

NY – Governor of New York State – The Honorable Andrew M. Cuomo

October 20, 2014

The Honorable Andrew M. Cuomo
Governor of New York State
NYS State Capitol Building
Albany, NY 12224

Dear Governor Cuomo,

I am writing on behalf of the Lyme Disease Association, a national non-profit that has a chapter and several associated Lyme organizations in New York. At this time, I request that you please sign the Lyme disease bill S07854/A07558B which passed both the NY Assembly and Senate this summer.

The LDA's history in New York includes the establishment with a partner Lyme group of the endowed Columbia University Lyme & Tick-Borne Diseases Research Center, the only Center in the world devoted to chronic Lyme disease. Besides Columbia, LDA has provided grant funds in NY to institutions including Stony Brook University, New York Medical College, Rockefeller, and New York University. In addition to LDA's work directly with patients through its groups there, we have first hand experience with the circumstances of New York patients and treating physicians, as LDA holds an annual continuing medical education (CME) Lyme conference, jointly sponsored by Columbia University. The conference faculties consist of researchers and physicians worldwide, the former who are publishing cutting edge studies on tick-borne diseases, and the latter, treating patients with various stages of Lyme. Doctors, researchers, advocates and patients attend these conferences to keep current on Lyme/tick-borne diseases science.

I personally have a unique perspective on the history of the legislative process in New York pertaining to this current legislation before you. Early in the 2000s, the Office of Professional Medical Conduct (OPMC) was targeting at the same time almost all of the doctors in NY who were treating chronic Lyme, even though the OPMC denied

it was targeting Lyme doctors because of the long-term treatment used for chronic Lyme disease. In 2001, I was invited to testify before the NY Assembly Health Committee Lyme Hearing and in 2002, before the NY Assembly Health, Education, & Codes Committee Lyme Hearing. In 2004, LDA was invited to help lead a team to attempt legislation passage for OPMC reform in New York State, based upon LDA's success in getting the first doctor protection legislation in the US passed in Rhode Island. I worked with NY advocates and a bipartisan team of NYS legislators to craft a bill for passage. In the end, we overcame many obstacles and were successful in advancing the bill through the Assembly, but it stalled in the Senate. Next we supported a bill for doctor protection that passed the Assembly and Senate. We attended many meetings in Albany with legislators, the NYS DOH, and the Governor's office on that bill, the then Governor Pataki's office informed our team that he did not favor legislation. Instead, he compromised and agreed to a document into which I supplied input, the 2005 OPMC memo, the text of which now comprises a basis of the current bill before you.

At that time, because of the prevailing political climate and lack of understanding of the magnitude of the Lyme problem by many NY state officials despite a number of meetings to provide them with such education, we agreed to settle for the memo which stated in part, "this memorandum is intended to memorialize and endorse the principles that are currently in place in the Office of Professional Medical Conduct regarding the investigation of physicians, physician assistants and specialist assistants who use treatment modalities that are not universally accepted by the medical profession, such as the varying modalities used in the treatment of Lyme disease and other tick-borne diseases.... Consequently, it is contrary to the policy and practice of the Office of Professional Medical Conduct to identify, investigate or charge a physician, physician's assistant or specialist assistant based solely on that practitioner's recommendation or provision of such treatment modality." The memo served its intended purpose for years. Unfortunately, like other internal policy statements, it eventually lost its clout, and physicians who primarily treat Lyme patients have again been investigated by the OPMC.

We must examine the changes which have occurred in the US, and, more specifically, in New York State since that time period, beginning with case numbers.

Beginning in 2008, some New York counties began to use an averaging system for the number of reported cases that occurred in that county, i.e., instead of validating all the cases of Lyme reported in that county and sending those figures to the

Centers for Disease Control & Prevention, CDC, the counties used data they had and came up with an average which they then reported to CDC. The years and number of counties which averaged are as follows: 2008, 2 counties; 2009, 12 counties; 2010, 17 counties; 2011, 14 counties; and 2012, 20 counties.

The problem with averaging is, CDC has told the LDA they cannot accept averaging into their MMWR surveillance report. Thus, no Lyme case numbers for 2012 were counted in national surveillance for the following counties (taken from Senate Legislative Task Force Report): Albany, Broome, Columbia,* Dutchess,* Greene,* Nassau, Onondaga, Orange, Putnam, Rensselaer, Rockland, Saratoga, Schenectady, Suffolk, Sullivan, Tompkins, Ulster,* Washington, and Westchester – * denotes counties in the top 10 counties nationwide in prior county rankings. Thus, one-third of NY counties' numbers were not included in the CDC national Lyme case reporting for 2012, impacting not only NYS numbers (formerly NY #1 nationally, now #3), but also the US total.

Not only is funding impacted when blatant underreporting occurs, but public and physician perception of the disease burden in NY and the US changes, i.e., there is less disease perceived, leading to fewer precautions, less diagnosis, and thus the disease does not get the attention it deserves on any front.

In 2013, CDC made two announcements confirming facts treating physicians and advocates already knew, Lyme has been vastly underreported, and it can and does cause death. The first in August said that about 300,000 cases of Lyme actually occur in the US annually. The second, in December, was confirmation of the sudden Lyme carditis deaths of 3 young apparently otherwise healthy people with undiagnosed Lyme, including one from NY– whose Lyme was uncovered through the transplant process.

Since the 2005 memo, the science has changed significantly. There have been a number of animal study publications, e.g. monkeys and mice, documenting persistence of infection after treatment, including Monica Embers, Tulane University, "Persistence of *Borrelia burgdorferi* in Rhesus Macaques following Antibiotic Treatment of Disseminated Infection," PLOS One, 2012; and Stephen Barthold, University of California, Davis, "Persistence of *Borrelia burgdorferi* Following Antibiotic Treatment in Mice," Antimicrobial Agents and Chemotherapy, 2008. There was an NIH/CDC webinar featuring researchers talking about the animal studies/chronicity; and there was the 2014 peer-reviewed publication of evidenced-based guidelines by

the International Lyme & Associated Diseases Society (ILADS), discussing the need for individualized treatment for chronic Lyme patients.

Congress held two US House hearings in Washington, DC, on Lyme disease, including testimony about a flawed process of NIH grant giving to researchers who may have held vested interests in the disease and did not believe in chronic Lyme and the intentional exclusion of other researchers who were open minded to the question of chronic Lyme. To view the hearing use the link below:
<http://archives.republicans.foreignaffairs.house.gov/hearings/view/?1455>

This past summer, the first specific Lyme bill was passed through the US House of Representatives, providing for a working group on tick-borne diseases –with patient representation and treating physician representation at the table, and requiring a balanced viewpoint and transparency of operation. LDA led the charge with a letter signed by 154 groups nationwide favorable to the bill. At the state level, recognizing the increased Lyme problem, several more states enacted doctor protection statutes.

In an effort to move the science forward, the Congressional appropriations committees directed the NIH to sponsor a scientific conference on Lyme and other TBD, and further expressed that the conference should represent the broad spectrum of scientific views on Lyme disease and should provide for public participation and input from individuals with Lyme disease. In response, the NIH contracted with the Institute of Medicine in 2010 to conduct a “workshop.” An excerpt from that report follows from Dr. Benjamin Luft, MD, State University of NY-Stony Brook: “the acknowledgement that Lyme disease may be a complex and chronic illness requires a comprehensive, multidisciplinary and patient-centered perspective. Patients are not interested in whether their illness is caused by *Borrelia burgdorferi* or another genotype of *Borrelia*. They want to be well again. Clinicians and researchers need to understand that the disease and its impact may intimately affect the severity and progression of symptoms. Because of the complexity of this disease, there is a need to develop better biological and clinical instruments to evaluate and measure the effectiveness of outcomes of treating its various manifestations...More than a quarter century after the discovery of Lyme disease, infectious disease specialists, neurologists, and psychiatrists still hold different conceptions of the disease. ...The natural history varies greatly from person to person, leading to an absence of consensus about what is ‘active’ disease and what is disease impact. The management of chronic illness, with waxing and waning symptoms poses a challenge to our

traditional office-based, single-specialty approach to management.”

Given this environment on the state of the science and the many complexities we know exist, but do not understand, it seems short-sighted to allow the targeting of physicians based solely upon the recommendation or the provision of a treatment modality that is not universally accepted by the medical profession. Physicians absolutely need to continue their medical education and to maintain high ethical standards, and certainly, they should have a healthy fear of how their decisions and recommendations will impact patient outcomes, but they should not be prevented from utilizing their knowledge, skills, and abilities in a prudent and thoughtful way to improve the well-being of patients.

Doctors' ability to treat should not be subject to the changing political climate which readily allows a policy memo to be followed or not, since policy does not have the full force of law behind it. The time is here to end the uncertainty for doctors and patients. Lyme is not going away. More people now need doctors to diagnose and treat them. Although estimates vary, literature shows 10-20% and more of patients fail an early course of treatment. Yet NYS has again initiated investigations of the group of doctors who treat chronic Lyme disease, leaving thousands of families struggling to get help, many out of work or out of school. Signing this bill will be the first step to helping patients prevent chronic Lyme and helping those with it to be productive members of society.

Thank you. I can be reached at President@LymeDiseaseAssociation.org.

Sincerely,

Patricia V. Smith

President