Activity Outline
FDA Drug Topics: An Overview of Naloxone and FDA's Efforts to Expand Access
September 29, 2020
FDA

Activity Coordinator:
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Description
This webinar is designed to aid healthcare professionals in understanding the forms of naloxone that are available for the emergency treatment of acute opioid overdose and will also increase knowledge of steps that FDA has taken to expand community access to naloxone.

References

- Naloxone hydrochloride nasal spray (Narcan Nasal Spray) labeling: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208411Orig1s002lbl.pdf
- Naloxone hydrochloride injection sol. (Evzio) labeling: https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/209862lbl.pdf
- New Recommendations for Naloxone https://www.fda.gov/drugs/drug-safety-and-availability/new-recommendations-naloxone
- Cohen BR, Mahoney KM, Baro E, Squire C, Beck M, Travis S, Pike-McCrudden A, Izem R, Woodcock J. FDA Initiative for Drug Facts Label for Over-the-Counter Naloxone. N Engl J Med. 2020 May 28;382(22):2129-2136. doi: 10.1056/NEJMsa1912403 https://www.nejm.org/doi/full/10.1056/NEJMsa1912403
- Guidance for Industry Label Comprehension Studies for Nonprescription Drug Products https://www.fda.gov/media/75626/download

Learning Objectives

- Describe what naloxone is, how it works, and the availability of products for treatment of acute opioid overdose
- Identify the steps FDA has taken to encourage prescribers to discuss naloxone with patients
- Explain FDA's work to support the development of an over-the-counter (OTC) naloxone product

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

Agenda
Day 1 September 29, 2020

Time	Topic	Speaker
1:00 - 2:00 PM	FDA Drug Topics: An Overview of Naloxone and FDA's Efforts to Expand Access	Barbara Cohen, MPA Mark Liberatore, PharmD, RAC Megan Moncur, MS

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 JA0002895-0000-20-081-L08-P, and ACPE Universal Activity Number JA0002895-0000-20-081-L08-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.

Attention Pharmacists and Pharmacy Techs: Failure to provide your correct NABP AND Date of Birth information, in the required format, may result in the loss of credit for this activity. NABP profile number should be the 6-7 digit profile number assigned by the CPE Monitor and your birth date should be in the MMDD format (e.g. 0721) Do not provide your pharmacy license number. Please click the "My Account" tab and then navigate to "Edit Contact Information" to verify that your information is correct.

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

- Cohen, Barbara, MPA, Social science analyst, FDA - nothing to disclose
- Liberatore, Mark, PharmD, RAC, Deputy Director for Safety, HHS/FDA/CDER/OND/ON/DAAP *My spouse received Salary from Wal-Mart, Inc. for a role as Employee. My spouse received Salary from Patient Care Pharmacy for a role as Employee. May reference off-label use.*
- Moncur, Megan, MS, Associate Director for Opioid Policy, FDA - 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
- 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/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.

Requirements for Certificate of Completion (Non CE)
Must attend 80% of the activity.