

Roadmap to Reform

Recommendations for Developing Public Policy Responses to the Challenges of Tick Borne Diseases



Lyme Action Network

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TO: New York State's Executive Leadership, Elected Representatives, and Public Policy Executives

FROM: Lyme Action Network
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Lyme disease, while considered “endemic” in New York State, has reached epidemic status with regard to both case estimates and actual number of cases. Thousands of victims, living in the shadows of this poorly understood disease, turn to the policy-makers of this state to intervene on their behalf. Greater awareness and better understanding of tick borne diseases will serve not only to encourage improved funding for much needed research to expand the body of knowledge on this urgent topic, but will also inspire enlightened public policy that will usher in a better informed, updated, and reasonable public health response to a disease that has adversely impacted so many people's lives and poses a considerable threat to our communities and economies in the near future.

The subject of Lyme and other tick-borne diseases is complex, multidimensional, and marked by a number of deeply contested issues. Not only are these diseases biological and medical issues, but also concerns that need to be viewed through the prisms of environmental policy, socio-economic impact, public health, medical ethics, and corporate competition. Disagreements among professionals about what Lyme disease is and what it is not, how it needs to be treated, and how to train medical professionals abound. Lessons learned from the early days of the AIDS epidemic, when suffering patients were told that their disease was imaginary, should be applied before history repeats itself with Lyme disease.

We offer this document as a compendium of evidence-based, vitally important information that is critical to a complete understanding of the varied dynamics of Lyme and other tick borne diseases in the pursuit of the best public policy possible for the sake of the victims, their families, and their communities, and ultimately, the well-being of New York State as a whole.

On behalf of the victims of tick borne diseases, including our own children, we thank you for carefully reviewing this report, and becoming part of a vitally necessary solution to a serious problem.

ROADMAP TO REFORM

Recommendations for Developing Public Policy Responses to the Challenges of Tick Borne Diseases

presented by

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"In the fullness of time, the mainstream handling of chronic Lyme disease will be viewed as one of the most shameful episodes in the history of medicine..."

- Kenneth B. Liegner, MD

OVERVIEW

With the recent revision by the Centers for Disease Control (CDC) in their estimates for cases of Lyme disease, in which the annual disease incidence was increased by a factor of ten - from 30,000 to over 300,000 new cases per year - public attention has been directed to a fact that has been well-known by the Lyme community for a long time: Lyme and other tick borne diseases are a serious public health crisis, impacting the medical and socioeconomic fabric of all communities that are or will find themselves overwhelmed by a disease that is too easy to catch, too hard to diagnose, and too hard to cure. These numbers represent the tip of the iceberg, as it is understood that the reporting criteria for Lyme disease, and the failure of many medical professionals to recognize, diagnose, and report it, actually preclude accurate diagnosis, and therefore treatment, of Lyme disease in more than half of all people infected with one or more tick-borne organism.¹

Based upon the data from 2 of the 3 health surveys the CDC used for their recent report, 1.1% of the respondents reported having Lyme disease, which computes to approximately 3.5 million people with Lyme disease nationwide. Applying those numbers to the population of New York leads to the very conservative estimate of the currently afflicted New York State population being in the 200,000 - 300,000 range.²

Using a different measure, the CDC reports that since 1990, approximately 100,000 cases of confirmed Lyme disease have been reported from New York State. Applying the recently adjusted multiplier (the CDC acknowledged that the number of cases should be calculated at ten times the "reported" numbers), the number of cases of Lyme disease in New York State from 1990 to 2011 exceeds 1 million. As New York is considered "endemic" for Lyme disease, it is likely that the actual number is significantly higher - possibly 2 or 3 times higher.

To put these numbers in perspective, the CDC reports an annual incidence of HIV/AIDS of 56,000 per year, and defines this as an epidemic. Currently, over \$3 billion of the NIH budget is directed towards HIV/AIDS research. With six times the reported incidence, a mere \$25 million is directed to Lyme disease research.³

The Lyme Action Network is a New York State based advocacy organization committed to encouraging the education and reforms essential to adequately address the matrix of issues being fomented by this public health crisis. We respectfully submit this report with specific recommendations as a **Roadmap to Reform**, a strategic and comprehensive program to address the problem that is already well underway in our state.

THE BACTERIAL BASICS

It is understood that the bacterium *Borrelia burgdorferi*, is the "cause" of Lyme disease. This organism is transmitted through the bite of a tick, but what exactly happens within the body once that pathogen enters a human host's blood is not well understood. The bacteria is widely recognized as one of the most intelligent and elusive known to science, and has been called a "biologic evil genius" (Dr. Kenneth Liegner; Dr. David Persing) for its ability to evade immune surveillance, exist in different morphological

forms, resist antibiotics, and persist within hosts in a dormant or non-reproductive state. Infection with this single organism may affect multiple organ systems, including the skin and the musculoskeletal, cardiovascular, digestive, reproductive, and nervous systems in humans. Due to its protean manifestations, symptoms are generally systemic and overlap those of other diseases. The effects of this disease are not completely predictable, and may affect individuals very differently.

It is important to note that *Borrelia burgdorferi* sensu lato, widely considered to be the “cause” of Lyme disease in the United States, is a single strain of a single species of the genus *Borrelia*. With over 100 recognized strains of *Borrelia burgdorferi* and numerous additional species, such as *B. garinii*, *B. miyamotoi*, *B. afzelii*, *B. americana*, and several others, it is highly likely that *Borrelia* species thought to be present only in Europe or other countries are in fact world-wide. However, this particular fact is largely ignored when it comes to development of diagnostic tests and protocols which rely almost exclusively on the detection of either antibodies against or DNA from *B. burgdorferi* sensu lato. It is also very important to note that *Borrelia* is only one of the several pathogens that can be transmitted to humans through the bite of a tick. Ticks in New York are also known to carry and transmit other bacteria, specifically *Anaplasma*, *Ehrlichia*, *Bartonella*, and *Mycoplasma*, the protozoa *Babesia*, and at least two encephalitis viruses, TBE and Powassan viruses. Therefore, although Lyme disease, as currently defined by the CDC, is largely considered to be an infectious disease caused by a single species of bacteria (*Borrelia*), the so-called “coinfections” may contribute significantly to course of the disease and the severity of symptoms. This avenue of research has been largely unexplored.

Since the time of John Locke, the pursuit of science has revolved around the scientific method, which promotes objectivity in gathering and interpreting data, to prevent bias from influencing scientific conclusions. However, as the commercial value of many scientific discoveries is realized, objectivity is often lost. Such is the case with Lyme disease. Years ago, when scientists were encouraged to share their work for the universal good, researchers would collaborate to solve problems. In today's scientific/commercial environment, labs compete for patents, discoveries are secret, and progress is not shared. It is an unfortunate reality of today's economics that the cooperative scientific systems upon which we've relied in the past to peel away the layers of medicine's most difficult mysteries, no longer exists. In its place, a highly competitive system pits professionals against each other in a race for grant monies, patents, and professional recognition. As far as Lyme disease goes, this system has not proven itself to be advantageous for the patient.

Public policy, scientific research, and community response with regard to Lyme disease need to proceed with the understanding that no one has all the answers yet; open minds and cooperation find solutions; political, commercial, and professional special interests and biases need to be removed from the problem-solving processes; and the scope and dimension of the problem demands a commensurately proportioned response.

THE CURRENT STATE OF AFFAIRS

In the collective consciousness of physicians and health consumers alike, Lyme disease has long been considered a simple bacterial infection that's "hard to catch but easy to cure" with a short course of antibiotics. However, for millions of people in the United States and around the world, that particular

“talking point” does not match the reality of their disease. Another finding from the recently reported CDC “Health” Survey was that 42% of patients diagnosed with Lyme disease remained ill after 6 months, and 12% reported illness that lasted for over 2 years. THIS Lyme disease, which does not fit nicely into the surveillance “definition,” is the true problem. Thus for a majority of Lyme disease patients, their experience does not match the standard medical opinion that their symptoms are the result of an infection by a single organism, that’s easily killed with antibiotics resulting in full recovery by the patient. Why many people don’t recover following short term antibiotic treatment is at the heart of a medical controversy over what Lyme disease truly is -- a simple bacterial infection easily treated with antibiotics, as many Infectious Disease specialists contend, or a complex infectious disease process that may involve multiple pathogens, that may not resolve with antibiotic treatment, which may lead to progressively worsening symptoms, increasing disability, and possible death.

Dr. Richard Horowitz, an internationally recognized expert on the complexities of tick-borne illnesses, discusses in his best-selling book "Why Can't I Get Better?" that the symptoms often and commonly attributed to "Lyme disease" are, in fact, frequently the result of infections by multiple pathogens (*Bartonella*, *Babesia*, *Ehrlichia*, *Anaplasma*, and others), affecting multiple organs and systems. Dr. Horowitz uses the term MSIDS, for Multiple Systemic Infectious Disease Syndrome, instead of Lyme disease, to describe patients with advanced disease effecting more than one body system, that doesn’t resolve following a single round of one antibiotic. As the CDC survey indicates, MSIDS is more descriptive of the 50% of diagnosed patients who still have symptoms 2 years after diagnosis and treatment for Lyme disease.

As the practice of medicine in this country drifts toward managed care, physicians and insurance companies are restricted to diagnosis and treatment strategies that are predicated on “guidelines.” In the case of Lyme disease, there are 2 sets of guidelines. Multiple sets of guidelines are not uncommon in the practice of medicine, with divergent opinions leading to treatment options for patients. Cancer is an example of a disease in which there are diverging options with regard to treatment. According the AMA by-laws, when different medical opinions exist, it is the duty of the physician to discuss all possible options with the patient and include the patient in the choice of which option to follow. This is not happening in the case of Lyme disease.

For Lyme disease, one set of guidelines was developed by the Infectious Disease Society of America (IDSA), a large, influential, private professional medical organization. The IDSA Guidelines have been accepted as the "standard of care" by the CDC for many years, although they rely on very limited and very specific, yet stunningly unreliable, diagnostic criteria; they restrict treatment to short term antibiotics; and they do not acknowledge or address the issue of what to do for patients whose illnesses fail to match their limited definition of disease and/or who fail their rigid treatment protocol. We are not all alike: this one-size-fits-all approach is simplistic, does not recognize new understandings and insights into tick borne diseases, and DOES NOT WORK.

The second set of guidelines, currently under revision, were developed by the International Lyme and Associated Diseases Society (ILADS), a professional organization composed of physicians and researchers who have extensive clinical and research experience on patients Lyme disease and who find the IDSA Guidelines unsatisfactory. Through their extensive and collective clinical experiences with tens of thousands of patients for whom the IDSA Guidelines have failed, the ILADS doctors have developed an

alternative set of clinical standards. The ILADS Guidelines recommendations include the following positions:

- acknowledgement of the highly unreliable nature of existing testing options;
- using clinical judgment in the diagnostic process;
- employing a treatment regimen that is appropriate for the clinical evaluation of the patient
- not restricting treatment of Lyme disease to a single short term antibiotic course;
- recognizing that persisting symptoms may, in fact, be due to persisting infection by the many causative agent(s) of tick-borne diseases.

The ILADS Guidelines were evidence-based and were reviewed and accepted by the National Guidelines Clearinghouse (an arm of the US Department of Health and Human Services) in 2004, and currently are under revision as required by law.

Most doctors know little or nothing about the ILADS Guidelines, as the most common channels of professional communication on the subject of Lyme disease tend to be controlled by a small group of "opinion leaders" within the IDSA. These Infectious Diseases "experts," several of whom are located in New York State, have built their reputations on the assertion that Lyme disease is hard to get and easy to diagnose and cure; these same individuals served on an IDSA panel convened to write the existing IDSA clinical diagnostic and treatment standards; as "opinion leaders" they control the peer-review process for scholarly publications of scientific research related to Lyme disease, particularly for "high-impact" professional journals relating to infectious disease; and they have served as experts on behalf of commercial corporate interests, such as insurance companies who refuse to pay for Lyme treatment. Their influence within the public and governmental agencies and professional organizations has enabled them to steer public research monies to their own labs over the past 20 years, and as the "experts" their views are often the only one sought when articles and stories about Lyme disease appear in the news or professional reports. This process has created a "closed system" of circular reasoning, benefitting one small group while ignoring other valid research that has been done in the US and the rest of the world.

Inappropriate collusion between the IDSA and the CDC and NIH oversight agencies has recently come to light through a FOIL discovery, supporting charges that there has been a long-standing culture of profound conflicts of interest among the panel of experts who are supposed to be guiding and overseeing public policy at the federal level. Instead, Review Board panelists are often competing with the applicants for funding, setting up a stunning conflict of interest environment where influence and connections have enormous potential to influence the review outcomes.

In 2008, then Attorney General of Connecticut (now Senator) Richard Blumenthal, investigated the original IDSA Guidelines committee. The investigation uncovered a matrix of professional and financial conflicts of interest.

Specifically, Blumenthal's findings included the following (www.ct.gov/ag/):

- The IDSA failed to conduct a conflicts of interest review for any of the panelists prior to their appointment to the 2006 Lyme disease guideline panel;
- Subsequent disclosures demonstrate that several of the 2006 Lyme disease panelists had conflicts of interest;
- The IDSA failed to follow its own procedures for appointing the 2006 panel chairman and members, enabling the chairman, who held a bias regarding the existence of chronic Lyme, to handpick a likeminded panel without scrutiny by or formal approval of the IDSA's oversight committee;
- The IDSA's 2000 and 2006 Lyme disease panels refused to accept or meaningfully consider information regarding the existence of chronic Lyme disease, once removing a panelist from the 2000 panel who dissented from the group's position on chronic Lyme disease to achieve "consensus";
- The IDSA blocked appointment of scientists and physicians with divergent views on chronic Lyme who sought to serve on the 2006 guidelines panel by informing them that the panel was fully staffed, even though it was later expanded;
- The IDSA portrayed another medical association's Lyme disease guidelines as corroborating its own when it knew that the two panels shared several authors, including the chairmen of both groups, and were working on guidelines at the same time. In allowing its panelists to serve on both groups at the same time, IDSA violated its own conflicts of interest policy.

In a statement, Blumenthal added, "The IDSA's 2006 Lyme disease guideline panel undercut its credibility by allowing individuals with financial interests -- in drug companies, Lyme disease diagnostic tests, patents and consulting arrangements with insurance companies -- to exclude divergent medical evidence and opinion. In today's healthcare system, clinical practice guidelines have tremendous influence on the marketing of medical services and products, insurance reimbursements and treatment decisions. As a result, medical societies that publish such guidelines have a legal and moral duty to use exacting safeguards and scientific standards."

It is important to note that IDSA included in its Lyme guidelines a statement calling them "voluntary" with "the ultimate determination of their application to be made by the physician in light of each patient's individual circumstances." However, Blumenthal's investigation revealed that insurance companies, including United Healthcare, Health Net, Blue Cross of California, Kaiser Foundation Health Plan and other insurers have used the IDSA guidelines as justification to deny reimbursement for long-term antibiotic treatment.

Research conducted by Kris Newby and Andy Abrahams Wilson for their revealing documentary, **Under Our Skin**, discussed in detail a trail of professional and fiduciary conflicts of interest on the part of the decision-making board members of the IDSA. Members of the IDSA panel entrusted to author the Guidelines for the Treatment of Lyme disease have such conflicts as: being stakeholders in existing patents; being paid professional advisors to insurance companies or other corporate stakeholders; having labs that benefit from grants issued by the CDC or NIH; and other conflicts that suggest significant bias. The IDSA and the cohort of people who support their petitions that their professional

competitors at ILADS be marginalized have a financial stake in maintaining the current status quo and eliminating or undermining as much competition as possible.

The inappropriate and perhaps illegal collusion between the IDSA, the NIH, and the CDC is well documented. The New York State DOH has, understandably, been influenced by the positions adopted by the IDSA and the CDC. The victims of Lyme disease who have been hurt by inappropriate cronyism seek to legitimately expand the science that needs to occur if we are to find a solution to this growing problem. The system that has thrived on bias, favoritism, and control needs to be dismantled and replaced with a structure that respects all points of view, and seeks unbiased open-minded solutions.

Even though many victims report improvement and cure when treated according to the ILADS Guidelines, this option and physicians who use it remain the target of attack by an influential group who have decided that there is only ONE way to address this problem -- the IDSA way.

THE CRUX OF THE PROBLEM AND STATE OF THE SCIENCE

At the root of an international, multi-disciplinary, contentious, and vociferous battle between proponents of the IDSA's position versus those supporting the ILADS position is a fairly simple question:

Are the ongoing, post-treatment symptoms (referred to as chronic Lyme, post treatment Lyme disease syndrome, tertiary or third stage Lyme disease, and other names) experienced by more than 50% of Lyme disease victims either totally or in part the result of persisting infection by *Borrelia burgdorferi*, or something else?

The Infectious Disease Society of America (IDSA) maintains that antibiotics effectively eradicate the bacteria from their human host and that post-treatment symptoms are the result of some as yet unknown autoimmune process. In spite of research showing that live, infectious *Borrelia* can be recovered from antibiotic-treated mice and primates, the IDSA "experts" maintain that this is not "convincing biologic evidence" that the bacteria may survive in the humans under the same conditions. Although the remarkable nature of *Borrelia* is well researched, with understanding that they employ amazing strategies for self-preservation that included dormant states and creation of biofilms, the IDSA experts continue to reject the probability that lingering Lyme disease symptoms may be attributed, in part or in whole, to persisting infection by one or more of the tick-borne "stealth" pathogens that survive in human hosts by altering the immune response and surviving antibiotic treatment.

While some evidence supports the theory that there is an immune derangement or an immune-mediated aspect to the pathology associated with infection in some patients, a mounting body of evidence contradicts the assertion that there is no persistent infection driving that immune derangement. Physicians and researchers point to studies done not only by independent researchers, but the early research performed by NIH and CDC researchers and the IDSA guideline-writers themselves, where it was shown that *Borrelia* infection can persist even after aggressive antibiotic therapy.⁴

Numerous studies clearly show that *Borrelia* can and does persist in mammalian (including human) tissues and organs in spite of antibiotic treatment. In fact, it is likely that, as new unbiased research is pursued, we will confirm that persistent infection AND inflammation/immune derangement may all co-exist and will ALL need to be addressed together. It is illogical and unreasonable to conclude, and structure public policy, on the argument that the bacteria are always eradicated after a single course of antibiotics with solid evidence indicating that the disease process is far more complex than originally thought, and not yet fully understood.

The preponderance of the scientific evidence published in peer-reviewed journals indicates that the model of Lyme disease endorsed by the IDSA, the Centers for Disease Control (and by extension the NYS Department of Health), that of a simple disease with a simple cure, is not only incorrect, but harmful to the public's health. Ticks transmit *multiple* bacterial, protozoal, and viral pathogens that are considered "stealth" pathogens (as opposed to better known "frontal" or "overt" pathogens like those that cause strep throat.) Stealth pathogens encroach slowly on the infected host, evade the normal immune responses that defend the human body against infection, and establish long term infections in protected niches in the body. In this regard, Lyme disease is more like tuberculosis than strep throat. Yet the "standard of care" is to treat Lyme disease more like strep throat (short term), than tuberculosis (long term).

Additionally, objective review, by this report's author and others, of several of the published studies generally touted as "biologic evidence" by the IDSA, reveals a lack of objectivity, demonstrate bias, and, in some cases, show evidence that in fact contradicts the stated conclusions of the studies.⁵

THE RIPPLE EFFECT - PROBLEMS GROWING IN ALL DIRECTIONS - AND RECOMMENDATIONS TO ADDRESS THEM

Emanating from the central, mismanaged issue of the CDC's failure to acknowledge, identify, and pursue honest solutions for an illness being experienced by hundreds of thousands of people, a panoply of serious secondary problems and conflicts have evolved. Individually, each is a major issue. In aggregate, given the endemic scope of tick-borne illness, the problems threaten to undermine a wide swath of our community's well-being.

Ten major issues that beg for immediate redress include (but are not limited to) the following:

1. The state of diagnostic testing for Lyme disease is dismal at best.

The current treatment guidelines supported by the IDSA and CDC are based on "two-tiers" of serological tests. The first "tier" (ELISA) has a documented accuracy of less than 50%. A negative result on the first tier means the more sensitive test, the Western Blot, will **not** be run. Therefore, 50% of people who actually have Lyme disease are undiagnosed, untreated, and their disease may progress to a chronic state with significant disability. This standard defies all logic.

As a result of the low prognostic value of the current serological tests, the Commonwealth of Virginia has passed legislation, signed into law in 2013, that requires physicians to inform their patients that a negative test does not mean they don't have Lyme disease.⁶

The second tier test, the Western Blot, has a sensitivity of almost 70%.⁷ This test, which identifies antibodies against specific *Borrelia* proteins, requires careful interpretation and, like the first tier, is not always reliable and can result in both false positive and false negative results. Findings can also vary over time, the reasons for which aren't always clear. (*Johnson & Stricker; Liegner*)

The interpretation of the Western Blot test varies from lab to lab. The CDC states that for the WB IgG, 5 “bands” must be present for a “positive” interpretation. However, other accredited laboratories have proven that certain antibodies are present ONLY in response to *Borrelia*. Although the CDC acknowledges that their strict criteria are for epidemiologic surveillance purposes and not for clinical diagnoses, this fact is ignored by many in the medical profession and by insurers who uses the CDC surveillance criteria as a basis for reimbursement.

What must also be considered, is that the tests for “Lyme disease” were designed to detect a person’s antibodies against a laboratory strain of a single species of *Borrelia burgdorferi*. Physicians who treat patients with antibiotic-refractory Lyme disease note that those patients are often infected with more than one pathogen. However, tests for these other pathogens are seldom ordered as part of the laboratory testing for “Lyme disease”. Additionally, the state of testing for the other tick-borne pathogens, particularly *Bartonella*, are even more dismal than for *Borrelia*.

Patients in New York are at a disadvantage when it comes to being tested for diseases. Several tests are not permitted in New York; other tests aren't covered by insurance in New York; and labs doing cutting edge work are not authorized by New York's DOH.

While it is reasonable and laudable that the NYS DOH is diligent in vetting tests and facilities, there is considerable speculation that, as the only state in the country that prohibits access to some of these tests and facilities, it might be a political agenda and not a scientific one that dictates advances and policy in this arena.

2. The state of medical education pertaining to tick-borne diseases is woefully lacking.

All medical professionals in New York State should be required to complete continuing education courses to bring them up to date with regards to new research and new findings in this field. Due to the political contentions surrounding this issue, medical professionals are significantly less informed than they might be in other areas. Requiring non-political, balanced information is critical to addressing new cases of disease as they present and can be more easily addressed. It is notable that on their web page for Lyme disease, the CDC provides a link to a “Free CME” (Continuing Medical Education) on Lyme disease. This CME module links directly to the IDSA Lyme disease web page, and when reviewed, the creators of the CME belong to the same small group who developed the diagnostic and treatment guidelines for Lyme disease, and also reveals their significant conflicts of interest. However, although there are two sets of evidence-based guidelines (with the other developed by ILADS), the CDC links to only one.

3. Thousands of cases of Lyme disease are not reported.

Below are the surveillance case definitions for Lyme used by the CDC:

Suspected:

- A case of EM (*erythema migrans* rash) where there is no known exposure (as defined above) and no laboratory evidence of infection (as defined above), OR
- A case with laboratory evidence of infection but no clinical information available (e.g., a laboratory report).

Probable:

- Any other case of physician-diagnosed Lyme disease that has laboratory evidence of infection (as defined above).

Confirmed:

- A case of EM with a known exposure (as defined above), OR
- A case of EM with laboratory evidence of infection (as defined above) and without a known exposure OR
- A case with at least one late manifestation that has laboratory evidence of infection.

Note that in each of the three categories, laboratory evidence of infection is required. However, **the existing two-tier diagnostic tests have an accuracy rate of only 50% to 70%. They are 30% to 50% inaccurate.** Thousands of Lyme victims are not meeting the surveillance criteria because the diagnostic testing is poor, and the CDC, and by extension, New York State's Department of Health, ignores this population. If a patient does not remember a tick bite, has not traveled to an "endemic" area, does not develop a "bull's-eye" rash, or has a negative serological test, the case will not be reported or included in disease statistics compiled by public health agencies. Under reporting of Lyme disease leads to underestimation of both disease risk and disease burden at all levels – individual, community, state, and national. In August 2013, the CDC reported that cases of Lyme disease were under-reported by a factor of at least 10 and increased their case estimates upward to over 300,000. As of yet, no measures have been taken by any public health agency in response to that data, despite the fact that Lyme disease is 6X more common than HIV/AIDS and 4X more common than influenza.

There is a wide and dangerous gap in the education of medical practitioners regarding the need to make a clinical diagnoses for Lyme and other tick borne diseases. A long-standing culture of misinformation has rendered many, if not most, general practitioners and infectious disease doctors confused about how to diagnose Lyme and other TBDs, and so, by default, they refer to the limited and problematic CDC's surveillance criteria for diagnoses.

It is also appropriate to note that most physicians are woefully undereducated about the lesser-known tick borne pathogens that are causing illness and death. These diseases are very prevalent in New York State, yet health care providers often know next to nothing about them. *Babesia*, a protozoa similar to malaria, and *Anaplasma*, a tick-borne bacteria, have been identified by the Red

Cross as a danger to the US blood supply, yet many medical professionals know little or nothing about them. The IDSA reassures the public that if the tick is removed within 24 or 36 hours, the victim doesn't need to worry. This assertion is misleading at best and blatantly wrong at worst, as several published studies have shown that for some pathogens such as Powassan virus, which is known to cause encephalitis, transmission from ticks to human can occur in as little as thirty minutes after tick attachment.

The discovery and evolving understanding of these diseases, especially those for which we have no known treatment yet, underscores the fact that tick borne disease is an emerging field of study for which we do not have all the answers (as the IDSA would like to suggest); solving the complex issues presented by these pathogens is a work-in-progress; and there is great urgency to apply very substantial research funds to many areas of study, directed to researchers from many institutions, not just the same institutions who have historically received research grant monies (often used to reinforce previous conclusions) at the expense of new efforts that could challenge those old conclusions.

4. Physicians who treat Lyme are under attack.

The failure of the customary medical process to address Lyme patients has become so severe that an organization of medical experts has evolved across the country to share research, experience, and treatment solutions. The physicians, traditionally trained and members of mainstream medical societies, as well as professional researchers and patient advocates, are working with armies of patients for whom the IDSA Guidelines have failed miserably. From this group, the International Lyme and Associated Diseases Society (ILADS) was formed. Patients tend to find their way to these Lyme experts through other Lyme patients, as most general practitioners and infectious disease specialists do not acknowledge their existence, and do not refer patients to them. Many of these Lyme doctors reside and practice in New York and are among a handful of international experts who have been sought out by other countries around the globe to consult on international Lyme disease problems.

In this country, and in this state, the work of these medical pioneers is denigrated and dismissed in a fashion that would be consistent with the Dark Ages. ILADS physicians regularly and systematically find themselves "under investigation" by the New York State DOH's Office of Professional Medical Conduct. Over the past decade, at any point in time, several ILADS doctors are being investigated, at a rate that is multiples above the general physician population. The investigatory procedure is intrusive, disruptive, and expensive.

It has become so prevalent that a small cadre of attorneys is now specializing in navigating these treacherous waters for the ILADS physicians.

China, Sweden, France and other countries look to the ILADS physicians, people who are specializing in the study of *Borrelia* and the co-infections that often accompany it, for advice on their countries' growing Lyme disease problems. These countries recognize that the denialist, head-in-the-sand attitudes of the IDSA aren't addressing the problems, and they are seeking solutions from the medical professionals who are redefining what we thought we knew about

Lyme disease and other TBDs. Ironically and tragically, these doctors, our best hope for fixing the problem, are finding themselves under attack and investigation in this state and in this country because they don't adhere to the IDSA Guidelines.

The strategy of targeting Lyme-treating physicians for investigation has become a prevalent practice in a number of states, especially those states with a strong IDSA presence. In New York, over 50% of the Lyme doctors have come under "investigation" due to reported complaints about their professional behavior. It is believed that most of these "complaints" do not come from patients, but rather from the professional competitors; insurance companies not wanting to pay for long term treatment prescribed by that doctor; or by irate members of the IDSA who were embarrassed when their diagnostic errors were revealed after patients were determined to have Lyme after an IDSA doctor proclaimed them not to have Lyme.

Lyme disease patients and physicians feel that the OPMC hearings are unjust because (a) the procedures used by the OPMC deny physicians due process and (b) the OPMC has, in the past revealed its bias against the ILADS treating doctors by declaring that the guidelines it uses to judge Lyme disease physicians "rarely if ever" indicate that more than 2-3 weeks of antibiotic treatment is needed to cure Lyme disease, parroting the claims of the IDSA and ignoring substantial scientific evidence to the contrary.⁸

The investigations are often "fishing expeditions," where the investigators start with a report of a small infraction and then hunt for more substance.

Physicians are well aware that treating Lyme disease may be fraught with difficulty. It is common knowledge that Lyme doctors receive unwelcome attention by the OPMC with great frequency, and many doctors refuse to diagnose or treat Lyme disease. The witch-hunt environment for this epidemic disease has had a chilling effect on practitioners who might want to help the effort. The result is that there are stunningly few medical practitioners available to treat the spectacular, and growing, number of patients suffering Lyme and other TBDs.

5. The Department of Health is Complicit in Anti-Trust Maneuvers.

In 2009, then Connecticut Attorney General Richard Blumenthal filed a suit against the IDSA citing profound conflicts of interest, both professional and financial, in the intertwining nature of the IDSA and the CDC with respect to the Treatment Guidelines for Lyme disease, the award of public research funds, and other overlaps that were considered inappropriate. In New York State, the exercise of harassing physicians and laboratories under the banner of the IDSA Guidelines, serves to advance the political agenda of the IDSA, at the expense of their competitors, most of whom are members of ILADS or who use the ILADS Guidelines to treat Lyme disease. It is important to remember that ILADS is a legitimate organization whose Guidelines have been reviewed and accepted for incorporation into the National Guidelines Clearinghouse. As mandated by law, they were removed when they expired after five years, and are currently being revised and resubmitted. (In contrast, the IDSA's 2006 Guidelines expired, were never revised as required by law, and have been allowed to remain on the NGC website, with a link from the CDC to this out-of-date set of Guidelines.)

There are two clearly divergent schools of thought in this matter. Physicians who disagree with, and who do not adhere to the IDSA Guidelines for Lyme and tick-borne diseases, should be enabled to practice, without harassment, discrimination, and abuse, in accordance with their understanding of the medical literature and their conscience.

This is not a reality in this state.

6. Citizens' Civil Rights are Routinely Being Denied.

The Americans with Disabilities Act of 1990 provides for two key rights that are being routinely violated in New York State:

A. Individuals with the condition referred to as Chronic Lyme, Post Lyme Treatment Syndrome, Late Stage Lyme disease, Lyme Complex, Multiple Systemic Inflammatory Disease, and other names are being denied appropriate attention and acknowledgement by the NYS DOH and other New York agencies.

Sec. 12132. Discrimination

Subject to the provisions of this subchapter, no qualified individual with a disability shall, by reason of such disability, be excluded from participation in or be denied the benefits of services, programs, or activities of a public entity, or be subjected to discrimination by any such entity.

B. Titles I and III of the ADA each prohibit not just discrimination against the disabled, but also against discrimination “to an individual or entity because of the known disability of an individual with whom the individual or entity is known to have a relationship or association”. Title II does not contain such language, however, the Department of Justice adopted this “association” protection in Title II’s implementing regulation found at 28 CFR 35.130(g):

“A public entity shall not exclude or otherwise deny equal services, programs , or activities to an individual or entity because of the known disability of an individual with whom the individual or entity is known to have a relationship or association.”

The validity of the association clause in the regulations promulgated under Title II was upheld in a recent Second Circuit, Innovative Health System v. City of White Plains, 117 F.3d 37 (2d Cir. 1997). Moreover, the purpose of the association provision is to protect health care providers:

This provision was intended to ensure that entities such as health care providers, employees of social services agencies, and others who provide professional services to persons with disabilities are not subjected to discrimination because of their professional association with persons with disabilities.

7. Patients are denied insurance coverage for some Lyme disease treatments.

Because of strict limitations imposed on physicians by insurance companies, many physicians who treat Lyme disease patients will not accept insurance. Additionally, even for patients who are diagnosed by a physician, there are limitations on antibiotics imposed by the insurance company. For example, most insurers will cover only a single month of IV antibiotic home infusion. If symptoms persist or worsen, subsequent treatment is an out-of-pocket expense.

The insurance industry bases reimbursement on diagnosis of Lyme disease according to the ICD-9 medical records coding system. The diagnostic code reported by physicians serves as the basis for insurance companies to permit or reject insurance coverage of treatments. In the case of Lyme disease, there is a single code that signifies a diagnosis of Lyme disease which corresponds closely to the IDSA/CDC reporting criteria. Patients who don't meet the IDSA diagnostic criteria, especially the requirement for a positive blood test, are often not diagnosed, leading to no code, leading to no insurance coverage for antibiotic treatment. Ironically, insurance companies invariably pay for the MRI, CT scans, dozens of blood tests, and other procedures when patients who actually have Lyme disease are not diagnosed. CDC data indicates that the number of people this may refer to may be as high as 50%. Therefore, insurance companies will actually pay significantly more for undiagnosed patients than they would for additional rounds of IV antibiotics.

Compounding the issue is the complementary nature of the other tick borne diseases, such as babesiosis, ehrlichiosis, anaplasmosis, and bartonellosis. These diseases all have different ICD-9 diagnostic codes, lack definitive diagnostic tests, and complicate the diagnosis and treatment process. Denying that an illness exists and refusing to provide insurance coverage for treatments that are known to provide relief is disgraceful.

Patients suffering with the long-term effects of a disease that persists even after treatment are often disabled and cannot work. Lyme victims who are unable to work often lose their health insurance coverage. Some victims hang on to their jobs for dear life, severely compromising their health, for the sake of retaining their health insurance.

Lyme victims' applications for disability insurance are denied at a rate of about 30% because their illness does not match the IDSA/CDC definition, which, as we indicated earlier, is so limited that it ignores an enormous percentage of the victim population.

This situation places an unethical and untenable burden on the patients who must pay thousands of dollars out of pocket for informed medical care -- if they can even find it, as many physicians shy away from treating Lyme disease due to the political atmosphere.

8. Econometric Impact: Now and Yet to Come

Two recent studies have focused on assessing the burden of disease, which is a measure of the financial costs associated with illness. Conducted among patients with Lyme disease, the studies found that the economics of Lyme disease are staggering, and the projected future impact will be

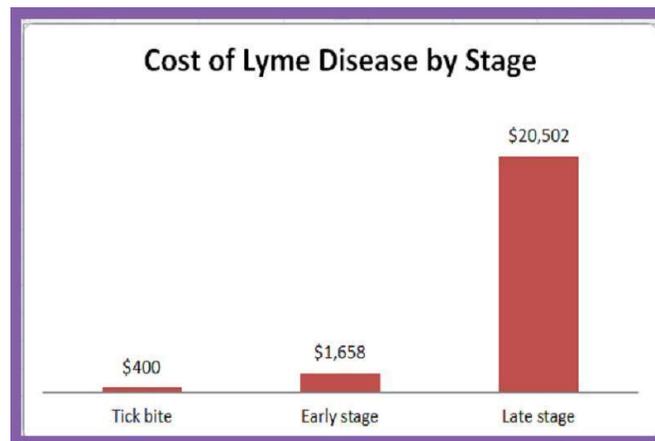
even more stunning if large-scale reformative actions aren't undertaken immediately to rein in the expanding problem.

In the first study, conducted in 2006 by Zhang and colleagues and adjusted in 2013 for inflation, the researchers found that the mean annual cost of illness was strikingly different depending upon the speed with which the diagnosis was made:

The costs are:

- \$400 if treated at the time of the tick bite
- \$1658 per year per patient for early Lyme disease, if caught in the early stages
- \$20,502 per year per patient for late Lyme disease. Year after year after year!

It is important to note that when a patient is accurately diagnosed and treated in the earliest stages of the disease, the chances for resolving the illness fully are significantly greater than can be expected in later stage disease. Therefore, the \$400 annual cost, and in many cases the \$1658 cost, tend NOT to recur year after year. In many cases, it's a one-year expense, and then it's done.



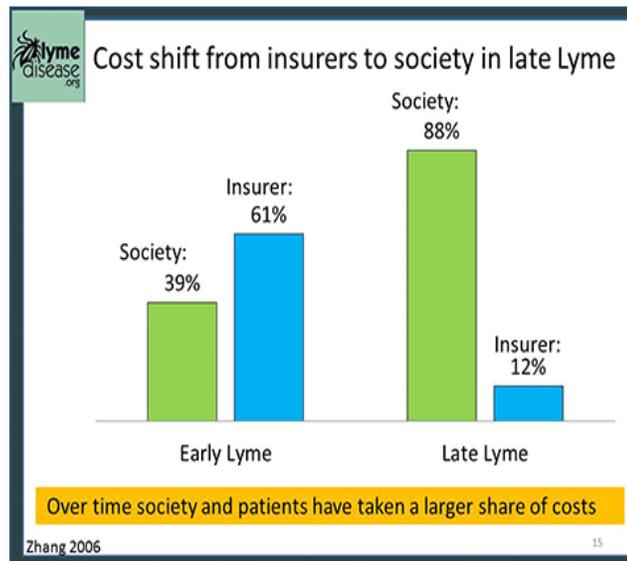
(Source: Zhang, X., Meltzer, M.I., Pena, C.A., Hopkins, A.B., Wroth, L., and Fix, A.D. (2006) Economic Impact of Lyme Disease, *Emerging Infectious Diseases*, 12(4), 653 – 660. Adj. for inflation 2006 - 13)

In contrast, for the people who have later stage Lyme disease, people who did not get accurate or effective early diagnosis and treatment, the recurrent burden of out-of-pocket expenses in excess of \$20,502 per year IS usually a recurring, out of pocket expense that can go on for years. Insurance rarely covers these expenses. Obviously, this kind of burden is completely untenable to most families, and the resulting medical and economic debacle that results requires the full attention of policy makers across the state and the country.

Annual Cost of Lyme Disease in the US		
	Zhang based on 2002	2012 Dollars (Inflation Adj)
Late stage per person	\$16,199	\$20,502
Early stage per person	\$1,310	\$1,658
Tick bite per person	\$316	\$400
Per Person Direct Medical Costs	\$2,970	\$3,759
Per Person Indirect Medical Costs, Nonmedical Costs & Loss of Productivity	\$5,202	\$6,584
Average Per Person Annual Cost of LD	\$8,172	\$10,343
# of cases in US	23,763	300,000
Annual Cost of Lyme Disease in US	\$203 Million	\$3.1BILLION

(Source: *The LYME POLICY WONK*, by Lorraine Johnson, JD, MBA)

The annual cost of Lyme disease has reached a level in excess of \$3.1 BILLION dollars annually. The majority of the burden of disease is being borne by individuals and public health systems, a burden that becomes more extreme with the more advanced cases.



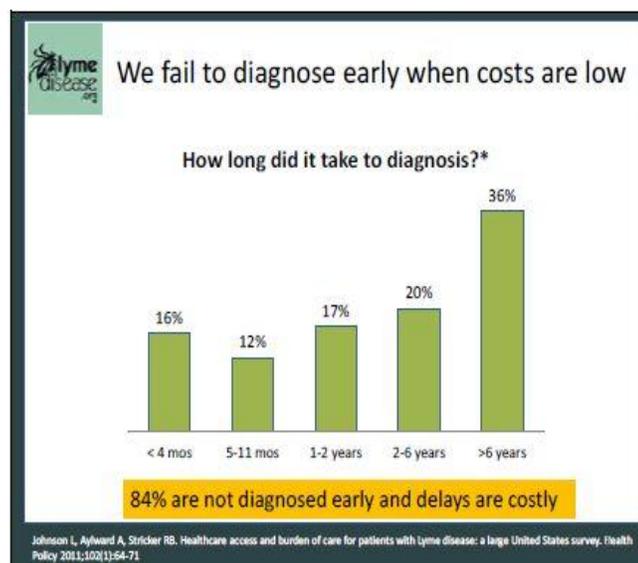
The scenario that is likely to unfold over the next few years should give public health officials pause:

- Victims fail to get an informed and accurate diagnosis from their family doctors...
- Victims fail to receive effective early treatment...
- The victim's disease (or diseases) progress....
- The victim's ability to work and support a family is compromised...

- Victims are denied health insurance coverage because "there is nothing wrong with them"; "There is no such thing as 'chronic Lyme disease' "...
- The victim's health continues to deteriorate -- loss of job and income a reality...Out of pocket expenses dedicated to finding cures for their illness ravage family finances...
- Eventually, individuals need to go on public assistance...

Unbelievably, there are many, many families where more than one person in the family is sick with Lyme disease, and these families are truly suffering. Many have lost their homes, and have had to turn to family for care and support, multiplying the burden and impact of the disease. These victims often have to choose who among them can go to the doctor, because there isn't enough money for all of them to get treated. They often share meds even though there is no telling what toxic stew of co-infections any of them may be suffering, and not knowing if the meds for one person are suitable for the others. They have no choice, and they hope for the best. This is a catastrophic scenario, and it's playing out in every community where the deer ticks reside.

In the second large study conducted in 2011 by Johnson and Stricker, a variety of experiences of confirmed Lyme disease patients was captured. The statistics are startling. Perhaps the most shocking metric is that which shows that of the 2424 respondents, only 11% of them received their diagnoses from Infectious Disease specialists, in spite of the fact that over 37% of them saw over 10 doctors trying to find out what was wrong with them! Fifty percent (50%) saw over seven doctors before being diagnosed.



A 1993 survey by Vanderhoof and Vanderhoof-Forchner found a positive correlation between the number of physicians seen and the delay of an accurate diagnosis. With this delay, the disease progresses, and the treatment becomes more difficult and expensive.

Fifty nine percent (59%) of respondents to the Johnson and Stricker study reported needing to travel in excess of 50 miles for treatment. Ten percent (10%) had to travel in excess of 500 miles.

Excerpted tables from this study are found on the next page.

Table 1
Demographic and medical status (n = 2424).

	n	%
Birth year		
1920–1929	3	0.1
1930–1939	67	2.8
1940–1949	368	15.2
1950–1959	779	32.1
1960–1969	645	26.6
1970–1979	347	14.3
1980–1989	190	7.8
1990–1995	25	1.0
Current region of residence ^a		
Northeast	861	35.5
Mid-Atlantic	447	18.4
New England	414	17.1
South	639	26.4
West South Central	134	5.5
East South Central	60	2.5
South Atlantic	445	18.3
West	615	25.4
Pacific	508	21.0
Mountain	107	4.4
Midwest	298	12.3
West North Central	169	7.0
East North Central	129	5.3
Missing	11	0.5
How long have you had Lyme disease?		
Less than 2 years	122	5.0
2–5 years	661	27.3
6–10 years	510	21.0
Greater than 10 years	1130	46.6
Missing data	11	0.5
Do you have chronic (6 months or more) subjective symptoms after receiving at least 21 days of treatment?	2302	95.0
How were you diagnosed?		
CDC positive by two-tier testing	397	16.4
CDC positive by Western Blot	603	24.9
Clinically diagnosed with other supporting laboratory tests	1424	58.7
What type of physician(s) first officially diagnosed you with Lyme disease? ^b		
Internist	329	13.6
Rheumatologist	95	3.9
Family physician	603	24.9
Infectious disease specialist	268	11.1
Lyme literate medical doctor (LLMD)	1057	43.6
Other	434	17.9
What type of physician(s) currently treats you? ^b		
Internist	374	15.4
Rheumatologist	113	4.7
Family physician	555	22.9
Infectious disease specialist	296	12.2
Lyme literate medical doctor (LLMD)	1431	59.0
Other	251	10.4
None reported	115	4.7

^a Regions and divisions based on those identified by the U.S. Department of Commerce Economics and Statistics Administration of the U.S. Census Bureau

[7].

^b Please note that percentages add to greater than 100% because some respondents endorsed multiple categories.



Table 2
Access to health care for Lyme disease (n = 2424).

	n	%
How many physicians did you see between your onset of symptoms and a Lyme diagnosis?		
1	165	6.8
2–3	419	17.3
4–6	590	24.3
7–9	337	13.9
10 or more	909	37.5
Missing data	4	0.2
What is the distance you currently travel for treatment of your Lyme disease?		
Less than 50 miles	975	40.2
51–100 miles	434	17.9
101–500 miles	547	22.6
Greater than 500 miles	218	9.0
Other	228	9.4
Missing data	22	0.9
Have you ever visited your local hospital for treatment of your Lyme disease?	963	39.7
[Of those who visited local hospital for treatment]: Had difficulty obtaining treatment at local hospital	787	81.7
Since your diagnosis with Lyme disease, have you applied for a medical insurance policy?	416	17.2
[Of those who applied for a medical insurance policy]: Were turned down for insurance based on Lyme diagnosis	166	39.9
Has your medical insurer ever required that you see an infectious disease specialist to cover your treatment?	311	12.8
Applied for private, state, or public disability benefits	739	30.5
[Of those who applied]: denied these benefits based on Infectious Diseases Society of America guidelines	285	38.6

9. Address the source of the problem: the ticks.

Just as the Task Force on West Nile Virus found with mosquitoes, addressing the vector (ticks) is a way to reduce Lyme disease transmission and therefore human incidence. Research funding for this long-ignored field of science would provide the greatest potential for broad-scope progress in addressing all the tick-borne diseases.

Over the past several years, a number of significant advances have emerged to address the problem of the tick population (for example, a "spit" vaccine which prevents ticks from attaching and transmitting any of the tick-borne diseases; an organic lawn fertilizer that is inhospitable to adult ticks). With predictable regularity, ideas that would appear to be viable, both scientifically and financially, have lost their funding. In some cases, professional conflicts between the applicant for funding and professional competitors sitting on the review panels, have been cited as the reason for lost funding. While it's impossible to know for sure what agendas or biases reviewers may or may not have, the scope of this problem calls for broad research reflecting varying approaches to the problems at hand.

10. Allocate money to the NYS DOH to be used for basic and applied research.

And insure that the funds are NOT diverted to support research that is designed solely to support the IDSA status quo.

CONCLUSION

The victims who have been battling tick borne diseases, their insurance companies, and a mainstream medical establishment that denies their illness are suffering like no other group in this country. These men, women, and children (who are at very high risk), through no fault of their own, have contracted an infectious disease that has become the center of a personal, political and commercial power struggle. These are sick people who need medical help and a reasonable, comprehensive, and responsive public health policy.

The people who are affected by these diseases, and especially by the ravages of late-stage Lyme disease, need the New York State Legislature and the Governor to institute a broad-based program of reforms to get a completely derailed system back on track. This need is URGENT and statewide.

Members of advocacy groups across the state and across the nation stand ready to provide the NYS Special Task Force with any documentation, testimony, insights, or other information that will be of assistance in developing a program of reforms that will set the standard for public response to an epidemic that is posing a national threat.

ROADMAP TO REFORM

Recommendations for Developing Public Policy Responses to the Challenges of Tick Borne Diseases

On behalf of the victims of Lyme disease in New York State, the Lyme Action Network respectfully submits these recommendations to the Senate Special Task Force on Lyme and Tick Borne Diseases.

RECOMMENDATIONS

Recommendation 1: Eliminate the “two-tier” testing system and revise the diagnostic algorithm for Lyme disease in New York State, in favor of the Western blot interpreted according to evidence-based standards, which indicate that the “5-band” interpretation of positive is overly restrictive for diagnosis. Additionally, diagnostic criteria for tick-borne coinfections (babesiosis, ehrlichiosis, anaplasmosis, bartonellosis, and mycoplasmosis) should be included in the algorithm.

Recommendation 2: Mandate that medical providers inform patients about the accuracy rate of the testing procedures; disclose poor predictive value of serological tests to patients; provide information on reference laboratory options available to them; and include patients in the decision-making process.

Recommendation 3: Mandate that reference laboratories report in full the results of the Western Blot for *Borrelia burgdorferi*, as well as the results of testing for other tick-borne coinfections. Mandate education for New York State physicians to ensure their understanding of laboratory testing procedures, the limitations of laboratory testing for Lyme disease, and how to interpret the full results of a Western blot test.

Recommendation 4: Until better testing is available, permit PCR testing for Lyme disease as a possible diagnostic tool and permit patients access to other testing options for possible coinfections.

Recommendation 5: As the CDC surveillance criteria was never intended to be a diagnostic guideline, New York State medical professionals should receive specific training and regular updates regarding the current best practices being employed in the field, by both IDSA AND ILADS practitioners, as well as other experts in the field; updates about new diagnostic tests; and thorough and unbiased continuing education for identifying, diagnosing, and treating Lyme and all other tick borne diseases. Medical licensure should incorporate a section on Lyme & TBDs in the infection control course that every health care practitioner in NYS is required to take and pass every 4 years. IT IS ESSENTIAL THAT ALL MEDICAL POINTS OF VIEW BE REPRESENTED IN TRAINING, NOT JUST THE IDSA PERSPECTIVE.

Recommendation 6: Protect physicians who use clinical judgment and treat outside of the IDSA guidelines from unwarranted investigation, harassment, and intimidation from the Office of Professional Medical Conduct of the NYS DOH. Mandate true due process in any actions, and require full disclosure of complainant's identity. Some other states allow the physicians to know who the complainant is, and what the nature of the complaint is. With the complaint process in New York State being employed to further political, not medical agendas, instituting due process would be a fair and reasonable response to past abuses of the system.

Recommendation 7: The Task Force needs to completely understand the issues confronting New York's victims of tick borne diseases and their care providers. To this end, conducting investigative hearings throughout the state would enable the Task force to understand the scope of the multi-dimensional problem from the victims' points of view.

Recommendation 8: The Task Force needs to ensure that special interests, influence, and professional conflicts of interest do not conspire to deny the residents of New York State the BEST opportunities to address the issue of ticks as vectors of several potentially disabling diseases. Employ the office the NYS Attorney General to litigate an end to the monopoly imposed and enforced by the IDSA with regard to diagnosis and treatment of Lyme disease. New York State Department of Health and the Office of Professional Medical Conduct must acknowledge that legitimate controversy exist in the field, and not allow the OPMC to be utilized to advance or protect the private interests of the IDSA and/or its members.

Recommendation 9: The Task Force needs to solicit the balanced and unbiased input of the leading Lyme disease experts and researchers in the country to formulate the plan for the future. Going forward, the plan should include the formation of diverse and multi-disciplinary New York State Task Force on Tick Borne Diseases to address all the complex issues associated with this problem.

Recommendation 10: Essential to any effort to ameliorate tick-borne disease is an integrative approach to decreasing tick populations in NYS. Therefore, the development and implementation of a successful Integrated Pest Management program is essential.

Recommendation 11: Fund research to a level appropriate for an epidemic of infectious disease. Direct research dollars for improved understanding of Lyme disease in all its forms, as well as for other tick borne diseases, with special emphasis on improving diagnostics and therapeutics through well-designed impartial, and well-implemented research studies.

Recommendation 12: Recognize the inherent limitations of any yet-to-be-released Lyme vaccine. It is unknown whether the new versions of the previously unsuccessful vaccine will be any better than its predecessor. While everyone hopes this effort is successful, no amount of success in vaccinating against Lyme disease will eliminate the infections of the other serious tick-borne diseases. A Lyme vaccine is only a single, limited bullet in what needs to be a much more robust arsenal to fight these diseases.

CITATIONS

^{1, 2} *Comparison of Lyme Disease Prevalence and Disease Reporting in an Endemic Area*, Holly Ahern, *Journal of Microbiology Research*, December 2013. Figured from CDC census data (census.gov)

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⁴ *Active Infection: Evidence of Persistence in Chronic Lyme Disease*, Steven Phillips, MD, *Testimony before IDSA Hearing*, July 30, 2009, http://www.ilads.org/lyme_disease/media/lyme_video_phillips.html

⁵ (http://lymedisease.org/news/lyme_disease_views/retreatment-study-flawed.html#sthash.YquJ0L6L.dpuf)

⁶ *Lyme Disease Testing Disclosure Act*, House bill 1933, March 2013

⁷ *Two-Year Evaluation of Borrelia burgdorferi Culture and Supplemental Tests for Definitive Diagnosis of Lyme Disease*, Peggy Coulter,¹ Clara Lema,¹ Diane Flayhart,¹ Amy S. Linhardt,¹ John N. Aucott, Paul G. Auwaerter,² and J. Stephen Dumler, *JOURNAL OF CLINICAL MICROBIOLOGY*, Oct. 2005, p. 5080–5084 Vol. 43, No. 10

⁸ Citation: from Letter by Ellen Lubarsky in "Lyme Times" Summer 2000, quoting a letter written to Lyme disease patients dated 12/21/99 by Ansel Marks, Executive Secretary of the OPMC, stating, "Rarely, if ever, have ... published guidelines indicated that anything more than two-three weeks of antibiotics are required to cure Lyme disease."