

2015 APHL[™] ANNUAL MEETING

and ninth government environmental laboratory conference

APHL Comments: Suggestions to Reframe LDT Guidance for Public Health Laboratories

Grace Kubin, PhD

Director, Laboratory Services Section

Texas Department of State Health Services



APHL's Activities

- **2010:** APHL member presented at FDA public meeting
- **May 2014:** Meeting with FDA
- **July 2014:** Meeting with Democratic Senators
- **July 31, 2014:** LDT Draft Framework released by FDA in a Notice to Congress
- **Oct 2014:** Meeting with FDA
- **Oct-Dec 2014:** Gathered feedback from APHL members on impact of FDA's framework

APHL's Activities

- **Jan 2015:** APHL members/staff presented at FDA's public meeting
- **Feb 2015:** APHL submitted comments and recommendations to FDA and encouraged member laboratories to submit comments
- **Apr 2015:** Diagnostic Test Work Group releases alternative framework
- **Apr 2015:** AMA Public Health Laboratory Exemption

LDTs & Public Health Laboratories

- Public health laboratories (PHLs) are *non-profit, mission based institutions* that provide data—*detection, characterization, and surveillance*—to inform public health actions
- PHLs use a mix of FDA-cleared and laboratory developed tests (LDTs)

LDTs: Critical to the Mission of PHLs

- Many LDTs are used by PHLs because there are not FDA-cleared equivalents
 - Newly emerging pathogens
 - Chikungunya, SARS, Eastern Equine Encephalitis
 - Low incidence diseases
 - Measles, mumps, pertussis
 - Newborn screening
 - Severe combined immunodeficiency

Potential Impact of Stringent Regulation of LDTs

- APHL believes in quality and accurate testing
- An overly burdensome regulatory process will limit the availability of tests to meet the needs of the public health laboratory community
- 510(k) and premarket approval paradigm that has regulated device manufacturers does not translate to governmental public health laboratories who **do not profit from LDTs**

Critical public health laboratory services will halt without modifications and increased flexibility for public health laboratories

APHL's Recommendations

1. Rethink Rare Diseases

Redefining rare disease based on prevalence

“The definition of a rare disease for the purpose of FDA continuing to provide enforcement discretion with respect to premarket review requirements for LDTs used for rare diseases shall be defined as:

Any disease or condition which affects less than 200,000 persons in the United States”

2. Utilize Precedents

The definition of a rare disease affecting less than 200,000 has set the precedent for the activities of the [Office of Rare Diseases Research](#) (ORDR) at the National Institutes of Health, which has a list of ~6,800 rare diseases.

Many diseases and conditions that are of public health importance are on this list

2. Utilize Precedents (cont'd.)

FDA will waive the documentation requirement for established rare diseases

APHL recommends that FDA CDRH utilize ORDR's list as a baseline for establishing what rare disease LDTs should be automatically entitled to rare disease enforcement discretion. Documentation by the public health laboratory will not be required if the LDT has a diagnostic intended use for a rare diseases on ORDR's list.

3. Reframe Regulation

Reframe Regulation for Governmental Public Health Laboratories

The 510(k) and premarket approval paradigm that has effectively regulated device manufacturers **DOES NOT** translate to an effective regulatory scheme for LDTs used in the public health system.

FDA must reframe LDT regulation to allow a functional public health laboratory system, while at the same time ensuring accurate and high quality testing.

4. PHLs in Healthcare System

Public health laboratories are an essential component of the healthcare system

- PHLs serve as reference laboratories to hospitals and clinical laboratories within their jurisdictions
- PHLs perform specialized, high quality testing for diseases of public health importance that hospital or clinical laboratories do not have the capability or capacity to perform