Lyme & Other Tick-Borne Diseases: 
Process Concerns About FDA Testing Guidance 
Public Process for Classification & Prioritization Section

Presented to 
FOOD & DRUG ADMINISTRATION 
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for 
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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
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.
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
    o 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
    o 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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