

**TICKING TIME BOMB:
AN UPDATE ON THE LYME AND TICK-BORNE DISEASE
EPIDEMIC IN NEW YORK STATE**



TASK FORCE ON LYME AND TICK-BORNE DISEASES
Senator Sue Serino, Chair

SENATE STANDING COMMITTEE ON HEALTH
Senator Kemp Hannon, Chair

October 2017

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Executive Summary

This year was particularly bad for ticks and tick-borne diseases (TBDs), with Lyme and other TBDs, including deadly cases of Powassan, reaching new areas of the state. The Senate Majority Coalition Task Force on Lyme and Tick-Borne Diseases, in conjunction with the Senate Standing Committee on Health, held a hearing in August to focus on the ongoing battle with Lyme and TBDs, as well as the dangers and steps to avert greater problems.

The Senate is a driving force for advancements in the field of Lyme and other TBDs. The creation of the Lyme and Tick-Borne Disease Task Force (Task Force) brought needed attention to the issue. The Task Force issued a report, which among other things called on the State Department of Health to issue an Action Plan treating Lyme and other TBDs with the same urgency it has for other vector-borne diseases. Senate members held forums across the state bringing together experts in the field. The Senate has continuously funded: (i) education and awareness campaigns, (ii) tick collection and testing, and (iii) annual conferences bringing together counties and experts to collaborate. The Senate also proposed and passed legislation to ensure health care providers treating Lyme are not unjustly targeted for their treatment techniques solely on the grounds that they are not generally accepted by the medical community. Despite these efforts, the field has seen inadequate advancement. Much more is needed to gain a deeper understanding of the diseases and progress in areas of diagnosis, treatment and prevention.

Given the serious consequences of infection, the wider geographic spread, and the need for consensus and advancements in the field, the August 2017 hearing brought together local and state officials, and other experts, to call for increased efforts on Lyme and tick-borne infections at all levels. Senators heard from the Commissioner of Health, local health officials, patients, physicians, and researchers.

Testimony focused on inadequacies in current practices regarding diagnosis and treatment, especially the inadequacy of current testing techniques. Patients told stories of despair, where the lack of a diagnosis left them in search of a reason for their ailments all whilst not being treated. Public health officials spoke of current efforts to educate more providers and the public. Scientists spoke of current research efforts and the need for more funding and resources to make greater strides.

This report provides a series of recommendations arising out of the testimony provided at the hearing. With these recommendations, the state will be able to address the obstacles and hurdles New Yorkers face today and work to advance the medical and scientific fields of Lyme and other TBDs.

Recommendations

Action Plan and Funding: Based on 2013 recommendations from this Task Force, and given the testimony presented at the 2017 hearing, the Task Force members again recommend that a comprehensive Action Plan be developed by the Department of Health in preparation for the 2018 Executive Budget cycle and to work with the Legislature to implement a multi-pronged approach of surveillance, prevention, detection, and intervention in Lyme and TBD cases on a statewide level.

New York State Specific Protocol and Notification: Given the reliability issues that were highlighted in the hearing surrounding the serology tests and challenges with provider education, the Senate recommends the Commissioner, in collaboration with health care professionals, establish a medical protocol for diagnosis and treatment, which shall address what providers should do in instances where a test is negative but symptoms persist. Further, patients should be notified that false negatives occur so they can fully understand their test results, and work with their provider to determine the best course of treatment and whether a second test is appropriate. By creating a standard notice to be distributed to all those tested, patients are educated on the symptoms, risks, and reliability of testing (S. 6926 Hannon/Serino).

Insurance Coverage: To accurately assess the costs of coverage of long term symptoms of Lyme, the Task Force recommends that the New York State Health Quality and Cost Containment Commission be reconstituted in the 2018-2019FY Executive Budget, to ensure a comprehensive assessment of insurance considerations by the Department of Financial Services (S. 2168 of 2017 Serino – passed Senate).

Testing for Children: Given that children are more likely to be in contact with ticks, and the general misdiagnosis potential for Lyme and other TBDs, the Task Force recommends increased testing in children who present with symptoms that are related to these types of illnesses.

Informational Technology: Recent developments in public health programs have increased the use of informational technology and social media to inform the public about the dangers of Lyme and TBDs, as well as enhanced reporting to public health authorities. The Task Force recommends that the Department of Health explore innovative means to encourage public awareness and increased surveillance techniques.¹

Pursue Anthem Foundation Initiatives: At Senator Hannon’s request during the hearing, Dr. Hersh, Chief Clinical of Empire Blue Cross Blue Shield followed up with ways in which Anthem, Empire BlueCross BlueShield’s parent company, could assist the Senate’s efforts to combat Lyme disease through its Foundation including:

¹ See: “Validation of ESPnet for use as an alternative to Lyme Disease Surveillance in Massachusetts.” (available at: <https://www.cdc.gov/ophss/chiic/projects/2015/ideas/validation-of-espnet-for-use-as-an-alternative-to-lyme-disease-surveillance-in-massachusetts.html>); see also “Tickborne Diseases of the United States App.” (available at: <https://www.cdc.gov/mobile/applications/MobileFramework/tickborne-diseases.html>).

- **Protocol for Lab Testing** – The most recent testing protocol for Lyme disease was issued in 1995 based on recommendations developed at the Second National Conference on Serologic Diagnosis of Lyme Disease held in October 1994. Anthem will pursue sponsoring a successor conference to review the most recent developments and make any needed changes to the recommendations. This work can help inform provider education.
- **Review National Claims Data on Lyme Disease Treatment** – Anthem covers 35 million lives nationally and has valuable information on potential best practices on both short- and long-term treatment, which might be pursued to inform treatment and insurance coverage of such treatment.
- **Sponsor a Peer-Reviewed Trial** – Anthem will explore the feasibility of sponsoring a peer-reviewed trial for the long-term treatment of Post-treatment Lyme Disease Syndrome (Chronic Lyme) for those patients who still experience symptoms after six months.
- **Develop Educational Materials for Health Care Providers** – Testimony at the hearing identified the need for better education of physicians, nurse practitioners and physician assistants in the area of best practices for diagnosing and treating Lyme disease. Anthem should develop educational materials for health care providers including CME courses and various forms of media efforts to educate on the importance of using symptoms and potential exposure rather than relying solely on testing. Education of the general public by Anthem regarding prevention, symptoms and the importance of effective treatment would also be valuable.

Federal Collaboration: Due to recent attention given to Lyme and tick-borne diseases at the federal level, it is recommended that there be increased dialogue between the State and our federal partners, including the CDC,² to issue guidance to medical providers about appropriate testing and treatments available as well as research and clinical trial opportunities.³

² Please note that the Centers for Disease Control were invited to participate in the August 2017 hearing and the invitation was declined.

³ As of June 8, 2017, released updated diagnostics through a webinar that can be found here: <https://www.cdc.gov/lyme/diagnostesting/HHS-research-updates.html>.

Lyme & Tick-Borne Diseases: New York Impacts

New York has found itself as an epicenter in the Lyme disease outbreak that has resulted in Lyme being the most commonly reported vector-borne illness in the United States. Lyme disease is caused through the transmission of the *Borrelia burgdorferi* bacterium carried by infected ticks. Ticks can attach to any part of the body, including areas that are hard to inspect such as the groin, scalp, and armpit areas. Lyme disease can result in a range of symptoms including, but not limited to, fever, rash, facial paralysis, and arthritis.ⁱ Given its similarities to other common infections, it is often mistaken for chronic fatigue syndrome, early Alzheimer's disease, fibromyalgia, lupus, and multiple sclerosis, among others.

At the August 2017 hearing, the Commissioner of Health noted that there are approximately, “8,000 cases of Lyme disease, 700 cases of anaplasmosis, 400 cases of babesiosis, 100 cases of ehrlichiosis, and 30 cases of other tick-borne illnesses that are reported to the Department annually.” He continued, “there are undoubtedly many more cases, particularly of Lyme disease, that are treated by community physicians and are not reported, or do not meet the case definition.”ⁱⁱ More information from the Department of Health can be found on its website: <https://www.health.ny.gov/diseases/communicable/Lyme/>. The CDC also provides information on Lyme and tick-borne diseases at: www.cdc.gov/ticks/tickbornediseases/index.html.

Although rare, Lyme disease can also be deadly, especially if it turns into Lyme carditis. In August of 2013, the death of a 17-year-old Poughkeepsie, New York boy was believed to be the result of a tick bite that caused Lyme disease to invade his heart. Lyme carditis occurs when Lyme disease bacteria infects the tissues of the heart, leading to disruption of the electrical signals from the heart's upper to lower chambers, an important process in the beating of the heart. Lyme carditis occurs in approximately 1% of reported Lyme disease cases and is evidenced in symptoms including light-headedness, fainting, shortness of breath, heart palpitations, and/or chest pain.

Infection rates and long-term consequences of Lyme infections do not have age limitations. In fact, Dr. Matt Frye, an entomologist with Cornell University testified that those most affected by Lyme disease are children, particularly boys, aged five to nine years old.ⁱⁱⁱ Doctors from Stony Brook University Hospital and Southampton Hospital further testified at the 2017 Senate hearing that, “specifically, 1,026 Lyme cases (based on ICD codes) were reported in our electronic medical records (EMR) for the period between 2010-2016. In that time, a total of 284 patients required hospitalization. In Pediatrics, we see inpatient admissions for Lyme disease as well, including Lyme carditis and Lyme meningitis.”^{iv4}

While Lyme disease is the most commonly reported vector-borne illness in the nation, it notably

⁴ Please note, the Division of Infectious Diseases recently announced a Tick-Borne Disease Referral Clinic at Stony Brook University Hospital that will service the local medical community and residents (https://medicine.stonybrookmedicine.edu/medicine/infectious_diseases/tick_clinic). The Pediatric Infectious Diseases Unit also receives tick-borne disease referrals (<https://www.stonybrookchildrens.org/lyme-disease> or call 631-444-KIDS (5437)).

does not occur nationally, but rather, is concentrated heavily in the Northeast and upper Midwest of the United States.^v In 2015, 95% of confirmed cases of Lyme disease were reported from a total of 14 states (Connecticut, Delaware, Maine, Maryland, Massachusetts, Minnesota, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, Virginia, Wisconsin). In fact, 94% of Lyme disease cases were reported in 12 states in 2010, including New York. In 2013, the CDC reported that New York had the second-highest number of confirmed Lyme disease cases (42,111 cases) in the United States during 2003-2012. Remarkably, the CDC estimates that the actual number of cases of Lyme disease is 10 times higher than the reported numbers, which causes grave concern for New Yorkers. The deer tick, or carrier, has been found in 42 counties of New York and is common in areas where deer and woodland mice can be found.

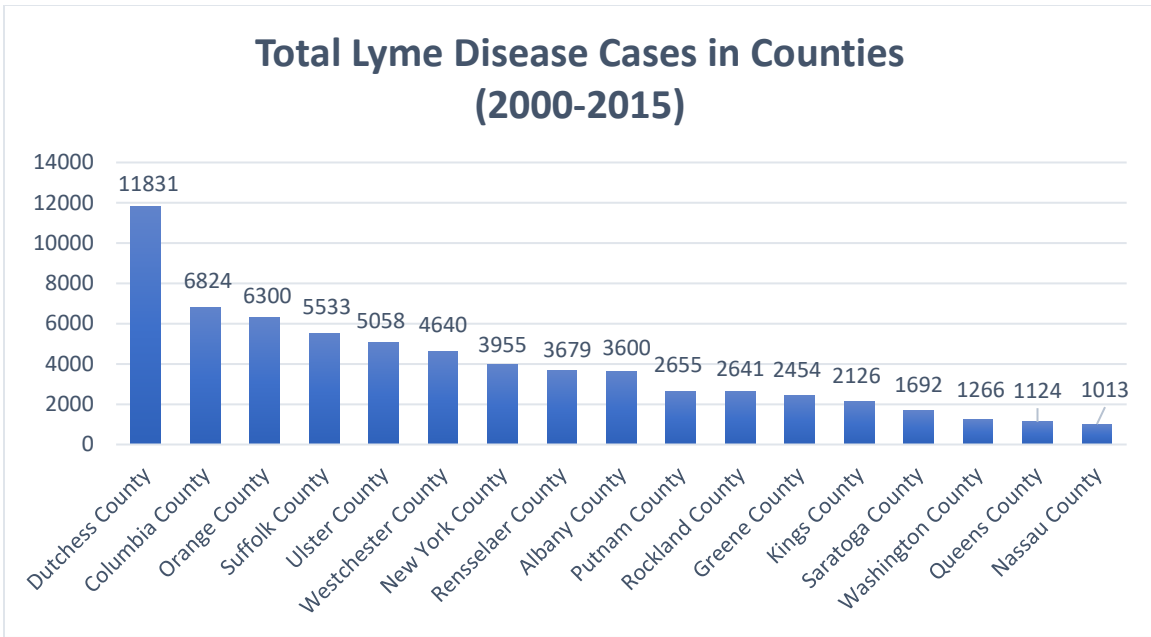
The geographic spread of Lyme disease in New York State, which was once largely confined to the Hudson Valley and Long Island, has been increasing over recent years. The Commissioner reiterated this at the 2017 hearing. He commented, “the geographic distribution has changed over the years, as well. Where Lyme was once a disease of Long Island and the lower Hudson Valley, it is now found all over the state, with increasing numbers in the Adirondack region and areas west of Syracuse. Diseases like anaplasmosis and babesiosis are following that same geographic pattern, with a 10- to 15-year lag behind Lyme disease.”^{vi}

Progression of Reported Cases of Lyme Disease Over Time



Source: Centers for Disease Control and Prevention^{vii}

As can be seen in the geographic mapping of infections, the distribution of illness has expanded north and west, increasing the public health threat to all other parts of New York State. The Department of Health from Broome County gave firsthand experience at the Senate hearing. Marianne Yourdon, R.N., testified that in the early years of infection, until 2007, there were no patients diagnosed with Lyme disease who were infected from the area. However, by 2011, the number of infections had almost tripled, and in 2016, it was reported that Broome County, located in the Southern Tier, had its highest infection count to date with almost 300 cases originating from the area.^{viii} Given these geographic trends, it is important that the State incentivize counties with histories of identification, treatment, and prevention to assist those counties who are facing increased infection rates as well as allocate additional resources for public awareness and educational materials.



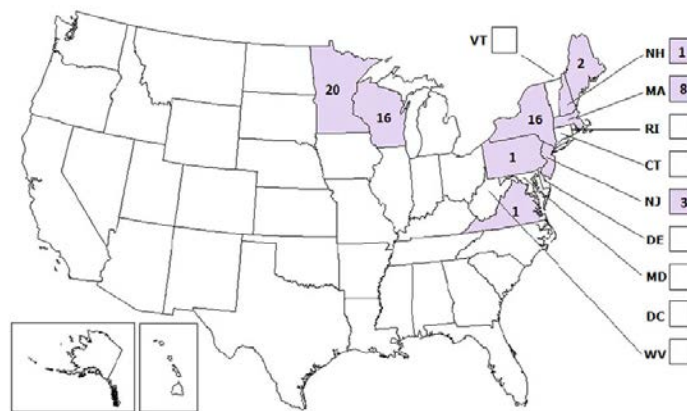
Source: Centers for Disease Control and Prevention^{ix}

Experience is important and has proven to be instrumental in mounting effective responses. As such, we encourage the State to invest even more in promising local projects, including the distribution of tick kits, as well as research collaboratives with public and private partners. New York continues to have the distinction of being home to award-winning research facilities and medical schools. While testimony described several new research projects underway, it is important that New York continue to capitalize on the opportunities that these institutions offer to help promote a better understanding of TBDs and treatment.

Human Powassan (POW) Virus: 2017 Infections & State Responses

While there has been significant, and justifiable, concern paid to the outbreak of Lyme disease in New York, other tick-borne diseases pose equally dangerous public health risks. Recently, deaths and serious infections in Upstate New York raise alarm at the tragic consequences that these infections can cause. According to the Centers for Disease Control and Prevention, 77 cases of POW virus disease were reported in the United States over the past 10 years, with most cases originating in the Northeast and Great Lakes regions.^x In fact, of the total 77 reported cases of POW virus between the years 2006-2015, New York has had 16 reported cases of the neuroinvasive disease cases - the second highest number in the country.

Powassan Neuroinvasive Disease Cases Reported by State, 2006-2015



Diagnosis and Treatment of Lyme and Tick-Borne Diseases

Patient Insight

Achieving an accurate diagnosis, enabling patients to receive proper treatment, was the main problem identified by patients. The need for an accurate diagnostic tool was a consistent theme all patients who testified discussed with great frustration. Martin Wilson, a patient, described to the senators at the hearing that his first indication of Lyme disease infection was in September 2009, but because of a negative Western blot test (which he emphasized was only 44% accurate), he did not receive an official diagnosis until October 2015. In that time, he saw 25 doctors, including five neurologists, six internists, four infectious disease specialists, two rheumatologists, and two cardiologists.^{xiii} This is an experience many patients recount.

The impacts of these serious infections are not just specific to the patient, as highlighted by the patients at the panel. Jill Auerbach testified, “my entire family was affected, our son a high school senior was horrified, it impacted his college education; it almost broke up my marriage, our finances were affected, and more.”^{xiv} She told her experience of having to leave her job as an IBM systems programmer and the devastating cognitive impacts, including paralyzing headaches, sleep loss, and “Lyme rage”.

Christina Fisk, President of the Lyme Action Network, told multiple stories of misdiagnoses, including that of a two-year-old boy who developed signature symptoms of Lyme disease but was discontinued from treatment because of a false negative blood test, resulting in serious health complications. She also shared a story of a young man who was diagnosed with late-stage neurological Lyme disease and was committed to a psychiatric institution, and who is currently not receiving treatment because family requests for treatment under new National Guideline Clearinghouse (NGC) protocols were denied.^{xv}

Common to all accounts was frustration over the lengthy diagnosis process, disappointment in the efficacy of current testing procedures, misinformation and a lack of consensus in the medical community, as well as barriers to coverage from health insurance providers.

With respect to health insurance coverage, senators heard from Craig Hersh, M.D., the Chief Clinical Officer of Blue Cross Blue Shield, who indicated that in his experience doctors were quick to order antibiotics for the authorized 28-day treatment, and that the current medical guidelines did not stand in the way of early treatment of Lyme disease.^{xvi} He acknowledged that the treatment of Chronic Lyme disease was controversial given disagreement as to whether Lyme disease symptoms were being treated, or other undiagnosed diseases were at issue. At Senator Hannon’s request during the hearing, Dr. Hersh followed up with ways in which Empire BlueCross BlueShield’s Foundation could assist the Senate’s efforts to combat Lyme disease. Several suggestions relative to accurate testing, research on effective clinical management and enhanced education and awareness were provided and are incorporated into the recommendation section of this report.

Physician Insight

Dr. Sunil Sood, representing the Infectious Disease Society of America (IDSA) and Dr. Steven Bock, representing the International Lyme and Associated Disease Society (ILADS) testified at the hearing. While these organizations have different perspectives and guidelines on Lyme and Chronic Lyme in particular, the organizations do agree that more accurate diagnostic tests are needed, as well as more funding to address the epidemic.

As a member of the joint IDSA-American College of Rheumatology-American Academy of Neurology panel, which is in the process of revising IDSA's current guidelines for the assessment, treatment and prevention of Lyme disease, Dr. Sood, is well versed in Lyme and TBDs. Dr. Sood cautioned against "over-testing and over diagnosis" which may lead to misdiagnosis and "dangerous treatments including long term antibiotic therapy." However, he also testified that "if acute serum is negative, you still have a high suspicion, you can go ahead and start treatment then repeat the serum test in 2-4 weeks. At that point you haven't lost that opportunity to treat nor harm... no harm in giving an early empiric course of antibiotics while waiting for confirmation of the diagnosis."

Dr. Bock, testified for ILADS where he serves as the organization's Membership Chairman. Based on his nearly 30 years of experience diagnosing and treating Lyme, Dr. Bock stressed that given the poor accuracy rate of both the initial ELISA and follow up Western blot test which make up the two tiered test (see Appendix D), negative test results should not rule out Lyme and TBDs and symptoms should be treated. "The ELISA test is only 49% sensitive. So that's like flipping a coin," he explained. "I see a lot of times people go to a physician with an EM rash and they say, well, you know what, we'll just test you and see if it's positive. No, they have an EM rash, they have Lyme – you have to treat them....With treatment, my main tenants are, treat Lyme clinically. You use the test to support your diagnosis."

Patients testified that their diagnoses of Lyme took extended periods of time, including one patient who went undiagnosed for a decade.^{xvii} The medical community expressed similar warnings regarding the unreliability of serological testing, and noted that clinical examinations were a vital part of the diagnostic process. Dr. Luis Marcos, the Director of the Adult Lyme and Tick-Borne Disease Center at Stony Brook Medicine stated, "a major challenge we encounter is the diagnosis of early Lyme disease by serological testing, since these tests can be negative in about 60% of early cases and if treated promptly, early conversion may be aborted. Thus, understanding the clinical signs and symptoms of Lyme disease is important for appropriate test ordering and treatment." As such, diagnosis of Lyme disease remains an important area of focus.

Bryon Backenson, Deputy Director of the Bureau of Communicable Disease Control at the Department of Health, explained that health care provider education has been challenging, particularly in areas of the state where Lyme and other TBDs have not traditionally been. "One of the issues is trying to have the physician trust their eyes and basically say, this is a bull's eye rash, this is Lyme disease, we know you were bitten by a tick." He explained how a rash may develop more quickly after a bite than the body's antibodies kick in, resulting in a negative test. "Often times you will wind up with physicians who will trust the test results sometimes more than they trust their eyes."

Current Research Efforts

Northeast Regional Center for Excellence in Vector Borne Diseases

In 2016, the Centers for Disease Control and Prevention funded the Northeast Regional Center for Excellence in Vector Borne Diseases as one of four national centers with a \$10 million award. A representative from Cornell testified about the center (www.neregionalvectorcenter.com), which is a collaborative project located at Cornell's Ithaca campus and includes over 60 vector-borne disease professionals working at over 20 different institutions in the Northeast region, including Columbia University, the New York State Department of Health, the Connecticut Agricultural Experiment Stations, and others.⁵ The goals of the Center are to promote a collaboration between researchers, health workers and educators to effectuate three goals:

- Workforce Training - Train a new cohort of public health entomologists with the knowledge and skills to rapidly detect, prevent and respond to vector-borne disease threats in the United States, including offering a new graduate degree program.
- Connecting with the Community - Build effective collaborations between academic communities and public health organizations across government for vector-borne disease surveillance, response and prevention
- Research Clusters - Conduct applied research to develop and validate vector-borne disease prevention and control tools and methods^{xix}

Tick Project

Senators also heard testimony from Dr. Richard Ostfeld, of the Cary Institute of Ecosystem Studies, regarding the Tick Project, an initiative to test environmental interventions designed to kill ticks in residential neighborhoods. The ongoing five-year study in Dutchess County, which is funded largely through a private foundation grant but also received early funding through a NYS Senate initiative grant sponsored by Senator Serino, has focused on two treatments that are currently being tested: (1) a naturally occurring fungus ("Met52"®) that kills ticks but is harmless to humans and animals; and (2) a device called a "bait box" that attracts mice and chipmunks and applies fipronil, which kills ticks on the host.^{xx} If successful, these treatments would present an option to control blacklegged tick abundance and thereby prevent exposure to tick-borne diseases.

LymeSeq

Testimony was also heard about the research on new diagnostic tests being conducted by a professor of microbiology at SUNY Adirondack, Holly Ahern, MS, MT(ASP). Professor Ahern presented her personal experiences with Lyme infection through the context of her daughter's infection and shed light on the real-life impacts of this serious infection. She testified that her daughter came home from college, "complaining of aches and pains, which escalated to searing

⁵ Please note, subsequent to the August 2017 hearing, the Chairs of the Standing Committee of Health and the Senate Lyme and Tick-Borne Disease Task Force met with representatives of Cornell University and the Department of Health for a comprehensive review and briefing on the CDC funded Center for Excellence.

headaches, a heart arrhythmia, feeling like she had electricity running up and down her arms and legs...”^{xxi} Professor Ahern indicated that her daughter waited almost a year for a diagnosis and faced a battle with her health insurance company for coverage. As a result of her personal experience, Professor Ahern has partnered with other researchers on a potential new diagnostic tool called LymeSeq. She has used funding provided by the New York State Senate Lyme and Tick-Borne Disease Task Force to build a biorepository of human blood samples that will be tested for tick-borne infections and then used to advance development of the molecular detection assay (LymeSeq), which will identify DNA and RNA from tick-borne microbes.^{xxii} Professor Ahern testified that this type of test will help to fill the gaps in diagnostic testing to allow physicians to determine the infection status of patients and increase the probability of an accurate diagnosis. Currently available tests, which are not very accurate, look for antibodies people may have to the tick-borne infections rather than evidence of the tick-borne microbes themselves. Additionally, Professor Ahern testified that “in the future, the biorepository will be available to other researchers to advance the state of the science for all tick-borne diseases.”

Treatment Modalities

Finally, testimony revealed national research underway to determine the best treatment modalities. When questioned by Senate Health Chair, Senator Kemp Hannon, the Chief Clinical Officer of Blue Cross Blue Shield, Dr. Craig Hersh, and counsel, Sean Doolan, indicated that there is a national coverage policy being developed by a body under the parent company of Empire Blue Cross Blue Shield, Anthem. It was further clarified that the body is using evidence based guidelines, internal and external experts and physicians, and research data and clinical trial data to explore different treatment modalities of Lyme disease for the national coverage policy.^{xxiii}

The need for research cannot be understated. At the 2017 hearing, Senators heard consistent accounts of more infected ticks in more areas of the state. Patients and medical providers testified of their frustration over the lack of reliable Lyme disease testing and inconsistent treatment guidelines. These research efforts underway are encouraging, but much more is needed.

Funding: Progress & Limitations

It cannot be overstated that there are considerable constraints on State funding as we continue to face increased demands across sectors. Nevertheless, it is important that New York continues to recognize the unique public health threats that Lyme and tick-borne diseases pose to residents, and the long-term consequences that these infections can have, particularly if not correctly diagnosed and treated early, including health, economic, and psychological impacts.

Despite assurances by the Commissioner of Health at the 2017 hearing that funding levels remain adequate for Lyme and TBDs at the Department, it is important that they not only reflect the actual costs of these illnesses, but also the commitment that our State has made to progress in their prevention, identification, and treatment. *While this is difficult given funding limitations, we recommend further funding given the public health threat posed to New Yorkers.*

For example, in response to the emergence of West Nile Virus, the New York State Department of Health issued an Action Plan. Similarly, with the Zika outbreak that began in 2015, New York announced a six-point Action Plan that included free starter kits of mosquito dunks (approximately 100,000), testing at Wadsworth Center Laboratory of collected mosquitos across 1,000 locations for surveillance, and the ability to deploy rapid response teams wherever local transmission is confirmed.^{xxiv} While these mosquito-borne viruses pose very serious health issues and should be considered important public health risks, the extent of Lyme and TBD cases in New York State are significant and demand comparable investments from the state and federal government.

Appendix A

Public Hearing Witness List

A full recording of the August 29th hearing can be found online at:

<https://www.nysenate.gov/calendar/public-hearings/august-29-2017/public-hearing-identify-and-determine-best-practices-0>

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Commissioner of NYS Department of Health

P. Bryon Backenson

Deputy Director, Bureau of Communicable Disease Control

Center for Community Health, NYS Department of Health

Dr. Ronald Limberger

Director, Division of Infectious Diseases

Wadsworth Center, NYS Department of Health

County Department of Health Panel:

Andrew Evans,

Dutchess County Department of Health

Jean Ralston, RD, MSN,

Putnam County Department of Health

Marianne Yourdon, RN,

Broome County Department of Health

Steven Bock, MD,

Hudson Valley Physician

International Lyme and Associated Diseases Society

Patient Panel:

Jill Auerbach,

Patient, Chair of the Hudson Valley Lyme Disease Association

Martin Wilson,

Patient, Long Island

Audrey Mitchell, (Video)

Patient, Central New York

Sunil Sood, MD,

Chairman of Pediatrics, Southside Hospital, Infectious Diseases Attending, Cohen Children's Medical Center, Professor of Pediatrics and Family Medicine, Hofstra Northwell School of Medicine

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Appendix B

Background of Lyme and Tick-Borne Diseases (TBDs) in New York

Since first identified in the 1970's, Lyme and other TBDs have posed a significant public health threat to New Yorkers, commanding considerable State focus and resources over time. Nevertheless, the misinformation about ticks and TBDs is not only prevalent across New Yorkers, but also remains a concern for public health authorities and the medical community today. Dr. Matt Frye, an entomologist from Cornell University, testified before the Senate hearing, reiterating that misinformation regarding the types of tick species, removal techniques, varying infections, and resultant symptoms is widespread—which can result in untimely medical intervention, a lack of proper precautions, and delay in treatment.^{xxv}

Because Lyme disease is often the primary focus of education and awareness, it is important that the medical community and government officials emphasize that it can also co-exist with other tick-borne illnesses, impacting treatment and symptom presentation; and these infections pose their own serious risks. Dr. Luis Marcos, from Stony Brook University Hospital noted at the 2017 Senate hearing, “we also need to understand Lyme disease in the context of co-infections with other tick-borne pathogens, because patients with Lyme and babesiosis may have worsening symptoms that may last for several months. Babesiosis, which has a longer incubation period than Lyme or other tick-borne diseases, may present later and could, therefore, not be diagnosed when the patient has acute Lyme disease. This is of particular importance as the antibiotics that treat Lyme and some other tick-borne infections will not also treat babesiosis.”^{xxvi}

TBDs can be either viral, bacterial or parasitic. Currently, the spectrum of tick-borne diseases that pose significant risks in New York include, but are not limited to:

Infection	Symptoms (this list is not exhaustive)	Presentation
<u>Anaplasmosis</u>	Fever, headache, chills, and muscle aches	Symptoms generally appear within 1-2 weeks of a bite from a blacklegged tick or western blacklegged tick
<u>Babesiosis</u>	Nonspecific flu-like symptoms including fever, chills, headache, and body aches	Symptoms generally appear within 1 week of a bite from a blacklegged tick
<u>Ehrlichiosis</u>	Fever, headache, fatigue, and muscle aches	Symptoms generally appear within 1-2 weeks of a bite from an infected tick (lone star tick)
<u>Lyme Disease</u>	Fever, headache, fatigue, and a characteristic skin rash called erythema migrans. If left untreated, infection can spread to the joints, heart, and nervous system.	The characteristic rash, erythema migrans (EM) generally begins at the site of a bite from an infected blacklegged tick, while other symptoms can occur days to months after the bite

Rocky Mountain Spotted Fever

Fever, headache, and rash

A rash can develop 2-4 days after the fever begins. Early signs and symptoms are not specific to Rocky Mountain Spotted Fever and can rapidly progress to a serious and life threatening condition. The infection can be carried by several species of ticks including the American dog tick, the Rocky Mountain wood tick, and the brown dog tick.

Powassan Virus

Fever, headache, vomiting, weakness, confusion, seizures, and memory loss. Long-term neurologic problems may occur.

The incubation period from tick bite to the onset of illness ranges from one week to one month.

STARI

Fatigue, fever, headache, muscle and joint pains, bull’s-eye rash

A bull’s-eye lesion develops around the site of a bite from the lone Star tick—usually within seven days of the tick bite.

Table 1 For information on other tick-borne related illnesses please see the websites for the Centers for Disease Control [<https://www.cdc.gov/ticks/diseases/index.html>] and the New York State Department of Health [<https://www.health.ny.gov/diseases/communicable/lyme/>].



Source: Centers for Disease Control and Prevention^{xxvii}

Blacklegged Tick

- Carries:
- Lyme
- Babesiosis
- Anaplasmosis
- Powassan

American Dog Tick

- Carries:
- Rocky Mountain spotted fever

Lone Star Tick

- Carries:
- Ehrlichiosis
- STARI

Note that many of the resultant infections associated with the spread of TBDs are dependent upon the type of tick that is the source of the infection. As the Commissioner noted in the August 2017 Senate hearing, this has varied given new trends in tick distributions across the State. He testified, “for most of the past 40 years, the deer tick (or blacklegged tick) has been the

most common tick in the state. The spread of many of the diseases previously mentioned is directly related to its increase in population and distribution across New York. However, in recent years, the lone star tick population has been rapidly increasing across Long Island, seemingly overtaking the deer tick population. While the lone star tick populations have gone up, the deer tick populations have gone down. This should result in a decrease in the number of cases of Lyme disease, anaplasmosis, and babesiosis in areas where deer tick populations are decreasing, and an increase in the number of ehrlichiosis cases where the numbers of lone star ticks is increasing. This pattern is already beginning on Long Island, and it remains to be seen if it will expand to other parts of the state, as well.^{xxviii}

As highlighted by the Commissioner of Health at the hearing, lone star ticks, which have traditionally been prevalent in southern states, are beginning to appear with more frequency in Long Island. While they may transmit ehrlichiosis and southern tick-associated rash illness (STARI), they also transmit alpha-gal into the host's bloodstream, prompting the release of IgE antibodies to attack the alpha-gal, which results in an allergy to red meat. It was noted by the Commissioner of Health, as well as doctors from Stony Brook University Hospital, that there have been several reports of this allergy on the eastern end of Long Island.^{xxix}

Appendix C

Timeline of Lyme & Tick-Borne Disease Epidemic

- 1975 – In Connecticut a cluster of children and adults residing in the Lyme, Connecticut area experienced uncommon arthritic symptoms (1976 circular letter).
- 1977 –The first 51 cases of Lyme arthritis were described, and the *Ixodes scapularis* (blacklegged) tick was linked to the transmission of the disease.
- 1982 – *Borrelia burgdorferi*, the bacterium that causes Lyme disease, was discovered and the first brochure addressing Lyme disease was developed by the Arthritis Foundation. Serology testing became widely available in Connecticut during 1984.
- 1988 – New York passed legislation (Chapter 500 of the Laws of 1988) creating the Tick-Borne Disease Institute within the DOH and appropriated \$250,000. The Institute was empowered to:
 - Develop and promote investigation into the cause, prevention, detection, spread, methods of treatment and cure of tick-borne diseases; and
 - Develop and promote an outreach campaign
 - Establish a Tick-Borne Disease Institute Research Council to make recommendations to the Institute
 - Establish the Tick-Borne Disease Institute Advisory Committee to advise the commissioner with respect to implementation of the state and which shall make recommendation regarding outreach campaign.
- 1991 - The first federal funding for Lyme disease surveillance, education, and research became available
- 1997 – The first Lyme disease vaccine became available. To help determine the efficacy of the vaccine, Lyme disease was made laboratory reportable in 1998. However, the manufacturer withdrew the vaccine from the market in 2001.
- 2002 – The vaccine efficacy study ended, and Lyme disease was removed from the list of laboratory reportable findings; however, it remained a physician reportable disease.
- October 2013 – New York State Senate created the Lyme and Tick Borne Diseases Task Force and released its first report with recommendations in 2014. Funding that year secured by the Senate totaled \$500,000 to fund many of the recommendations of the Task Force including such things as:
 - Tick surveillance and data mining
 - County Collaborative
 - Research symposiums
 - Education and Outreach
- December 2013 – Initial meeting of the Task Force members
- January 2014 – First meeting of the Task Force with scientific experts in the field to discuss the background on Lyme and Tick-Borne diseases and efforts to address the illnesses.
- April 1, 2014 – Enabling language articulated in legislation sponsored by Senator Patty Ritchie (Chapter 483 of the Laws of 2014) for the establishment of the 21st Century Workgroup for Disease Elimination and Reduction
- June 11, 2014 – Meeting of the Task Force to discuss recommendations to be presented to the Department of Health for incorporation in a State Action Plan on Lyme and Tick-Borne Diseases
- June 2014 – New York State Senate resolution was adopted calling on the federal

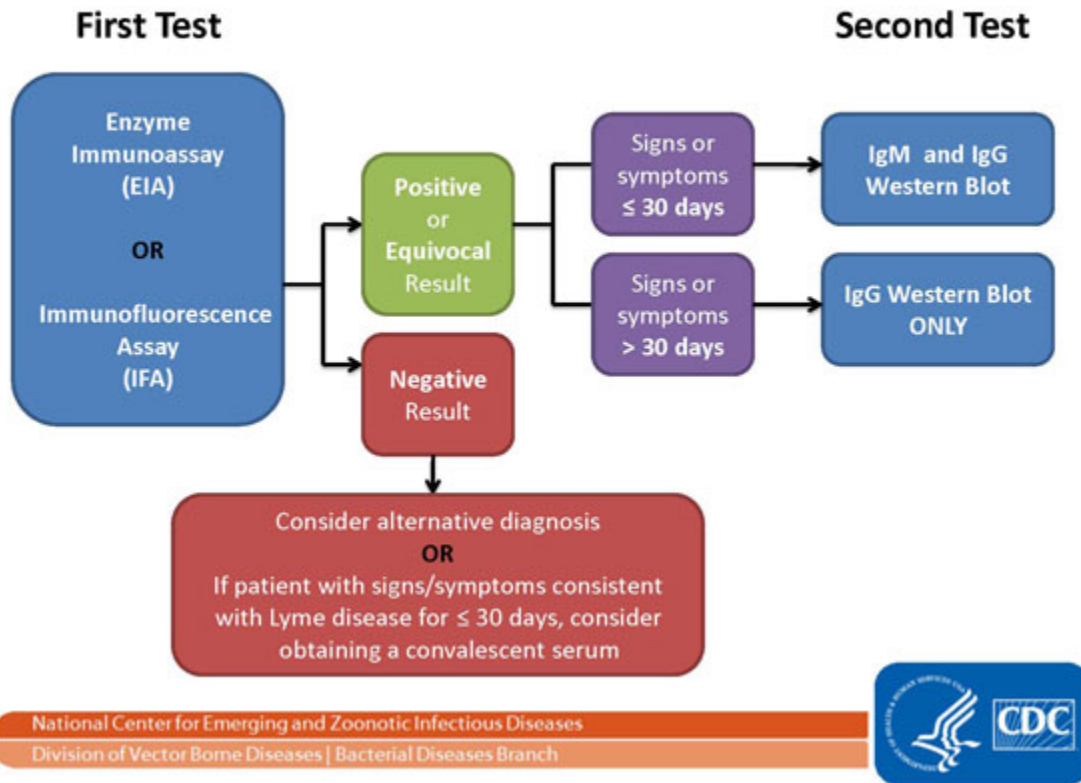
government to address Lyme and Tick-Borne diseases with provisions including: (a) a call on the Centers for Disease Control to reevaluate its guidance on Lyme and other tick-borne diseases; and (b) a call on the National Institutes of Health, the Department of Defense, and other federal agencies to provide more funding for these diseases considering the high number of cases found each year.

- June 2014 – The New York State Senate passed legislation sponsored by Senator Kemp Hannon (Chapter 532 of the Laws of 2014) that would ensure that the New York State Office of Professional Medical Conduct shall not identify, investigate, or charge a practitioner based solely on their recommendation or provision of a treatment modality that is currently not universally accepted by the medical community.
- May 18, 2015 – Meeting of the Task Force during which a representative from the NYS Department of Health (Bryon Backenson) provided a status and funding update to Task Force members regarding the Department’s progress in combatting the spread of Lyme and tick-borne diseases.
- June 2015 – The New York State Senate passed legislation sponsored by Senator Sue Serino (Chapter 167 of the Laws of 2016) that required the Department of Health to design a Lyme and tick-borne disease prevention program to promote awareness and prevention methods.
- June 2015 – The New York State Senate passed legislation sponsored by Senator Sue Serino (Chapter 109 of the Laws of 2016) that required the Commissioner of Education to collaborate with the Commissioner of Health and the Commissioner of Environmental Conservation to develop instructional tools and materials to assist in the education and awareness program to protect children from Lyme disease and tick-borne infections to be available at schools and libraries.
- July 2015 – Representative Chris Gibson authored a portion of the federal bill, the 21st Century Cures Act, which prioritized federal research on Lyme and other tick-borne illnesses and established a Working Group to consider the treatment of these illnesses. President Obama later signed the 21st Century Cures Act into law in December 2016.
- June 1, 2016 - Meeting of the Task Force during which representatives from Cornell's College of Agriculture and Life Sciences updated members on their statewide prevention and awareness initiatives
- June 2017 – Meeting of the Task Force for a presentation by Cornell University and members of Cornell Cooperative Extension to discuss ongoing efforts at the local level to help educate New Yorkers regarding Lyme and tick-borne diseases.
- August 29, 2017 – The Task Force, in conjunction with the Senate Standing Committee on Health convened a public hearing to consider the current issues surrounding Lyme and tick-borne diseases in New York State. Participants included the Commissioner of Health, medical professionals, academic researchers, and patients.
- August 29, 2017 – The New York State Department of Health announced plans to expand awareness, outreach, and collection efforts for tick-borne illnesses including the posting of current and retrospective tick collection and testing results on Health Data NY, collaboration with the Department of Environmental Conservation to include information materials in hunter education and licensure programs, and a 2018 release of a tick-borne disease surveillance and response plan.

Appendix D

CDC Lyme Diagnosis Protocol

Two-Tiered Testing for Lyme Disease



Source: Centers for Disease Control and Prevention^{xxx}

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- ⁱ “Signs and Symptoms of Untreated Lyme Disease.” Centers for Disease Control. Available at: https://www.cdc.gov/lyme/signs_symptoms/index.html (last visited 09/11/2017).
- ⁱⁱ Testimony of Commissioner Howard Zucker, MD, JD. New York State Department of Health. New York State Senate Public Hearing (August 29, 2017). Copies available upon request.
- ⁱⁱⁱ Testimony of Matthew Frye, Ph.D. Entomologist, Cornell University. New York State Senate Public Hearing (August 29, 2017). Copies available upon request.
- ^{iv} Testimony of Luis Marcos, MD, FACP, MPH. Stony Brook University. New York State Senate Public Hearing (August 29, 2017). Copies available upon request.
- ^v “Data and Statistics.” Centers for Disease Control and Prevention. Available at: <https://www.cdc.gov/lyme/stats/index.html> (last visited 09/01/2017).
- ^{vi} Testimony of Commissioner Howard Zucker, MD, JD. New York State Department of Health. New York State Senate Public Hearing (August 29, 2017). Copies available upon request.
- ^{vii} “Data and Statistics.” Centers for Disease Control and Prevention. Available at: <https://www.cdc.gov/lyme/stats/index.html> (last visited 09/01/2017).
- ^{viii} Testimony of Marianne Yourdon, RN. Broome County Department of Health. New York State Senate Public Hearing (August 29, 2017). Copies available upon request.
- ^{ix} “Data and Statistics.” Centers for Disease Control and Prevention. Available at: <https://www.cdc.gov/lyme/stats/index.html> (last visited 09/01/2017).
- ^x “Powassan Virus.” Centers for Disease Control and Prevention. Available at: <https://www.cdc.gov/powassan/index.html> (last visited 09/11/2017).
- ^{xi} See: <https://www.cdc.gov/powassan/statistics.html>
- ^{xii} Testimony of Commissioner Howard Zucker, MD, JD. New York State Department of Health. New York State Senate Public Hearing (August 29, 2017). Copies available upon request.
- ^{xiii} Testimony of Martin Wilson, patient. New York State Senate Public Hearing (August 29, 2017). Copies available upon request.
- ^{xiv} Testimony of Jill Auerbach, patient. Hudson Valley Lyme Disease Association. New York State Senate Public Hearing (August 29, 2017). Copies available upon request.
- ^{xv} Testimony of Christina Fisk. Lyme Action Network. New York State Senate Public Hearing (August 29, 2017). Copies available upon request.
- ^{xvi} Testimony of Craig Hersh, MD. Empire Blue Cross Blue Shield. New York State Senate Public Hearing (August 29, 2017).
- ^{xvii} Testimony of Jill Auerbach, patient. Hudson Valley Lyme Disease Association. New York State Senate Public Hearing (August 29, 2017). Copies available upon request.
- ^{xviii} Testimony of Luis Marcos, MD, FACP, MPH. Stony Brook University. New York State Senate Public Hearing (August 29, 2017). Copies available upon request.
- ^{xix} Testimony of Matthew Frye, Ph.D. Entomologist, Cornell University. New York State Senate Public Hearing (August 29, 2017). Copies available upon request.
- ^{xx} Testimony of Richard S. Ostfeld, Ph.D. Cary Institute of Ecosystem Studies. New York State Senate Public Hearing (August 29, 2017). Copies available upon request.
- ^{xxi} Testimony of Professor Holly Ahern, MS, MT(ASCP). SUNY Adirondack. New York State Senate Public Hearing (August 29, 2017). Copies available upon request.
- ^{xxii} Testimony of Professor Holly Ahern, MS, MT(ASCP). SUNY Adirondack. New York State Senate Public Hearing (August 29, 2017). Copies available upon request.

^{xxiii} Testimony of Craig Hersh, MD. Empire Blue Cross Blue Shield. New York State Senate Public Hearing (August 29, 2017).

^{xxiv} See: <https://www.ny.gov/6-step-new-york-state-zika-action-plan/6-step-new-york-state-zika-action-plan>

^{xxv} Testimony of Matthew Frye, Ph.D. Entomologist, Cornell University. New York State Senate Public Hearing (August 29, 2017). Copies available upon request.

^{xxvi} Testimony of Luis Marcos, MD, FACP, MPH. Stony Brook University. New York State Senate Public Hearing (August 29, 2017). Copies available upon request.

^{xxvii} “Tickborne Diseases of the United States.” Centers for Disease Control and Prevention. Available at: <https://www.cdc.gov/ticks/tickbornediseases/tickID.html> (last visited 10/22/2017).

^{xxviii} Testimony of Commissioner Howard Zucker, MD, JD. New York State Department of Health. New York State Senate Public Hearing (August 29, 2017). Copies available upon request.

^{xxix} See Testimony of Commissioner Howard Zucker, MD, JD. New York State Department of Health. New York State Senate Public Hearing (August 29, 2017). Copies available upon request; Testimony of Luis Marcos, MD, FACP, MPH. Stony Brook University. New York State Senate Public Hearing (August 29, 2017). Copies available upon request.

^{xxx} “Two-step Laboratory Testing Process.” Centers for Disease Control and Prevention. Available at: <https://www.cdc.gov/lyme/diagnostesting/labtest/twostep/index.html> (last visited 10/22/2017).