MICHIGAN
LYME DISEASE
ASSOCIATION

Lyme Bill Opportunities

June 13th, 2019

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Dear House & Committee Members,

My name is Carrie Nielsen and I serve as Secretary on the board for the Michigan Lyme Disease Association also known as the MLDA. I come to you today to represent our board to address and oppose 8 out of 8 of the Lyme related Bills.

I first want to point out that the MLDA is one of the country's first state non-profits for Lyme Disease, which formed back in 1989. In the last several years we have donated funds toward numerous research projects for Departments of Fisheries & Wildlife AND Large Animal Clinical Sciences of Michigan State University totaling over $105,000.00, for the state of Michigan. This has been done through our board of trustees who are all volunteers and are sick with Lyme Disease as well. All monies spent on the research projects is from proceeds created by various fundraising events put on by the MLDA. We work hard for every dollar we raise and it takes a large effort by all to make it successful. In addition to research projects, we provide the majority of Lyme brochures and literature to health departments, physicians and patients in our state. We've hosted several medical conferences, some with Continuing Education credits and some without. In November of this year, we are scheduled to host another conference. The MLDA has also raised awareness by putting billboards around the state, we've given educational speeches, and setup educational booths to offer support for Lyme Disease around Michigan. With this being said, the state of Michigan has looked to the MLDA as being the content experts by educating and raising awareness for the public. The Michigan Lyme Disease Association has been HEAVILY involved in our state and will continue to be in the future.

We can all agree resolving these complex issues is paramount; however, we do not feel the often repetitive, non-essential, loosely worded Lyme bills will accomplish these goals.

In their current form the bills are not relevant in some cases, are not a top priority in others, are incomplete, lack funding to accomplish their goals and lack substance. Often when bills of a similar nature were passed in other states their goals were never accomplished.

Rather than legislation coming to our rescue, the wording in the bills serves to strengthen the current policies set forth by the CDC by way of the Michigan Department of Health and Human Services. These are the very policies that have restricted the ability of patients to be diagnosed and treated for Lyme and tick-borne diseases for several decades, as well as responsible for supporting the denial of insurance coverage.

In the future, it is our goal to work together with you by presenting fresh, innovative and essential ideas for Lyme-related legislation specifically designed to improve the health of those suffering today and protect those who contract Lyme in the future. This package of bills, the thoughtful gesture that they are, unfortunately do not accomplish these goals.

Thank you for your consideration and your continuing support.

Sincerely,

Carrie Nielsen
Secretary
Michigan Lyme Disease Association

Bill 4603 - Requires health care professionals to report cases of Lyme disease.

Lyme disease reporting has been going since 1990. It's already a requirement by the Michigan Health Departments and Centers for Disease Control (CDC). We are not in need of a bill to make Lyme Disease reporting mandatory. It already is a reportable disease. (see attached)

The bill requires those who don't report a case of Lyme disease within 24 hours of the diagnosis to pay a fine ($10 - $100). Aside from being unreasonable and unnecessary, the law is not able to be enforced and there is no accountability.

Patients see an average of 10 to 12 doctors before being diagnosed (National Average). Which of these doctors would be required to report? Would it be the one that saw the rash, and already stated there is no Lyme in MI? The doctor that tested the patient, but stated it's a false positive, due to Lyme not being present in MI? Or lastly, the doctor that finally puts it all together, and begins treatment (which can take years in many cases).

Bill 4604 - Insurance Coverage

The bill doesn't specify what kind of treatment, prescribed by whom, or how long of duration for the treatment. In addition, it doesn't address the diagnosis process. Insurers typically do cover some treatment and the diagnostic costs for Lyme disease, so the bill is redundant. It also contains too many loop holes and not enough specifics to be effective.

In order for any Insurance bill to be effective it needs to include "Medical Necessity" as determined by the treating physician.

As for insurers, it simply states insurers are to "provide coverage for Lyme disease treatment". This leaves too many loop holes and not enough specifics to be effective.

HB 4605 - Doctor Protection

This is open to interpretation as to who can treat in "accordance with their scope of practice". The bill doesn't protect our patients. For example: Is an OGBYN allowed to treat if needed, or is that beyond the scope of practice?

The other concern we have is this bill doesn't address what is considered to be "long term" treatment and is left for interpretation. Each person's meaning of this is different.

This verbiage needs to be worked on.

HB 4606 - Blood, Tissue & Organ Testing

The FDA recently (2018) approved testing donated blood for Babesia (tick borne disease). The blood is to go through a two step testing process before being utilized. (see attached)

If donated blood, tissue or organs are infected with bacteria, parasites (example- Babesia sp.), other foreign material, or unsafe organisms, they would not be used in a transplant or transfusion situation, hence, no reason to have a bill addressing the situation.

The Red Cross, FDA, CDC and others have been reviewing the data and various modes of transmission for other tick borne diseases to determine the best way to screen for potentially transmittable diseases, including Lyme disease.

There have been NO reported cases of Lyme being transfused from one person to another through a blood donation, tissue, or organ transplant.

HB 4607 - Requires Health Care Professionals to perform an Elisa & Western-Blot blood test, after explaining all the details about testing, treatment and complications.

The current protocol already uses the Elisa and Western Blot. The labs are only required to run the Western Blot, if the Elisa was positive.

The language in this bill is quite difficult to follow. Asking a doctor (who has limited time with his patients) to explain the issues with testing to their patients, along with supplying a list of treating physicians AND give written materials before they run the test is unreasonable. Furthermore, who will be creating the list of treating physicians and keep it updated? This bill is illogical for not only healthcare providers but also patients.

HB 4608 - This bill makes it mandatory for the Michigan Department of Health to determine the best way to diagnose and treat Lyme disease, and to inform healthcare providers how to treat Lyme patients.

We see NUMEROUS issues with this bill.

HB 4609 - Social welfare act - Treatment services for Lyme disease.

Why was this added into the bill? This bill does not specify what type of diagnostics or treatment and looks to be setting prices (by percentages) for various treatments and conditions. We don't want to dictate or interfere with what doctors charge, in the way of payment.

HB 4659 - Require Signs on Trails and in Parks

We have no objections to signs being in Parks, however, our concern with this bill is that there is no appropriations for funding or any extra manpower that will be needed to install the signs.

2019 REPORTABLE DISEASES IN MICHIGAN – BY CONDITION

A Guide for Physicians, Health Care Providers and Laboratories

Report the following conditions to the Michigan Disease Surveillance System (MDSS) or local health department (see reverse) within 24 hours (unless otherwise noted) if the agent is identified by clinical or laboratory diagnosis.

Report the unusual occurrence, outbreak or epidemic of any disease or condition, including healthcare-associated infections.

Acute flaccid myelitis (1)
Anaplasmosis (Anaplasma phagocytophilum)
Anthrax (Bacillus anthracis and B. cereus serovar anthracis) (4)
Arboviral encephalitides, neuro- and non-neuroinvasive:
Chikungunya, Eastern Equine, Jamestown Canyon, La Crosse, Powassan, St. Louis, West Nile, Western Equine, Zika (6)
Babesiosis (Babesia microti)
Blastomycosis (Blastomyces dermatitidis)
Botulism (Clostridium botulinum) (4)
Brucellosis (Brucella species) (4)
Campylobacteriosis (Campylobacter species)
Candidiasis (Candida auris) (4)
Carbapenemase Producing – Carbapenem Resistant Enterobacteriaceae (CP-CRE): Klebsiella spp., Enterobacter spp., and Escherichia coli (5)
Chancroid (Haemophilus ducreyi)
Chickenpox / Varicella (Varicella-zoster virus) (6)
Chlamydial infections (including trachoma, genital infections, LGV) (Chlamydia trachomatis) (3, 6)
Cholera (Vibrio cholera) (4)
Coccidioidomycosis (Coccidioides immitis)
Cryptosporidiosis (Cryptosporidium species)
Cyclosporiasis (Cyclospora species) (5)
Dengue Fever (Dengue virus)
Diphtheria (Corynebacterium diphtheriae) (5)
Ehrlichiosis (Ehrlichia species)
Encephalitis, viral or unspecified
Escherichia coli, O157:H7 and all other Shiga toxin positive serotypes (5)
Giardiasis (Giardia species)
Glanders (Burkholderia mallei) (4)
Gonorrhea (Neisseria gonorrhoeae) (3, 6)
Guillain-Barre Syndrome (1)
Haemophilus influenzae, sterile sites only- submit isolates for serotyping for patients < 15 years of age (5)
Hantavirus
Hemolytic Uremic Syndrome (HUS)
Hemorrhagic Fever Viruses (4)
Hepatitis A virus (Anti-HAV IgM, HAV genotype)
Hepatitis B virus (HBsAg, HBeAg, anti-HBc IgM, HBV NAAT, HBV genotype; report all HBsAg and anti-HBs (positive, negative, indeterminate) for children ≤ 5 years of age) (6)
Hepatitis C virus (all HCV test results including positive and negative antibody, RNA, and genotype tests) (6)
Histoplasmosis (Histoplasma capsulatum)
HIV (tests including reactive immunoassays (e.g., Ab/Ag, TD1/TD2, WB, EIA, IA), detection tests (e.g., VL, NAAT, p24, genotypes), CD4 counts/percents, and all tests related to perinatal exposures) (2,6)
Influenza virus (weekly aggregate counts)
Pediatric influenza mortality, report individual cases (5)
Novel influenza viruses, report individual cases (5,6)
Kawasaki Disease (1)
Legionellosis (Legionella species) (5)
Leprosy or Hansen's Disease (Mycobacterium leprae)
Leptospirosis (Leptospira species)
Listeriosis (Listeria monocytogenes) (5,6)
Lyme Disease (Borrelia burgdorferi)
Malaria (Plasmodium species)
Measles (Measles/Rubeola virus)
Melioidosis (Burkholderia pseudomallei) (4)
Meningitis: bacterial, viral, fungal, parasitic and amebic
Meningococcal Disease (Neisseria meningitidis, sterile sites) (5)
Middle East Respiratory Syndrome (MERS-CoV) (5)
Mumps (Mumps virus)
Orthopox viruses, including: Smallpox, Monkeypox (4)
Pertussis (Bordetella pertussis)
Plague (Yersinia pestis) (4)
Polio (Poliovirus)
Prion disease, including CJD
Psittacosis (Chlamydophila psittaci)
Q Fever (Coxiella burnetii) (4)
Rabies (Rabies virus) (4)
Rabies: potential exposure and post exposure prophylaxis (PEP)
Rubella (Rubella virus) (6)
Salmonellosis (Salmonella species) (5)
Severe Acute Respiratory Syndrome (SARS) (5)
Shigellosis (Shigella species) (5)
Spotted Fever (Rickettsia species)
Staphylococcus aureus, vancomycin intermediate/ resistant (VISA (5)/VRSA (4))
Streptococcus pneumoniae, sterile sites
Streptococcus pyogenes, group A, sterile sites, including Streptococcal Toxic Shock Syndrome (STSS)
Syphilis (Treponema pallidum) (6)
Tetanus (Clostridium tetani)
Toxic Shock Syndrome (non-streptococcal) (1)
Trichinellosis (Trichinella spiralis)
Tuberculosis (Mycobacterium tuberculosis complex); report preliminary and final rapid test and culture results (4)
Tularemia (Francisella tularensis) (4)
Typhoid Fever (Salmonella typhi) and Paratyphoid Fever (serotypes Paratyphi A, Paratyphi B (tartrate negative), and Paratyphi C) (5)
Vibriosis (Non-cholera vibrio species) (5)
Yellow Fever (Yellow Fever virus)
Yersiniosis (Yersinia enterocolitica)

LEGEND

(1) Reporting within 3 days is required.
(2) Reporting within 7 days is required.
(3) Sexually transmitted infection for which expedited partner therapy is authorized. See www.michigan.gov/hivstd for details.
(4) A laboratory shall immediately submit suspect or confirmed isolates, subcultures, or specimens from the patient being tested to the MDHHS Lansing laboratory.
(5) Isolate requested. *Enteric:* If an isolate is not available from non-culture based testing, the positive broth and/or stool in transport medium must be submitted to the MDHHS Lansing laboratory. *Respiratory:* Submit specimens, if available.
(6) Report pregnancy status, if available.
Blue Bold Text = Category A bioterrorism or select agent, notify the MDHHS Laboratory immediately: (517) 335-8063

This reporting is expressly allowed under HIPAA and required by Michigan Public Act 368 of 1978, 333.5111

FDA NEWS RELEASE

FDA approves first tests to screen for tickborne parasite in whole blood and plasma to protect the U.S. blood supply

For Immediate Release:

March 06, 2018

The U.S. Food and Drug Administration today approved the Imugen *Babesia microti* Arrayed Fluorescent Immunoassay (AFIA), for the detection of antibodies to *Babesia microti (B. microti)* in human plasma samples, and the Imugen *Babesia microti* Nucleic Acid Test (NAT), for the detection of *B. microti* DNA in human whole blood samples. These tests are intended to be used as donor screening tests on samples from individual human donors, including volunteer donors of whole blood and blood components, as well as living organ and tissue donors.

"The U.S. blood supply remains the safest in the world thanks in part to the FDA's ongoing work to enforce standards for blood collection and to identify and respond to potential threats to the nation's blood supply. While babesiosis is both preventable and treatable, until today, there was no way to screen for infections amongst blood donors," said Peter Marks, M.D., Ph.D., director of the FDA's Center for Biologics Evaluation and Research. "Today's actions represent the first approvals of *Babesia* detection tests for use in screening donors of whole blood and blood components, and other living donors."

Babesiosis is caused by *Babesia* parasites that are transmitted by *Ixodes scapularis* ticks, also known as blacklegged or deer ticks. *B. microti* is the main species that causes infection in the U.S. There are about 1,000 to 2,000 cases of babesiosis reported in the U.S. each year, with the majority reported from states in the Northeast and upper Midwest. *Babesia* can also be transmitted by transfusion of blood or blood components collected from an infected donor.

The vast majority of people infected with *B. microti* do not have symptoms and are never diagnosed. Some people develop flu-like symptoms, such as fever, headache and body aches. The U.S. Centers for Disease Control and Prevention (CDC) warns that for certain people, especially those with a weak immune system, it can be a severe, life-threatening disease and that while bloodborne transmission of babesiosis is thought to be uncommon, it is the most frequently reported transfusion-transmitted parasitic infection in the U.S. and remains an important concern.

The investigational use of *Babesia* donor testing has been in place since August 2012 in selected *Babesia* endemic areas under investigational new drug applications (INDs). The use of the investigational tests has resulted in the removal of a significant number of infected units from the blood supply. The data collected from this testing and from additional studies performed by the manufacturer prevented the release of hundreds of potentially infectious donations and demonstrated that the tests are effective in screening donors for *B. microti* infection. The tests approved today are not intended for use in the diagnosis of babesiosis infections.

These applications were granted Priority Review (/patients/fast-track-breakthrough-therapy-accelerated-approval-and-priority-review/priority-review), under which the FDA's goal is to take action on an application within six months where the agency determines that the product, if approved, would significantly improve the safety or effectiveness of treating, diagnosing or preventing a serious condition.

There currently is no FDA guidance for the testing of donor samples for *Babesia*. However, the FDA is planning to issue draft guidance with recommendations for reducing the risk of transfusion-transmitted babesiosis later this year.

The approval of the Imugen *Babesia microti* AFIA and NAT tests was granted to Oxford Immunotec, Inc. Both assays are in-house tests that can only be performed at the Norwood, Massachusetts facility.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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