FDA Drug Topics: FDA’s Bad Ad Program

Melinda McLawhorn, PharmD, MPH, BCPS, RAC
Office of Prescription Drug Promotion (OPDP)
United States Food & Drug Administration
Objectives

• Discuss FDA’s role in regulating prescription drug promotion and advertising

• Describe the role that healthcare professionals (HCPs) can play in protecting the public health by recognizing prescription drug promotion and advertising that is potentially false or misleading

• Explain how HCPs can effectively report potentially false or misleading prescription drug promotion to the FDA through the Bad Ad Program
FDA’s Mission

• The FDA is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices; and by ensuring the safety of our nation’s food supply, cosmetics, and products that emit radiation.

• FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.
FDA’s Mission

• The FDA is also responsible for advancing the public health by helping to speed innovations that make medical products more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health.
FDA Organization

Office of the Commissioner

Center for Food Safety & Applied Nutrition

Center for Drug Evaluation & Research

Center for Biologics Evaluation & Research

Center for Devices & Radiological Health

Center for Veterinary Medicine

National Center for Toxicological Research

Center for Tobacco Products

Office of Regulatory Affairs
Mission of the Office of Prescription Drug Promotion (OPDP)

• To protect the public health by helping to ensure that prescription drug information is truthful, balanced, and accurately communicated.

• This is accomplished through comprehensive surveillance, compliance, and education programs, and by fostering better communication of labeling and promotional information to both healthcare professionals and consumers.
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 approves ads
• FDA regulates “good taste”
What does OPDP regulate?

• Prescription drug promotional materials made by or on behalf of the drug’s manufacturer, packer, or distributor, including:
  • TV and radio commercials
  • Sales aids, journal ads, and patient brochures
  • Drug websites, e-details, webinars, 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 material facts about the product being promoted, including facts about consequences that may result from the use of the drug
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 prescribing information (PI)

• OPDP does NOT “approve” promotional materials
Categories of Promotional Materials

• **Labeling**
  - Brochures, booklets, mailing pieces, exhibits, slide decks
  - Supplied or disseminated by the manufacturer, distributor, packer, or on their behalf
  - Accompanied by the approved product labeling

• **Advertising**
  - Advertisements in published journals, magazines, newspapers, and other periodicals
  - Broadcast (e.g., TV, radio, telephone communication systems)
  - Contains a “Brief Summary” of the drug’s side effects, contraindications, and effectiveness
Categories of Promotional Materials

<table>
<thead>
<tr>
<th>Help-Seeking</th>
<th>Do not make any representations about a specific product</th>
</tr>
</thead>
<tbody>
<tr>
<td>Institutional</td>
<td></td>
</tr>
<tr>
<td>Reminder</td>
<td></td>
</tr>
<tr>
<td>Product Claim</td>
<td></td>
</tr>
</tbody>
</table>
Help-Seeking or Disease Awareness
Institutional

Inspired by the vision of a healthier world

We are Astellas, established in 2005 with the merger of two leading Japanese pharmaceutical companies—Yamanouchi and Fujisawa. And already ranked 2 in Japan and among the top 20 worldwide, with locations in over 30 countries, including the US.

At Astellas Pharma US, Inc., our commitment is to develop innovative, relevant products that people truly need. Our mission is to change tomorrow by bringing about a healthier world today.
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 Black Box Warning
Reminder
Product Claim Materials

• Include representation or suggestion relating to the advertised drug product

• Must include a balanced risk and efficacy presentation (“fair balance”)

• Must be accompanied by the Brief Summary or PI
Product Claim

Oh no! I've lost an inch.
But I've found a way to fight osteoporosis with Actonel.

Wait a minute. Did you lose something? Like maybe an inch or so of height? You're not the only one. After menopause, shrinking can be a sign of osteoporosis, the result of tiny fractures over time.

Little by little, osteoporosis can make your bones weak and brittle, even if you take calcium every day.

That's how fractures can happen!

But Actonel once-a-week helps protect your bones from osteoporosis. It won't get back your lost inch. But it will help you fight fracture.

How do your bones measure up? Get more information at Actonel.com and ask your doctor if Actonel is right for you.

Actonel is a prescription medication to treat and prevent postmenopausal osteoporosis. Some risk factors for osteoporosis include Caucasian or Asian race, family history, small frame or smoking.

You should not take Actonel if you have low blood calcium, have severe kidney disease, or cannot sit or stand for 30 minutes. Stop taking Actonel and tell your doctor if you experience difficult or painful swallowing, chest pain, or severe or continuing heartburn, as these may be signs of serious upper digestive problems. Side effects are generally mild or moderate and may include back or joint pain, stomach pain or upset, or constipation. Follow dosing instructions carefully.

Please see important information on the following page.
Brief Summary

**ACTONEL® (Alendronate) Tablets Patient Information**

**ACTONEL® (Alendronate sodium tablets) 5 mg and ACTONEL® (Alendronate sodium tablets) 35 mg for Osteoporosis**

Briefly, ACTONEL® helps keep your bones strong and healthy. In general, bone loss occurs naturally as you age, especially in older women. However, some people and women can develop osteoporosis. Untreated osteoporosis can be prevented, and with proper therapy it can be treated.

**What is the most important information I should know about ACTONEL?**

ACTONEL can cause problems in your stomach and require the dose that contains the daily and 20mg doses, such as resolve, aseptic meningitis, hemorrhagic meningitis, and aseptic meningitis. While it is possible to eat or drink calcium and vitamin D supplements and to exercise.

**What is ACTONEL?**

ACTONEL is a prescription medication used to prevent and treat osteoporosis in postmenopausal women ("ospondal osteoporosis"). It is used to treat osteoporosis in women who have had menopause and who have severe bone loss. It is not known if ACTONEL is right for you. It is not known whether the effects of ACTONEL are the same in all women. Your health care provider may monitor the thickness of your bones and other x-rays to check your progress.

**Who should not take ACTONEL?**

Do not take ACTONEL if you:
- Have a blood disorder, such as thrombocytopenia, diabetes mellitus, or liver disease.
- Have kidney disease.
- Have an allergy to any ingredients in ACTONEL.
- Have a blood disorder, such as thrombocytopenia, diabetes mellitus, or liver disease.
- Have kidney disease.
- Have an allergy to any ingredients in ACTONEL.
- Have a blood disorder, such as thrombocytopenia, diabetes mellitus, or liver disease.
- Have kidney disease.
- Have an allergy to any ingredients in ACTONEL.

**Tell your doctor before using ACTONEL if:**
- You are pregnant. You do not know if ACTONEL can harm your developing child.
- You are breastfeeding. You do not know if ACTONEL can harm your baby. You will need to decide whether to stop breastfeeding or not take ACTONEL.
- You have kidney problems. ACTONEL may not be right for you.

**How should I take ACTONEL?**

The following instructions are for both ACTONEL 5 mg daily and ACTONEL 35 mg (once weekly):

- Take ACTONEL with 8 ounces of water or other liquid 30 minutes before eating breakfast, lunch, dinner, or bedtime. Do not take ACTONEL with more than 8 ounces of water or other liquid.
- Take ACTONEL only after you have swallowed it and do not eat or drink anything for at least 30 minutes after taking ACTONEL.

**What are the possible side effects of ACTONEL?**

- There may be some side effects of ACTONEL, such as:
  - Gastritis and/or bleeding stomach ulcers
  - Gastritis and/or bleeding stomach ulcers
  - Gastritis and/or bleeding stomach ulcers
  - Gastritis and/or bleeding stomach ulcers

**What if I have other questions about ACTONEL?**

For the latest information about ACTONEL, always ask your doctor or pharmacist before you take any new medications, even if they are nonprescription or herbal. You can get additional information from healthcare professionals for more information, call 1-800-852-6838 or visit our Web site at www.actonel.com.

**What are the ingredients of ACTONEL?**

ACTONEL contains several ingredients:

ACTONEL contains:

- Alendronate sodium, calcium, fluoride, magnesium, zinc, and other minerals.
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
Total # of Promotional Pieces

- **2018**: 73,016
  - HCP: 35,057
  - Consumer: 37,959
- **2019**: 76,684
  - HCP: 37,643
  - Consumer: 39,041
What does OPDP do?

- Advice to industry
- Advice within FDA
- Guidance and policy development
- Research
- Surveillance and compliance
Common Violations

• Make claims that are not appropriately supported

• Misrepresent data from studies

• Overstate the drug’s benefits

• Omit or downplay risk information
Common Violations

• Omit material facts about the drug

• Fail to present a “fair balance” of risk and benefit information

• Misbrand an investigational drug
Warning Letter Example:

Zolpimist (zolpidem tartrate) oral spray (C-IV)
Example: Zolpimist

Indication: Indicated for the short-term treatment of insomnia characterized by difficulties with sleep initiation. Zolpidem tartrate has been shown to decrease sleep latency for up to 35 days in controlled clinical studies.... The clinical trials performed in support of efficacy were 4-5 weeks in duration with the final formal assessments of sleep latency performed at the end of treatment.
Example: Zolpimist

• Warning and Precautions: CNS depressant effects and next day impairment, need to evaluate for co-morbid diagnoses, severe anaphylactic and anaphylactoid reactions, abnormal thinking and behavioral changes, use in patients with depression, respiratory depression, and withdrawal effects

• The most common adverse reactions reported with Zolpimist were drowsiness, dizziness, diarrhea, and “drugged feelings”
**Product Information**

- Zolpipist® (zolpidem tartrate) is a patented, FDA approved bioequivalent version of the market leading sleep aid, Ambien® in an oral spray formulation.

- Zolpidem is the most commonly prescribed agent for the treatment of insomnia with a market share of approximately 70%, with over 1.2 billion zolpidem tablets prescribed in 2010 in the US.

- Zolpipist® is engineered to outperform the oral tablets

- Using a proprietary and patented technology we deliver the drug as a fine mist into the mucosal membranes lining the cheeks in the mouth (buccal delivery). This mode of delivery offers some very clear advantages as compared to other delivery methods:

- Fast onset of action; Zolpipist® induces sleep three times faster than oral tablets – 10 minutes as compared to 30 – 40 minutes for oral tablets.

- No food effect that mitigates the efficacy of other zolpidem products
Warning Letter Example:

Diclegis (doxylamine succinate and pyridoxine hydrochloride)
Example: Diclegis

- Indication: Treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management.

- Limitations of Use: Has not been studied in women with hyperemesis gravidarum.

- Contraindications: Diclegis is contraindicated in women with known hypersensitivity to doxylamine succinate, other ethanolamine derivative antihistamines, pyridoxine hydrochloride or any inactive ingredient in the formulation, as well as in women who are taking monoamine oxidase inhibitors (MAOIs).
Example: Diclegis

• Warning and Precautions regarding activities requiring mental alertness and concomitant medical conditions.

• The most common adverse reaction reported with Diclegis was somnolence.
OMG. Have you heard about this? As you guys know my #morning sickness has been pretty bad. I tried changing things about my lifestyle, like my diet, but nothing helped, so I talked to my doctor. He prescribed me #Diclegis, and I felt a lot better and most importantly, it’s been studied and there was no increased risk to the baby. I’m so excited and happy with my results that I’m partnering with Duchesnay USA to raise awareness about treating morning sickness. If you have morning sickness, be safe and sure to ask your doctor about the pill with the pregnant woman on it and find out more www.diclegis.com; www.DiclegisImportantSafetyInfo.com

Please note: image of Diclegis bottle will be prominent enough to read established name
Surveillance

• OPDP's normal surveillance activities include:

  • Monitoring drug promotional materials sent to us by industry
  • Monitoring medical convention exhibit halls
  • Monitoring drug promotion on the internet and social media
  • 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 HCPs’ offices and industry-sponsored dinner and lunch programs.

- That’s one of the reasons why we developed the Bad Ad Program
• An FDA-sponsored outreach program designed to educate HCPs about the role they can play in helping FDA ensure that prescription drug advertising and promotion is truthful and not misleading

• 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:
    • Educational online course
    • Case studies for educational settings
    • Media campaigns and conference outreach
Educational Online Program

• 1-hour, self-paced training

• 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

• Case studies based on real OPDP Untitled and Warning Letters

• Designed to be used as part of an educational curriculum or training

• Includes the violative promotional material, the resulting Untitled or Warning letter, the FDA-approved PI, and a facilitator guide
Reporting Potential Drug Promotion Issues

• Bad Ad Hotline
  • Any HCP can report potentially misleading promotion to OPDP by:
    • sending an e-mail to BadAd@fda.gov or
    • calling 855-RX-BADAD (855-792-2323)

• 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 a compliance action.

• If OPDP finds the promotion to be false or misleading, we will move forward with a risk-based compliance 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.
• Phone: 855-RX-BADAD
   (855-792-2323)

• E-Mail: BadAd@fda.gov

• More Info: www.fda.gov/BadAd