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## Medical Countermeasures Initiative Update

June 20, 2018

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## New research studies Zika virus transmission

### FDA-supported study informs medical countermeasure development

To develop effective medical countermeasures ([MCMs](#)) to treat and protect against emerging threats, including the Zika virus, the scientific community must first learn more about how the pathogen (in this case, virus) infects the human body, and how it affects infected patients, including potential donors of transplantable cells, tissues, or organs.

Despite presenting as a mild illness in most patients, Zika has broader public health implications, including its potential impact on developing fetuses when pregnant women become infected. To learn more about how Zika virus impacts a variety of tissues and organs in the developing fetus, FDA partially funded a [research project by the University of California, Davis](#) (UCD).

As outlined in a [publication](#) today in the journal *Nature Communications*, this work is a step toward development of a relevant model of fetal Zika virus neurologic disease, providing proof-of-concept information on factors that determine the severity of disease and the efficacy of interventions to guide clinical trials for Zika medical countermeasures, and informing FDA regulatory activities.

#### Related links:

- [Zika virus response updates from FDA](#)
- [Companion Studies to Define the Distribution and Duration of Zika Virus Infection in NHPs](#) (PDF, 5.6 MB) - final report from the UC Davis FDA project, 2017
- [MCM-related extramural research at FDA](#)
- [Information on Zika virus and pregnancy from CDC](#)
- [Blood & Tissue Safety: Geographic areas at increased risk for Zika virus transmission through blood or tissue donation](#) (CDC)

*Image: A scientist works in the lab at the UC Davis California National Primate Research Center. (Image courtesy of CNRPC, via [video](#))*

## FDA statements on biopreparedness

Recent remarks from FDA officials testifying before the U.S. House of Representatives, Committee on Energy and Commerce:

- Anna Abram, FDA Deputy Commissioner for Policy, Planning, Legislation, and Analysis on [Examining the Reauthorization of the Pandemic and All-Hazards Preparedness Act](#) (June 6, 2018)
- Rear Admiral Denise Hinton, FDA Chief Scientist, on [The State Of U.S. Public Health Biopreparedness: Responding To Biological Attacks, Pandemics, And Emerging Infectious Disease Outbreaks](#) (June 15, 2018)

### Events

- **June 21, 2018:** [HHS Tick-Borne Disease Working Group](#) (public webcast) - The Working Group will focus on subcommittee findings and will review and provide input on the content of the five chapters that will be submitted into the Working Group Congressional Report.
- **June 21-22, 2018:** [Public Health Law on the Frontlines: Countering Law and Policy Challenges to State and Local Innovations](#) (Washington, DC), hosted by the O'Neill Institute for National and Global Health Law, Georgetown University - FDA Regulatory Counsel Greg Measer will discuss public health emergencies. *(fee)*
- **June 22, 2018:** [Blood Products Advisory Committee public meeting](#) (Silver Spring, MD and [webcast](#)) - The Committee will hear presentations on FDA Center for Biologics Evaluation and Research (CBER) research programs including the Laboratory of Emerging Pathogens.
- **June 25-26, 2018:** [2018 Center for Biologics Evaluation and Research \(CBER\) Science Symposium](#) (Silver Spring, MD and [webcast](#)) - participants will discuss scientific topics related to the regulation of biologics, and highlight science conducted at CBER by showcasing how scientific research informs regulatory decision-making. Topics include emerging and re-emerging diseases, and new technologies. The [program book](#) (PDF, 1.7 MB) is now available.
- **New! June 26, 2018:** Live CE webinar - [FDA Drug Topics: FDA's Web Resources Available to Health Care Providers Who Prescribe and Dispense Medications with Risk Evaluation and Mitigation Strategies \(REMS\)](#), 1:00 - 2:00 p.m. ET - [register](#) for instructions on how to attend
- **New! July 11, 2018:** From HHS - [Healthcare Challenges After Radiological Incidents webinar](#) (PDF, 452 KB), 2:00 - 3:15 p.m. ET - HHS ASPR's Technical Resources, Assistance Center, and Information Exchange ([ASPR TRACIE](#)) is hosting a webinar with panelists to discuss the impact and potential solutions of different event types and provide guidance and lessons learned in assessing, triaging, treating, and following-up on casualties of radiological and nuclear emergencies.
- **July 18-19, 2018:** [Blood Products Advisory Committee public meeting](#) (Silver Spring, MD and [webcast](#)) - The Committee will meet in open session to discuss and provide advice regarding bacterial risk control strategies for blood collection establishments and transfusion services to enhance the safety and availability of platelets for transfusion.
- **August 13-14, 2018:** [Pediatric Medical Device Development public meeting](#) (Silver Spring, MD and [webcast](#)), to identify strategies to enhance the medical device ecosystem to cultivate development and innovation of devices that serve the unique needs of pediatric populations. To attend in-person, register by **4:00 p.m. ET August 6, 2018**.
- **New! August 19-25, 2018:** From FEMA - [Strategic National Stockpile \(SNS\) Preparedness Course](#) (Anniston, AL) - A five-day course designed to give federal, state, and local officials information on how to best plan and prepare for a public health emergency and how to use and manage the SNS in response to a terrorist attack, natural disaster, or technological accident. Personnel attending this course should be involved with SNS planning and coordination at the federal, state, regional, or local level. FEMA pays travel expenses for students (except federal employees).

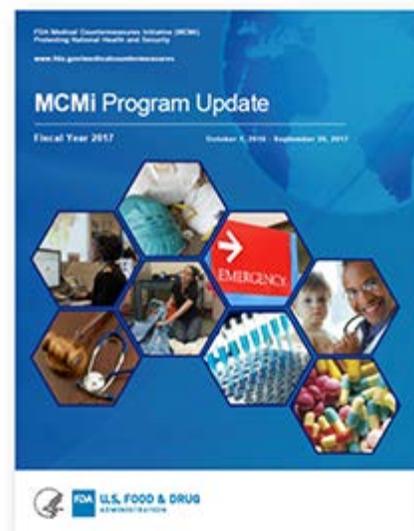
## Information for industry

- Draft guidance: [Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program](#) (PDF, 265 KB) - This draft guidance explains the ways submitters can request feedback from, or a meeting with, FDA regarding potential or planned medical device or device-led combination product submissions. The FDA Q-Submission Program is a system that tracks different types of requests for feedback from or interaction with FDA regarding planned regulatory submissions as well as requests for certain types of formal designations that are not standalone marketing submissions or research authorizations. When final, this guidance will replace the Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff guidance issued in September 2017. [Comment](#) by **August 6, 2018**. (June 7, 2018)
- Draft guidance: [Limited Population Pathway for Antibacterial and Antifungal Drugs](#) (PDF, 128 KB) - The LPAD pathway is intended to encourage the development of certain antibacterial and antifungal drugs to help address the critical public health and patient care concern that has resulted from the current decline in antibacterial drug research and development as serious antibacterial and antifungal drug-resistant infections increase. FDA is committed to using the tools at its disposal, including the LPAD pathway, to help encourage the development of safe and effective drug products that address unmet needs of patients with serious bacterial and fungal infections. [Comment](#) by **August 13, 2018**. Also see: [Statement from FDA Commissioner Scott Gottlieb, M.D., on FDA's efforts to foster discovery and development of new tools to fight antimicrobial-resistant infections](#) (June 12, 2018)
- [Alternative or Streamlined Mechanisms for Complying With the Current Good Manufacturing Practice Requirements for Combination Products: Proposed List Under the 21st Century Cures Act](#) - As required by the [21st Century Cures Act](#), FDA is proposing a list of alternative or streamlined mechanisms for complying with the current good manufacturing practice (CGMP) requirements for combination products. Combination products are products composed of two or more different types of medical products (drug, device, and/or biological product). [Comment](#) by **September 11, 2018**. (June 13, 2018)
- As of **October 1, 2018**, [CBER will use secure email](#) for regulatory communications with product sponsors. FDA has resources to help sponsors easily set up secure email. (June 13, 2018)

**More:** [MCM-Related Guidance by Date](#)

## In case you missed it

- [MCMi Fiscal Year 2017 Program Update](#) - FDA and our partners work every day to help facilitate development of and access to safe, effective medical countermeasures to counter emerging threats. Learn more about the steps we're taking to protect national health and security in this report.
- [FDA seeks permanent injunction against company selling unapproved hand sanitizers that claim to prevent infections from numerous pathogens](#) - FDA filed a complaint against Innovative BioDefense, Inc. of Lake Forest, California, and Colette Cozean, the company's president and chief executive officer, to prohibit them from selling Zylast topical antiseptics with claims that they are effective against infection by pathogens such as norovirus, rotavirus, flu virus, Methicillin-Resistant *Staphylococcus aureus* (MRSA), and Ebola. Claims that a hand sanitizer can protect consumers against infection from pathogens are drug claims and therefore, these products are regulated by the FDA as drugs. These products from Innovative BioDefense, Inc. have not been proven to be safe and effective for these uses and are not approved by the FDA. (June 6, 2018)



- Statement from FDA Commissioner Scott Gottlieb, M.D., on [new guidance to help manufacturers implement protections against potential attacks on the U.S. food supply](#) - Food facilities covered by the Food Safety Modernization Act (FSMA) Intentional Adulteration (IA) rule will be required to develop and implement a food defense plan that identifies their significant vulnerabilities and mitigation strategies for those vulnerabilities. Also see [Draft Guidance for Industry: Mitigation Strategies to Protect Food Against Intentional Adulteration](#) (June 19, 2018)
- Statement from Douglas Throckmorton, M.D., deputy center director for regulatory programs in FDA's Center for Drug Evaluation and Research, on [the agency's response to ongoing drug shortages for critical products](#), including IV fluids, injectable opioid analgesics, and EpiPens (June 19, 2018)
- [FDA's New Efforts to Advance Biotechnology Innovation](#) (June 6, 2018)
- From HHS/ASPR - HHS has launched [DRIVE \(the Division of Research, Innovation, and Ventures\)](#), a new, transformative public-private engagement model designed to accelerate innovation and incentivize investors and innovators to tackle health security threats. Learn more about [partnering opportunities](#), and view the [DRIVE EZ-BAA](#) (respond by May 31, 2019).
- From NACCHO - To help medical countermeasure (MCM) coordinators navigate the first months of their roles, the National Association of County & City Health Officials (NACCHO) created a new [MCM Coordinator Start-Up Guide](#). (June 13, 2018)
- Interested in working at FDA? Follow [@FDAJobs](#) on Twitter, or visit [www.fda.gov/jobs](#).



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