Activity Outline
FDA Drug Topics: Research Funding Opportunities to Reduce Preventable Harm
January 28, 2020
FDA

Activity Coordinator:
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Series Description

This series of educational webinars is designed to aid physicians, physician assistants, nurses, pharmacists, pharmacy technicians, certified public health professionals, other health care professionals, and students, to provide better patient care by knowing how to find relevant FDA regulatory information that will improve drug safety. This webinar will introduce the FDA's Drug shortage program, explain how the agency is addressing drug shortages and speak to the various challenges that lead to drug shortages.

Lecture Description
The CDER Safe Use Initiative funds research projects aimed at "reducing preventable harm from drugs." This webinar will discuss the types of projects Safe Use funds, the application process, and important dates in the FY2020 funding cycle. Examples of successful projects funded by Safe Use will be provided.

References

- Core Elements of Anticoagulation Stewardship programs. Available for download at: https://acforum.org/web/education-stewardship.php
- FDA Broad Agency Announcement, FDABAA-20-00123.
- Karter AJ, Warton EM, Lipska KJ, et al. Development and Validation of a Tool to Identify Patients With Type 2 Diabetes at High Risk of Hypoglycemia-Related Emergency Department or Hospital Use. JAMA Intern Med. 2017 Oct 1;177(10):1461-1470. doi: 10.1001/jamainternmed.2017.3844.
- Paul IM, Reynolds KM, Delva-Clark H, et al. Flow Restrictors and Reduction of Accidental Ingestions of Over-the-Counter Medications. Am J Prev Med. 2019 Jun;56(6):e205-e213. doi: 10.1016/j.amepre.2018.12.015. Epub 2019 Apr 17.
- Safe Use Initiative – Extramural Research page.

Series Objectives

- HCPs will be able to locate, understand, describe and utilize FDA's drug safety information and learn how to participate in the process of improving drug safety and public health.

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

- Explain the criteria for applying for funding through the Safe Use Initiative
- Outline the stages of the Broad Agency Announcement (BAA) evaluation process
- Describe qualities that make for a strong research project

Target Audience
This activity is intended for physicians, pharmacists, pharmacy technicians, nurses, and physician assistants.

Agenda

Lecture 1 January 28, 2020

Time	Topic	Speaker
1:00 - 2:00 PM	Research Funding Opportunities to Reduce Preventable Harm	Scott Winiecki, MD

Continuing Education Accreditation

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.

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 JA0002895-0000-20-006-L04-P, and ACPE Universal Activity Number JA0002895-0000-20-006-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).

AAPA

This activity is designated for 1.00 AAPA Category 1 CME credits. FDA Center for Drug Evaluation and Research has been authorized by the American Academy of PAs (AAPA) to award AAPA Category 1 CME credit for activities planned in accordance with AAPA CME Criteria. PAs should only claim credit commensurate with the extent of their participation.

Requirements for Receiving CE Credit

Physicians, physician assistants, 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.

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, physician assistants, 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

- Winiecki, Scott, MD, medical officer, FDA *My spouse received Salary from Mercy Hospital, Baltimore, MD for a role as Employee.*

Planning Committee

- Burke, Kara, PharmD, Team Leader/Pharmacist, FDA/CDER/OCOMM/DDI - nothing to disclose
- Cao, Christian, MPAS, PA-C, Safety Evaluator Team Leader, FDA/CDER/OSE/DPV - nothing to disclose
- DeFronzo, Kimberly, RPh, MS, MBA, Consumer Safety Officer, FDA/CDER/OCOMM/DDI - nothing to disclose
- Kapoor, Rama, MD, M.D., Medical Officer, FDA - nothing to disclose
- Navin, Lesley, RN, MSN, Consumer Safety Officer, FDA/CDER/DDI - nothing to disclose

CE Consultation and Accreditation Team

- Lisa Thompson, MSHA, MBA, CE Consultant, 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.