Dear Rep Woods,

I would like to point out that my email you hit “Reply All” to regarding the announcement from Galaxy Diagnostics is identifying the “Limitations of serological diagnostic tests”

From the Galaxy announcement:

“Galaxy validation data (unpublished) shows that the Nanotrap® Urine Test will often confirm active infection in patients with negative TTT (Two-Tiered Testing) results.”

Over the past three decades there has been a controlling of the narrative and a suppression of the truth/facts/scientific references in order to propagate the long-established racketeering scheme that has misclassified Lyme as a simple nuisance disease (hard to catch and easily treated) [1]

I certainly hope that this Study Commission will not tolerate outside influence and a continuation of this method to keep the public and medical community in the dark and will be open to discuss everything relating to Lyme disease in order to reach a balanced conclusion in the final report.

Respectfully submitted,

Carl Tuttle

Reference

1. Lyme Disease Is Hard to Catch And Easy to Halt, Study Finds

New York Times By GINA KOLATA Published: June 13, 2001
http://www.nytimes.com/2001/06/13/us/lyme-disease-is-hard-to-catch-and-easy-to-halt-study-finds.html

Excerpt: But some who have treated hundreds of patients with long-term antibiotics, like Dr. Sam L. Donta of Boston University Medical Center, were not convinced. The antibiotics in the studies were not given for a long enough time, Dr. Donta said, and he would have chosen different ones. Perhaps all that the studies show, he said, is"that this particular treatment doesn't work."

On 12/06/2020 5:03 PM Gary Woods <gary.woods@leg.state.nh.us> wrote:

HB 490 – Commission on tick-borne Diseases

The following is a reorganization of HB 490 section III (a) in a way that may help us understand our charge. It is offered as a point of departure for discussion.

Looking forward to seeing everyone on the 9th at 9am

Rep. Woods

III. The Commission shall:

(a)Consider expert studies and testimony on the role of :

1. Clinical diagnosis
2. Limitations of serological diagnostic tests
    1. IDSA
    2. ILADS
    3. CDC
    4. TBDWG
3. Complexities presented by co-infections relating to symptomology, diagnosis, and treatment

    (i.e. what other entities can mimic tick-borne diseases or what treatments mask tick-borne diseases)

    In determining the presence or absence of Lyme and other tick-borne diseases.

From: CARL TUTTLE <runagain@comcast.net>
Sent: Friday, November 13, 2020 11:04 AM
To: Gary Woods <Gary.Woods@leg.state.nh.us>; Christina Dyer <Christina.Dyer@leg.state.nh.us>; Dr. Ben Chan <benjamin.chan@dhhs.nh.gov>; Dr. Frank Hubbell <bearhubbell@aol.com>; Dr. Jeff Parsonnet <jeffrey.parsonnet@hitchcock.org>; Dr. Lynn Durand <ldurand@crhc.org>; Dr. Rex Carr <rcarrmd@comcast.net>; Jeb Bradley <Jeb.Bradley@leg.state.nh.us>; Kathie Fife <kathie@kathiefife.com>; Michelle Wagner <mwagner@naminh.org>; Susan Ticehurst <Susan.Ticehurst@leg.state.nh.us>
Cc: lgardella@ehr.org <lgardella@ehr.org>; James Cianci <James.Cianci@leg.state.nh.us>
Subject: Galaxy Diagnostics Launches the Most Sensitive Test Available for Direct Detection of Lyme Disease

To Members of the NH Lyme Study Commission,

Please see the letter below addressed to the Chief Scientific Officer of Galaxy Diagnostics. The contents of the letter relate to the activity of the commission under Section **141-C:6-a**

Carl Tuttle
---------- Original Message ----------
From: CARL TUTTLE <runagain@comcast.net>
To: "ebbreits@ncsu.edu" <ebbreits@ncsu.edu>
Cc: "contact@galaxydx.com" <contact@galaxydx.com>, "liotta.lance@gmail.com" <liotta.lance@gmail.com>, "rdunlap@ceresnano.com" <rdunlap@ceresnano.com>, "aluchini@gmu.edu" <aluchini@gmu.edu>, "amanda.elam@galaxydx.com" <amanda.elam@galaxydx.com>, "jen.miller@galaxydx.com" <jen.miller@galaxydx.com>
Date: 11/13/2020 10:33 AM
Subject: Galaxy Diagnostics Launches the Most Sensitive Test Available for Direct Detection of Lyme Disease

Galaxy Diagnostics Launches the Most Sensitive Test Available for Direct Detection of Lyme Disease ($295)

https://www.prnewswire.com/news-releases/galaxy-diagnostics-launches-the-most-sensitive-test-available-for-direct-detection-of-lyme-disease-301169364.html

"Galaxy validation data (unpublished) shows that the Nanotrap® Urine Test will often confirm active infection in patients with negative TTT (Two-Tiered Testing) results."

Nov 13, 2020

GALAXY DIAGNOSTICS
6 Davis Drive, Suite 201
Research Triangle Park, NC 27709
Attn: Edward Breitschwerdt, DVM, Chief Scientific Officer
Dear Dr. Breitschwerdt,

Thank you for announcing the Nanotrap® Urine Test for Lyme disease. For nearly four decades now the only FDA approved test for Lyme disease is the indirect two-tiered antibody test. (Humans do not produce antibodies for 4-6 weeks after a tick bite) Direct detection methods to identify the causative agent responsible for the disease have been avoided, criticized, shelved and outright rejected by the US Centers for Disease Control.

Examples:

1. Culture test from Advanced Laboratory Services:

Assessment of New Culture Method for Detection of Borrelia Species from Serum Assessment of Lyme Disease Patients Barbara J. B. Johnson, Mark A. Pilgard and Theresa M. Russell https://www.ncbi.nlm.nih.gov/pubmed/23946519

Barbara Johnson of the CDC claims contamination is the major issue with this new culture method. Why didn't the CDC work with Advanced Laboratory Services to correct any issues and perfect this laboratory testing method?

2. National Institute of Standards and Technology (NIST)

New Experimental Test Detects Signs of Lyme Disease Near Time of Infection February 11, 2016 https://www.nist.gov/news-events/news/2016/02/new-experimental-test-detects-signs-lyme-disease-near-time-infection

Response from a recent communication with Illarion Turko, Research Chemist: *"This project did not receive further development and is on-hold for now."*

3. 16S rRNA sequence analysis As soon as Dr. Sin Lee published his findings of persistent infection from serum samples he received from the CDC, all communication stopped.

$57 million claim against the CDC on Lyme test: https://www.change.org/p/the-us-senate-calling-for-a-congressional-investigation-of-the-cdc-idsa-and-aldf/u/20864023

Nested PCR and Sequencing for Lyme disease through**Milford Molecular Diagnostics**can detect early infection with as few as 25 bacteria per mL of blood.

Source:http://www.dnalymetest.com/faq.html

In contrast,**the CDC announced the Development of a Novel Genus-specific Real-time PCR Assay for Detection and Differentiation of Bartonella Species and Genotypes** http://www.ncbi.nlm.nih.gov/pubmed/22378904

DNA testing is being used for Bartonella and now Zika:

CDC Lauds New DNA Test for Zika in Blood http://www.medpagetoday.com/InfectiousDisease/GeneralInfectiousDisease/58622?xid=nl_mpt_DHE_2016-06-18&eun=g750897d0r

There is a double standard for Lyme disease in reference to DNA testing.

Per the testimony of Clinical Psychologist Dr. Richard Shulik reporting on patient experience with Lyme testing in New Hampshire: (Personal Dropbox storage area) https://www.dropbox.com/s/8gxit7rqeyo1tux/Dr%20Shulik%20Letter%20Jan%202010.pdf?dl=0

"Many of them (Lyme Patients) also found themselves in long-running disputes with disability insurance providers who accused them of malingering and who even refused to recognize their diagnosis of Lyme disease when it was confirmed. To say the least, these are nightmarish experiences which I would not wish upon anyone."

_____

Dr. Breitschwerdt, there appears to be a concerted effort to deny a Lyme disease diagnosis when patients do not meet the CDC's strict criteria for positive serologic results. Any other test no matter how accurate is intentionally overlooked to avoid financial responsibility for active disease.

Patient testimony all across America is describing a disease that is destroying lives, ending careers while leaving its victim in financial ruin. [1] Patients who end up disabled by Lyme are left to fend for themselves. Any test that identifies failed treatment (chronic Lyme) contradicts the existing false paradigm; chronic Lyme does not exist.

Question:

Does Galaxy Diagnostics intend to file for FDA approval of the Nanotrap® Urine Test?

Respectfully submitted,

Carl Tuttle Lyme Endemic Hudson, NH

Cc: Galaxy CEOAmanda Elam Ross Dunlap, CEO and a co-founder of Ceres Nanosciences.

Reference:

[1] By way of introduction, I am the Change.org petition organizer calling for a congressional investigation into the mishandling of Lyme disease. For the past decade I have investigated the mishandling of Lyme disease after ending up bedridden on oxygen and near death in the fall of 2008.

The petition has generated over 1100 pages of heart wrenching comments from horribly disabled

patients around the globe. Latest comment file:PDF (Please feel free to download from my Dropbox account)

Tuttle directs pointed questions to TBD Working Group member Shapiro

https://www.lymedisease.org/carl-tuttle-tbdwg-comments/