FDA Moves to Regulate All Lyme Tests

FDA is moving forward in the process of finalizing its new Laboratory Developed Test (LDT) Guidance proposal. The proposal would move LDTs from under the jurisdiction of Clinical Laboratory Improvement Amendment (CLIA) regulated by Medicare & Medicaid Services to under the jurisdiction of the Food & Drug Administration (FDA). The FDA now regulates non-LDT lab tests under “medical devices,” and “approves” or “clears” tests. Non LDTs are tests which are sold to other laboratories while LDTs are generally tests which are developed and used in one lab, commonly called specialty labs.

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For the last several months, the LDA has been working a parallel track with other Lyme leaders and on its own to try to understand the implications of such a move for patient access and try to ameliorate any downsides to patients on moving Lyme test under this Guidance.

To that end, the LDA has been on 2 phone calls with FDA officials and other advocates. LDA also contacted a number of Lyme specialty labs about the issue. The LDA made a slide presentation to the FDA’s public workshop on the Guidance on Jan 8-9, 2015, and had a representative available at the 2 day workshop. All presentations at the workshop to the FDA panels were limited to 4 timed minutes and had a category restriction. The LDA and LDo cooperated to present different categories since the speaking time was so limited. **CLICK HERE FOR LDA SLIDES** Two representatives of IGenex Labs, CA, also presented at the workshop.

The LDA also contacted the offices of Congressman Christopher Smith (NJ), House Lyme

Caucus Chair, and Senator Richard Blumenthal (CT), both of whom have worked with LDA on Lyme issues before. Congressman Smith's office held a meeting with FDA officials to discuss concerns we had raised and continues to follow-up on unsettled issues. Senator Blumenthal wrote a letter to FDA expressing concerns LDA and LDo had voiced on the guidance.

The LDA has also submitted input to the US House of Representatives Energy & Commerce Committee's *21st Century Cures* initiative, specifically "21st Century Cures – A Modernized Framework for Innovative Diagnostic Tests." **CLICK HERE FOR LDA LETTER TO ENERGY & COMMERCE COMMITTEE**

Concerns the LDA has are that

1. the peer review process which will be used to categorize tests and risks could be biased. This concern is based on the prior use of "experts" in Lyme disease.

2. the process used for collecting adverse events (MAUDE) currently used by FDA for approved/cleared tests is already flawed– FDA cannot determine which test kits are being reported. Yet under the proposed Guidance, the LDTs would be dumped into the same flawed MAUDE system. That action could put the newly cleared LDTs at a disadvantage, because the LDTs put into the MAUDE system would be subject to greater scrutiny, since FDA would have the ability to more readily act upon the complaints.

3. government agencies have touted that all Lyme tests should be FDA approved, and through our analysis of FDA's process, we discovered that FDA cannot point to any "approved" Lyme tests; they are all "cleared" which means substantially equivalent to a predicate test–to what test exactly, no one knows, since they cannot point to any original predicate test for Lyme that was not itself also based on substantial equivalence.

4. specialty lab tests will be removed from the market during the review process, citing safety reasons, which can be, e.g., too many positives.

CLICK HERE FOR LDA LETTER TO FDA WITH 73 GROUPS SIGNED ON

2016 UPDATE FROM FDA

FDA DELAYS FINALIZATION OF LAB-DEVELOPED TEST DRAFT GUIDANCE

The FDA announced in November 2016 that it would wait for the new administration and halt the finalization of guidance that would have changed the way laboratory-developed tests are regulated.

http://raps.org/Regulatory-Focus/News/2016/11/18/26218/FDA-Delays-Finalization-of-Lab-Developed-Test-Draft-Regulations/