Activity Outline
FDA Drug Topics: FDA Oncology Center of Excellence's Project Facilitate: An Overview of the Oncology Expanded Access Program
October 29, 2019
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, 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 provide a high-level overview on Expanded Access and address the roles of oncology healthcare providers in the submission of an Expanded Access Request. The webinar will also introduce the newly launched Project Facilitate of the Oncology Center for Excellence and explain its role in supporting oncology healthcare providers utilizing the Expanded Access pathway.

References

- Lemery, S., Mailankody, S., Kazandjian, D., Demiette Smit, M., Blumenthal, G., Kim, T., Keegan, P., McKee, A., Pazdur, R. (2016, June). Food and Drug Administration analysis of 1332 single patient and emergency use expanded access (compassionate use) requests for patients with cancer over a duration of three years (2012-2014). Abstract accepted and poster presented as American Society of Clinical Oncology Annual Meeting, Chicago, IL.
- Reagan-Udall Foundation (n.d.). Expanded Access Navigator. Retrieved from https://reaganudall.org/

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:

- Define expanded access and the key requirements for an expanded access request for an individual patient.
- Summarize key responsibilities of the oncology healthcare provider when considering expanded access for a patient.
- Identify resources available to healthcare professionals considering submission of an oncology expanded access request for an individual patient.

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

Agenda

Lecture 1 October 29, 2019

Time	Topic	Speaker
1:00 - 2:00 PM	FDA Oncology Center of Excellence's Project Facilitate: An Overview of the Oncology Expanded Access Program	Natasha Kormanik, MSN, RN, OCN Mitchell Chan, PharmD, BCPS

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.

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 JA0002895-0000-19-020-L04-P, and ACPE Universal Activity Number JA0002895-0000-19-020-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. 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. Physician's, 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

- Chan, Mitchell, PharmD, BCPS, RPM, FDA *I received Stocks from TEVA Pharmaceuticals for a role as Stockholder.* Divested of stock in 2019.
- Kormanik, Natasha, MSN, RN, OCN, Regulatory Health Project Manager, OHOP/DHP - 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
- Giroux, Virginia, MSN, FNP-BC, Associate Director for Accreditation, FDA/CDER/OEP/DLOD - nothing to disclose
- Navin, Lesley, RN, MSN, Consumer Safety Officer, 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. My spouse received Salary from Johns Hopkins Surgery Centers for a role as Employee.*

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.