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Emergency Use Authorizations

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Quality Improvement Forum Call

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Overview

- Emergency Use Authorization (EUA) authority
- EUA issuance process
- Zika EUAs
- APHL and public health laboratory role

EUA AUTHORITY

Legal Authority

- Established under Project BioShield Act of 2004 (Public Law 108-276)
- Amendments through:
  - Pandemic All-Hazards Preparedness Act
  - Pandemic All-Hazards Preparedness Reauthorization Act
- Issued under §564 of the Federal Food, Drug and Cosmetic Act (FD&C)

Project BioShield Act

- Established in 2004 to accelerate research, development and purchasing
- Three major provisions:
  - Expedited procurement and grant making
  - Government purchasing of countermeasures
  - Authority to temporarily use medical countermeasure under emergency use authorization (EUA)

Pandemic All-Hazards Preparedness

- PAHPA 2006 (Public Law 109-417)
  - Established ASPR, BARDA, development and acquisition of countermeasures
- PAHPRA 2013 (Public Law 113-5)
  - Authorized funding for PHEP and HPP CoAgs
  - Increased flexibility of BioShield Act
  - Enhanced authority of FDA to support rapid response to national emergencies

§564 of FD&C: EUA

- Establishes key legal authorities to prepare and respond to CBRN agents including emerging infectious diseases
- Emergency use of unapproved medical countermeasures
  - Drugs
  - Biological products
  - Devices

Additional Flexibilities

- Ability to waive otherwise applicable current good manufacturing requirements
- Ability to extend expiration dates
- Authority to permit emergency dispensing
- Permits CDC to create and issue emergency use instructions
- Ability to waive Risk Evaluation and Mitigation Strategies requirements

EUA ISSUANCE PROCESS

Determination of an Emergency or Threat

- The HHS Secretary must determine there currently exists, or there is significant potential for an emergency as determined by:
  - Department of Homeland Security (domestic or abroad)
  - Department of Defense (military)
  - Department of Health and Human Services (public health)

Declaration of an Emergency

- Close consultation with ASPR, Director of NIH and Director of CDC
- HHS Secretary declares an emergency under §564 that triggers an EUA
- FDA Commissioner authorizes the emergency use of unapproved products or an unapproved use of an approved product

Pre-EUA Activities and Submissions

- Early engagement with potential EUA products
- Prior to submitting a formal request
- Discussions of potential suitability for EUA consideration
- Example:
  - Defense Threat Reduction Agency Ebola assay

Requests for EUAs

- Most requests are submitted by government entities
- Non-government requesters should seek support for government stakeholders for coordination
- EUAs may be issued during or in advance of an emergency

Information Recommendations

- Data needed to support an EUA may vary
  - Intended use
  - Approval status
  - Need
  - Safety and effectiveness data
  - Risk benefit analysis
  - Chemistry, manufacturing and controls
  - Quantity of finished product available
  - Product labeling

Criteria for EUA Authorization

- The following criteria must be met:
  - Serious or life-threatening condition
  - Evidence of effectiveness
  - Risk-benefit analysis
  - No alternatives
- Alternative regulatory mechanism exist if not all criteria are met
- FDA is positioned to issue EUAs quickly

Conditions of Authorization

- Information relating to EUA product for healthcare administrators
- Patients are informed of the EUA
  - Known potential benefits and risks of the emergency use product
  - Available alternatives, benefits and risks
- Monitoring and reporting of adverse events

EUA for Diagnostics Devices

- EUA must indicate point-of-care use or laboratory use only
- Waived tests will be determined by totality of scientific evidence
- Complexity categorization lasts the duration of the emergency or threat
- Independently determined from CLIA regulations

Issuance

- FDA commissioner issues letter
- Announcement in Federal Register upon issuance or termination
- Amendments to EUAs generally announced

Duration and Termination

- Periodic review circumstance and appropriateness
- The Secretary's declaration of an emergency will terminate upon
  - Circumstances have ceased
  - A change in the approval status of the product such that an EUA is no longer needed

Current EUAs for Diagnostics

- Zika Virus (4)
- Enterovirus D68 (1)
- Ebola Virus (11)
- H7N9 Influenza (3)
- Middle East Respiratory Syndrome Coronavirus (2)

http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm182568.htm#current

ZIKA EUA

Zika Timeline

- **Dec 2015**: PHLs begin establishing testing
- **Jan 19, 2016**: CDC distributes LDT protocol to PHLs
- **Jan 22, 2016**: CDC activates Incident Management System
- **Feb 1, 2016**: WHO declares international public health emergency

Zika Timeline

- **Feb 26, 2016**: HHS Secretary Burwell declares significant potential for a public health emergency
  - Authorizes use of *in vitro* diagnostics
  - CDC MAC ELISA issued EUA
- **Mar 17, 2016**: CDC Trioplex RT-PCR issued EUA

Zika Timeline

- **Apr 28, 2016**: Focus Diagnostics, Inc. RNA Real-Time RT-PCR issued EUA
- **May 13, 2016**: altona Diagnostics RealStar® Zika Virus RT-PCR Kit issued EUA

- Potential amendments to EUAs as the situation evolves

ROLE OF PUBLIC HEALTH LABORATORIES

APHL and Public Health Laboratories

- Collaboration and partnership with CDC
  - Testing algorithms
  - Data collection
  - Guidance documents
- Laboratory Response Network
  - Deployment of protocols and kits
- Collaboration and partnership with FDA
  - Package inserts and fact sheets

Resources

- FDA Draft Guidance: Emergency Use Authorization of Medical Products and Related Authorities
- FDA EUA Website
- FDA Food Drug & Cosmetic Act Website

2016 Annual Meeting Session

Thursday June 9 @ 9:00am

EUAs, LDTs and Zika Response: Challenges for Public Health Laboratories, FDA and CDC

QUESTIONS?

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