Dear Rep Marsh,

I sent the registered letter below to Dr. Jose Montero, past Director of the NH Department of Health in 2010 and
coordinated an onsite meeting which included Dr. Lynn Durand, .currently a member of our study commission.

The letter identifies five cases where a negative Elisa led to patient harm. These cases were summarized by a
Lyme knowledgeable practitioner.

If you are interested in the agenda and who attended that meeting ten years ago you can click on the link below
and it will take you to my personal Dropbox storage area where I have archived the document: (perhaps after reading
that document you'll understand my frustration)
https://www.dropbox.com/s/5lo985nkt39sb1z/Dept%20of%20Health%20Agenda.pdf?dl=0

Please see the email thread below sent to Representative Woods.

I would like this communication posted to the Commission website under the Right-to-Know law.

Respectfully submitted,

Carl Tuttle

Date: 10/05/2020 9:32 AM
Subject: Re: PDF file for the records of the HB490 Lyme Disease Study Commission

Dear Rep Woods,

Thank you for reaching out to me this weekend regarding a possible dedicated website for documents presented to the Commission. While those details are being worked out, I would like to share the following complaint sent in 2010 to Dr. Jose Montero, past Director of the NH Department of Health.

Any new testing (serology) brought to market today does not have to go through the FDA approval process as long as it performs at least equal to an existing FDA approved test as described in the document included in my previous email. (Page 23 510(K) premarket submission)

The letter below will give you an idea of how well our existing FDA approved Lyme test

works in the field.

Sincerely,

Carl Tuttle
Hudson, NH

Registered Complaint

July 7, 2010

New Hampshire Department of Health and Human Services
29 Hazen Drive
Concord, NH03301-4604
Attn: Jose T. Montero, MD, Director

Dr Montero,

This certified letter serves as legal notice that you as New Hampshire's chief epidemiologist are being notified of ongoing health risks in the State of New Hampshire. First, there appears to be an alarming number of Lyme cases within a 500 yard radius of our home located on David Dr in the town of Hudson. We know of nine individuals who have been treated for Lyme disease with two additional cases suspected.

The second serious health risk which I will identify below is a plague of ignorance within the medical community as it relates to Lyme diagnosis. The following case studies collected from a Lyme literate practice point out that misdiagnosis is rampant with lab interpretation as the number one area of significant confusion.

Case# 1

Male age 27 with no known tick bite but many mosquito bites. FIVE previous ELISA tests were all NEGATIVE. The patient was sick with fatigue, headaches and cognitive issues for 1.5 years and missed a year of school before seeing a Lyme literate practice and given the more sensitive Western blot test. Western blot was CDC POSITIVE for Lyme disease.

Note: The ELISA test is unreliable as proven in this case but patients are routinely refused the more specific Western blot when the ELISA is negative. We have first hand experience as my wife was denied a Western blot through her primary care physician, Dr XXXXXX XXXXX affiliated with Dartmouth Hitchcock Hospital.

Case# 2

Female age 60 diagnosed with ALS in 2008. ELISA test was NEGATIVE. When given the Western blot test last month the patient tested CDC POSITIVE for Lyme disease.

Case# 3

Male age 8 with knee pain and swelling. Underwent four knee surgeries. Seen by rheumatology and diagnosed with idiopathic knee pain “growing pains”. ELISA test results were NEGATIVE through the patient’s primary care office.

A recent Western blot was positive for Lyme disease.

Case# 4

Female age 18 was told she had an infected bug bite and was prescribed Keflex through the patient’s primary care office. ELISA test was done weeks later and results were NEGATIVE. Patient missed thirty six days of school. A Western blot which was not provided by the PCP was positive for Lyme disease. Improvement started two weeks into treatment with proper antibiotics.

Note: This patient stored a picture of the bug bite on her cell phone which was clearly a bull’s-eye rash but unrecognized by the PCP.

Case# 5

Male age 39 with fatigue and swelling joints for 1.5 years. ELISA test results were NEGATIVE through the patient’s primary care office. A recent Western blot was CDC POSITIVE for Lyme disease.

Many of these patients presented with the most obvious of Lyme symptoms, i.e. joint pain/swelling and fatigue yet proper diagnosis and treatment was missed by a medical community misinformed through unreliable diagnostic testing and restrictions against the use of the more sensitive Western blot.

Interpretation of the Western blot is another area of significant confusion. Strict criteria were created in 1994 for surveillance of Lyme disease and only those patients who met the strict case definition were reported to the CDC. So if you did not meet those criteria your Western blot stated NEGATIVE. (See my wife’s attached Western blot results attachment # 1)In February of 2005 the CDC issued a cautionregarding testing for Lyme disease:

Health-care providers are reminded that a diagnosis of Lyme disease should be made after evaluation of a patient's clinical presentation and risk for exposure to infected ticks, and, if indicated, after the use of validated laboratory tests.

In 2008 the CDC updated its Lyme Case Definitionstating the following:

“This surveillance case definition was developed for national reporting of Lyme disease; it is not intended to be used in clinical diagnosis”

Dr Montero, you were recently interviewed on New Hampshire Public Radio where you made reference to the CDC’s “updated Case Definition” (9 minutes into the archived program)You believed that one reason New Hampshire has the highest rate of Lymein the country might be due to a change in case definition. So you obviously are aware that the case definition is not intended to be used in clinical diagnosis. For some reason Dr Montero your colleagues did not get that memo.

Case in point: My daughter’s primary care physician (Dr XXXXXXX XXXXXXXX, XXXXX XXXXXXXXXX) called to inform her she did not have Lyme disease based on the results from Quest Diagnostics NEGATIVE Western blot. (See attachment # 2) Dr XXXXXXXX did not see my daughter nor did she discuss symptoms prior to informing her she did not have Lyme disease.This story is not unique and has been repeated over and over as we hear the same scenario at the monthly Greater Manchester Lyme Support Group meetings.

Lyme literate Infectious Disease Specialists recognize that it is not necessary to meet the case definition in order to diagnose Lyme disease.

I would like to point out that your department sent a health alert to doctors across the state on June 21st (Attachment# 3) SUBJECT: “Tick-borne Disease in New Hampshire – Update.” Why is there no mention within that health alert that the CDC case definition was developed for national reporting of Lyme disease and it is not intended to be used in clinical diagnosis? Wouldn’t it make sense to pass along this important fact?

Imagine designing a screening test where negative results are seen 95% of the time? This is happening in your state under your watch Dr Montero. If you are finding this difficult to believe I urge you to attend one of the monthly Lyme Support Group meetings and learn first hand how misinformed your medical community is as it relates to the diagnosis of Lyme disease. Let me remind you of the following statement found within your web site: “The Department of Health and Human Services’ Mission is to join communities and families in providing opportunities for citizens to achieve health and independence.”

The fact that each Lyme case (suspected or confirmed) has to be reported to the Department of Health and Human Services should leave a paper trail worthy of investigation. All of Quest Diagnostic’s NEGATIVE Western blot results should lead directly to those cases that have been misdiagnosed. We know of cases where physicians are telling patients that their POSITIVE IGeneX lab reports are unreliable. IGeneX Laboratoryis the foremost authority for Lyme disease testing in the country and CLIA-certified and inspected by the Department of Health and Human Services for Medicare testing. IGeneX lab’s Western blot includes bands 31 and 34 which are highly specific to Lyme (Borrelia burgdorferi) and were originally chosen for vaccine development. Quest diagnostics and other commercial testing labs exclude these two

critical bands.

Misdiagnosis has created a backlog of late stage Lyme patients with a waiting list to see a Lyme literate doctor in some cases approaching six months. Misdiagnosed patients are missing the narrow window of opportunity for successful short term treatment.

I have serious reservations as to whether or not the medical community could self-police itself in light of a possible professional embarrassment and that's why I have sent additional registered letters to the Attorney General and Governor's office. A study of the lab results in your department and follow-up phone calls directly to the patient should reveal what is taking place. This is a serious issue that affects all New Hampshire citizens and should not be taken lightly.

For public review, a web site has been constructed with this letter as its home page as a record of the complaint. In addition, an effort to identify those physicians who misdiagnose Lyme disease and publicly post their names along with scanned lab test results is currently being considered.

The misdiagnosis of Lyme disease has to stop Dr Montero. You and others reading this letter are just a tick bite away from Lyme disease in this state as things stand now. The Lyme community is requesting that you take an active role in preventing this ongoing tragedy. When are we going to restructure testing andtraining of the uninformed providers? We have presented the facts without exaggeration and would like to know how you intend to address this serious issue.

New Hampshire Lyme Community

Carl Tuttle

Hudson, NH 03051

p.s. I visited the Hudson Animal Hospital today to ask a few questions about Lyme tests for pets. As it turns out they now include Heartworm, **Lyme**and **Ehrlichia**(tick transmitted disease) as **routine tests**with annual physicals. The receptionist reported that there is a serious problem with Lyme in the Robinson Pond area.

We do not receive routine Lyme tests. You could argue that our pets are receiving better healthcare than we are.

On 10/03/2020 10:27 AM CARL TUTTLE <runagain@comcast.net> wrote:

Oct 3, 2020

The New Hampshire House of Representatives
Health, Human Services and Elderly Affairs
Attn: Representative Gary Woods, Chair for the HB490 Commission

Dear Representative Woods,

I would like to submit the attached PDF file to be included in the records of the **HB490 Study Commission** as it is a compilation of facts/references gathered over the past decade.

I recommend reading this document prior to the first meeting.

The public and our medical community have been misguided by a number of inaccuracies from the US Centers for Disease Control and disseminated through the NH DOH Lyme disease website and Health Alerts.

Two examples:

#1. ".....approximately **70-80% of patients**, illness first manifests with a red "bull's-eye" rash."

In reference to the incidence of bull-eye rash, the state of Maine is reporting an average of a **48.25%** incidence of rash-related Lymeover a four-year period (they've only been making this report for 4 years). See page 3 or 4 of each document below:

http://lldc.mainelegislature.org/Open/Rpts/rc155_5_r4_2009.pdf --- **2009, 59%**
http://www.maine.gov/dhhs/mecdc/infectious-disease/epi/vector-borne/lyme/documents/lyme-legislature-2010.pdf-- **2010, 43%**
http://www.maine.gov/dhhs/mecdc/infectious-disease/epi/vector-borne/lyme/documents/2011-lyme-legislature.pdf-- **2011, 42%**
http://www.maine.gov/dhhs/mecdc/infectious-disease/epi/vector-borne/lyme/documents/2012-lyme-legislature.pdf-- **2012, 49%**

I would like to point out that the lead author of the first study Dr. Gensheimer served as an Epidemic Intelligence Service Officer with the national Centers for Disease Control and Prevention prior to her assuming her current position in Maine

All Tuttle family members progressed to late stage debilitating Lyme as none of us developed the bull's-eye rash. Most people never notice the tick that gave them Lyme disease.

#2. "If a tick is not attached to your skin for at least **24-36 hours**, your chance of getting Lyme disease is extremely small."

A. Clinical evidence for rapid transmission of Lyme disease following a tick bite

Eleanor D. Hynote, Phyllis C. Mervine, Raphael B. Stricker
Diagnostic Microbiology and Infectious Disease, online
before print, November 20, 2011.

http://dx.doi.org/10.1016/j.diagmicrobio.2011.10.003

Abstract

Lyme disease transmission to humans by Ixodes ticks is thought to require at least 36–48 h of tick attachment. We describe 3 cases in which transmission of Borrelia burgdorferi, the spirochetal agent of Lyme disease, appears to have occurred in less than 24 h based on the degree of tick engorgement, clinical signs of acute infection, and immunologic evidence of acute Lyme disease.

B. Patmas, MA, Remora, C. Disseminated Lyme Disease After Short-Duration Tick Bite. JSTD 1994; 1:77-78

Patmas and Remora reported on a case of Lyme disease that was transmitted after only 6 hours of attachment by a deer tick.

C. Lyme borreliosis: a review of data on transmission time after tick attachment
Michael J Cook
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4278789/

The claims that removal of ticks within 24 hours or 48 hours of attachment will effectively prevent LB are not supported by the published data, and the minimum tick attachment time for transmission of LB in humans has never been established.

Dr. Willy Burgdorfer said at a Lyme disease conference at Bard College in 1999 that about 5-10% of ticks that are carrying Lyme disease have a systemic infection and have the disease in their saliva and can transmit it as soon as they bite. He said, "**There is no safety window**." That means that all statements that say it takes "at least" so many days or hours for a tick to transmit Lyme disease are false.

Source: https://www.lymedisease.org/kathy-white-cdc-phone-2/

Respectfully submitted,

Carl Tuttle

Hudson, NH

Cc: Gov Chris Sununu, Sponsors of HB490