Activity Outline
FDA Drug Topics: An Introduction to Drug Safety Surveillance and the FDA Adverse Event Reporting System
April 10, 2018
Webinar

Series 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.

Lecture Description
This webinar will introduce the many phases of drug safety surveillance from the earliest stages of drug development through post approval, and will focus on how DPV conducts pharmacovigilance, develops safety signals, and communicates our findings.

References

- Arthur N et al. The Importance of Pharmacovigilance – Safety Monitoring of Medicinal Products. WHO 2002.
- Drug Safety Communications: http://www.fda.gov/Drugs/DrugSafety/ucm199082.htm
- FDA Patient Safety News: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/index.cfm
- Guidance for Industry- post-marketing Safety Reporting for Human Drug and Biological Products including Vaccines, March 2001: http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Vaccines/ucm074850.htm
- Guidance for Industry- Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment, March 2005: http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126834.pdf
- MedWatch: The FDA Safety Information and Adverse Event Reporting Program: http://www.fda.gov/Safety/MedWatch/default.htm

Series Objectives

- Explain how to utilize FDA's Drug Information, medication safety resources, and regulatory guidances to improve delivery of patient care and optimize outcomes.
- Describe and inform health care providers of recent labeling, policy and regulatory changes which would impact prescribing and medication management to optimize patient care.

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

- Describe postmarketing and drug safety surveillance
- Explain the role of MedWatch for reporting and collecting postmarketing safety information
- Summarize the analysis of various types of postmarket safety data

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

Agenda

Lecture 1 April 10, 2018

Time	Topic	Speaker
1:00 - 2:00 PM	An Introduction to Drug Safety Surveillance and the FDA Adverse Event Reporting System	Anne Tobenkin, PharmD

Continuing Education Accreditation

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INTERPROFESSIONAL CONTINUING EDUCATION

In support of improving patient care, FDA Center for Drug Evaluation and Research is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC) to provide continuing education for the healthcare team.

IPCE CREDIT™

This activity was planned by and for the healthcare team, and learners will receive 1.00 Interprofessional Continuing Education (IPCE) credit(s) for learning and change.

CME

FDA Center for Drug Evaluation and Research designates this live activity for a maximum of 1.00 *AMA PRA Category 1 Credit(s)* ™ . Physicians should claim only the credit commensurate with the extent of their participation in the activity.

CPE

This knowledge-based activity has been assigned ACPE Universal Activity Number JA0002895-0000-18-036-L04-P, and ACPE Universal Activity Number JA0002895-0000-18-036-L04-T for 1.00 contact hour(s).

CNE

FDA Center for Drug Evaluation and Research designates this activity for 1.00 contact hour(s).

Requirements for Receiving CE Credit

Physicians, pharmacists, nurses, pharmacist techs, and those claiming non-physician CME: participants must attest to their attendance and complete the final activity evaluation via the CE Portal (ceportal.fda.gov). For multi-day activities, participants must attest to their attendance and complete the faculty evaluation each day. Final activity evaluations must be completed within two weeks after the activity - no exceptions.

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

Important Note regarding completion of evaluations and receiving credit
Attendees have 14 days from the last day of the activity to log in, complete the required evaluation(s) and attest to your attendance to claim credit. Physicians and nurses may then view/print statement of credit. Pharmacists should log into the CPE monitor 10 weeks after the last session of the activity to obtain their CE credit.

Disclosure

Faculty

- Tobenkin, Anne, PharmD, Safety Evaluator, FDA/CDER/OSE/DPV - nothing to disclose

Planning Committee

- Burke, Kara, PharmD, Pharmacist, FDA/CDER/OCOMM/DDI - nothing to disclose
- DeFronzo, Kimberly, RPh, MS, MBA, Consumer Safety Officer, FDA/CDER/OCOMM/DDI - nothing to disclose
- Giroux, Virginia, MSN, FNP-BC, Associate Director for Accreditation, FDA/CDER/OEP/DLOD - nothing to disclose
- Navin, Lesley, RN, MSN, CSO, FDA/CDER/DDI - nothing to disclose
- Weinstein, Edward, M.D., Ph.D., Medical Officer, CDER FDA *My spouse received Salary from EndoCentre of Baltimore for a role as Employee.*

CE Consultation and the Accreditation Team

- Gorinson, Justin, B.S., CHES, ORISE Fellow, FDA/CDER/OEP/DLOD - nothing to disclose
- Giroux, Virginia, MSN, FNP-BC, Associate Director for Accreditation, FDA/CDER/OEP/DLOD - nothing to disclose
- Zawalick, Karen, CE Team Leader, FDA/CDER/OEP/DLOD - nothing to disclose

Registration Fee and Refunds
Registration is complimentary, therefore refunds are not applicable.