

June 6, 2018

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## Every day, FDA prepares for public health emergencies

### New Medical Countermeasures Initiative (MCMi) report

FDA and our partners work every day to help facilitate development of and access to safe, effective medical countermeasures (MCMs) to counter emerging threats. Learn more about MCMi, and the steps we're taking to protect national health and security in the new [FY 2017 MCMi Program Update](#).

#### Related links:

- [FY 2017 MCMi Program Update](#) (PDF, 2.6 MB)
- [About MCMi](#)
- [Public Health Emergency Medical Countermeasures Enterprise](#) (PHEMCE)

*Image: FDA is forging innovative partnerships to address national and global public health challenges. Learn more in our FY 2017 program update (cover pictured) or visit: [www.fda.gov/medicalcountermeasures](http://www.fda.gov/medicalcountermeasures).*

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## FDA's work to mitigate shortages of intravenous drugs, shorten supply disruptions and better predict vulnerabilities

### Statement from FDA Commissioner Scott Gottlieb, MD

Without question, one of the most frustrating challenges that health care providers and patients must contend

with is when a drug that's medically necessary and critical to patient care is unavailable due to a shortage. We know that the uncertainty over how long a drug will be in shortage, how to ration supplies in the meantime, or worse, how to prepare for a sudden event that might place unforeseen demands on a product that's in short supply, adds burdens and stress on providers and patients.

[Read the full statement](#)

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## Events

- **June 15, 2018:** [2nd NIH-FDA Joint Agency Microbiome Meeting](#) (College Park, MD and webcast) - This meeting will present ongoing microbiome research being undertaken at the NIH and FDA. Advance [registration](#) required.
  - **New! 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)*
  - **New! 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 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. [Register](#) to attend in-person or online by **June 18, 2018**; early registration recommended because seating and webcast connections are limited.
  - **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**.
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## Information for industry

- FDA issued a draft guidance, [Q12 Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management](#) (PDF, 451 KB) encouraging companies to use innovative manufacturing tech and processes, making it easier for them to manage post-approval changes across different global markets by reducing unnecessary regulatory burdens and costs. This streamlined, harmonized approach will promote continual product improvement and a more stable supply chain to ensure patients have access to the drug products they need. FDA is committed to ensuring patients have access to safe and effective drug products without disruption. Innovations and improvements in manufacturing processes can help avoid drug shortages while ensuring it meets FDA's rigorous quality standards. [Comment](#) by **December 15, 2018**. *(May 31, 2018)*
- FDA launched a number of improvements to the [Adverse Event Reporting System \(FAERS\) dashboard](#). The FDA is committed to improving the FAERS dashboard and is implementing these changes based on user feedback received since the dashboard was launched in September 2017. The changes

encompass a wide-range of items, such as enabling the selection of multiple products for a search and the downloading of search results, as well as enhancing display formats so more information is shown in one screen. For more information on using the FAERS dashboard, see the [FAERS webinar](#) (recording) and the [FAERS dashboard FAQ page](#). (June 4, 2018)

- FDA has announced the availability of a draft guidance for industry, [Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products](#) (PDF, 184 KB). This draft guidance provides recommendations to industry on formal meetings between FDA and sponsors or applicants relating to the development and review of biosimilar or interchangeable biological products regulated by the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER). The previous guidance for industry, Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants, issued on November 18, 2015, has been withdrawn. Submit [comments](#) by **September 4, 2018**. (June 5, 2018)
- Diagnostic test/IVD developers: if you missed the May 24, 2018 webinar Final Guidances on Next Generation Sequencing-based Tests, transcripts and materials are [now available](#).

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

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### In case you missed it

- [Testimony](#) of Anna Abram, FDA Deputy Commissioner for Policy, Planning, Legislation, and Analysis before the House Committee on Energy and Commerce, Subcommittee on Health on Examining the Reauthorization of the Pandemic and All-Hazards Preparedness Act (June 6, 2018)
- [Statement from FDA Commissioner Scott Gottlieb, MD, on federal preparedness and FDA's response efforts to the Ebola virus outbreak in the Democratic Republic of Congo](#) - also see [Ebola Preparedness and Response Updates from FDA](#) (May 30, 2018)
- Interested in working at FDA? Follow [@FDAJobs](#) on Twitter, or visit [www.fda.gov/jobs](#).
- FDA has [proposed](#) an important series of new steps to modernize the organization and functions of the Center for Drug Evaluation and Research (CDER) Office of New Drugs. Also see [FDA Proposes Process Modernization to Support New Drug Development](#) (June 4, 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. (June 5, 2018)
- From NIH - [NIH scientists show how tularemia bacteria trick cells to cause disease](#) - Findings could play a role in developing effective treatment strategies. (May 30, 2018)
- From CDC - [Crisis and Emergency Risk Communications in a Strategic National Stockpile Response](#) - This 49-minute webinar provides public health planners with key considerations related to crisis and emergency risk communications, and to an emergency medical countermeasure response that will inform, direct, and enhance comprehensive Strategic National Stockpile response plans. It identifies potential communication opportunities and challenges unique to Strategic National Stockpile planning and response operations; and describes the public's information and communication needs before, during, and after an incident requiring medical countermeasures from the Strategic National Stockpile. (recorded Feb. 2018)



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