

**Remarks:
World Wide Lyme Rally & Protest
Friday, May 10, 2013
Union Square
New York City**

“Chronic Lyme disease does not exist”.

There are four possibilities to explain why a person might hold this view:

They can be ‘dumb as bags of rocks’.

They can be character-disordered, with excessively rigid thinking, and perfect, impenetrable circular logic.

They can be corrupt.

They can be sociopaths.

One thing is for damn sure: they are truly lousy clinicians.

In 1991 the Lyme disease organism, *Borrelia burgdorferi*, was grown from the cerebrospinal fluid of my patient Vicki Logan at the Centers for Disease Control in Fort Collins, Colorado despite prior treatment with intravenous antibiotics. Her case made the front page of the New York Times Science Times in August of 1993.

In 2012, the Embers Rhesus monkey study demonstrated conclusively in a primate model closest to man, that Lyme infection can persist despite application of intravenous antibiotics and that animals can be seronegative on antibody studies despite harboring persistent active infection.

Lyme disease is the first infectious disease of truly epidemic proportions that emerged hand in hand with another new phenomenon affecting the health of Americans: the penetration of managed care in to the health care market place.

An infection that can be chronic and require a long-term treatment approach does not fit the ‘business model’ of managed care: predictable premiums, predictable costs, predictable profit. With managed care it became feasible to control costs by defining away the chronic infectious aspects of Lyme disease.

The Infectious Diseases Society of America Clinical Practice Guidelines for Lyme Disease which appeared in 2000 and 2006, insist that chronic Lyme disease does not exist. These guidelines have proven an effective tool for the health insurance industry to justify denial of reimbursement to patients for treatments that their doctors prescribe.

Health plans and insurers and hospitals *red flag* physicians not conforming to IDSA guidelines for sanctioning and often report them to State Boards of Medical Practice to ‘break their knees’. This cowardly and despicable ‘modus operandi’ is an assault on physicians’ most prized possession: professional autonomy and independent medical judgment.

Hospitals, once proud and independent entities with endowments and a tradition of ‘charity care’ have been ‘captured’ by the insurance industry and are now, often, little more than ‘corporate profit centers’.

Health plans do not want thinking, feeling professionals: they want ‘trained monkeys’ on a ‘commoditized’ health care

assembly line, following electronic medical record-prompted ‘algorithms’ designed to maximize corporate profit.

The Hippocratic Oath has now become a ‘quaint anachronism’ superseded by a new *Corporate* Medical Ethic. “He who pays the piper calls the tune”.

IDSA guidelines also serve as a shield for medical neglect, protecting physicians who fail to diagnose or treat (or treat adequately) patients with chronic Lyme disease, who suffer irreversible neurologic injury as a result.

In 2008, Connecticut State Attorney General Richard Blumenthal undertook an investigation of the way in which the 2006 IDSA Lyme guidelines were developed and found significant flaws in the IDSA’s guideline development process and many undisclosed conflicts of interest.

Attorney General Blumenthal opted to negotiate a settlement with the IDSA with the creation of a Lyme Disease Review Panel to revisit the IDSA guidelines.

Unfortunately, all panel members were hand-picked by the IDSA and physicians earning more than \$10,000/year caring for persons with Lyme disease were excluded from the panel. As a result no physician who actually cared for persons with chronic Lyme disease served on the Lyme Review Panel.

In retrospect, a negotiated settlement instead of litigation, was a strategic error because the review was under the complete control of the IDSA. Consequently, no meaningful changes in

the guidelines were recommended. The fox was guarding the chicken coop!

However, Attorney General Blumenthal's investigation and the presentations of evidence before the IDSA Lyme Disease Review Panel were of some utility. When the Institute of Medicine brought forth its monograph on the development of trustworthy practice guidelines, it pointed to the IDSA Lyme Disease guidelines as an example of a guideline development process 'gone awry'.

Raymond J. Dattwyler, signatory to the 2006 Lyme disease guidelines which assert that chronic Lyme disease does not exist states exactly the opposite in a United States patent that issued almost contemporaneously with the IDSA Guidelines.

Allen C. Steere, signatory to the 2006 IDSA Lyme Disease Guidelines which declare chronic Lyme disease does not exist, states exactly the opposite in his published scientific articles and private letters. He sought a correction when his first name was incorrectly listed in the 1993 Logan Science Times article as "Robert" and advised the Times his opinion had been incompletely reported and requested it be clarified. According to the Times correction: "he says that the small percentage of patients who have inflammation of the brain despite standard antibiotic treatment do have persistent infection."

You cannot have it both ways!

When a physician signs on to a practice guideline that directly contradicts their position in their own published peer-reviewed journal articles, statements in the public record, private letters and in their own United States Patents, does that signify medical and scientific misconduct?

Additionally, Dr. Dattwyler served as an expert consultant to Empire Blue Cross Blue Shield in its defense against the Logan lawsuit which sought to compel Empire to cover the cost of treatment for chronic Lyme disease. This was not disclosed in the published IDSA 2006 Lyme guidelines.

Gary Wormser, lead IDSA Lyme guidelines author, quashed all abstracts on chronic Lyme disease from being accepted at the 2002 International Lyme Conference at the Hyatt Hotel in New York City. When I asked him if the conference was sponsored by the CDC, he adamantly denied it. This was important because if it was known to be a CDC-sponsored event it might have been possible for legislators to intervene to open up the process.

Dr. Wormser either did not know that the event was CDC-sponsored (which seems highly implausible) or he chose to conceal that fact from me. Materials distributed at the time of the conference showed the event was, in fact, CDC-sponsored. During the conference, whenever attendees attempted to bring up the issue of chronic Lyme disease, they were censored, and microphones were shut off so their challenges could not be heard.

When a physician acts in a way to suppress expression of opposing views in a government-sponsored international scientific conference, does that constitute an abuse of power? Does it constitute medical and scientific misconduct?

Honest science does not need to suppress opposing views.

Vicki Logan and other patients sued Empire Blue Cross Blue Shield to cover the cost of needed treatment. The case was settled out of court with terms that were confidential. Whatever the settlement was, it did not include Vicki's right to

be reimbursed for the cost of intravenous antibiotic therapy, which she needed.

During the litigation, a deposition under oath was taken by Empire Blue Cross Blue Shield Senior Vice President Richard Sanchez, M.D. He testified that Empire's accountants, Deloitte & Touche, advised Empire that their review physicians needed to issue more denials in order to increase its profitability. Empire was transitioning from a not for profit to a for profit entity. They raised the bar to make it more difficult for patients with costly conditions, such as Lyme disease, to get reimbursement for treatment. His testimony indicated that Empire senior personnel knew that some patients who actually had Lyme disease would be denied treatment and that some would suffer as a result. He said it was 'rationalized' that patients could appeal their denials and that that was a way that Empire physicians could 'sleep at night'. But he also acknowledged that some patients might be unable to negotiate the tortuous appeals process and might 'fall by the wayside' and might sustain irreversible injury as a result.

Empire Blue Cross & Blue Shield ultimately did transition to a 'for profit' entity. Empire executives got 'golden parachutes' worth hundreds of millions of dollars in personal profit. Vicki Logan got a 'handbasket to hell'.

When patients suffer, deteriorate neurologically and die due to corporate decisions, who is responsible? Is there impunity? Or is there a *penalty*?

There's the case of a 6 year-old Fairfield County, Connecticut child whose mother pleaded with her pediatrician to treat for a fully engorged deer tick attachment on the side of her neck Spring of 1995. The pediatrician refused. Flu-like symptoms developed that summer, and headache, stiff neck and swelling

of the glands draining the tick bite site developed in the Fall. Personality change, hypersomnolence and later, *status epilepticus* developed. Seizures were so severe that pentobarbital coma was required to control them. She came under the care of Charles Ray Jones, MD, who referred her to me for a spinal tap. At the time of the tap, Lyme Western blot in serum at Stony Brook showed 4/5 CDC-specific IgG bands, but her ELISA screening test was negative. Dr. Jones treated her with intravenous antibiotics. Although she had sustained a degree of irreversible neurologic injury from her illness, she was making good progress on IV antibiotics for several months. Intracorp's review physician refused to authorize reimbursement to the family for continuation of intravenous antibiotics even though she was still improving. After cessation of intravenous antibiotics, intractable *status epilepticus* recurred, she was admitted to a tertiary care hospital and died within one month. An autopsy was performed. Both Dr. Charles Ray Jones and I independently telephoned the health officer charged with Lyme disease epidemiology for the Connecticut Department of Public Health, pleading with him to take the case. The purpose of our request was not to punish any physician, but to learn from the case. His response to me was: "Well.....what evidence was there, really, that this child had Lyme disease?" and declined to accept the case.

So, you take the one physician in Connecticut who cares for all the children sick with chronic Lyme disease who has never harmed a child, but only helped, and put him through an attempted public crucifixion. And the court allows pediatrician John Senechal, who expressed vituperative malice towards Dr. Jones, to sit on the Committee determining Dr. Jones' fate?

But when a physician fails to treat a child with an engorged deer tick bite despite a mother's plea and fails to recognize Lyme disease when the child becomes ill including *status*

epilepticus and the child dies within 30 days of discontinuance of IV antibiotics made necessary by the decision of an insurance company review physician, and *two* physicians report the case to the Connecticut Department of Public Health, you **DON'T** investigate?

What is **wrong** with this picture?

I call on Dr. Jewel Mullen, Commissioner of the Connecticut Department of Public Health, to investigate this case *now* and determine *why* there was a failure to investigate it in 1997.

I call on Connecticut Governor Dannel Molloy to direct the Department of Public Health to disclose how many hundreds of thousands of taxpayers' dollars have been wasted by the Connecticut Medical Examining Board's attempt to burn Dr. Charles Ray Jones at the stake. Bring this travesty of justice to an end!

In 2005 a memorandum of understanding with the New York State Department of Health's Office of Professional Medical Conduct (OPMC) was reached through the efforts of Assemblymen Joel Miller and Adam Bradley and Assemblywoman Nettie Meyersohn in conjunction with Governor Pataki's Chief Counsel, not to investigate physicians merely because they held a minority opinion concerning diagnosis and treatment of Lyme disease.

Recently, in New York State, six physicians who care for persons with chronic Lyme disease have been simultaneously under investigation by the OPMC. What message does this send to other physicians? What implications does this have for

persons with chronic Lyme disease to access proper care within the State of New York and elsewhere?

If nothing else, it indicates that a memorandum of understanding is inadequate to protect physicians and the patients with chronic Lyme disease who depend on them for care.

Force of law is necessary to accomplish this, and to compel insurers to pay for treatment their physicians have determined is medically necessary for this condition.

Legislation containing some or all of these elements has been passed or is currently under consideration in a number of States. Insurers can never be trusted to do the right thing for patients with chronic Lyme disease. Such decisions must be taken out of the hands of the insurance industry.

Then, there's the case of Jennifer Lilly. She sustained a tick bite while in western New Jersey, followed by a classic Bull's Eye rash, and severe headache. She was told by a succession of physicians she *could* not have Lyme disease because her screening tests for Lyme disease were negative and she received no treatment during the first three years of her illness. When I saw her, I diagnosed Lyme disease based on her history and instituted treatment at her initial visit. Her Lyme ELISA at SUNY Stony Brook was still negative, but her IgM and IgG Western blots were fully diagnostic. Most likely because of the delay in her diagnosis, lesions were evident on an MRI of her brain and this formerly highly productive woman has had to seek disability.

When the Frederick County, Maryland Department of Health contacted me to complete a Lyme disease reporting form, I decided to accompany it with a detailed letter which I copied to Dr. Thomas Frieden, former New York City Health Commissioner, and now Director of the Centers for Disease Control, since Jennifer's case was a *glaring* example of the deficiencies of the two-tiered system of Lyme disease testing recommended by the CDC and responsible for so much patient *suffering*. Dr. Frieden *never* personally responded to my letter.

Presently we have underway a vast, *de facto* nation- and world-wide "Tuskegee Experiment" of *untreated* or *under-treated* chronic Lyme disease.

Neither the United States Public Health Service, predecessor to the CDC, nor the medical profession brought the Tuskegee Experiment to a halt. Senator Edward Kennedy's hearings held in 1972 ended that shameful episode. *Moral force* brought the ignominious Tuskegee Experiment to an end.

In the year 2000, due to fortuitous circumstances, and unbeknownst to Dr. Dattwyler, I gained access to CDC-funded experimental methods in his research laboratory for more than 140 specimens of frozen cerebrospinal fluid on my patients. Whereas only 2% of specimens tested positive on standard spinal fluid tests, some 62 % of specimens tested positive on one or more of the four experimental assays used. Ironically, Vicki Logan's CSF tested more than 7 times higher than the positive cut-off for detection of Outer surface protein C antigen, in the very laboratory of Empire Blue Cross & Blue Shield's own expert consultant.

I asked Laboratory Supervisor, Priscilla Munoz, how they knew these methods were valid. She replied that the three

collaborating research laboratories shared aliquots of samples and found excellent reproducibility between the three labs. The results of these CDC-funded studies on direct detection of OspA and OspC antigen and IgG and IgM borrelia-specific immune complexes in spinal fluid have never been published. Why not? Did someone at CDC “deep six” the results of this research project? If so, who made this decision, and why?

I demand the “raw data” from these CDC-funded research studies, which have never seen the light of day, be made public immediately.

Thomas Frieden, as Director of CDC can ‘set the tone’ for the agency. I call on him, to ‘step up to the plate’ and fix the mess created by CDC. Dr. Frieden can ‘redeem’ the reputation of CDC, which is composed of fine physicians and scientists. Dissociate CDC from the disgraced IDSA Lyme disease guidelines. **Otherwise, step down!**

I call on NYS Attorney General Eric Schneiderman to undertake an additional, independent, in depth and far reaching investigation with subpoena power and testimony under oath, of the 2006 IDSA Lyme Disease Guidelines and of the health insurance industry, in order to determine whether or not, in the matter of chronic and seronegative Lyme disease, there has been collusion to perpetrate a premeditated, systematic and pervasive health care fraud upon the citizens of New York State he has a sworn duty to protect.

Has anyone here been shafted by MEDCO???. Investigate MEDCO!!! When there exist two schools of thought, you endorse only *that* school of thought that maximizes short term profit, *regardless* of individual patient circumstances or the *suffering* that it causes?

Remember A.I.D.S.? Persons with H.I.V. were abused, despised and neglected until ACT-UP-activists threw blood on the steps of St. Patrick's Cathedral.

Only then did things begin to change. Because of that activism, \$2 billion/year has been expended on A.I.D.S. research and treatment over the past several decades and real progress has been made.

Contrast that with some \$20 million/year spent on Lyme disease by the Federal government. Why are resources commensurate with the threat posed by Lyme disease not being allocated? Start funding to the tune of \$2 billion /year for Lyme and tick-borne diseases and, *trust* me, you'll see progress!

Federal funds should not be *squandered* further on those who are ideologically committed to the false proposition that chronic Lyme disease does not exist.

Paul Starr, who graduated Columbia College a year ahead of me, correctly predicted the 'coming of the corporation' in his prescient book "The Social Transformation of American Medicine".

But Starr also commented that the future of American Medicine is ours to shape by the choices that we make.

Patients have the Power. But, they must be united and not squabbling with one another. They must be pro-active, militant and resolute.

There are lots of things patients can do. They can *write* to their State Assemblypersons and State Senators. They can *MEET* with their State Assemblypersons and State Senators.

**They can do the same with their U.S. Congress-persons & Senators
& their states' Governors.**

**They can write to Connecticut Governor Molloy and tell him to
“call off the dogs”!**

**They can write to Attorney General Schneiderman with details
of their cases and how they have been mistreated by insurers
girded by IDSA guidelines that are scientifically,
therapeutically and morally bankrupt and which *endorse* and
enable medical neglect as a ‘standard of care’ for persons with
chronic Lyme disease.**

**They can write to Governor Cuomo, President Obama and
First Lady Michelle Obama, persons of *conscience* and
compassion, urging them to act.**

Sometimes, a *little* ‘rebellion’ is necessary.

Thank you for your attention.

Kenneth B. Liegner, M.D.