

Registered Complaint

July 7, 2010

New Hampshire Department of Health and Human Services
29 Hazen Drive
Concord, NH 03301-4604
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 [caution](#) regarding 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 Definition](#) stating 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 Lyme](#) in 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 XXXXXXXX XXXXXXXXX, XXXXX XXXXXXXXXXXXX) 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 Laboratory](#) is 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 and training 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.