COLUMBIA UNIVERSITY
MEDICAL CENTER

BRIAN A. FALLON, MD
Director
212.543.5487 Tel
baf1@columbia.edu

KATHY M. CORBERA, MD
Associate Director
212.543.6508 Tel
kmc104@columbia.edu

Lyme Disease Research Program
1051 Riverside Drive
New York, NY 10032
212.543.6515 Fax

www.columbia-lyme.org

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RE: Bill 5747

To the Public Health Committee:

I am writing to express my strong support for re-instatement of the mandatory laboratory reporting of Lyme Disease in the state of Connecticut. I reside and work in Connecticut. I also direct the Lyme and Tick Borne Diseases Center at Columbia University in New York. I am writing as both a concerned scientist and as a resident of this state.

The problem is this. If you look at the case reports for Lyme Disease to the CDC from Connecticut, the average annual case rate over the 3 year period between 2000-2002 was 4,000 cases/year. The average annual case rate in Connecticut over the next 3 year period of 2003-2005 was 1057 cases/year. This represents a 71.7% drop in the state of Connecticut. What happened? It's not that Connecticut had less Lyme Disease during this period. It's that the reporting requirements changed.

If you make the more appropriate assumption that the case rate for Lyme disease over the last 3 years increased at the same rate as it did for all other states (excluding CT), then the increase in CT over the last 3 years should have been exactly as it was nationally in all other states – ie, 28.6%. In other words, the rate reported for CT to the CDC based on these assumptions over the last 3 years should actually have been 5,144 cases/year. The actual reported rates over the last 3 years for CT as noted above was 1057/cases year. Compared to what we should have been reporting if active lab surveillance were in place, this represents a 79.5% decline. This obviously terribly misrepresents the problem of Lyme Disease in this state. Based on national statistics, it is more likely that there would have been a 28.6% increase.

What did this change from mandatory laboratory reporting do to the statistics for the rate of Lyme Disease in the country as a whole? Looking at the same 3 year periods, you see according to the currently reported statistics (2000-2002 vs 2003-2005), a gradual increase nationally in the case rate from 19,507 cases/year to 21,460 cases/year. That represents a 9.1% increase. This however under-represents the increase for the following reason:

- If you make the conservative assumption that the rate of Lyme disease increase in Connecticut actually remained static rather than declining (ie, assume that the rate remained exactly the same as it had for the prior 3 year period when mandatory lab reporting was required), then you see that the national case rate for 2003-2005 should actually be 23,940. That would represent a 22.7% increase in cases nationally over the prior 3 year period.
- If you make the more reasonable assumption that the increase in the case rate for CT was the same as the increase in the case rate for all other states, then the CT average for the last 3 years should have gone up to 5,144 cases/year and the national average with CT included (assuming that mandatory reporting had been kept in place) should have gone up to 25,084 cases/year for the last 3 years.

That would mean that the case rate nationally for the most recent 3 year period would have increased by 28.6% compared to the prior 3 year period.

In other words, which is more troubling? A case rate for Lyme disease nationally that increases by 9.1% or one that increases by 28.6? Which is more likely to lead to alarm bells in Congress that we have a nationally increasing epidemic? **An increase in the case rate of 28.6% is likely the correct figure for the country as a whole.** If this figure is correct, then the actual case rate for the United States should be 3x higher than is currently presented by the CDC data. **The problem is that because of the loss of mandatory reporting, the state of CT's contribution to the CDC national reporting is resulting in a gross under-representation of the actual problem of Lyme disease in this country.** This leads to a lack of concern about Lyme disease in government and a lack of funding allocated to Lyme research.

For the above reasons, based purely on the statistics provided by the CDC and a set of reasonable assumptions, it is clear that CT needs to reinstate mandatory laboratory reporting.

The second issue I wish to address is one regarding seronegative Lyme disease. This refers to the clinical situation in which one has a patient who has the typical clinical features of Lyme disease but is testing negative on current tests. Much of this problem emerges from variability in the sensitivity of laboratory tests.

As part of a NIH-funded study we conducted at Columbia, we learned that patients with seronegative Lyme disease often have nearly identical clinical profiles to patients with sero-positive Lyme disease. Of 525 patients who had been diagnosed and treated for Lyme disease and who met the CDC clinical criteria but who never met the CDC laboratory criteria, the symptom profile and prior treatment history were virtually identical. What this means is that there are many patients who are being diagnosed and treated for Lyme disease due to chronic multisystemic symptoms but who do not meet the CDC laboratory criteria. It could be that these patients are being mistreated and in fact do not have LYme disease. It could also be, given that their symptom profile meets CDC criteria for clinical Lyme disease, that they did have Lyme disease but are not being counted as such due to the stringency in the CDC's laboratory surveillance monitoring criteria. That means the physicians who follow the CDC laboratory criteria will fail to diagnose patients who do in fact have Lyme disease and need treatment.

Would it be helpful to have a better grasp of how many of these patients do exist? Yes. It would give us a much better understanding of the incidence of Lyme disease in Connecticut. Would this be a straight-forward task? No. If the blood testing criteria become more lenient, we will have fewer false negatives but also more false positives. One solution might be to make only a very modest change in the reporting criteria. For example, instead of requiring 5 of 10 CDC bands on the IgG Western blot, one could require 4 of 12 bands (including the 10 CDC bands as well as two other bands recognized as specific for Borrelia burgdorferi - the 34 KD band and, among non vaccinated individuals the 31 Kd band). There are many criteria sets to consider if one were to develop a less stringent but still reasonable set of laboratory criteria for a second tier of reporting. I would recommend that a panel of experts be convened to examine this issue. I would be happy to participate if such a panel were convened as we have a very large data set of Western blot test results on patients with histories of Lyme disease.

Brian A. Fallon, MD
Columbia University

Residence: 108 Old Orchard Park
Fairfield, CT 06824