**Activity Outline**
**DDI Webinar Series: Fluoroquinolone Safety Labeling Updates**
**April 4, 2017 1:00-2:00pm EDT**
**Webinar**

**Description**
This series of educational webinars is designed to aid physicians, physician assistants, nurses, pharmacists, pharmacy technicians, students, and other healthcare professionals to provide better patient care by knowing how to find relevant FDA regulatory information that will improve drug safety. This webinar will discuss the July 2016 FDA approved labeling changes to the systemic fluoroquinolone antibacterial drugs.

**Series Learning Objectives**
1. Explain how to utilize FDA's drug information, medication safety resources, and regulatory guidance documents to improve delivery of patient care and optimize outcomes.
2. Describe and inform health care providers of recent labeling changes which would impact prescribing and medication management to optimize patient care.

**Session Learning Objectives**
After completion of this activity, the participant will be able to:

1. Describe the disabling and potentially irreversible constellation of adverse events that have been associated with the use of systemic fluoroquinolones
2. Recognize the importance of stopping the fluoroquinolone antibacterial drug at the first sign that a patient is experiencing a serious adverse reaction.
3. Describe situations in which risks of fluoroquinolones outweigh benefits.
4. Recognize the small treatment benefit of antibacterial drug therapy for ABS, ABECB, and UTI.
5. Describe the clinician's difficulty in identifying the disabling and potentially irreversible adverse reactions associated with fluoroquinolones.

**Target Audience**
This activity is intended for physicians, physician assistants, nurses, pharmacists, pharmacy technicians, students, and other healthcare professionals.

**Schedule**

| Time | Title | Lecturer(s) |
|---|---|---|
| Time: 1:00 PM to 2:00 PM | DDI Webinar Series: Fluoroquinolone Safety Labeling Updates | Joseph G. Toerner, MD, MPH<br>Debra Boxwell, PharmD |

**Continuing Education**
The Food and Drug Administration, Center for Drug Evaluation and Research is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

The Food and Drug Administration – Center for Drug Evaluation and Research designates this live activity for a maximum of 1 *AMA PRA Category 1 Credit(s)*™. Physicians and Physician Assistants should claim only the credit commensurate with the extent of their participation in the activity.

The FDA-Center for Drug Evaluation and Research is accredited by the Accreditation Council for Pharmacy Education as a Provider of continuing pharmacy education. (ACPE Universal Activity No. 0601-0000-17-052-L05-P and ACPE Universal Activity No. 0601-0000-17-053-L05-T). This program meets the criteria for 1 contact hour(s) of pharmacy education and pharmacy technician education.

This activity is a knowledge-based activity. These CE activities are primarily constructed to transmit knowledge (i.e., facts). The facts must be based on evidence as accepted in the literature by the health care professions.

FDA, Center for Drug Evaluation and Research is an approved provider of continuing nursing education by the Maryland Nurses Association, an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation.
This 1 contact hour Education Activity is provided by FDA, Center for Drug Evaluation and Research. Each nurse should claim only the time that he/she actually spent in the educational activity.

**Requirements for receiving CE credit**
Physicians, nurses, pharmacists, and pharmacy technicians, and those claiming non-physician CME: attendance is verified by Adobe Connect login or by a sign-in sheet, and completion of the final activity evaluation. Final activity evaluations must be completed within two weeks after the activity.

Pharmacists and Pharmacy Technician participants: partial credit cannot be awarded therefore you must attend the entire activity to receive CPE credit. No exceptions. Pharmacists and Pharmacy Technicians will need their NABP e-profile ID number as well as their DOB in MMDD format in order to claim CE credit.

**Statements of Credit**
Physicians and Nurses Statements of Credit for CE will be issued 10 weeks after the last session of this activity. Pharmacists and Pharmacy Technicians should log into the CPE monitor 10 weeks after the last session of the activity to obtain their CE credit.

**Disclosure**
Faculty:
- Debra Boxwell, PharmD, Safety Evaluator, FDA/CDER/OSE/OPE/DPV-nothing to disclose
- Joseph G. Toerner, MD, MPH Deputy Division Director, OMPT/CDER/OND/OAP/DAIP-nothing to disclose

Planning Committee:
- Kara Burke, PharmD, Consumer Safety Officer, FDA/CDER/OCOMM/DDI-nothing to disclose
- Kimberly DeFronzo, RPh, MS, MBA, Consumer Safety Officer, FDA/CDER/OCOMM/DDI-nothing to disclose
- Virginia Giroux, MSN, ARNP, CE Program Administrator, FDA/CDER/OEP/DLOD-nothing to disclose
- Lesley Navin, RN, MSN, Consumer Safety Officer, FDA/CDER/OCOMM/DDI-nothing to disclose
- Danielle Molnar, PharmD, Consumer Safety Officer, FDA/CDER/OCOMM/DDI – nothing to disclose
- Edward Weinstein, MD, Medical Officer, Office of New Drugs, Division of Anti-Infective Products-nothing to disclose

CE Consultation and Accreditation Team
- Justin Gorinson, CHES, ORISE Fellow, FDA/CDER/OEP/DLOD-nothing to disclose
- Karen Zawalick, CE Consultation and Accreditation Team Leader, FDA/CDER/DLOD-nothing to disclose

**Registration Fees and Refunds**
Registration is complimentary therefore refunds are not applicable.

**Requirements for Certificate of Completion (Non CE)**
Must attend 80% of the lectures (verified by a sign-in sheet).

**References**

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- MedWatch Safety Alerts: http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm479348.htm
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