FDA Drug Information Curriculum Case Study: Instructor's Guide

FDA Useful Drug Information for Clinicians: Practicing clinicians seek available information on a new drug before making a treatment decision

LEARNING OBJECTIVES

- Identify an online resource for FDA's drug review materials found at: www.fda.gov.
- Determine if a drug or biologic marketed in the U.S. has been discussed at an FDA advisory committee meeting.
- Gain an understanding of the FDA advisory committee's evaluation of a product's benefits and risks.
- Explain the characteristics of a new molecular entity (NME).
- Gain an understanding of risk evaluation and mitigation strategies (REMS) and their role.

TOPICS

FDA Drug Information Resources; Drugs@FDA; Risk Evaluation and Mitigation Strategy (REMS); FDA CardioBeat; FDA Drug Shortages Program

ASSUMPTIONS

This case study is based on the assumption that the target audience is undergraduate students or health professionals who are unfamiliar with FDA drug information resources.

SUGGESTED APPROACH

1. Preparing Students: Students are expected to read the case study prior to the training session.

2. Engaging Students: The training session should consist of a discussion of the case study.

3. Immersing Students: The training session should emphasize group discussion of the case study. Students should be encouraged to use their mobile devices to access the drug resources apps mentioned in the case study and navigate to the FDA websites referenced in class.

STUDENT ACTIVITIES

Before Class

Review the following websites:

1. Drugs@FDA
   http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm

2. FDA Advisory Committee http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/default.htm

3. REMS@FDA
   http://www.accessdata.fda.gov/scripts/cder/rems/index.cfm

4. Drug Shortages Program
   http://www.fda.gov/Drugs/DrugSafety/DrugShortages/

Answer the following questions before class:

1. What is Drugs@FDA?

   Answer: Drugs@FDA is a searchable database of drug product labels and approval-related documents, including reviews, approval letters, and current and archived labels.

2. True or False: Advisory Committee members are FDA employees.

   Answer: **False**. Advisory committees are made up of outside experts that provide FDA with independent opinions and recommendations on applications to market new drugs and on FDA policies. The marketing applications they review include data about the safety and effectiveness of human drugs. The committees receive summary information about the drug applications and copies of FDA's review of the application documents. Based on this information, advisory

committees may recommend approval or disapproval of a drug's marketing application. FDA generally follows an advisory committee's recommendation, but is not required to do so.

3. A risk evaluation and mitigation strategy (REMS) may consist of:
   a. Medication Guide
   b. Communication Plan
   c. Elements to Assure Safe Use (ETASU)
   d. Implementation Plan
   e. Cost of the drug
   f. All of the above
   g. a, b, c, and d

Answer: **g.** a, b, c, and d

In Class

Suggestions for in-class discussion:

1. Visit FDA's Cardiovascular Disease web page and discuss the information patients can find there. http://www.fda.gov/forpatients/illness/cardiovascular/default.htm

2. Using the REMS@FDA website, choose a drug product and discuss the different parts of the product's REMS.

3. Break into groups. Choose an advisory committee from the FDA Drug Committees site. Look through the materials listed for the previous year, and select a meeting to report on. Review the agenda, briefing documents, minutes, and any other available information relevant to the meeting. Report your findings on the purpose of the meeting and the committee's final recommendations to the class.

4. Pharmacy and Therapeutics Committee Meeting: For this project, you and your group members will prepare a report on a drug of interest to present to a P&T Committee at a hospital. Select a drug product listed in the Drugs@FDA database and research it using the FDA resources mentioned in the case study (also listed below). You will present your findings to the class, who will act as the P&T Committee and make the final decision on whether or not to include your selected drug in the hospital's formulary.

   a. Using the Drugs@FDA database:
      i. Review the product's label information
      ii. Review the product's approval history, letter, and other review documentation available on Drugs@FDA

   b. Using the REMS@FDA website, review any REMS documents and associated materials for the drug product (if they exist)

   c. Visit the FDA Advisory Committee website. Check to see if your drug was reviewed by an advisory committee. If it was, review all of the relevant meeting materials available.

   d. Check to see if the drug is listed in the FDA Drug Shortages database.

After Class

1. Sign up to receive CardioBeat updates http://www.fda.gov/forpatients/illness/cardiovascular/default.htm

2. Identify an upcoming advisory committee meeting and view the webcast. Submit a one-page summary of the meeting to the instructor.

3. Download the drug shortages app http://www.fda.gov/drugs/drugsafety/drugshortages/default.htm

Additional References

FDA Basics Drugs
http://www.fda.gov/AboutFDA/Transparency/Basics/ucm192696.htm

FDA Basics Webinar: A Brief Overview of Risk Evaluation and Mitigation Strategies (REMS)
http://www.fda.gov/AboutFDA/TransparencyBasics/ucm325201.htm

FDA Basics Webinar : Drug Shortages http://www.fda.gov/AboutFDA/Transparency/Basics/ucm422040.htm