**Activity Outline**

# FDA Grand Rounds:

# Serious and Actionable Risks, Plus Disclosure: Investigating an Alternative Approach for Presenting Risk Information in Prescription Drug Television Advertisements

**May 11, 2017**
**12:00 PM-1:00 PM**
**FDA White Oak, Room 2031**

**Series Description**
The FDA Grand Rounds is webcast every other month to highlight cutting-edge research underway across the agency and its impact on protecting and advancing public health. Each session features an FDA scientist presenting on a key public health challenge and how FDA is applying science to its regulatory activities.

**Session Description**
Prescription drug advertising regulations require that broadcast advertisements containing product claims communicate the product's major side effects and contraindications in either the audio or audio and visual parts of the advertisement (21 CFR 202.1(e)(1)). This is often referred to as the "major statement." The length of the major statement varies by product and can be quite long for certain products, especially those with a significant risk profile.

There is concern that as currently implemented in direct-to-consumer (DTC) ads, the major statement is often too long, which may result in:
- reduced consumer comprehension,
- minimizing important risk information and,
- potentially, therapeutic non-compliance due to fear of side effects.

At the same time, there is concern that DTC TV ads do not include adequate risk information or leave out important information. These are conflicting viewpoints. A possible resolution is to limit the risks in the major statement to those that are serious and actionable, and include a disclosure to alert consumers that there are other product risks not included in the ad.

This presentation discusses the results of FDA empirical research on the effectiveness of this "limited risks plus disclosure" strategy.

**Session References:**
**Aikin, K.J.,** Southwell, B.G., Paquin, R.S., Rupert, D.J., O'Donoghue, A.C., Betts, K.R., & Lee, P.K. (2016). Correction of misleading information in prescription drug television advertising: The roles of advertisement similarity and time delay. *Research in Social and Administrative Pharmacy*, 1-16. doi:10.1016/j.sapharm.2016.04.004

**Aikin, K.J.,** O'Donoghue, A.C., Squire, C., Sullivan, H.W., & Betts, K.R. (2016, summer). An empirical examination of the FDAAA-mandated "Toll Free Statement" for consumer reporting of side effects in Direct-to-Consumer television advertisements. *Journal of Public Policy and Marketing*, *35*(1), 108-123.

**Series Objectives**:
1. Discuss the research conducted at the FDA
2. Explain how FDA science impacts public health

**Session Learning Objectives** After completion of this activity, the participant will be able to:
1. Describe how Social Science can inform approaches to regulatory problems.

2. Identify the “major statement” in direct-to-consumer broadcast ads.
3. Describe the impact of “limited risks plus disclosure strategy” on consumer perceptions of product risks and benefits.
4. Discuss how “limited risks plus disclosure strategy” may contribute to regulatory strategy around communication of important information about prescription drugs.

**Target Audience**
This activity is intended for physicians, pharmacists, nurses and other scientists within the agency and external community.

**Schedule**

| Date/Time/Place | Lecture Title | Lecturer |
|---|---|---|
| Thursday, May 11, 2017<br>12:00 PM-1:00 PM<br>Bldg 2, Rm 2047 | FDA Grand Rounds:<br>Serious and Actionable Risks, Plus Disclosure: Investigating an Alternative Approach for Presenting Risk Information in Prescription Drug | Kathryn (Kit) Aikin, Ph.D. |

**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 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. 0601-0000-17-060-L04-P). This program meets the criteria for 1 contact hour(s) of pharmacy 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, pharmacists, nurses and those claiming non-physician CME: attendance is verified by a sign-in sheet and completion of the final activity evaluation. For multi-day activities, participants must sign in every day. Final activity evaluations must be completed within two weeks after the activity.

Pharmacy participants: partial credit cannot be awarded therefore you must attend the entire activity to receive CPE credit. 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.

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

**Disclosure**
**Faculty**
Kathryn (Kit) Aikin, Ph.D., Senior Social Science Analyst, Team Lead, FDA/OPDP, has nothing to disclose.

**Planning Committee**
Emannuel Fadiran, PhD, RPh, Intramural Research Program Director, FDA/OC/OWH, has nothing to disclose.
Eileen Parish, MD, Medical Officer, FDA/OC/OCS/OSPD, has nothing to disclose.
Rokhsareh Shahidzadeh, MSN, RN, Senior Regulatory Health Education Specialist, OC/OCS/OSPD, has nothing to disclose.
Leslie Wheelock, MS, RN, Director OSPD, FDA/OC/OCS/OSPD, has nothing to disclose.

**CE Consultation and Accreditation Team**
Traci Bryant, MAT, Education Specialist, FDA/CDER/OEP/DLOD, has nothing to disclose.
Virginia Giroux, MSN, ARNP, CE Program Administrator, CDER/DLOD, has nothing to disclose.
Karen Zawalick, CE Team Leader, FDA/CDER/OEP/DLOD, has 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**: May 11, 2017

**Remote Access Instructions:**

To register for the webcast, please click the link below and then follow the instructions. After you register you will receive a link to access the live webinar by logging in with your username and password which you create when you register.
https://collaboration.fda.gov/may112017reg/event/registration.html

For technical assistance please contact Jeffery Rexrode at Jeffery.Rexrode@fda.hhs.gov.

**LMS Registration link:**
https://lms.learning.hhs.gov/Saba/Web/Main/goto/RegisterCatalog?offeringId=class000000000124095&oneClickLearningON=true

**Reasonable Accommodations**

The FDA provides reasonable accommodations for all individuals with disabilities who apply for training or developmental opportunities. If you need a reasonable accommodation for any part of the training application process please notify the training contact for this particular event. Reasonable accommodation requests are granted on a case-by case basis. Should you need sign language interpretation to attend this event, please send the request to Interpreting.Services@oc.fda.gov.