FDA’s Bad Ad Program
Empowering HCPs to Recognize and Report False or Misleading Drug Promotion

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Objectives
- Understand FDA’s role in regulating prescription drug promotion and advertising
- Understand the role that healthcare professionals (HCPs) can play in protecting the public health by ensuring that prescription drug promotion and advertising is truthful and not misleading
- Understand how HCPs can effectively report misleading prescription drug promotion to the FDA through the Bad Ad Program

FDA’s Mission - part 1
- The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation’s food supply, cosmetics, and products that emit radiation, and by regulating the manufacture, marketing, and distribution of tobacco products.

FDA’s Mission - part 2
- The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods, and to reduce tobacco use to improve health.
FDA Structure

Food and Drug Administration

CDER Review (Approving) Divisions

Office of New Drugs
- Division of Cardiovascular and Renal Products
- Division of Neurology Products
- Division of Psychiatry Products
- Division of Botanical Drug Products
- Division of Anesthesia, Analgesia, and Addiction Products
- Division of Metabolism and Endocrinology Products
- Division of Anti-Infective Products
- Division of Antiviral Products
- Division of Hematology Products
- Division of Pulmonary, Allergy, and Rheumatology Products
- Division of Dermatology and Dental Products
- Division of Gastroenterology Products
- Division of Reproductive and Urologic Products
- Division of Medical Imaging Products
- Division of Nonprescription Drug Products
- Division of Oncology Products
- Division of Transplant and Ophthalmology Products

Office of Prescription Drug Promotion (OPDP)

- To protect the public health by ensuring prescription drug information is truthful, balanced, and accurately communicated.

- This is accomplished through a comprehensive surveillance, enforcement, and education program, and by fostering better communication of labeling and promotional information to both healthcare professionals and consumers.

Advertising Myths and Misconceptions

- FDA “legalized” DTC advertising in the late 1990’s
- Industry spends most of its advertising budget on DTC advertising
- FDA has the authority to ban DTC advertising
- FDA can restrict DTC advertising to certain types of products
- FDA approves ads
- FDA regulates “good taste”
What does OPDP regulate?

- Written and broadcast prescription drug promotional materials made by the company which include:
  - TV and radio commercials
  - Sales aids, journal ads, and patient brochures
  - Drug websites, e-details, webinars, Epocrates, and email alerts

Regulatory Authority: FD&C Act

- Prescription drug promotion must...
  - Not be false or misleading
  - Have balance between efficacy and risk information
  - Reveal facts material with respect to consequences that may result from the use of the drug as recommended or suggested

Regulatory Authority

- Code of Federal Regulations (CFR)
  - 202.1 - Prescription Drug Advertising
  - 312.7 - Preapproval Promotion
  - 314.550 - Subpart H, Accelerated Approval for Drugs
  - 601.40 - Subpart E, Accelerated Approval for Biologics

Regulatory Authority

- Post-Approval Regulations located in 21 CFR 314.81(b)(3):
  - Require the submission of all promotional materials at the time of initial dissemination or publication
  - Must include Form FDA-2253 and current PI

*OPDP generally does NOT “pre-clear” promotional materials
Categories of Promotional Materials

- **Labeling**
  - Audio, video, or printed matter (e.g., brochures, booklets, mailing pieces, exhibits, slides)
  - Supplied or disseminated by the manufacturer, distributor, packer, or any party acting on behalf of the sponsor
  - Accompanied by the approved product labeling

- **Advertising**
  - Advertisements in published journals, magazines, newspapers, and other periodicals
  - Broadcast (e.g., TV, radio, telephone communication systems)
  - Accompanied by a “Brief Summary” of the approved product labeling

Help Seeking

- May discuss a medical condition or disease state
- May include a company name
- May **NOT** include drug names

Help-Seeking Ad

Categories of Promotional Materials

- **Help-Seeking Institutional Reminder**
  - Cannot make any representations about a specific product

- **Full Product**
Institutional

- Company name
- Area of research
- May NOT mention drug names

Reminder

- Must include proprietary and established name
- May call attention to drug name but may NOT contain any representation or suggestion relating to the advertised drug product
- May include dosage form, package contents, price, name of manufacturer, packer, distributor
- Not permitted for drug with a Boxed Warning
Full Product Claim Ads
- Include representation or suggestion relating to the advertised drug product
- Must include a balanced risk presentation ("fair balance")
- Must include the Brief Summary or PI

Broadcast Advertising
- "Major Statement"
  - Information relating to the major side effects and contraindications
- "Adequate Provision"
  - Provides for dissemination of the PI
  - Recognizes the inability of broadcast advertisements of reasonable length to present and communicate this information effectively
Adequate Provision

Currently acceptable adequate provision:
- Toll-free number
- Simultaneously running magazine ad
- Reference to a healthcare provider
- Website

Total # of promotional pieces

What does OPDP do?
- Advice to industry
- Advice within FDA
- Guidance and policy development
- Research
- Surveillance and enforcement

False or Misleading Promotion

- Generally makes a drug appear better or safer than clinical testing has actually demonstrated
- Is against the law
- May have public health consequences, e.g.
  - Providers writing inappropriate prescriptions
  - Patients using medication incorrectly or for the wrong purpose
  - Medicare fraud
  - Adverse events
Common Violations

- Omitting risk information
- Downplaying drug risks
- Distorting scientific research
- Overstating the efficacy of a drug
- Using suggestive language or imagery that gives a false overall impression

Surveillance and enforcement

- OPDP’s normal surveillance activities include:
  - Monitoring drug promotional materials sent to us by industry
  - Monitoring medical convention exhibit halls
  - Reviewing complaints submitted by industry competitors

Limitations to surveillance

- However, these surveillance activities do not allow us to monitor certain types of drug promotion, such as what occurs in places such as physician offices and industry-sponsored dinner and lunch programs.

That’s one of the reasons why we developed the Bad Ad Program

Bad Ad’s dual mission:

1. Education and outreach
2. Hotline (email and telephone) for HCPs to report potential violations
**Bad Ad Education and Outreach**
- Pharmaceutical companies spend billions of dollars each year to promote drugs, yet many HCPs are not trained to identify false or misleading promotion.
- Main educational outreach includes:
  - 1-credit CME course
  - Case studies for educational settings
  - Media campaigns and conference outreach

**Bad Ad CME Program**
- 1-hour, self-paced training for 1.00 ANCC contact hours for nurses and nurse practitioners.
- Training modules include:
  - Video presentations by OPDP reviewers
  - Video presentation on “the psychology of influence” by an expert psychologist consultant
  - Simulated interactive scenarios to test knowledge including a pharmacy scenario
- Over 1,000 course completions to date and excellent overall feedback

**Bad Ad Case Studies**
- Three case studies based on real OPDP enforcement actions that originated via Bad Ad.
- Designed to be used as part of an educational curriculum or training.
- Includes the violative promotional material, the resulting enforcement letter, the FDA-approved PI, and a facilitator guide.

**What should you do if you see misleading drug promotion?**
- **Bad Ad Hotline**
  - Any HCP can report potentially misleading promotion to OPDP by:
    - sending an e-mail to BadAd@fda.gov or
    - calling 877-RX-BADAD (877-792-2323)
  - Can be submitted anonymously. However, FDA encourages you to include contact information in case follow-up is necessary for more information.
What will OPDP do with your complaint?

- Once a Bad Ad complaint is received, OPDP will evaluate it to determine if it meets the criteria needed to take an enforcement action.

- If OPDP finds the promotion to be false or misleading, we will move forward with a risk-based enforcement strategy to put a stop to the promotion ourselves, or refer it for further criminal investigation.

- If the report does not meet the required criteria at the time, it will serve as valuable information in focusing our ongoing surveillance activities.

Enforcement Action Example:

DermaSmoothe (fluocinolone acetonide)

- Indication: Topical treatment of moderate to severe atopic dermatitis in pediatric patients, 3 months and older for up to 3 weeks
  - Also states to apply the least amount of Derma-Smoothe to cover the affected areas, and not to apply to the diaper area, face, axillae, or groin unless directed

- Warning: The systemic absorption of topical corticosteroids can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency...Children may be more susceptible to systemic toxicity from equivalent doses due to their larger skin surface to body mass ratios.
Learning Objectives

• Identify the types of adverse events and product problems healthcare professionals can report to MedWatch
• Explain how to submit a report to MedWatch
• Learn about tools that MedWatch can provide
FDA Regulates $1 Trillion Worth of Products a Year

Every morning when you wake up and
brush your teeth
put in your contact lenses
microwave your breakfast
take your medicine
feed your pet
select a lipstick
go grocery shopping
get a flu shot or a mammogram….

You have been touched by the
U. S. Food and Drug Administration.

What is MedWatch?

1. A way to send information IN to FDA

2. A way to get safety information OUT from FDA

www.fda.gov/medwatch

Why Report?

“Every product that FDA approves carries some risk…Sometimes there are risks that only come to light after a medical product gets on the market and is used in a larger number of patients, for a longer period of time, and in patients whose health characteristics are different from those of the patients studied before approval.”

- Norman Marks, M.D., retired MedWatch Medical Officer
MedWatch: Safety Information IN

• One person can make a difference

What should I report?

Any event that:
- Is fatal
- Is life-threatening
- Is permanently disabling
- Requires/prolongs hospitalization
- Causes a birth defect
- Requires intervention to prevent permanent impairment or damage

Potential Harm

Potential Errors

• Prescribing
  – handwriting, abbreviations

• Label/Packaging
  – placement of information, expression of strength/dose, readability of label, lack of appropriate labeling during repackaging

• Miscommunication of Orders/Nomenclature
  – sound alike, look alike
How do I report?

• Online
• Mail/Fax
• By Phone
  1-800-332-1088

MedWatch Form

Quality is Key: Case #1

• Health care worker ST reported male patient A3 started Drug X at 5 mg daily for type 2 diabetes on February 11, 2015.
• The patient developed liver failure.

Question: Does Case #1 contain the four elements?

☐ Yes
☐ No
Quality is Key: Case #1

- Health care worker ST reported male patient A3 started Drug X at 5 mg daily for type 2 diabetes on February 11, 2015.
- The patient developed liver failure.

Quality is Key: Case #2

- 50-year-old male ABC123 with type 2 diabetes, hyperlipidemia, and hypertension. No history of liver disease.
- Started Drug X on February 11, 2015.
- Other medications: Drug Y and Drug Z.
- Labs drawn on Feb 11 revealed liver enzymes, INR, creatinine, and bilirubin all within normal limits.
- No alcohol use.
- 8 weeks after starting Drug X patient presented to ER with 6 day history of jaundice, dark urine, and nausea/vomiting.
- He was admitted to ICU and subsequently diagnosed with acute liver failure.
- Drug X stopped upon admission.
- Viral hepatitis was ruled out.
- 7 days after stopping the medication, all lab values returned to normal.
- Reported by ST

MedWatch Learn: Teaching Tool

[Link to MedWatch Learn website]

What happens to my report?

[Image of a question mark]

Did you see it??
Safety Info Out

Request Change to Design, Packaging, Manufacturing
Pharmacovigilance: Further Studies or Trials
MedWatch Safety Alert Example

Drug Safety Labeling Changes

Safety Info Out

Request Labelling Changes
Enhance Education

MedWatch: Safety Information OUT

MedWatch: Safety Information OUT

June 2018

Drug Safety Labeling Changes

ISSUE: FDA notified health professionals, providers and caregivers for infants, that lidocaine viscous solution should not be used to treat infants and children with teething pain as it was approved for treating pain, and use in infants and young children can lead to serious harm, including death.

Lidocaine viscous solution is a powerful anesthetic on the gums that are not necessary or even useful because they went out of the body's natural pain pathway. This can cause severe, possibly fatal, reactions.

In infants, young children and babies of 3 to 5 years of age, who were given oral lidocaine viscous solution, the medication has been shown to be effective in relieving pain.

THE SOLUTION: FDA has asked manufacturers to withdraw lidocaine viscous solution from the market, and no longer to market it. It has also asked providers and caregivers to no longer prescribe or recommend the product for treating teething.

RECOMMENDATION: Parents and caregivers should not prescribe or recommend this product for treating teething.

Controlled trials have shown that the use of lidocaine viscous solution for the treatment of childhood pain is not effective in relieving pain.

In the case of infants and young children, the use of lidocaine viscous solution is not effective in relieving pain.

How do I sign up?

MedWatch: The FDA Safety Information and Adverse Event Reporting Program

www.fda.gov/medwatch
MedWatch: Safety Information OUT

❖ AJHP Quarterly Boxed Warning Highlights

Key MedWatch Takeaways

❖ Key MedWatch Takeaway #1: Send information to FDA
   • Nurses should report problems
   • Quality reports are key
   • MedWatch Learn tool to practice reporting

❖ Key MedWatch Takeaway #2: Get safety information from FDA
   • Sign Up to receive alerts
   • Use the MedWatch website for safety info