Emergency Legal Preparedness and FDA Response to Zika Virus

ABA Washington Health Summit

December 12, 2016

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Office of Counterterrorism and Emerging Threats
Office of the Commissioner

Counterterrorism and Emerging Threats

- Protecting the U.S. from threats
  - Chemical, biological, radiological, nuclear (CBRN)
  - Emerging infectious diseases
- Ensuring that medical countermeasures (MCMs) to counter these threats are safe, effective, and secure
  - Drugs, vaccines, devices (e.g., diagnostic tests, personal protective equipment (PPE))
- Office of Counterterrorism and Emerging Threats
  - Facilitate the development and availability of safe, effective MCMs
  - Serve as point of entry on policy and planning for global health security, counterterrorism, emerging threats
  - Identify and resolve complex scientific and regulatory challenges for MCMs within FDA and with USG partners

Overview of Public Health Legal Preparedness

Public Health Legal Preparedness

- Term first appeared in late 1990s; subset of public health preparedness
- Recognizes essential role law plays in protecting the public from catastrophic health events
  - Core foundation to ensure U.S. is prepared to prevent, respond to, and reduce adverse effects of public health emergencies
- May impact a range of players during disasters
  - e.g.) health officials, hospitals, health care practitioners, businesses, MCM manufacturers, public, etc.

Moulton et al. *Journal of Law, Medicine & Ethics*. 2003;31; The National Action Agenda for Public Health Legal Preparedness. *Journal of Law, Medicine & Ethics*. 2008;36(1).

Levels (and Layers) of Authority

- Global
  - WHO (Director-General) (e.g., IHR, PHEIC declaration)
  - Individual countries (substantial variation in laws, capabilities, declarations)
- Federal (e.g., President, Cabinet Secretaries)
  - e.g.) emergency laws, declarations
- State (e.g., Governor, Secretary of Health)
  - e.g.) traditional public health powers (police powers), emergency laws and declarations (much variation)
- Local (e.g., Mayor, County Executive, Health Officer)

Examples of Tools

- Declarations
- Executive orders
- Isolation and quarantine authorities (federal and state)
- Volunteer and other liability protections
- Emergency use authorities for MCMs
- 1135 waivers
- Mutual aid agreements—Emergency Management Assistance Compact (EMAC)

Examples of Federal Legal Preparedness Authorities

- Public Health Service (PHS) Act (42 U.S.C. 201 et seq.); Federal Food, Drug, and Cosmetic (FD&C) Act (21 U.S.C. 201 et seq.); Social Security Act (42 U.S.C. 301 et seq.)
- Public Health Threats and Emergencies Act (2000) (PL 106-505)
- Bioterrorism Act (2002) (PL 107-188)
- Smallpox Emergency Personnel Protection Act (2003) (PL 108-20)
- Project BioShield Act (2004) (PL 108-276)
- Public Readiness and Emergency Preparedness (PREP) Act (2005) (PL 109-148)
- Pandemic and All-Hazards Preparedness Act (2006) (PL 109-417)
- Pandemic and All-Hazards Preparedness Reauthorization Act (2013) (PL 113-5)
- 21st Century Cures Act (2016)

Why are legal/regulatory mechanisms for emergency use of MCMs needed?

Without these mechanisms, certain preparedness and response activities at the local, state, and/or federal levels could otherwise violate provisions of the FD&C Act:

- Some MCMs needed for a response might not be approved, licensed, or cleared by FDA (e.g., Ebola, Zika)
- Some MCMs needed for a response might be approved by FDA, but not for the emergency use (e.g., for a new indication)
- Some might be approved for the emergency use, but:
  - Need to be dispensed (e.g., at PODs) without individual prescriptions and/or by someone who is not a licensed health care professional, and with emergency use instructions (e.g., fact sheets)
  - MCMs might be used beyond their manufacturer-labeled expiration date
- Also, to ensure that available Public Readiness and Emergency Preparedness (PREP) Act protections apply

FDA Authorities to Facilitate Access to MCMs

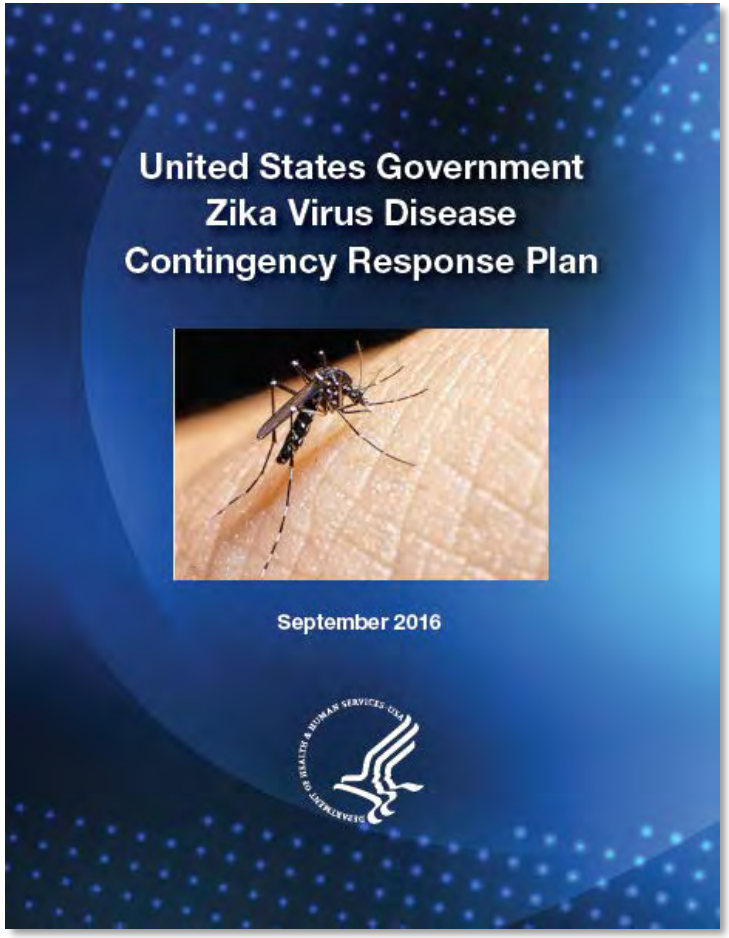
- Emergency Use Authorization (EUA)
  - FD&C Act § 564
  - Allows FDA to authorize for use in CBRN emergencies the use of unapproved MCMs or the unapproved use of approved MCMs
  - Established by Project BioShield Act (2004); amended by PAHPRA (2013)
- Other emergency use authorities
  - FD&C Act §§ 564A, 505-1, and 564B
  - Allows FDA to authorize emergency dispensing, expiry dating extensions, and waivers of CGMP and REMS requirements, and CDC to issue emergency use instructions, for approved MCMs without rendering a product unapproved, adulterated, or misbranded
  - Established by PAHPRA (2013)
- Expanded access to investigational drugs and devices
  - Investigational New Drug Application (IND) (21 CFR Parts 312.300-320)
  - Investigational Device Exemption (IDE) (21 CFR Part 812)

EUA Authority (FD&C Act § 564)

- With an EUA, FDA can authorize for use in CBRN emergencies:
  - The use of unapproved MCMs or
  - The unapproved use of approved MCMs (e.g., for a new indication)
- When scientific evidence is available to support MCM use in a CBRN emergency, issuing an EUA enables response stakeholders to use, or prepare to use, an MCM without violating the FD&C Act; also helps to ensure applicable PREP Act coverage
- Overview of requirements for EUA issuance:

1. DHS, DoD, or HHS Secretary makes a specific type of **determination**
2. HHS Secretary issues a **declaration** that circumstances exist to justify EUA issuance based on 1 of the 4 types of determinations (*this is not a PHS Act § 319 Public Health Emergency declaration*)
3. FDA ensures EUA **criteria for issuance** are met and issues the EUA when appropriate

Public Health Law in Action: Zika Virus Response


United States Government
Zika Virus Disease
Contingency Response Plan
September 2016


ZIKA
STRATEGIC RESPONSE PLAN
REVISED FOR JULY 2016 – DECEMBER 2017
World Health Organization
June 2016
Photo: PAHO/Harold Ruiz

Global Zika Virus Response

- Global
  - WHO: Declared a Public Health Emergency of International Concern (PHEIC) because of clusters of microcephaly and other neurological disorders in some areas affected by Zika virus (2/1/16; ended 11/16)
  - Various countries (e.g., Brazil, Mexico, Peru)
- Federal
  - HHS declarations
    - "a public health emergency of national significance exists within the Commonwealth of Puerto Rico relating to pregnant women and children born to pregnant women with Zika" (PHS Act § 319) (8/12/16)
    - EUA determination/declaration (FD&C Act § 564) (2/26/16); EUAs issued
  - CMS (e.g., *Guidance for the Deployment of the Emergency Use Approval [sic] (EUA) Zika Virus Tests*)
  - Zika Response and Preparedness Act (PL 114-223)
- State/Local (e.g., Florida, Puerto Rico, Hawai'i)

FDA Roles & Responsibilities

Inter-Agency Coordination/Policy Development

International Coordination

Facilitating Product Development and Availability

Monitoring Fraudulent Product Claims

FDA Zika Virus Response

- FDA is fully engaged with USG and other partners in responding to the Zika virus outbreak
- Currently, no FDA-approved, licensed, or cleared medical products available to prevent, treat, or diagnose Zika virus
- Prepared to leverage our authorities to help accelerate the development and availability of safe and effective medical products for Zika virus
- Primary areas of activity include:

  (1) Blood safety
  (2) Clinical diagnostic tests
  (3) Vaccine and therapeutic development
  (4) Vector control
  (5) Fraudulent product monitoring

Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components

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Guidance for Industry

This guidance is for immediate implementation.

FDA is issuing this guidance for immediate implementation in accordance with 21 CFR 10.115(g)(2) without initially seeking prior comment because the agency has determined that prior public participation is not feasible or appropriate.

Blood Safety

- Protecting the safety of the blood supply and human cells and tissues used for medical, surgical, or reproductive procedures
  - Guidance
    - (Feb. 2016) *Recommendations for Donor Screening, Deferral, and Product Management to Reduce the Risk of Transfusion-Transmission of Zika Virus* (and *March 2016 Questions and Answers*)
    - (March 2016) *Donor Screening Recommendations to Reduce the Risk of Transmission of Zika Virus by Human Cells, Tissues, and Cellular and Tissue-Based Products*
    - (Aug. 2016) *Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components*
      - As a further safety measure, FDA now recommends universal testing of donated whole blood and blood components for Zika virus in the U.S. and its territories
      - **Replaces donor screening guidance issued in Feb. and March 2016**
  - Investigational tests to screen blood donations (March & June 2016)
    - Together, these tests have enabled blood donor screening to be put in place to help maintain the safety of the U.S. blood supply

FDA

CDC's Response to **Zika**

Only Some People Need **Zika Testing**

Zika virus testing is recommended only for certa
If you have questions or think you should be tes
to your healthcare provider.

If you have symptoms of Zika or are a pregnant wo
or wi

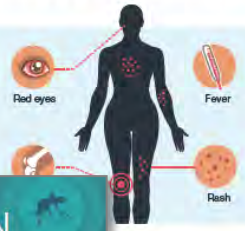
- You
- You

www.cdc.
CS266846A July 2

CDC's Response to **Zika**

WHEN TO TEST FOR ZIKA VIRUS

As a healthcare provider, you decide if a patient should be tested for Zika virus infection. The algorithm below will help you determine whether or not to test your patient for Zika virus infection. For information on which test to use, see CDC's interim guidance.



If your patient is

- Experiencing or has recently experienced symptoms of Zika*
- An asymptomatic pregnant woman

Ask the following questions

Does the patient live in or has the patient recently traveled to an area with Zika? → **YES**

Test for Zika

s the patient had unprotected sex with a partner ho has lived in or traveled to an area with Zika? → **YES**

Zika

d review their local and state health jurisdiction guidelines regarding testing of patients with without known travel or sexual exposures.

mend Zika virus testing for asymptomatic

pregnant

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

CDC's Response to **Zika**

ZIKA SCREENING TOOL FOR PREGNANT WOMEN

(To be administered by nurse, check-in receptionist, or other healthcare provider)

All pregnant women should be assessed for possible Zika virus exposure[1] at each prenatal care visit. Use this tool to evaluate pregnant women for exposure to Zika virus and for signs and symptoms of Zika virus disease to determine whether testing is indicated.

NOTE: If your pregnant patient has questions about Zika testing, educational factsheets are available on CDC's website: http://www.cdc.gov/zika/hc-providers/pregnant-woman.html

Assess for Possible Exposure[1] to Zika Virus Infection

(See references on back for more information.)

Circle response:

Do you live in or do you frequently travel (daily or weekly) to an area with active Zika virus transmission[2]?	YES | NO
Have you traveled to an area with Zika[2] during pregnancy or just before you became pregnant [8 weeks before conception or 6 weeks before your last menstrual period]?	YES | NO
Have you had sex (vaginal, anal, or oral sex) without a condom or shared sex toys with a partner(s) who lives in or has traveled to an area with Zika[2]?	YES | NO

If your pregnant patient answered **"NO"** to ALL questions, she is at low risk for exposure to Zika.

If Pregnant Patient Answered "Yes" to Any Question, Assess for Signs and Symptoms of Zika Virus Disease

Circle response:

Do you currently have or have you had (in the last 12 weeks) fever, rash, joint pain, or conjunctivitis (red eyes)?	YES | NO

If your pregnant patient answered **"YES"** to having any of these signs or symptoms, she might have symptomatic Zika virus infection. Test in accordance with CDC guidance for symptomatic persons[3].

If your pregnant patient answered **"NO"** to having any signs or symptoms, she has been exposed and might have an asymptomatic Zika virus infection. Test in accordance with CDC guidance for asymptomatic pregnant women[3].

References:

1. Possible exposure to Zika virus that warrants testing includes one or more of the following:
   a. Living in an area with active transmission
   b. Travel to an area with active transmission
   c. Sex (vaginal, anal, and oral sex) without a condom or the sharing of sex toys with a person who traveled to or lives in an area with Zika.
2. Visit CDC's website to see areas with active Zika transmission: http://www.cdc.gov/zika/geo/index.html
3. **Please see the algorithm on the back from CDC's Updated Interim Guidance for Health Care Providers Caring for Pregnant Women with Possible Zika Virus Exposure to guide testing and interpretation of results.** (http://www.cdc.gov/mmwr/volumes/65/wr/mm6529e1.htm?s_cid=mm6529e1_e)

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

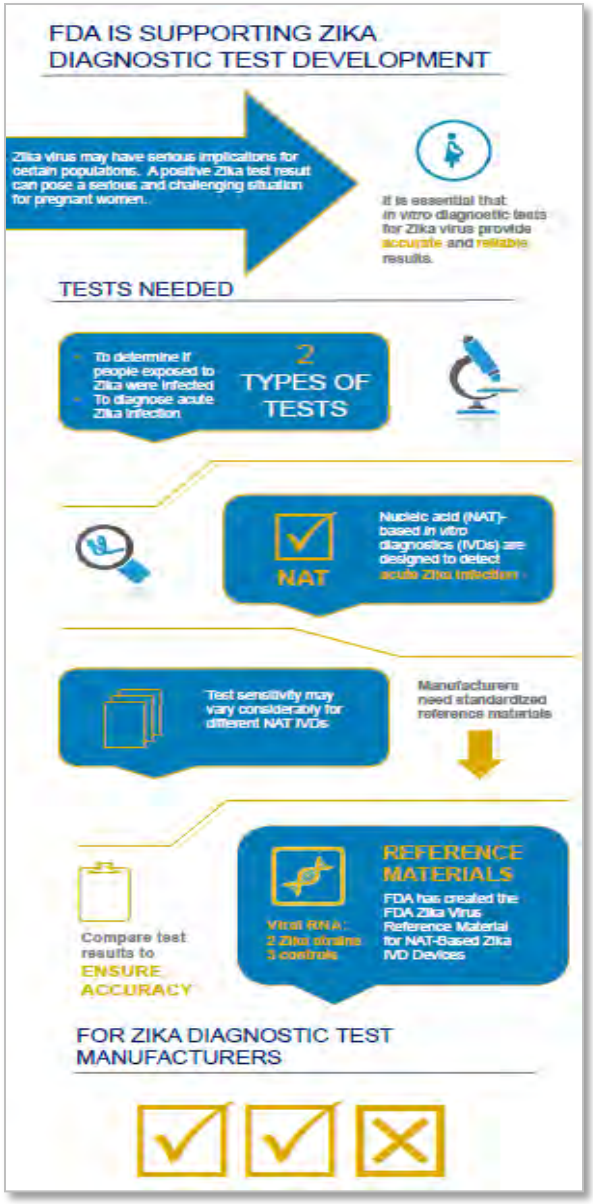
Clinical Diagnostic Tests

- Facilitating the development and availability of medical diagnostic tests
  - No FDA-cleared diagnostic tests for Zika virus are currently available
  - To date, FDA has issued 14 EUAs to allow use of CDC and commercially developed Zika diagnostic tests:
    - 2 serologic tests (to assess whether individuals who may have recently been exposed to Zika virus were actually infected)
    - 12 PCR tests (to diagnose acute/active Zika infection)
  - Issuance of these EUAs was based on:
    - **HHS Secretary's § 564 determination** that "there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves Zika virus"
    - **HHS Secretary's § 564 declaration** that "circumstances exist justifying the authorization of the emergency use of in vitro diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection"

Clinical Diagnostic Tests

- FDA encourages commercial diagnostic developers and researchers developing laboratory developed tests for Zika virus to submit an EUA request—FDA will work interactively with developers to support such requests

- For additional Zika EUA information:
  - EUAs (various dates of issuance): http://www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm182568.htm
  - HHS Determination and Declaration (2/26/16): https://www.gpo.gov/fdsys/pkg/FR-2016-03-02/pdf/2016-04624.pdf



FDA

LETTER

Vaccine protection against Zi

Rafael A. Larocca[1]*, Peter Abbink[1]*, Jean Pierre S. Peron[2], Paolo M. de A. Za
Michael Boyd[1], David Ng'ang'a[1], Marinela Kirilova[1], Ramya Nityanandar
Christine A. Bricault[1], Erica N. Borducchi[1], Patricia B. Giglio[1], David Jette

VACCINES

Rapid development of a DNA vaccin for Zika virus

Kimberly A. Dowd,[1]* Sung-Youl Ko,[2]* Kaitlyn M. Morabito,[2] Eun Sung Yang,[2]
Rebecca S. Pelc,[1] Christina R. DeMaso,[1] Leda R. Castilho,[2,3] Peter Abbink,[4]
Michael Boyd,[4] Ramya Nityanandam,[4] David N. Gordon,[1] John Robert Gallagher,[5]
Xuejun Chen,[2] John-Paul Todd,[2] Yaroslav Tsybovsky,[6] Audray Harris,[5]
Yan-Jang S. Huang,[7] Stephen Higgs,[7] Dana L. Vanlandingham,[7] Hanne Andersen,[8]
Mark G. Lewis,[8] Rafael De La Barrera,[9]
Martha C. Nason,[11] Dan H. Barouch,[4] M
John R. Mascola,[2] Theodore C. Pierson,[1]

Zika virus (ZIKV) was identified as a cause o
the Americas and Caribbean that began in 2
disease and travel-related exposures, a vac
age and their partners is imperative. We fou
premembrane and envelope proteins of ZIK
primates, and protection against viremia af

The NEW ENGLAND JOURNAL of MEDICINE

Perspective

SEPTEMBER 29, 2016

Considerations for Developing a Zika Virus Vaccine

Hilary D. Marston, M.D., M.P.H., Nicole Lurie, M.D., M.S.P.H, Luciana L. Borio, M.D., and Anthony S. Fauci, M.D.

The rapid spread of Zika virus through the Americas and its devastating consequences for pregnant women and infants have precipitated an international, multisectoral response.

nation averts congenital anomalies will most likely require postlicensure studies.

Prevention of congenital anomalies through vaccination of women

VACCINES

Protective efficacy of multiple vaccine platforms against Zika virus challenge in rhesus monkeys

Peter Abbink,[1]* Rafael A. Larocca,[1]* Rafael A. De La Barrera,[2] Christine A. Bricault,[1]
Edward T. Moseley,[1] Michael Boyd,[1] Marinela Kirilova,[1] Zhenfeng Li,[1] David Ng'ang'a,[1]
Ovini Nanayakkara,[1] Ramya Nityanandam,[1] Noe B. Mercado,[1] Erica N. Borducchi,[1]
Arshi Agarwal,[1] Amanda L. Brinkman,[1] Crystal Cabral,[1] Abishek Chandrashekar,[1]
Patricia B. Giglio,[1] David Jetton,[1] Jessica Jimenez,[1] Benjamin C. Lee,[1] Shanell Mojta,[1]
Katherine Molloy,[1] Mayuri Shetty,[1] George H. Neubauer,[1] Kathryn E. Stephenson,[1]
Jean Pierre S. Peron,[3] Paolo M. de A. Zanotto,[3] Johnathan Misamore,[4]
Brad Finneyfrock,[4] Mark G. Lewis,[4] Galit Alter,[5] Kayvon Modjarrad,[2,6]
Richard G. Jarman,[2] Kenneth H. Eckels,[2] Nelson L. Michael,[2]
Stephen J. Thomas,[2]† Dan H. Barouch[1,5]†‡

0.0001, coefficient of correlation $R = 0.88$, Spearman rank correlation test; fig. S3). Only minimal antibody-dependent cellular phagocytosis responses were observed. The majority of PIV-vaccinated monkeys (Fig. 1, C and D), but not sham control animals (fig. S4), also developed modest cellular immune responses, primarily to Env, as measured by interferon (IFN)–γ enzyme-linked immunospot (ELISPOT) assays.

To assess the protective efficacy of the PIV vaccine against ZIKV challenge, we infected PIV-immunized and sham control monkeys by the subcutaneous route with 10^6 viral particles [vp; 10^3 plaque-forming units (PFU)] of ZIKV-BR or ZIKV-PR ($n = 4$ per group) (*15*). Viral loads after ZIKV challenge were quantitated by reverse transcription polymerase chain reaction (*15*), and viral infectivity was confirmed by growth in Vero cells. ZIKV-specific MN50 titers increased after chal-

Vaccine and Therapeutic Development

- Advancing the development of investigational vaccines and therapeutics
  - There are no FDA-licensed or approved vaccines or treatments for Zika virus
    - Several investigational vaccines are under development, including early human clinical trials
  - FDA is actively working with our Federal colleagues at CDC, NIH, and the Biomedical Advanced Research and Development Authority (BARDA) and with the private sector on advancing development and availability
  - We are prepared to evaluate the safety and efficacy of any investigational vaccines and therapeutics that might be developed to help mitigate this outbreak

U.S. FOOD & DRUG ADMINISTRATION

FDA Releases Final Environmental Assessment for Genetically Engineered Mosquito

Update

August 5, 2016

The FDA has completed the environmental review for a proposed field trial to determine whether the release of Oxitec Ltd.'s genetically engineered (GE) mosquitoes (OX513A) will suppress the local *Aedes aegypti* mosquito population in the release area at Key Haven, Florida. After considering thousands of public comments, the FDA has published a final environmental assessment (EA) and finding of no significant impact (FONSI) that agrees with the EA's conclusion that the proposed field trial will not have significant impacts on the environment.

Vector Control

- Reviewing proposals for innovative strategies to help limit the ability of mosquitoes to spread disease
  - Investigational New Animal Drug (INAD) file from Oxitec, Ltd., for its genetically engineered (GE) line of *Aedes aegypti* mosquito (OX513A) with the intent of suppressing the population of mosquitoes at the release site(s)
    - March 2016: FDA released a draft Environmental Assessment (EA) and preliminary Finding of No Significant Impact (FONSI) for a field trial of the GE mosquito in Key Haven, FL; FDA reviewed thousands of public comments
    - August 2016: FDA released final EA and FONSI agreeing with draft EA's conclusion the field trial will not have significant impacts on environment
      - **FDA's finalization of the EA and FONSI does not mean that Oxitec's GE mosquitos are approved for commercial use.** Oxitec is responsible for ensuring all other local, state, and federal requirements are met before conducting the proposed field trial, and the community has decided to vote on whether to proceed with the trial
    - http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/ucm446529.htm

Fraudulent Product Monitoring

- Protecting the public from fraudulent products
  - Unfortunately, during outbreak situations, fraudulent products claiming to prevent, treat, or cure a disease almost always appear
  - FDA monitors for fraudulent products and false product claims related to the Zika virus and takes appropriate action to protect consumers
  - Consumers who have seen fraudulent products or false claims are encouraged to report them to FDA
    - http://www.fda.gov/Safety/ReportaProblem/ucm059315.htm

Looking Ahead...

Additional Resources

- **FDA Zika Response Updates Website**
  - http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMIssues/ucm485199.htm
- **FDA Medical Countermeasures Initiative (MCMi)**
  - www.fda.gov/medicalcountermeasures
- **FDA EUA Website** (*official updates, current & terminated EUAs, guidance*)
  - www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm182568.htm
- **FDA Draft Guidance on EUAs and other MCM Emergency Use Authorities**
  - http://www.fda.gov/RegulatoryInformation/Guidances/ucm125127.htm (April 2016)
- **FDA MCM Emergency Use Authorities Website**
  - http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm411432.htm
- **PREP Act (HHS)**
  - http://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx

EUAs Issued by FDA (cont. on next slides)			
Year	MCM	Requester	Status
Anthrax (*Bacillus anthracis*)			
2005	Anthrax Vaccine Adsorbed (AVA)	DoD	Terminated
2008 (*reissued 2009, 2010, 2011*)	Doxycycline hyclate 100 mg oral tablets (in National Postal Model home/workplace kits)	HHS (ASPR/BARDA)	Current (2011 version)
2011	Doxycycline (oral forms) for mass dispensing	HHS (CDC)	Current*
2009 H1N1 Influenza Pandemic			
2009-2010	Antivirals (3)	HHS (CDC)	Terminated (all H1N1 EUAs)
	IVDs (18)	Various	
	Disposable N95 respirators	HHS (CDC)	
Novel Influenza A (H7N9) Virus			
2013	CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay	HHS (CDC)	Current
2014	Lyra Influenza A Subtype H7N9 Assay	Quidel Corp.	Current
2014	A/H7N9 Influenza Rapid Test	Arbor Vita Corp.	Current

* To be terminated due to April 2016 issuance of doxycycline emergency dispensing order, CGMP waiver, and CDC EUI (under sec. 564A of the FD&C Act).

For the most current FDA EUA information, see: www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm182568.htm.

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MEDICAL COUNTERMEASURES INITIATIVE

EUAs Issued by FDA (cont.)			
Year	MCM	Requester	Status
Middle East Respiratory Syndrome Coronavirus (MERS-CoV)			
2013 (*reissued 2014*)	CDC Novel Coronavirus 2012 Real-time RT-PCR Assay	HHS (CDC)	Current
2015 (*reissued 2016*)	RealStar MERS-CoV RT-PCR Kit U.S.	altona Diag. GmbH	Current
Enterovirus D68 (EV-D68)			
2015	CDC EV-D68 2014 rRT-PCR Assay	HHS (CDC)	Current
Zika Virus			
2016 (amended 2016)	CDC Zika MAC-ELISA (IgM)	HHS (CDC)	Current
2016 (amended 2016)	CDC Zika Trioplex rRT-PCR Assay	HHS (CDC)	Current
2016 (amended 2016)	Zika Virus RNA Qualitative Real-Time RT-PCR	Focus Diag., Inc.	Current
2016 (amended 2016)	RealStar Zika Virus RT-PCR Kit U.S.	altona Diag. GmbH	Current
2016 (amended 2016)	Aptima Zika Virus assay	Hologic, Inc.	Current
2016	Viracor-IBT Laboratories, Inc.'s Zika Virus Real-time RT-PCR Test	Viracor-IBT	Current
2016	VERSANT® Zika RNA 1.0 Assay (kPCR) Kit (Siemens Healthcare Diagnostics	Siemens Healthcare Diagnostics Inc.	Current
2016	xMAP® MultiFLEX™ Zika RNA Assay	Luminex Corporation	Current
2016	ZIKV Detect™ IgM Capture ELISA	InBios International, Inc.	Current

For the most current FDA EUA information, see:
www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm182568.htm.

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EUAs Issued by FDA (cont.)			
Year	MCM	Requester	Status
Zika Virus (cont.)			
2016 (amended 2016)	LightMix® Zika rRT-PCR Test	Roche Molecular Systems, Inc.	Current
2016	Sentosa® SA ZIKV RT-PCR Test	Vela Diagnostics USA, Inc.	Current
2016	Zika Virus Detection by RT - PCR Test	ARUP Laboratories	Current
2016	Abbott RealTime ZIKA	Abbott Molecular Inc.	Current
2016	Zika ELITe MGB® Kit U.S.	ELITechGroup Inc. Molecular Diagnostics	Current

For the most current FDA EUA information, see:
www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm182568.htm.

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Ebola EUAs Issued by FDA (cont.)			
Year	MCM	Requester	Status
2014 (*reissued 2014*)	DoD EZ1 Real-time RT-PCR Assay	DoD	Current
2014 (*reissued 2015*)	CDC Ebola VP40 rRT-PCR Assay	HHS (CDC)	Current
2014 (*reissued 2015*)	CDC Ebola NP rRT-PCR Assay	HHS (CDC)	Current
2014 (*reissued 2015*)	FilmArray NGDS BT-E Assay	BioFire Defense, LLC	Current
2014	FilmArray Biothreat-E test	BioFire Defense, LLC	Current
2014 (*reissued 2014*)	RealStar Ebolavirus RT-PCR Kit 1.0	altona Diag. GmbH	Current
2014	LightMix Ebola Zaire rRT-PCR Test	Roche Molecular Systems, Inc.	Current
2015 (*reissued 2016*)	ReEBOV Antigen Rapid Test	Zalgen Labs, LLC	Current
2015	Xpert Ebola Assay	Cepheid	Current
2015	OraQuick Ebola Rapid Antigen Test (use with whole blood)	OraSure Technologies, Inc.	Current
2016 (reissued 2016)	OraQuick Ebola Rapid Antigen Test (use with cadaveric oral fluid)	OraSure Technologies, Inc.	Current
2016	Idylla Ebola Virus Triage Test	Biocartis NV	Current

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For the most current FDA EUA information, see:
www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm182568.htm.

Thank you!

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