Transforming Professional Medical Education: Role of FDA

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Disclosure Statement

I have no financial relationships with proprietary entities that produce health care goods and services

The opinions and information in this presentation are my own and do not necessarily reflect the views and policies of the FDA
FDA Role in Continuing Medical Education (CME)

• CME essential part of staying informed as a practitioner

• Need to Distinguish Promotion and Education
  – FDA has recognized separate role in regulating promotion
    • See Dr. Zuckerman’s talk
  – FDA has emerging role in using CME as one component of our work to improve safe use of medical products

- Balance
- Objectivity
- Independence
- Scientific Rigor

--From slides by Bram Zuckerman
FDA Use of Educational Tools to Improve Medical Product Use

- FDA Education of Prescribers and Patients
  - Focused on product labeling
    - Product Labeling
    - Medication Guide

- Web postings, Webinars, Articles, Meetings, Podcasts, Tweets, Blogs....
Attention Prescribers:
FDA seeks your help in curtailing the U.S. opioid epidemic

FDA is asking all prescribers of opioids to ensure they have thorough knowledge of the FDA-approved product labeling for the opioids they prescribe, and to ensure they have adequate training in opioid therapy. Below is our Open Letter to prescribers. We encourage all prescribers to help curb our nation's opioid epidemic!

View and print full article - Attention Prescribers: Curtailing Opioid Epidemic [PDF - 137KB]

Summary

- In light of the expanding opioid epidemic in the U.S., FDA urges prescribers to take advantage of training on opioid prescribing, available as of March 1, 2013. This voluntary training will be provided at little to no cost through accredited continuing education activities supported by independent education grants.

- Taking advantage of training opportunities on opioid therapy, now and in the future, is one of three key roles that FDA sees for prescribers in helping to curtail this pervasive problem. The other two are: knowing the content of the most current drug labels for the opioids they prescribe, and educating patients about the appropriate use of opioids, their potential risks, and proper disposal techniques.

- FDA-approved drug labels are frequently updated based on additional science, new benefit-risk information, or public health implications regarding the medication. Labels of extended release and long-acting opioid drugs were

FDA New Use of Continuing Medical Education for REMS

• CME represents new opportunity for FDA to product information to prescribers
  – FDA-developed CME materials
    • CME entitled: “An Introduction to the Improved FDA Prescription Drug Labeling - Additional Information”
  – CME materials developed as a part of Risk Evaluation and Mitigation Strategy REMS)
Opioids: FDA Risk Evaluation and Mitigation Strategy (REMS)

Go to FDA.GOV and type opioid REMS in search box

or

Opioid REMS

• Focus is long-acting and extended-release opioids (ER/LA opioids)
  – Intended to improve the use and reduce the abuse of these drugs

• As a part of the REMS, manufacturers were required to make CME materials available for prescribers and patients based on FDA-approved materials
  – CME for prescribers to encourage participation
  – CME developed by accredited CE providers, based on core messages developed by FDA/NIDA/SAMHSA (‘Blueprint’)
  – Continuing Education materials now available
    • https://search.er-la-opioidrems.com/Guest/GuestPageExternal.aspx
    • http://www.er-la-opioidrems.com/thewUI/rems/home.action
What is SCOPE of Pain?

SCOPE of Pain is a series of continuing medical education/continuing nursing education activities designed to help you safely and effectively manage patients with chronic pain, when appropriate, with opioid analgesics. Our program consists of:

- A 3-module web-based activity,
- 10 live conferences held around the US that will include Policy and Resource Panels, and
- Train-the-trainer sessions, and a subsequent trainer-delivered series of non-pharmacologic health center-based grand rounds workshops.

The FDA has mandated manufacturers of extended release/long-acting (ER/LA) opioid analgesics, as part of a comprehensive Risk Evaluation and Mitigation Strategy (REMS), to make available comprehensive prescriber education in the safe use of these medications based on the FDA curriculum known as the Blueprint for Prescriber Education for Extended Release and Long-Acting Opioid (ER/LA) Analgesics. Our curriculum covers all aspects of this blueprint and more to provide a comprehensive educational program.

Who is this for?

Physicians, nurse practitioners, physician assistants, registered nurses, nurses, dentists, and pharmacists

Why do I need SCOPE of Pain training?

Chronic pain affects approximately 100 million in the US, making it one of the most common reasons for patients to seek medical care. Unfortunately, pain management, including the appropriate use of opioids, is not well covered in medical training. Moreover, there are inadequate numbers of pain management specialists to help generalist providers manage these patients.

Partly in response to the problem of under-treatment of pain, over the past decade,
Issues Related to this Use of CME

• Resources needed to create and manage CE

• Impact of CE as educational tool to manage risks as a part of REMS
  – Who takes CE?
  – Does the CE influence practice appropriately?

• Acceptance by prescribers
  – CE as incentive
  – Best methods to reach prescribers?
Summary

• CME is an essential part of the continuum of physician medical education
• FDA has historically used CME in limited ways to educate on prescription of drugs as part of our larger educational efforts
• Use of CME as a part of the Opioid REMS represents new approach to education
  – Grounded in need the delivery of balanced, scientifically-accurate information to prescribers
  – Ongoing work to identify how best to use CME