Activity Outline
DDI Webinar Series: An Overview of FDA's Expanded Access Process and the New Individual Patient Expanded Access Application
July 12, 2016 1:00-2:00pm EST
WO CSU Bldg 2, Rm 2049

Description
This series of educational webinars are designed to aid Healthcare Professionals, Pharmacy, Nurse Practitioner, Physician Assistant and Medical students to provide better patient care by knowing how to find relevant FDA regulatory information that will improve drug safety. This DDI webinar will discuss and summarize the purpose of FDA's expanded access program, including the types of expanded access requests accepted by FDA, the requirements for requesting individual expanded access and the costs physicians may charge patients for single patient expanded access. The speakers will review and explain how to submit single patient IND expanded access requests to the FDA using the new FDA Form 3926. The instructional level is intermediate.

References
- Expanded Access - www.fda.gov/expandedaccess
- Expanded Access: Criteria for an Investigational Product to be Made Available For Widespread Use Under a Treatment Protocol or Treatment IND/ Treatment IDE - http://www.fda.gov/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/ucm431769.htm
- Individual Patient Expanded Access Applications: Form FDA 3926 Draft Guidance for Industry - http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM432717.pdf
- FAQ: ClinicalTrials.gov - What is "Expanded Access"? - https://www.nlm.nih.gov/services/ctexpaccess.html
- Practical, Legal, and Ethical Issues in Expanded Access to Investigational Drugs, NEJM 2015, 372:279-286, January 15, 2015 (Darrow, Sarpatwari, Avorn & Kesselheim - http://www.nejm.org/doi/full/10.1056/NEJMhle1409465
- MedWatch - http://www.fda.gov/Safety/MedWatch/
- Regulations - 21 CFR 314.80 Post-marketing reporting of adverse drug experiences at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=314.80
- FDA website: Potential Signals of Serious Risks/New Safety Information Identified from the FDA Adverse Event Reporting System (FAERS) at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=314.80
- FDA website: Post-market Drug and Biologic Safety Evaluations at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/ucm204091.htm
- Report to the FDA Commissioner from the Task Force on Risk Management May 1999: Managing the Risks from Medical Product Use: Creating a Risk Management Framework Part 3: How Does FDA Conduct Post-marketing Surveillance And Risk Assessment? http://www.fda.gov/Safety/SafetyofSpecificProducts/ucm180549.htm
- FDA's response to IOM 2006 Report on The Future of Drug Safety – Promoting and Protecting the Health of the Public (2007) http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM171627.pdf
- FDA report to Congress – Changing the Future of Drug Safety: FDA Initiatives to Strengthen and Transform the Drug Safety System, July 2009 http://www.fda.gov/downloads/Safety/SafetyofSpecificProducts/UCM184046.pdf
- ISMP(Institute for Safe Medication Practices) website – FDA Safety Alerts at http://www.ismp.org/Tools/FDASafetyAlerts.asp
- ISMP QuarterWatch – Monitoring FDA MedWatch reports at http://www.ismp.org/quarterwatch/default.aspx
- National Patient Safety Foundation: Improving Root Cause Analyses and Actions to Prevent Harm at http://www.npsf.org/?page=RCA2
- Farley DO et al; Adverse Event Reporting Practices by U.S. Hospitals: Results of a National Survey. Quality and Safety in Health Care 2008; 17:416-423.
- Joint Commission http://www.jointcommission.org
- AHRQ (Agency for Healthcare research and Quality), Patient Safety Network (PSNet): Voluntary Patient Safety Event Reporting (Incident Reporting), August 2014 https://psnet.ahrq.gov/primers/primer/13.

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 changes which would impact prescribing and medication management to optimize patient care.

Session Learning Objectives After completion of this activity, the participant will be able to:
1. Summarize the purpose of FDA's expanded access program
2. Identify the types of expanded access requests accepted by FDA
3. Describe the requirements for requesting individual expanded access
4. Explain how to submit single patient IND expanded access requests to the FDA using the new FDA Form 3926
5. Describe the costs physicians may charge patients for single patient expanded access.

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

Schedule

Time	Title	Lecturer(s)
Time: 1:00 PM to 1:05 PM	Introduction	Lesley Navin, RN, MSN
Time: 1:05 PM to 2:00 PM	An Overview of FDA's Expanded Access Process and the New Individual Patient Expanded Access Application	Richard Klein Peter Lurie MD, MPH Colleen Locicero RPh

Continuing Education
The Food and Drug Administration, Center for Drug Evaluation and Research is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

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

The FDA-Center for Drug Evaluation and Research is accredited by the Accreditation Council for Pharmacy Education as a Provider of continuing pharmacy education. (ACPE Universal Activity No. 0601-0000-16-062-L05-P and ACPE Universal Activity No. 0601-0000-16-063-L05-T). This program meets the criteria for 1 contact hour(s) of pharmacy education and pharmacy technician education.

This activity is a knowledge-based activity. These CE activities are primarily constructed to transmit knowledge (i.e., facts). The facts must be based on evidence as accepted in the literature by the health care professions.

FDA, Center for Drug Evaluation and Research is an approved provider of continuing nursing education by the Maryland Nurses Association, an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation.
This 1 contact hour Education Activity is provided by FDA, Center for Drug Evaluation and Research. Each nurse should claim only the time that he/she actually spent in the educational activity.

Requirements for receiving CE credit
Physicians, nurses, pharmacists, and pharmacy technicians, and those claiming non-physician CME: attendance is verified by Adobe Connect login or by a sign-in sheet, and completion of the final activity evaluation. Final activity evaluations must be completed within two weeks after the activity.

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

Statements of Credit
Physicians and Nurses Statements of Credit for CE will be issued 10 weeks after the last session of this activity. Pharmacists and Pharmacy Technicians should log into the CPE monitor 10 weeks after the last session of the activity to obtain their CE credit.

Disclosure
Faculty:
- Richard Klein, Director, Patient Liaison Program FDA/CDER/OHCA – nothing to disclose
- Peter Lurie MD, MPH, Associate Commissioner for Public Health Strategy and Analysis, Office of the Commissioner FDA/CDER – nothing to disclose
- Colleen Locicero RPh, Associate Director for Regulatory Affairs, FDA/CDER/ODE1 – nothing to disclose
- Lesley Navin, RN, MSN, Consumer Safety Officer, FDA/CDER/OCOMM/DDI, nothing to disclose

Planning Committee:
- Kara Burke, PharmD, Consumer Safety Officer, FDA/CDER/OCOMM/DDI-nothing to disclose
- Kimberly DeFronzo, RPh, MS, MBA, Consumer Safety Officer, FDA/CDER/OCOMM/DDI-nothing to disclose

- Lesley Navin, RN, MSN, Consumer Safety Officer, FDA/CDER/OCOMM/DDI-nothing to disclose
- Edward Weinstein, MD, Medical Officer, Office of New Drugs, Division of Anti-Infective Products-nothing to disclose
- Sarah Ikenberry, MA, Health Communications Specialist, FDA/CDER/OCOMM/DHC-nothing to disclose

CE Consultation and Accreditation Team

- Virginia Giroux, MSN, FNP-BC, CE Program Administrator, FDA/CDER/DLOD-nothing to disclose
- Justin Gorinson, ORISE Fellow, FDA/CDER/OEP/DLOD-nothing to disclose
- Rokhsareh Shahidzadeh, MSN, RN, Regulatory Health Education Specialist, FDA/CDER/OEP/DLOD-nothing to disclose
- Karen Zawalick, CE Consultation and Accreditation Team Leader, FDA/CDER/DLOD-nothing to disclose

Registration Fees and Refunds
Registration is complimentary therefore refunds are not applicable.

Requirements for Certificate of Completion (Non CE)
Must attend 80% of the lectures (verified by a sign-in sheet).

Initial Release Date: June 16, 2016