Tick-borne diseases are a large and growing public health concern

I am providing this testimony as a scientist, professor emerita of microbiology, and co-founder of a Lyme disease advocacy organization in New York State. I am also the cofounder and Chief Scientific Officer of Aces Diagnostics, a start-up company founded to research, develop and commercialize a diagnostic test for Lyme disease that people will be able to access through traditional diagnostic medicine routes. I have also served on several state and federal committees convened to address the growing problem of tick-borne diseases in the United States, most recently the 2022 HHS Tick Borne Disease Working Group (TBDWG) and the 2023 New York State Lyme and Tick Borne Disease Working Group.

But foremost, I am a mom who witnessed her daughter transition from a vibrant college student/athlete, who had just returned from Nationals after setting college records in swimming and achieving All American status, to bed bound, paralyzed on one side, hypersensitive to light and sound and in terrible pain, over the course of only a few weeks. She lost years of her life – because her case of Lyme disease was not diagnosed or appropriately treated when she was first bitten and infected by that tick.

Lyme disease is a vector-borne disease transmitted by ticks. In my daughter's case, we saw the tick, removed it and took her to our doctor, who recommended what was then – and still is – considered to be the standard of care for tick bites: wait to see if a huge rash or other symptoms such as a fever develop before getting a test or initiating antibiotic treatment.

She developed a small rash that didn't fit the established criteria because it didn't look like a bulls-eye. Months later, symptoms including fever, profound fatigue, widespread pain, and other symptoms occurred, but these were attributed to a viral illness. By the time she was diagnosed with Lyme disease and started antibiotic treatment, she had been infected for a very long time with the Lyme bacteria, which are known for their ability to rapidly spread, persist, and drive inflammation in connective tissue-rich places in the body such as the joints, heart and nervous system. Once established in these tissues, Lyme infections become antibiotic tolerant.

In my daughter's case, because early diagnosis was missed, she developed a long-term chronic illness that antibiotics alone could not resolve. This illness goes by many names, including Post Treatment Lyme Disease Syndrome (PTLDS), chronic Lyme disease, persistent Lyme disease, and is often just labeled "medically unexplained symptoms."

I am here today because I wish to prevent this from happening to other people, their children, relatives, or friends.

Infectious diseases transmitted by ticks and other insect vectors are a recognized public health concern. In the U.S. 90% of all vector borne disease are transmitted by ticks. The diseases ticks transmit are not rare, and are not "hard to catch and easy to cure" a catchphrase from the early 2000's that has been proven wrong. Some tick-borne diseases cause long term debilitating symptoms, and some are fatal, like Powassan virus which took the life of Kay Hagan, the U.S. Senator after whom this bill is named. Unfortunately, the chronic illness suffered by many Lyme

disease patients leads to death by suicide. I am beyond thankful that my daughter was not one of those cases.

Just being bitten by a tick can be a life altering event. Alpha-gal syndrome (AGS) is an emerging, tick bite–associated allergic condition characterized by potentially life-threatening hypersensitivity to a sugar molecule found in beef, dairy, other mammalian meats and derived products. Currently the CDC is not tracking cases of AGS so the geographic distribution and number of cases are largely unknown. However, the CDC estimates that a half million or more people may already be affected, and acknowledges this may be an underestimate. More data and research are needed to understand how many people are affected by this condition.

Tick-borne diseases occur in all states, regardless of whether the state is considered endemic or non-endemic, or whether the state leans toward Red or Blue. For example, the risk of acquiring Lyme disease from a tick in the state of Ohio, considered a low incidence or non-endemic state, is now equal to that of Connecticut – one of the states with the most reported cases of Lyme disease annually. This is based on research from Ohio State University in which they captured and tested ticks to detect the pathogens they carry. They found 48% of the 600 ticks tested carried the bacteria that causes Lyme disease, compared to just 2% of the ticks which tested positive in 2010, the last time this type of study was done. This represents a **2,300% increase** in ticks capable of transmitting Lyme disease in just 15 years.

Ohio, a state considered non-endemic for Lyme disease, recorded only 1,800 cases in 2024 in contrast to the bordering highly endemic state of Pennsylvania (16,000). Does it make sense that there are so few cases of Lyme disease where half the ticks carry the Lyme bacteria ? It's far more likely that because the current decision tree for medical diagnosis of Lyme disease includes considering endemicity before making a clinical decision, cases go undiagnosed or are misdiagnosed as something else.

California is another example of how surveillance data can be misleading and needs to be improved. California is considered a non-endemic state, but has one of the highest numbers of Lyme disease-related insurance claims in the U.S. In 2016, while California reported only 90 cases to the CDC, there were 46,820 privately insured claims for Lyme disease, indicating a major disparity between actual healthcare utilization and official CDC numbers.

Lyme disease is by far the most common tick-borne and vector-borne disease in the U.S., but it also ranks high among bacterial infectious diseases overall. When you compare the CDC estimate of 476,000 diagnosed cases of Lyme disease with the number of cases of all other bacterial infections tracked by the CDC, Lyme disease ranks third (#3). Only chlamydia (#1) and gonorrhea (#2) rank higher on the list. Syphilis is number four. This suggests that the risk of acquiring a tick-borne disease is on par with getting a sexually transmitted disease. This also represents a major disparity – that a disease which is hard to catch and only common in a few state would have more cases diseases with a far more popular route of transmission.

In addition to Lyme disease, Babesia is a tick-borne parasite that is a close relative to the one that causes malaria. Symptoms of babesiosis are similar to malaria, and infection can result in

long term chronic illness. Fewer than 2,000 cases of malaria are reported in the U.S. each year compared to 25,000 estimated cases of babesiosis.

But why does there appear to be little public health interest in Babesia, given that there are ten times more cases of babesiosis than malaria in the U.S.?

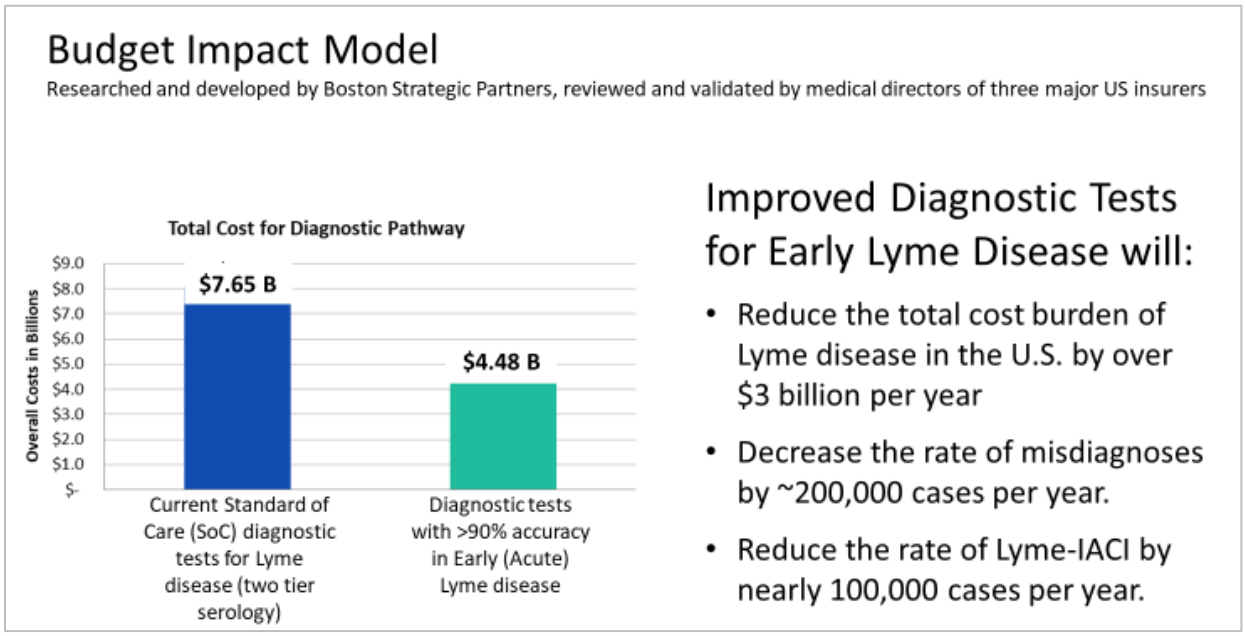
Maybe it's because malaria is transmitted by mosquitoes that fly, land on your arms or legs where you can see them, and make you itch when they bite. People in every state are well aware of mosquitoes and know they can transmit diseases. We've all been well educated about the mosquito-borne diseases that have changed human history, and humans have been trying for centuries to eradicate them. So the threat is obvious.

For Lyme and other tick-borne diseases, the threat is less obvious. Ticks don't fly, they stay on the ground and sneakily climb aboard and tuck into places where they are unlikely to be seen. When they bite, they inject an anaesthetic so you don't feel them bite and the bite doesn't itch. Based on patient registry data, only 50% of patients with Lyme disease actually saw the tick that bit them.

These are only a few of the reasons why reauthorization of the Kay Hagan Tick Act should be a priority. This legislation provides continuation of funding for university-based vector-borne disease Centers of Excellence and supports research on ways to prevent tick bites, improve mosquito and tick control methods, and train a new generation of public health professionals. The Tick Act also provides grants to State health departments to enhance their ability to track and report tick-borne diseases, which will improve national disease surveillance and prevention efforts.

Reauthorization would also enable implementation of the Kay Hagan Tick Act supported *National Strategy to Prevent and Control Vector Borne Diseases in People*, and provide funds for research and development of improved diagnostics and new therapeutic approaches for Lyme and other tick and mosquito-borne diseases. Because symptoms of Lyme disease (and babesiosis) are variable and non-specific, laboratory tests are needed to aid diagnosis. False-negative test results are common with Lyme disease, particular in the early period of infection.

As shown below, healthcare costs in the U.S. that can be attributed to undiagnosed or misdiagnosed Lyme disease because of false negative lab test results exceeds $8 billion per year. An accurate diagnostic test that enables early diagnosis would decrease that burden by 41.5%.



Lyme disease cases are under-diagnosed and under-reported

Lyme disease is a challenging diagnosis because the existing standard of care focuses almost entirely on cases that begin with a distinctive skin rash.

If Lyme disease is diagnosed early within a week or two of infection and appropriately treated with an antibiotic, the majority of patients recover. However, research shows that even after prompt diagnosis and appropriate treatment, 15 – 20% of patients will develop a Lyme-associated chronic illness with debilitating symptoms: profound fatigue, joint and/or muscle pain, sound and light sensitivity, and moderate to severe levels of "brain fog," that persist for more than 6 months and greatly impair quality of life.

The percentage of cases that progress to chronic illness is even higher in those who are diagnosed months or sometimes years after the initial infection occurred. Estimates range from 20 – 30% to even higher when data from patient registries such as MyLymeData with over 20,000 Lyme disease patients enrolled, is included.

A report by the National Academies of Science, Engineering and Medicine meeting in 2023 examined the issue of Infection-Associated Chronic Illness (IACI) – a health threat that gained acceptance in patients who suffered with Long Covid. The goal was to better define and advance research and treatment of post-infection chronic illnesses associated with bacterial or viral infections, including Lyme disease. A follow up consensus study report in 2025 focused specifically on Lyme-Infection Associated Chronic Illness (Lyme-IACI). I urge all members of this body interested in learning more about this issue to access these reports, which are linked in this document.

At present, there are no broadly accepted treatment protocols for patients with Lyme-IACI). Thus, early diagnosis and prompt and appropriate antibiotic treatment of Lyme disease should be considered an important aspect of patient care. However, diagnosis of Lyme disease during the early stages of the infection remains challenging, even in states where it is presumed that health care providers have more experience with the disease.

I was appointed to the Testing and Diagnostics Subcommittee of the 2018 U.S. Department of Health and Human Services Tick Borne Disease Working Group (TBDWG). As discussed in the Report to Congress, the subcommittee considered and identified key issues related to the existing medical guidelines that dictate both the diagnosis and treatment of Lyme disease. We reviewed the available science and spoke with experts on Lyme diagnosis. We concluded that the diagnostic criteria, which had remained largely the same for over 30 years, failed in several ways.

For one, the distinct skin rash that resembles a “bulls-eye” is not reliable as a disease marker for Lyme disease. Medical guidelines suggest the rash appears in the classic bulls-eye form in 70% of Lyme disease cases, other studies show this rate to be much lower. According to MyLymeData, a patient registry with over 20,000 participants, only 45% of patients recall seeing a rash, and 30% or more never developed a visible rash at all. Even in confirmed Lyme disease cases, there is significant variability in how the rash actually looks in terms of its size, shape, color, and pattern. The appearance of the rash also varies according the sex and skin color of the patient

Even healthcare providers in areas where Lyme disease more commonly occurs have difficulty recognizing a skin rash as an erythema migrans, and I would like to provide a direct example that shows this to be true.

The pictures below are shown with permission of the parents. The mothers of these kids saw the rash and were concerned that the rashes might be Lyme disease. Both saw health care

providers – one went to an Urgent Care center, the other to a pediatrician – in upstate New York, an area considered to be "highly endemic" for Lyme disease.

Yet in both cases, the parents were told that the rash was probably due to dermatitis or an insect or spider bite, NOT Lyme disease. Why? Because no attached tick had been observed on the child at or near the site of the rash.

While both rashes look like an EM rash and occurred in an area of the US where Lyme disease is common, neither child was initially diagnosed with Lyme disease or prescribed an antibiotic.

Another factor complicating Lyme disease diagnosis is the recommended laboratory test for Lyme disease, which is two-tier serology. "Two-tier" involves two separate tests – the first being a sensitive but not very specific immunoassay that detects a general antibody response to the infection. Diagnostic standards developed for Lyme disease in 1994 – 30 years ago – hold that this test must return an equivocal or positive result before a second, more specific test is performed which must also be positive to support a diagnosis of Lyme disease.

The usefulness of this approach as a diagnostic tool for Lyme disease has been under debate pretty much from the beginning of the disease's history in the U.S. in the 1980s. As discussed in the Testing and Diagnostics Subcommittee Report and full Report to Congress – two-tier serology was noted for poor clinical accuracy. In other words, it misses many cases.

Most sources agree that the sensitivity of the two-tier test is very low – less than 30% accurate – during the early stages of the infection. Sensitivity refers to the ability of a diagnostic test to designate a person with a disease as positive – in the case of Lyme disease, a sensitivity of 30% means that only 3 out of 10 people who actually have Lyme disease will have a positive test result.

For late-stage Lyme arthritis, the form of Lyme disease discovered in the U.S. in the early 1980s that the test was developed to detect, two-tier serology is fairly accurate. But for other presentations (neurological), the sensitivity is much lower.

A 2016 biostatistical review of over 50 studies on the characteristics of available test kits for Lyme disease found that across all disease stages and presentations, the tests were accurate in 59.5% of cases. A summary of the sensitivity of the various test kits is shown in the table below:

Test method	Sensitivity	95% CI
ELISA	62.3%	56.6%–68.1%
C6	53.9%	48.3%–61.1%
Western Blot	62.4%	54.2%–70.7%
Two-tier	53.7%	49.9%–57.4%
ALL	59.5%	55.6%–63.5%

Source: "Commercial test kits for detection of Lyme borreliosis: a meta-analysis of test accuracy." (Cook MJ and Puri BK. Int J Gen Med. 2016;9:427-440).

Because the two major criteria for diagnosing a case of Lyme disease – the EM rash and the two-tier test – are not good disease indicators, it is likely that most cases of Lyme disease are not diagnosed during the early, most treatable stage of the disease.

In 2022, I served on the HHS TBDWG Access to Care Subcommittee which submitted a Report to Congress in 2022. Our work focused on the barriers to care that exist for Lyme disease patients.

The rigid and unchanging medical bias that oral antibiotics cure every case of Lyme disease is one such barrier to care. A study funded by the U.S. National Institutes of Health on cases of pediatric Lyme disease was published in 2023. Language in the abstract asserts that the data showed a majority of children diagnosed with Lyme disease recovered after standard antibiotic treatment, and only a "**notably small percentage**" of the children continued to have symptoms after treatment. The press release by the NIH-funded physician-researchers that accompanied this paper asserted "this study supports previous data showing an **excellent overall prognosis for children** with Lyme disease, which should help **alleviate understandable parental stress associated with lingering non-specific symptoms** among infected children."

So how would YOU define a "notably small percentage" of children who continue to have symptoms after diagnosis and antibiotic treatment for Lyme disease. Less than 1% maybe?

A review of the actual data indicates that the researchers, who are infectious disease physicians, considers a "notably small percentage" to be **22%** (nearly 1 in 4 kids). That is the percentage of children who did not return to health for months after receiving the standard treatment for early Lyme disease. Approximately 1 in 10 (9%) of the children in the study demonstrated "functional impairment" – debilitating symptoms such as profound fatigue, neurological and neuropsychological issues and ongoing pain – which continued for more than 6 months. Is this truly "excellent progress" – knowing that your child might be the 1 in 4 that develop persisting symptoms – and "alleviate your parental stress?"

That exact message alleviated my parental stress over my daughter's tick bite 15 years ago – but not so much now.

As Michael J. Fox, a Parkinson's Disease patient and 2024 Presidential Medal of Freedom recipient, put it: "This message is so simple, yet it gets forgotten. The people living with the condition are the experts."

Thank you for the opportunity to provide this testimony.