Lyme & Other Tick-Borne Diseases: Process Concerns About FDA Testing Guidance

Public Process for Classification & Prioritization Section

Presented to

FOOD & DRUG ADMINISTRATION

Public Workshop-

Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs) Jan. 8-9, 2015

NIH Campus, Bethesda, Maryland

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for

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on

January 9, 2015

Lyme Disease Association, Inc. (LDA)

- Lyme Disease Association
  - Provides grants for research
    - Which has led to 35 peer reviewed science journal publications to date
  - Holds annual CME medical conferences for doctors and researchers
  - Is different than most other participants here, but shares a common interest with them
    - To ensure patient access to effective diagnostics & treatments

Issues Specific to Lyme Disease

- Controversy surrounding Lyme disease
  - Vested interest in tests
  - Quality of tests generally poor
  - Inconsistent test quality information even from government agencies
  - Agencies often say tests are sensitive while peer review often says otherwise
- All aspects of Lyme need to be questioned including the quality of tests and reliability of information – regardless of the source

Expert Panel Recommendations on Risks, Classification, Enforcement Prioritization

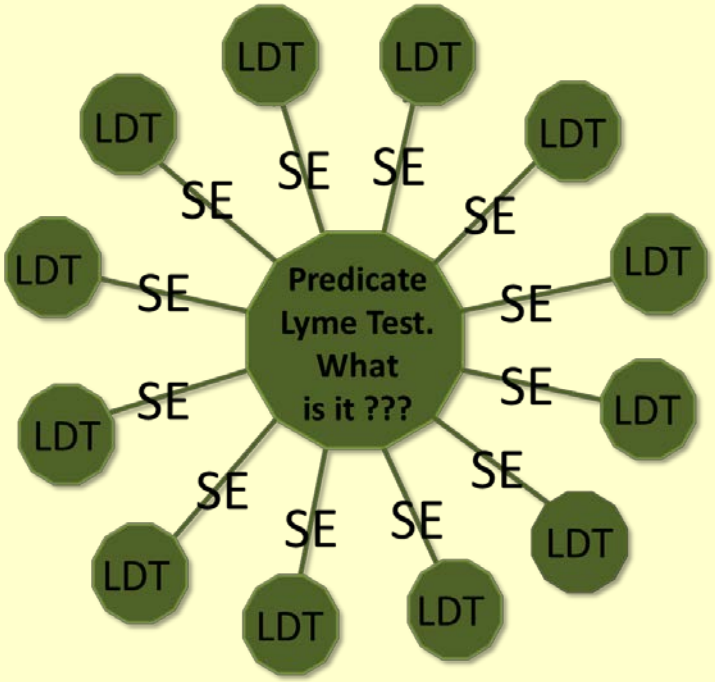
- Lyme has a history of bias of “experts”
  - Leads to concern about composition of panels
    - Screening of potential panel members for conflicts of interest
    - Representation of different perspectives to minimize bias

Risk Evaluation Concerns

- **Quality and efficacy of FDA-cleared Lyme tests are not well understood**
- **How do you evaluate risk if you do not have a good grasp on test performance?**

– Almost all FDA-cleared Lyme tests were based on substantial equivalence, which in the case of Lyme, sets a low bar

– For Lyme, we can't even identify what the predicate test was



SE-Substantially Equivalent
LDT-Laboratory Developed Test

Risk Evaluation Concerns

- Risk Communication on the Label
  - Labeling information should be evaluated with consideration given to prominently including, if not already provided
    - Information on purposes for which Lyme tests were developed
      - e.g., surveillance, screening or diagnosis
    - Limitations of tests
      - e.g., low sensitivity
    - Warnings regarding interpretation
      - e.g., a negative result does not necessarily mean that an individual does not have Lyme disease and further evaluation may be necessary

Risk Evaluation Concerns

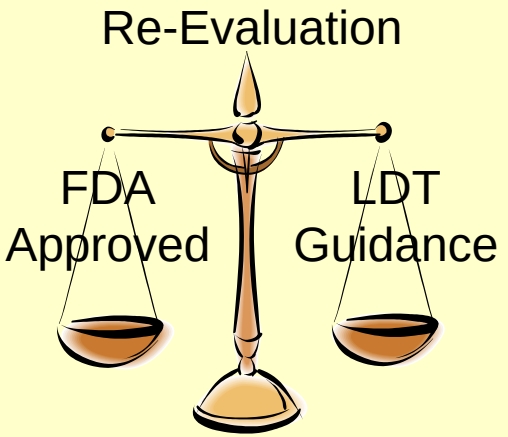
- The consequences of antibiotic use in Lyme need to be realistically evaluated, including consequences of delayed treatment
  - Needs to be a balanced assessment of consequences of false positives and false negatives
    - Excessive focus from some parties on adverse consequences of false positives, while minimizing patient and treating physician concerns with the serious health consequences of false negatives
  - Possible public health risks, such as the potential for development of antibiotic resistance, should not be misrepresented
    - Evidence does not support the use of antibiotics in Lyme as a significant contributor to the problem of resistance, contrary to frequent claims

Risk Evaluation Concerns

- Need to recognize that adverse events reporting for Lyme diagnostics is problematic
  - The existing adverse events system (MAUDE) has been very poor at identifying and capturing performance problems with cleared tests
  - Cannot even determine what specific tests were used by labs, since non-specialty labs often use >1 test
  - Issues regarding adverse events reporting for Lyme should be addressed simultaneously for FDA cleared tests and newly regulated LDTs

Evaluation of Risks - Conclusion

- Guidance necessarily focuses on LDTs that have not been subjected to FDA review
- In the case of Lyme diagnostics, tests previously cleared by FDA must be reevaluated
  - To level the playing field & protect patient interests
  - New public information requirements for LDTs should also be applied to existing FDA cleared tests if such information is not already available to the public



Thanks

- LDA thanks the FDA for the opportunity to present today at this testing guidance workshop

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