

## LYME DISEASE ADVOCACY ORGANIZATION MEETS WITH FDA

BOSTON, MA (October 25, 2021) — Nonprofit grassroots organization TruthCures met with Food & Drug Administration (FDA) officials last week to discuss issues related to notoriously inaccurate Lyme disease diagnostic tests. The group's executive director, Laura Hovind, and associate Lahra Tillman were joined by Carl Tuttle, an appointee to New Hampshire Governor John Sununu's Lyme Disease Study Commission, and their legal counsel, a former federal prosecutor. Kenneth Liegner, M.D., a longtime treating physician, published author and renowned Lyme disease expert participated remotely to demonstrate the deficiencies of the Lyme disease diagnostic method and the harm it does to patients.

At issue are 27 years worth of FDA-cleared Lyme disease diagnostic tests. Lyme disease is a bacterial illness caused by the bite of an infected tick. TruthCures claims the diagnostics are wholly inadequate because they are designed to detect only a small minority of cases predisposed to developing "Lyme arthritis," a less-severe manifestation of the disease. They cited published literature and historical federal meeting documents that indicate the sicker Lyme disease cases are immunosuppressed and rarely test positive by the criteria that have been in place for nearly three decades.

"We are extremely pleased with the FDA's response so far and are encouraged by how quickly they understood the problem and began thinking of solutions available to them within the regulatory framework," said Tillman.

In a detailed presentation, the group explained how Lyme disease researchers' financial interests in patents for the various bacterial components of diagnostic tests and vaccines have been prioritized over public health. They also shared results of an independent analysis by a diagnostics regulatory expert indicating there may have been irregularities with the process by which Lyme disease diagnostic tests were relabeled in the late 1990s. "We are very concerned that patients were left out of the equation when changes were made to the testing protocol," said Hovind.

The group requested the FDA's assistance in investigating the manipulated diagnostic protocol and its far-reaching effects, as well as coordinating with other agencies to evaluate related accepted standards they claim are inadequate. "As a public servant myself, I applaud the FDA investigators' efforts to understand and act on information provided by concerned citizens," noted Amy Kissinger, a member of TruthCures' board of directors. "We are confident in their dedication to do the right thing in terms of the regulatory component of our claims."

Added Hovind, "Our goal has always been to expose the truth and clear the way for accurate tests so the millions suffering this devastating disease can get the diagnosis and treatment they need. This development should give them hope that someone is striking at the root of the problem, and change is on the way."

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TruthCures is a registered 501(c)3 nonprofit organization dedicated to restoring a valid case definition for Lyme disease so all affected people can be accurately diagnosed and successfully treated. For more information, visit truthcures.org or email truth@truthcures.org.