

Activity Outline
FDA Drug Topics: FDA's Bad Ad Program
May 19, 2020
FDA

Activity Coordinator:

Lesley Navin (Lesley.Navin@fda.hhs.gov), Kimberly DeFronzo (Kimberly.Defronzo@fda.hhs.gov), Kara Burke (Kara.Burke@fda.hhs.gov),

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.

Lecture Description

There are a number of innovative opportunities to collaborate with the FDA. This webinar will focus on the FDA's Bad Ad Program. It will provide an overview of prescription drug promotion and its regulation along with information on how health care professionals can report potentially false or misleading prescription drug promotion to the FDA.

References

- The reference below is to support the claim in the speaker notes that states, "In fact, the pharmaceutical industry spent more than \$24 billion on drug promotion in 2017, with more than \$18.5 billion allotted for marketing to HCPs." Kantar Media. Syneos Health™ PromotionalAnswers. Data on file (2018).
- U.S. Food and Drug Administration. (2020). Truthful Prescription Drug Advertising and Promotion. Available at <https://www.fda.gov/drugs/office-prescription-drug-promotion/truthful-prescription-drug-advertising-and-promotion>.
- U.S. Food and Drug Administration. (2020). Warning Letters and Notice of Violation Letters to Pharmaceutical Companies. Available at: <https://www.fda.gov/drugs/enforcement-activities-fda/warning-letters-and-notice-violation-letters-pharmaceutical-companies>.

Series Objectives

- Explain how to utilize FDA's drug information, medication safety resources, and regulatory guidance, 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:

- Discuss FDA's role in regulating prescription drug promotion and advertising.
- Describe the role that healthcare professionals (HCPs) can play in protecting the public health by recognizing prescription drug promotion and advertising that is potentially false or misleading.
- Explain how HCPs can effectively report potentially false or misleading prescription drug promotion to the FDA through the Bad Ad Program.

Target Audience

This activity is intended for physicians, pharmacists, pharmacy technicians, nurses, cph - certified public health, and physician assistants.

Agenda

Lecture 1 May 19, 2020

Time	Topic	Speaker
1:00 - 2:00 PM	FDA's Bad Ad Program	Melinda McLawhorn, PharmD

Continuing Education Accreditation



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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 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 JA0002895-0000-20-006-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.

CPH

Up to 1.00 CPH Recertification Credits may be earned at this event.

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

- McLawhorn, Melinda, PharmD, Team Leader, FDA/CDER/OMP/OPDP - nothing to disclose

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, 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/DL0D - nothing to disclose
- Zawalick, Karen, CE Team Leader, FDA/CDER/OEP/DL0D - nothing to disclose

Registration Fee and Refunds

Registration is complimentary, therefore refunds are not applicable.