowledge, was the first reported case of cerebellar injury associated with Lyme disease. There have subsequently been a number of reports of cerebellar involvement as a consequence of Lyme disease reported in the worldwide peer-reviewed published scientific literature (**88 Arav-Boger R et. al. Cerebellar ataxia as the presenting manifestation of Lyme disease. Pediatr Infect Dis J. 2002 Apr;21(4):353-6 & 89 Mario-Ubaldo M. Cerebellitis associated with Lyme disease. Lancet. 1995 Apr 22;345(8956):1060 & 90 Neophytides A et. al. Subacute Cerebellitis in Lyme disease. Int J Clin Pract. 1997 Nov-Dec;51(8):523-4**).

If the NYC 2002 IX International Lyme conference were strictly a private affair under the auspices of New York Medical College, then Gary Wormser could do as he pleased. If it were known to be CDC-sponsored, then patients and excluded physicians and scientists might have had leverage through their legislators to compel the organizers to open up the process to include a diversity of views.

The materials announcing the up-coming conference gave no indication whatsoever of CDC/government sponsorship. However, materials distributed at the actual Hyatt conference conspicuously indicated it was sponsored by the CDC, as other international Lyme conferences had been (**91 - IX International Conference on Lyme Borreliosis and other tick-borne diseases. Chairman: Gary P. Wormser, M.D. August 18-22, 2002. Grand Hyatt, New York. Greeting Page & Listing of Corporate Support - see binder**). Dr. Wormser's actions effectively censored information on chronic Lyme disease submitted by me and some forty other contributors from the

program of the IX International Conference (92 Liegner KB [Editorial] ICLB should allow for expression of a diversity of views in the Lyme Times [Supplement]. Rejected Abstracts from the IX International Conference on Lyme Borreliosis and Other Tick-Borne Diseases August 18-22, 2002 - see binder).

Arbitrary Categorization of "Non-utility" of PCR in the Diagnosis of Lyme disease and "Moth-balling" of Promising Experimental Direct Detection Methods for the Diagnosis of the Lyme Disease

Improved methods of diagnosis for Lyme disease have been devised by some of this nation's finest biomedical researchers. These include polymerase chain reaction (PCR) for detection of the DNA of the Lyme organism in tissues or bodily fluids (93 Rosa PA, Schwan TG. **A specific and sensitive assay for the Lyme disease spirochete *Borrelia burgdorferi* using the polymerase chain reaction.** *J Infect Dis* 1989;160(6):1018-29 & 94 Priem S et.al. **An optimized PCR leads to rapid and highly sensitive detection of *Borrelia burgdorferi* in patients with Lyme borreliosis.** *J Clin Microbiol* 1997;35(3):685-90) and the other research methods previously discussed (18,19,20,21,23,24,25).

PCR methodology is the one clinically commercially available methodology which has the capability of **proving** active Lyme disease whether a patient is seronegative or seropositive and whether or not a patient has been previously treated.

Bear in mind that before a laboratory is permitted to be utilized by New York State physicians, it must be "vetted" and approved as to the validity of its methodologies and quality control by the New York State Department of Health. The latter has approved use of PCR for the diagnosis of Lyme disease. PCR methodology is well accepted as a useful tool for the diagnosis of many other infectious diseases.

PCR methodology is used as proof of syphilis in Wormser's 1994 NEJM article (81), yet Wormser as chief author of IDSA Lyme Disease Guidelines discourages use of PCR methodology for clinical diagnosis of Lyme disease.

Other promising direct detection methodologies **(18,19,20,21,23,24,25)** could have been supported for further development as research tools or, if of proven value, fast-tracked into the realm of clinically commercially-available diagnostic test methods. Instead these promising methods have been "moth-balled" for political and socioeconomic reasons.

Use of IDSA Guidelines by the Insurance Industry to Deny Reimbursement for Treatment and for Disability to Persons with Lyme Disease, especially chronic Lyme disease.

I have previously demonstrated how, in the Logan case, insurance company "guidelines" have enabled them to deny reimbursement for care. Insurers often cite academic opinion to justify their position. In the Logan case the position of Empire Blue Cross & Blue Shield led to an inability to treat her for the condition she had, whether as an in-patient or out-patient. Delayed application of additional treatment no doubt led to additional irreversible neurologic injury. The actions of Empire's medical executives and physician reviewers set in motion a chain of circumstances that ultimately led to her death.

Aetna Guideline 215 is a typical example of how insurers make use of IDSA guidelines to deny reimbursement for care which may be necessary. I append these guidelines for your review **(94 - see binder)**.

MEDCO pharmacy benefit managers which typically handle prescriptions for medications used chronically (e.g. 90 days supply or more) within the past year have begun refusing to honor prescriptions for long term antibiotics written by physicians for the treatment persons with chronic Lyme disease, citing adherence to IDSA guidelines. Please see my correspondence with a pharmacist at MEDCO concerning this with their responses. MEDCO dismisses the Lyme Disease Guidelines of the International Lyme and Associated Diseases Society and attends only to the IDSA Guidelines, ignoring the legitimate controversy within the field as to the nature of Lyme disease and how it ought to be treated. I held a telephone conversation with Catherine Custer, pharmacist at MEDCO to discuss this matter further with her. When I inquired **who** had actually **made** this decision, her response was this was a "group decision". **(95 Correspondence between Catherine Custer, R.Ph. and Dr. Liegner - see binder)**.

The 2006 IDSA Lyme Disease Guidelines has an important "caveat" in small print on the first page of the guidelines as follows: ***"It is important to realize that guidelines cannot always account for individual variation among patients. They are not intended to supplant physician judgment with respect to particular patients or special clinical situations. The Infectious Diseases Society of America considers adherence to these guidelines to be voluntary, with the ultimate determination regarding their application to be made by the physician in light of each patient's individual circumstances"*** (7).

Although insurers may claim these decisions are strictly "benefit" decisions, they have the practical consequence of making treatment non-feasible for some individuals. These actions improperly undermine the treating physician, substitute the judgment of the insurer for that of the physician and deprive patients of their rights to make autonomous choices given the legitimate controversy in the field. In the examples cited, both AETNA and MEDCO misuse the IDSA Lyme Disease Guidelines in a **formulaic** manner specifically warned against by the IDSA Guidelines' own caveat.

IDSA guidelines limit not only health insurers' liability for reimbursement for care to their insureds, they also enable long-term disability insurers to deny benefits to policy-holders who may become unable to work secondary to the effects of chronic Lyme disease. By denying such an entity as chronic Lyme disease exists, insurers can discount the entire basis of their compromised functioning, question the legitimacy of their limitations and stall or successfully dispute their claim. Private disability insurers as well as state entities (such as workers compensation and state retirement plans) will go to extraordinary lengths to attempt to deny benefits. One Maine patient finally prevailed but her case was taken all the way to Maine's Supreme Court, which declined to review it, letting stand a lower court's decision in her favor **(96 - see binder with letter from Maine Supreme Court declining to review the case)**.

Hospitals Unwelcoming for Patients with Chronic Lyme Disease

Hospitals also may be reluctant to provide services to persons with chronic Lyme disease if the existence of the entity is denied by "august" bodies such as the IDSA and CDC and they are aware that insurers are likely to deny reimbursement to hospitals for the care provided therein.

Furthermore, hospital Pharmacy and Therapeutics Committees often include infectious diseases specialists for "input" and opinion as to what treatments are deemed "appropriate". Most infectious diseases specialists cleave unto the 2006 IDSA Lyme Disease Guidelines. Consequently, intensive or prolonged treatment of hospitalized persons with chronic and/or neurologic Lyme disease may be frowned upon or interfered with and physicians endeavoring to treat such patients in the in-patient setting may face risk of being sanctioned.

I was "called on the carpet" by the Vice-President for Medical Affairs at Northern Westchester Hospital (the infectious diseases specialist who later served as the OPMC's zealous witness against Dr. Burrascano) for treating Vicki Logan intensively when she was gravely ill in 1992. Fortunately for me, report of pericardial biopsy had just returned demonstrating spirochetes compatible with borrelia in inflamed pericardial tissues (**97 - see binder**). He backed off, commenting "Oh, this is a complicated case".

In 2010 one of my patients, a nonagenarian psychoanalyst with very well documented chronic Lyme disease and babesiosis who had pursued a relapsing course became psychotic a few months after discontinuing oral antibiotics. Despite his psychotic delusions he was able to very astutely and rationally analyze and discuss cases with one of his colleagues, suggesting that he was not demented *per se*. Psychosis is a well-known possible neuropsychiatric manifestation of central nervous system Lyme disease (**98 Fallon BA & Nields JA. Lyme Disease: A Neuropsychiatric Illness. Am J Psychiatry. 1994 Nov;151(11):1571-83**). Infectious diseases specialist Debra Spicehandler at Northern Westchester Hospital Center deemed it appropriate to give this gentleman the benefit of the doubt and treat him with intravenous antibiotics. He was transferred to a nursing home in the Riverdale section of the Bronx. When he became agitated he was taken to the

Emergency Room at Columbia Presbyterian Hospital Medical Center in northern Manhattan. There he came under the care of an infectious diseases attending who insisted on removal of the patient's previously placed intravenous catheter and on discontinuance of **any** further intravenous or oral antibiotic therapy. This contravened the wishes of the patient and his family. I discussed the situation with this physician and tried to persuade him treatment was justifiable but he was *adamant* not only would he not treat the patient but he would see to it that *no* physician on his service would treat this gentleman with antibiotics. The patient was discharged to a nursing home where, despite psychopharmacotherapy he remained delusional until his death of a myocardial infarction a few months later. No autopsy was performed. A letter from the patient's family with their perspective of the conduct of the infectious diseases attending at Columbia Presbyterian in relation to their father while he was hospitalized accompanies (99 - **see binder**).

Cost-shifting by Insurers

Denial of reimbursement for necessary treatment can result in the deterioration of citizens to the point they become disabled, cannot work, earn income, pay taxes or maintain their private insurance coverage. Eventually they must resort to social security disability and Medicaid. The stratagem of denial of chronic Lyme disease and reimbursement for the cost of its treatment maximizes private insurers' short term profit but costs are shifted to the public sector. As their conditions worsen these individuals often endure severe personal suffering as do their families. Wendell Potter, former CIGNA public relations executive has pointed out in his book **Deadly Spin** that death of insureds with costly illness occasioned by insurer denials can be cost-effective for an insurer when they are shielded from financial or legal consequences of their actions by ERISA (100 Potter W. **Deadly Spin - An Insurance Company Insider Speaks Out on How Corporate PR is Killing Health Care and Deceiving Americans. Bloomsbury Press. New York 2010**).

War over Lyme disease

That a state of war exists in the Lyme disease arena is not hyperbole. The two sides spar in dueling articles and Letters to the Editor in peer-reviewed journals. For example, Stricker and Johnson's article in *Philosophy, Ethics, and Humanities in Medicine* in 2010 (2) was followed soon after by Aurwaerter et. al.'s article in *The Journal of Clinical Ethics* (101 Auwaerter PG et. al. **Scientific evidence and best patient care practices should guide the ethics of Lyme disease activism. J Med Ethics 2011;37(2):68-73 - see binder**).

Powerful players attempt to maintain the *status quo* using any means at their disposal. This includes use of peer-reviewed journals disseminating the drum-beat of IDSA/insurance company dogma of "non-existence" of chronic Lyme disease whether seropositive or seronegative, control of editorial and review activities to suppress publication of opposing points of view and malevolent use of corporate media.

Forbes magazine reporter on health matters David Whelan, penned a 2007 article laced with *ad hominem* attack ridiculing the concept of chronic Lyme disease (102 Whelan D. **Ticks Aren't The Only Parasites Living Off Patients in Borreliosis-prone Areas. Forbes. March 12, 2007 - see binder**). In his book Deadly Spin (100), Wendell Potter, describes his delight as head of public relations for CIGNA when the same David Whelan, a master of obfuscation, soft-pedaled CIGNA's responsibility for the death of 17 year-old Nataline Sarkisyan following CIGNA's denial of reimbursement for a liver transplant in Whelan's January 8, 2008 Forbes article: Does Cigna Deserve All The Blame? (103 - see binder)

The Chicago Tribune in 2010 ran an article which portrays patients believing they have chronic Lyme disease as deluded or gullible and the physicians treating them as exploitative menaces to public health (104 Callahan P & Tsouderos T. **Chronic Lyme disease: A dubious diagnosis. Chicago Tribune. December 8, 2010 - see binder**). Patient-advocate Tina Garcia responded cogently and persuasively to the Chicago Tribune piece (105 Garcia Tina. **Blog - see binder**). The Knight Science Journalism Tracker (which assesses objectivity and fairness in science journalism) critiqued the Chicago Tribune article, finding it highly

biased and inflammatory (106 Raeburn P. Chicago Tribune Off Balance on Chronic Lyme Disease. Knight Science Journalism Tracker. April 1, 2011 - see binder).

Hitler's & Goebbels' "Big Lie" is the approach: if statements are repeated long enough and loud enough people will believe them. In Deadly Spin (100) Wendell Potter makes explicit the extraordinary lengths to which health insurers go in applying unethical public relations techniques. Corporate media assets are used as tools to deceive and manipulate the public as well as legislators. The Forbes and Chicago Tribune pieces on chronic Lyme disease should be recognized for what they are: pure propaganda, not deserving the appellation journalism.

Empire Blue Cross & Blue Shield ultimately gained approval for change from "not-for-profit" to "for-profit" status. Because of the special status granted Blue Cross & Blue Shield at inception an estimated 1 billion dollars of excess funds were expected to accrue to the benefit of the public through establishment of a foundation promoting health-related priorities. Through political maneuvering which involved then Governor Pataki and the NYS legislature these funds (which eventually totaled some 4-5 billion dollars) were designated to raise the wages of members of District 1199 Health & Hospital Workers Union represented by Dennis Rivera and for a variety of other purposes for a cash-starved New York State. 1199 SEIU union members voted *en bloc* for Governor Pataki, the only time in recent memory the generally Democratic membership of the union would support a Republican governor for re-election. This episode amply demonstrates the profound influence insurers can have on the political process(64).

While Empire C.E.O.s and Executive Medical Directors got golden parachutes amounting to hundreds of millions of dollars in personal profit (107 E-mail from Charles Bell, Consumer's Union with print-out and hyper-links - see binder), Vicki Logan got a handbasket to hell.

Suggested Remedies

March 23, 2011 The Institute of Medicine Committee on Standards for the Development of Trustworthy Clinical Practice Guidelines published a monograph entitled "Clinical Practice Guidelines We Can Trust" (**108 - Institute of Medicine (U.S.), Committee on Standards for Developing Trustworthy Clinical Practice Guidelines. Clinical practice guidelines we can trust / Committee on Standards for Developing Trustworthy Clinical Practice Guidelines, Board on Health Care Services, Institute of Medicine of the National Academies; Robin Graham [et.al.], editors. National Academies Press, 2011.**) proposing improved process to assure that medical guidelines are properly crafted. IDSA's Lyme Disease Guidelines were cited as an example of what can happen when the process of guideline development goes awry (**109 - see binder**). Hopefully the IOM's report will serve as corrective for future Clinical Practice Guideline development, including those pertaining to Lyme disease.

We are in a period of "paradigm change" concerning Lyme disease. However, this sociological and historical process takes time (**110 Kuhn TS. The Structure of Scientific Revolutions. Chicago, Ill. University of Chicago Press. 1996**). Semmelweis's observations in the 1840s demonstrated that physicians going directly from the autopsy room to the delivery room caused childbed fever (puerperal sepsis). His conclusions derived from careful observation of patients and preceded the rise of the germ theory or the works of Koch, Pasteur or Lister. His correct inferences and his proof that puerperal sepsis could be prevented by physician hand-washing in chloride of lime were **resisted** by the medical profession for **decades** resulting in avoidable deaths of many thousands of young women (**111 Carter KC. Childbed fever: a scientific biography of Ignaz Semmelweis. Westport, Conn. Greenwood Press. 1994**).

Very recently, two collaborating groups of investigators reported the isolation of viable Lyme disease spirochetes from primates (Rhesus monkeys) after intensive antibiotic treatment including intravenous antibiotics (**112 Embers ME, Barthold SW et.al. Persistence of *Borrelia burgdorferi* in Rhesus Macaques following Antibiotic Treatment of Disseminated Infection. PLoS One 7(1):e29914**). One would think these data would persuade even the most

doctrinaire, that chronic Lyme disease due to persistent infection despite antibiotic treatment is a plausible nosologic entity. Can we wait decades or longer until scientific consensus catches up with the reality of chronic Lyme disease due to chronic persistent infection?

Internal insurance company review processes are fatally flawed with conflict of interest in the area of Lyme disease. Physicians having similar "mind-sets" concerning chronic Lyme disease tend to comprise both internal insurance company reviewers and the NYS External reviewers. I am unaware of a **single** instance in which a New York State External Review rendered a decision favorable to a patient with chronic Lyme disease.

Some process must be put in place that allows dispassionate determinations of medical necessity for reimbursement to insureds in cases of Lyme disease, especially chronic Lyme disease. *Insurers can not be trusted with these decisions which should be taken out of their hands.*

A process must be put in place to allow expedited decisions for "carve outs" for persons in nursing homes and/or hospitals covered by Medicaid or Medicare, when they require prolonged intravenous antibiotic therapy for serious central nervous system Lyme disease.

Consideration should be given to establishment of a NYS Ombudsman to whom persons with Lyme disease or their family members can turn when they are not being fairly dealt with by individual physicians or physician groups, hospitals, managed care organizations or insurers.

Citizens of the State of New York, by total numbers, have been more severely affected than those of any other state in the nation. June 1995 NYS Commissioner of Health Barbara DeBuono sent out an advisory apprising all New York State physicians that risk of Lyme disease likely existed in **every** county of New York State (**113 - see binder**). Accordingly, it is in New York State's self-interest to support high quality basic and applied research concerning Lyme and tick-borne diseases within its own borders in order to protect its citizens.

Mandatory education is needed for all New York State health professionals concerning Lyme and tick-borne diseases. Medical and nursing school curricula must include an honest and open representation of a *wide range of responsible views* about the nature of Lyme disease and the range of options for treatment. Areas of uncertainty and disagreement as well as areas where further research is needed all require open discussion.

A course concerned with Lyme and tick-borne diseases analogous to the state mandated "Infection Control" course (which practitioners are required to up-date every 4 years) should be required for licensed practitioners in New York State with curriculum modeled after that fashioned for medical and nursing students. Minnesota physician Elizabeth Maloney has authored a suitable course of study which has received approval for 4 CME (Continuing Medical Education) credits by the American Association of Family Physicians (**114 - Maloney, Elizabeth L. "Understanding Lyme Disease". Accredited by The American Academy of Family Practice for 4.0 CME Credits**).

"Incubator" research facilities to advance medical knowledge in this field, acquire patent rights for diagnostic tests and/or better treatment modalities or preventive technologies could redound in part or in whole to the financial benefit of New York State and bestow renown to the State for its vision and scientific and humanitarian commitment.

Dr. Benjamin Luft of the Department of Infectious Diseases at SUNY Stony Brook is well-equipped to direct and/or collaborate in such advanced research for better diagnostic tests and therapeutic approaches for Lyme disease and other tick-borne diseases. Properly organized and publicized research efforts could also attract investment by private industry such that a public-private partnership could ensue. Also, private citizens, if assured that honest research was being conducted, might well be desirous of contributing funds from their own resources, quite apart from any funds which might derive from NYS tax revenues.

Columbia University already hosts a Lyme and Tick-borne Diseases Research Center headed by research psychiatrist Brian A. Fallon, M.D., M.P.H. and supported with private funds raised the Lyme Disease Association and Time for Lyme. This Center, which can draw from the extensive research capabilities of the Columbia's medical center and university-at-large would benefit from additional support from the State. Recently, Dr. Fallon collaborated with UMDNJ scientist and first-author Steven E. Schutzer and others on a publication reporting on application of cutting-edge proteomic diagnostics to cerebrospinal fluid analysis, with ability to distinguish between patients with chronic fatigue syndrome and post-treatment Lyme disease **(115 Schutzer SE et. al. Distinct Cerebrospinal Fluid Proteomes Differentiate Post-Treatment Lyme Disease from Chronic Fatigue Syndrome. PLoS One 2011;6(2)e17287:1-6.)**

A world-class pathologic laboratory for diagnosis of Lyme and tick-borne diseases in human tissues is needed as well as a training program to educate pathologists in the special methods required to properly evaluate human tissues for Lyme and other tick-borne diseases. Ironic is it indeed that in depth cutting-edge pathologic studies are available in this country for mice, monkeys and horses but not human beings **(116 Hodzic et.al. Persistence of *Borrelia burgdorferi* following Antibiotic Treatment in Mice. Antimicrobial Agents & Chemotherapy. May 2008, Vol. 52(5)1728-36 & 117 Imai DM et. al. Lyme Neuroborreliosis in 2 Horses. Vet Pathol Online 1 February 2011; p 1-7 & 118 Roberts ED et.al. Chronic Lyme disease in the rhesus monkey. Lab Invest 1995;72(2):146-60).** To the best of my knowledge, not a single pathologist is currently *active* in the United States expert in the pathology of human Lyme disease. Dr. Andrew Dwork, a neuropathologist already employed by the New York State Psychiatric Institute could spear-head an effort to establish such a laboratory and training program. Dr. Judith Miklossy, who has pioneered application of cutting-edge methods to the study of Lyme disease as it affects human nervous system **(119 Miklossy J. Biology and Neuropathology of dementia in syphilis and Lyme disease. Handb Clin Neurol. 2008;89:825-44)** could provide valuable consulting input as could David Dorward, Ph.D. who pioneered the Rocky Mountain Lab Antigen Capture Assay for Lyme disease **(18)**.

Process needs to be put in place to assure the New York State Office of Professional Medical Conduct (OPMC) conducts investigations of physicians who care for patients having Lyme disease and other tick-borne diseases only when and *if* truly appropriate as with any other physician. Ideologically-driven complaints centering about contested conceptualizations of the nature of Lyme disease, economically-driven insurance company complaints and malicious complaints should be recognized as such and interdicted. Making known to physicians the specific source(s) of complaints against them would allow them to confront their accusers as would be their right in a court of law. It would also serve to discourage malicious or inappropriate reporting by giving physicians the option of legal action against individuals or entities seeking to misuse the OPMC for illegitimate purposes.

Persons disabled by Lyme disease might benefit from a dedicated unit at a NYS facility, such as Helen Hayes Hospital, with staff fully educated about Lyme disease to help them recover. Additionally, there is a definite need for a combined medical and psychiatric in-patient unit where psychiatrically disturbed persons with Lyme disease requiring intensive medical and psychiatric treatment can be cared for safely by well-informed staff.

The epidemic of Lyme disease in New York State poses many difficult challenges for all affected by it whether as patients, family members, physicians, hospitals, insurers or government, including legislators. Most problems have solutions but these can only be sought when the problems are acknowledged for what they are. Needed is a **"Manhattan Project"** for Lyme disease with allocation of resources commensurate with the serious threat it poses to New York State citizens.

Unfortunately, thus far, the Federal government's response to Lyme disease has been woefully inadequate. While CDC is composed of many fine individual physicians and scientists, denial of the existence of chronic and seronegative Lyme disease by CDC, as an agency of government, has harmed many in New York State and elsewhere.

Means to Fund Proposals

One option that might be feasible is for legislators to direct the New York State Health Foundation (NYSHealth) formed as a consequence of the conversion of Empire BlueCross BlueShield from "not for profit" to "for profit" entity to commit substantial funds to the purposes of Lyme and tick-borne disease R & D **and** improving clinical care for citizens in New York State affected by Lyme disease.

NYSHealth, for example, has committed to a five-year Diabetes Campaign to improve clinical care and patient outcomes for New York State citizens with diabetes. NYSHealth also endorsed and rewarded Empire BlueCross BlueShield's Quality-in-Sights Primary Care Diabetes Incentive Program. Laudable in and of itself as this program might be, diabetics were not the group *systematically* denied benefits to which they should have been entitled by Empire Blue Cross and Blue Shield over at least a decade and a half.

Alternatively, a tax or surcharge could be levied against all insurers doing business in the State of New York, redirecting some of the profits extracted by the industry from its insureds suffering from Lyme disease, while prohibiting insurers from passing such a tax or surcharge along to the general public through increased insurance rates.

Conclusion

New York State legislators and the executive branch of government must grapple with and attempt to solve the difficult problems posed by Lyme and other tick-borne diseases using New York State resources, engaging the talents and enthusiasm of NYS scientists and physicians, while enlisting private industry and voluntary public contributions.

Listen to your constituents who have been bearing the brunt of ignorance, bias and discrimination surrounding Lyme disease. Who will be next to be told their care is "experimental", "not medically necessary" or "not a wise use of scarce resources"?

Respectfully submitted,

Kenneth B. Liegner, M.D.

Member, Treatment Panel, N.I.H. State-of-the-Art
Conference on Lyme Disease, March 1991, Bethesda, MD.

Co-Chair, Treatment Poster Discussion Section,
Fifth International Conference on Lyme
Borreliosis, May/June 1992, Arlington, VA.

Participant, N.I.A.I.D. Consultations on Chronic
Lyme Disease, February & October, 1994, Rockville, MD.

Member, Program Committee, 7th International
Conference on Lyme Borreliosis, San Francisco, CA.,
Spring 1996.

Presenter to Infectious Diseases Society of America
Lyme Disease Review Panel, July 30, 2009, Washington,
D.C.