



**U.S. FOOD & DRUG
ADMINISTRATION**

Medical Countermeasures Initiative Update

April 12, 2018

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FDA's "Ask Me Anything
about **Biosimilars**"

with Dr. Leah Christl, Center for Drug
Evaluation and Research

www.Reddit.com/r/Pharmacy
Thursday, April 12 2018, @ 2 - 3:30PM ET

"Ask me anything" about biosimilars

Today! April 12, 2018

The discussion will cover topics of interest primarily to pharmacists, including the biosimilar development and approval process, product labeling, and more. Pharmacists and the public may [submit questions about biosimilars](#) on Reddit until 3:30 p.m. ET April 12, 2018, and FDA's Dr. Leah Christl of the Center for Drug Evaluation and Research (CDER) will answer live **2:00 - 3:30 p.m. ET**. To ask questions, you will need a free Reddit [account](#).

Related links:

- [Biosimilars](#) (information from FDA)
- [Biosimilar Patient and Prescriber Outreach Materials](#)
- [What is a Biosimilar?](#) (PDF infographic, 285 KB)
- [Online courses, webinars, and FDA staff presentations on biosimilars](#)

*Image: FDA's "Ask Me Anything about Biosimilars with Dr. Leah Christl, CDER.
www.reddit.com/r/pharmacy - Thursday, April 12, 2018 @ 2 - 3:30 p.m. ET*

CDC Vital Signs: Containing Unusual Resistance

More than 23,000 Americans die each year from infections caused by germs resistant to antibiotics. Early, aggressive responses to every case of unusual antibiotic resistance can protect people and reduce the number of drug-resistant infections. Learn about CDC's Containment Strategy in a new [Vital Signs report](#). (April 3, 2018)

Image (CDC): Be on guard to contain the first spark. Unusual antibiotic-resistant germs are resistant to all or most antibiotics tested, making them hard to treat, and are uncommon in a geographic area or the US, or have special genes that allow them to spread their resistance to other germs. Learn more in the CDC Vital Signs report.

Be on Guard to Contain the First Spark

UNUSUAL ANTIBIOTIC-RESISTANT GERMS

- Resistant to all or most antibiotics tested, making them hard to treat, and
- Uncommon in a geographic area or the US, or
- Have special genes that allow them to spread their resistance to other germs

Examples of unusual resistance: Vancomycin-resistant *Staphylococcus aureus* (VRSA), *Candida auris*, and certain types of "nightmare bacteria" such as carbapenem-resistant Enterobacteriaceae (CRE).

Events

- **April 16, 2018:** [Evaluating Inclusion and Exclusion Criteria in Clinical Trials](#) (Washington, DC and webcast) - register by **today, April 12, 2018**
- **April 17-20, 2018:** [Preparedness Summit](#) (Atlanta, GA) - The theme for the conference is Strengthening National Health Security: Mastering Ordinary Responses, Building Resilience for Extraordinary Events. (fee)
- **New! April 23, 2018:** [Science Board to the Food and Drug Administration public meeting](#) (Silver Spring, MD and [webcast](#)) - discussion will include how FDA can leverage its existing tools and authorities, and work with stakeholders, to better address the complex scientific, public health, and technology challenges it faces today
- **New! May 7, 2018:** [1918 Pandemic Flu Symposium - 100 years of Influenza Pandemics and Practice: 1918-2018](#) (Atlanta, GA), hosted by the Rollins School of Public Health at Emory University, in partnership with CDC - registration required
- **New! May 10, 2018:** [Tick-Borne Disease Working Group public meeting](#) (webcast) - For its fourth meeting, the [Working Group](#) will focus on the findings and basis for the draft reports from the work of the six Subcommittee Working Groups that were established on December 12, 2017.
- **May 24, 2018:** [FY 2018 Generic Drug Research Public Workshop](#) (Silver Spring, MD and [webcast](#)) - FDA will take information obtained from the public workshop into account in developing fiscal year 2019 regulatory science initiatives. Register by **April 24, 2018**.
- **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.
- **June 25-26, 2018:** [2018 Center for Biologics Evaluation and Research \(CBER\) Research 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.
- **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

Information for industry

- Draft guidance: [Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials](#) (PDF, 90KB) - This draft guidance discusses the ethical and scientific issues when considering the inclusion of pregnant women in clinical trials of drugs and biological products. This draft guidance is intended to advance scientific research in pregnant women, and discusses issues that should be considered within the framework of human subject protection regulations. [Comment](#) by **June 8, 2018**. (April 9, 2018)
- Guidance for industry: [E11\(R1\) Addendum: Clinical Investigation of Medicinal Products in the Pediatric Population](#) (PDF, 354 KB) - The guidance was prepared under the auspices of the International Council for Harmonisation (ICH), and is an addendum to the guidance published in 2000 entitled E11 Clinical Investigation of Medicinal Products in the Pediatric Population. This addendum complements and provides clarification and current regulatory perspective on topics in pediatric drug development. For more information, view the [Federal Register notice](#). (April 11, 2018)

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

In case you missed it

- [We're Committed to Guarding Against the Intentional Adulteration of Food and Implementing the New Rule Efficiently](#) - FDA Voice blog post by FDA Commissioner Scott Gottlieb, MD - "The U.S. food supply is among the safest in the world. But to keep it safe we must recognize that our foods are vulnerable – not just from unintended contamination, but from those who would seek to deliberately do us harm. Ensuring that we're prepared to minimize the risk of an intentional attack on our food supply is a goal that we share with the food industry and consumers." (March 28, 2018)
- Saline shortage update from Commissioner Gottlieb - The firms in Puerto Rico that produce saline have been back online for months and are all producing IV saline; along with two additional firms that received expedited review from the FDA and have also recently begun producing IV saline. [Read more on Twitter](#); also see [Drug Shortages](#) (April 8, 2018)
- Are you a veteran and curious about clinical trials? Watch as U.S. Army Retired Staff Sergeant Quinyardo McClain [shares his experience](#), in a new public service announcement from FDA's Office of Minority Health.
- FDA is [requesting nominations](#) for voting and/or nonvoting consumer representatives to serve on advisory committees and/or panels for which vacancies currently exist or are expected to occur in the near future. Submit materials by **May 11, 2018**.
- The FDA Center for Biologics Evaluation and Research (CBER) is seeking a [Director, Office of Blood Research and Review \(OBRR\)](#). Apply by **April 30, 2018**.
- From HHS - [HHS sponsors its largest exercise for moving patients with highly infectious diseases](#) - The largest patient movement exercise in U.S. Department of Health and Human Services' history began on April 10, 2018 to test the nationwide ability to move patients with highly infectious diseases safely and securely to regional treatment centers.
- From NIH - [Research offers clues for improved influenza vaccine design](#) (April 6, 2018); and [NIAID-funded scientists identify new SARS-like coronavirus from bats in China](#) (April 4, 2018)
- Save the date! The Smithsonian's National Museum of Natural History will [host an exhibition](#) *Outbreak: Epidemics in a Connected World*, opening **May 18, 2018**. The exhibition will explore zoonotic diseases —like Zika and influenza—and the links between human, animal, and environmental health.

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U.S. Food and Drug Administration
10903 New Hampshire Avenue, Silver Spring, MD 20993
1-888-INFO-FDA (1-888-463-6332)

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