Testimony for LD 906

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Dear Senator Baldacci, Representative Meyer and Members of the Health and Human Services Committee:

This testimony is in support of LD 906, "An Act to Ensure Physicians Receive Full Diagnostic Test Data Concerning Tick-borne Diseases". I was honored to testify before Senator Susan Collins at the United States Senate hearing considering the now-enacted Kay Hagan TICK Act to develop a national strategy to address vector-borne diseases, including tick-borne diseases. . As a physician who often treats Lyme Disease and other tick-borne diseases such as babesiosis, anaplasmosis, ehrlichiosis, and additional coinfections, I have come to realize that making the initial diagnosis can be more challenging than other infectious diseases. Sometimes it's easy: the patient presents with a "bull's eye rash", has flu symptoms outside of winter, remembers a recent tick bite, and testing is positive.

This is the exception.

The typical case of Lyme Disease is atypical. Current data shows that less than 25% of Lyme patients recall a tick bite and that the classic bull's eye rash (erythema migrans) occurs less than 50% of the time. (ILADS Evidence-based Guidelines, Cameron et al, 2014) There are 38 symptoms associated with tick-borne disease, and some are quite vague such as fatigue, brain fog, nausea, headache, etc. Many other medical conditions can cause similar symptoms. Physical examination is usually normal.

Laboratory testing is often employed by the clinician to help solve this diagnostic dilemma. Unfortunately the tests are not as reliable as we would like them to be. The Centers for Disease Control (CDC) currently recommends a two-tier test (Morbidity and Mortality Weekly Report/MMWR, August 16, 2019). Step one is to perform a rapid test (e.g. Enzyme Immunoassay (EIA) or ELISA, similar to a rapid COVID test). If this test is positive or equivocal ("maybe yes, maybe no"), the CDC recommends performing either another EIA or Western Immunoblot test.

The Western immunoblot is often a problem for practitioners. Without going into too much detail, this test looks for several different antibodies made by the immune system to fight Lyme Disease. Unfortunately other infections can also cause some of those antibodies to be positive, as can the now-discontinued Lymerix vaccine. This is known as a "false positive", meaning the test says the patient has Lyme when they do not. To add further confusion, the bacteria that causes Lyme Disease can hide from and suppress the immune system. In this case the antibodies are not made and the test is a "false negative", meaning the test says the patient does not have Lyme when they actually do.

Furthermore, the standards set by the CDC for population-based surveillance do not apply to individual clinical medical care. In other words, a Western immunoblot may be considered positive by some clinicians even if it does not meet the CDC criteria originally created for research purposes, not real-life medicine. The two-tiered testing method has been shown in the literature to be horribly inaccurate, **missing the diagnosis more than 90% of the time** (J CLin Microbiol 1997; 35: 537-543; Cameron DJ. Proc International Sci Conf Lyme, 1999; Clin Infec Dis 1997; 25(Supp 1), S31-34; Acta Clin Belg 1998; 53, 178-83; MMWR 44 1995; 590-91).

Obviously there is a lot of nuance and depth of knowledge required by the clinician when interpreting these tests. **Unfortunately many laboratories do not currently supply the clinician with this level of detail; they just report the test as "positive" or "negative".** Testing methodology also varies from lab to lab – some have better machines and technicians than others. Having been frustrated by the lack of clinical usefulness of these locally-available lab tests, I usually send out my patient's blood work to Clinical Laboratory Improvement Amendments (CLIA)-approved specialty laboratories that provide me with much more detailed results. This ensures more timely diagnosis and earlier treatment for my patients, with better outcomes.

Maine is currently ranked first for Lyme Disease incidence rate (116 per 100,000). By its own admission, the CDC reports that only 10% of cases are actually diagnosed. In other words, its strict surveillance criteria for diagnosis are missing 90% of cases! In 2021 there were 1,508 Lyme cases reported in Maine, meaning 15,000 +/- patients actually got Lyme Disease.

We can do better.

Over reliance on these inaccurate laboratory tests prevents timely diagnosis. I can't count how many times I've heard my patient say, "Oh, my doctor told me my test was negative so I know I don't have Lyme." If clinicians were given more detailed reports and educated themselves as to how to interpret them, they would better serve the people of this great state and prevent more disease. This bill would simply provide clinicians with more information…it doesn't tell them how to practice medicine. I fully support it and hope that the Maine legislature will enact further laws to assist improved tick-borne disease treatment. Thank you very much, and Be Well.

Sean McCloy
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LD 906

Note corrected typo at last paragraph: "it DOESN'T tell them how to practice medicine" [emphasis added]