FDA Public Hearing - Oversight of Laboratory Developed Tests

July 28, 2010

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FDA Public Hearing

Oversight of Laboratory Developed Tests

July 19, 2010
Food and Drug Administration

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on behalf of

Genetic Alliance

www.geneticalliance.org

Transforming health through genetics

10,000 organizations in network

1,000 are disease advocacy orgs

What Matters?

- Access to safe and effective treatments
- Acceleration of solutions for thousands of diseases
- Policies and systems that support all of the above

What about LDTs?

- Diagnostics are revolutionary if used effectively
- Medicine can be transformed through diagnostics

In vitro diagnostics different than devices

Current system ill-suited to enable efficient approval or clearance of advanced diagnostics tests, with meaningful claims that reflect how the test result will be used in patient management.

Classification framework

Relative risk of information provided by diagnostics

Severity of disease

Context of the use

Standard is flexible and dynamic

- Supported by evidence that has been deemed "competent and reliable" to make the intended us claim
- Level of evidence that is consistent with what experts in the relevant field have determined to be sufficient for decision making at the time the test is under development

Create a Flexible System

- Black and white about safety and efficiency does not work
- Determine methods to communicate what is known and not known
- Pay attention to rare diseases
- Do not disrupt patient care, which includes acceptance of currently marketed tests by payers

Bottom Line

- Mandatory diagnostic test registry
- Risk-based classification
- Context critical
- Sensitive to rare disease/personalized medicine