FDA Office of Health and Constituent Affairs- Collaborating with FDA

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FDA Office of Health and Constituent Affairs

October 6, 2016

Presentation Overview

- Introduce the FDA Office of Health and Constituent Affairs (OHCA)
- Share examples of collaborations to advance FDA messages
- How you can engage with FDA

FDA Regulates Over $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.

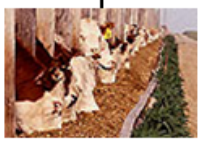
Office of the Commissioner

Office of Foods

Office of Medical Products & Tobacco

Office of Global Regulatory Operations & Policy

Center for Food Safety & Applied Nutrition



Center for Veterinary Medicine

Center for Devices & Radiological Health

Center for Biologics Evaluation & Research

Center for Drug Evaluation & Research

Center for Tobacco Products

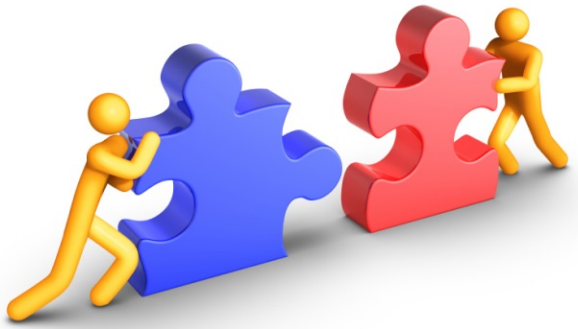
Office of Regulatory Affairs

Office of Health and Constituent Affairs

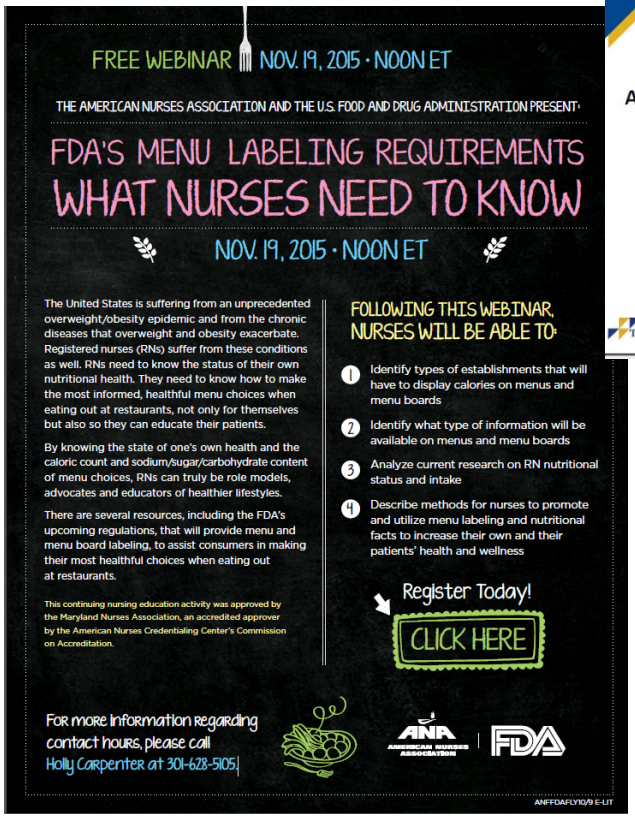
OHCA works to help patients, patient advocates, and their healthcare professionals connect with FDA science and policy staff.

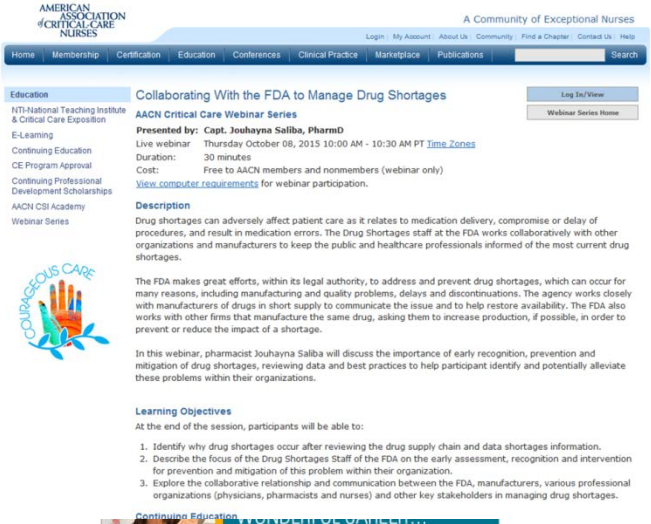
Collaboration and Engagement Examples

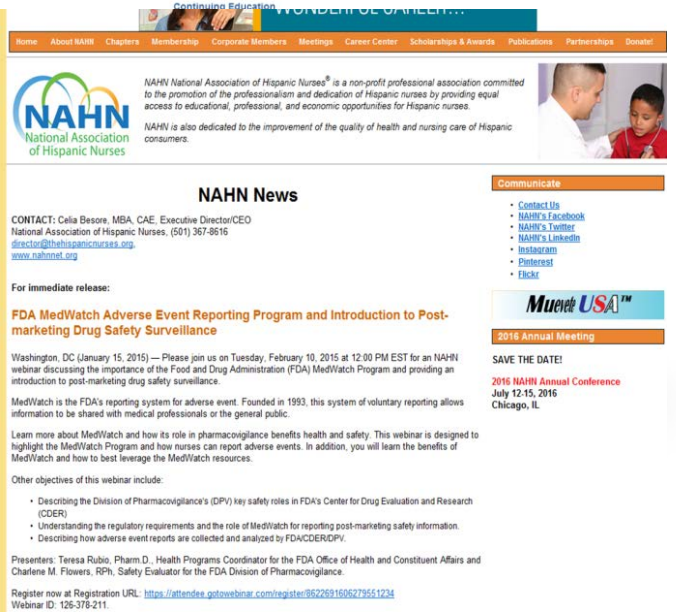
- Webinars
- Publishing
- Memorandum of Understanding
- MedWatch



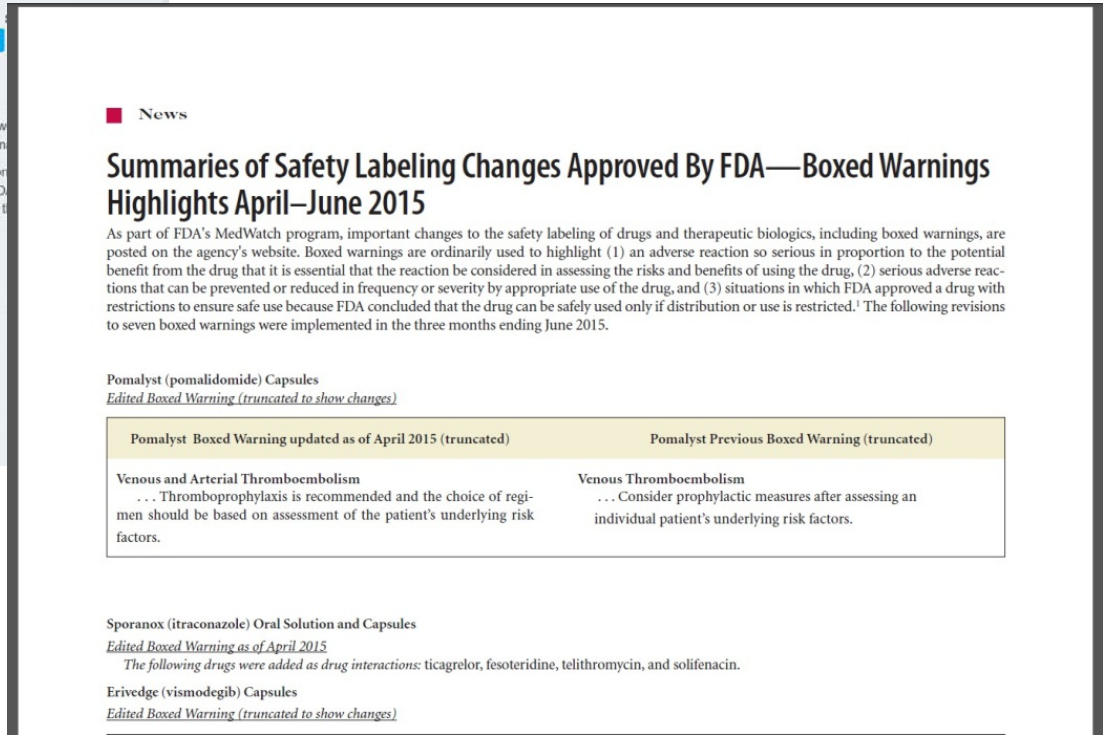
Advance our Reach *through* Webinars







Advance our Reach *through* Publishing



News

Summaries of Safety Labeling Changes Approved By FDA—Boxed Warnings Highlights April–June 2015

As part of FDA's MedWatch program, important changes to the safety labeling of drugs and therapeutic biologics, including boxed warnings, are posted on the agency's website. Boxed warnings are ordinarily used to highlight (1) an adverse reaction so serious in proportion to the potential benefit from the drug that it is essential that the reaction be considered in assessing the risks and benefits of using the drug, (2) serious adverse reactions that can be prevented or reduced in frequency or severity by appropriate use of the drug, and (3) situations in which FDA approved a drug with restrictions to ensure safe use because FDA concluded that the drug can be safely used only if distribution or use is restricted.[1] The following revisions to seven boxed warnings were implemented in the three months ending June 2015.

Pomalyst (pomalidomide) Capsules

Edited Boxed Warning (truncated to show changes)

Pomalyst Boxed Warning updated as of April 2015 (truncated)	Pomalyst Previous Boxed Warning (truncated)
Venous and Arterial Thromboembolism . . . Thromboprophylaxis is recommended and the choice of regimen should be based on assessment of the patient's underlying risk factors.	**Venous Thromboembolism** . . . Consider prophylactic measures after assessing an individual patient's underlying risk factors.

Sporanox (itraconazole) Oral Solution and Capsules

Edited Boxed Warning as of April 2015

The following drugs were added as drug interactions: ticagrelor, fesoteridine, telithromycin, and solifenacin.

Erivedge (vismodegib) Capsules

Edited Boxed Warning (truncated to show changes)

Advance our Reach *through* Memorandum of Understanding (MOU)

http://www.medscape.com/partners/fda/public/fda

AOA and Entertainment Industries Council (EIC) Co-Sponsorship Agreement

http://www.medscape.com/partners/fda/public/fda

Engaging with FDA: MedWatch

1. A way to send information *IN* to FDA

2. A way to get safety information *OUT* from FDA

www.fda.gov/medwatch

MedWatch- What should I report?


Drugs


Medical Devices


Biologics


Cosmetics


Combination Products


Special Nutritional Products

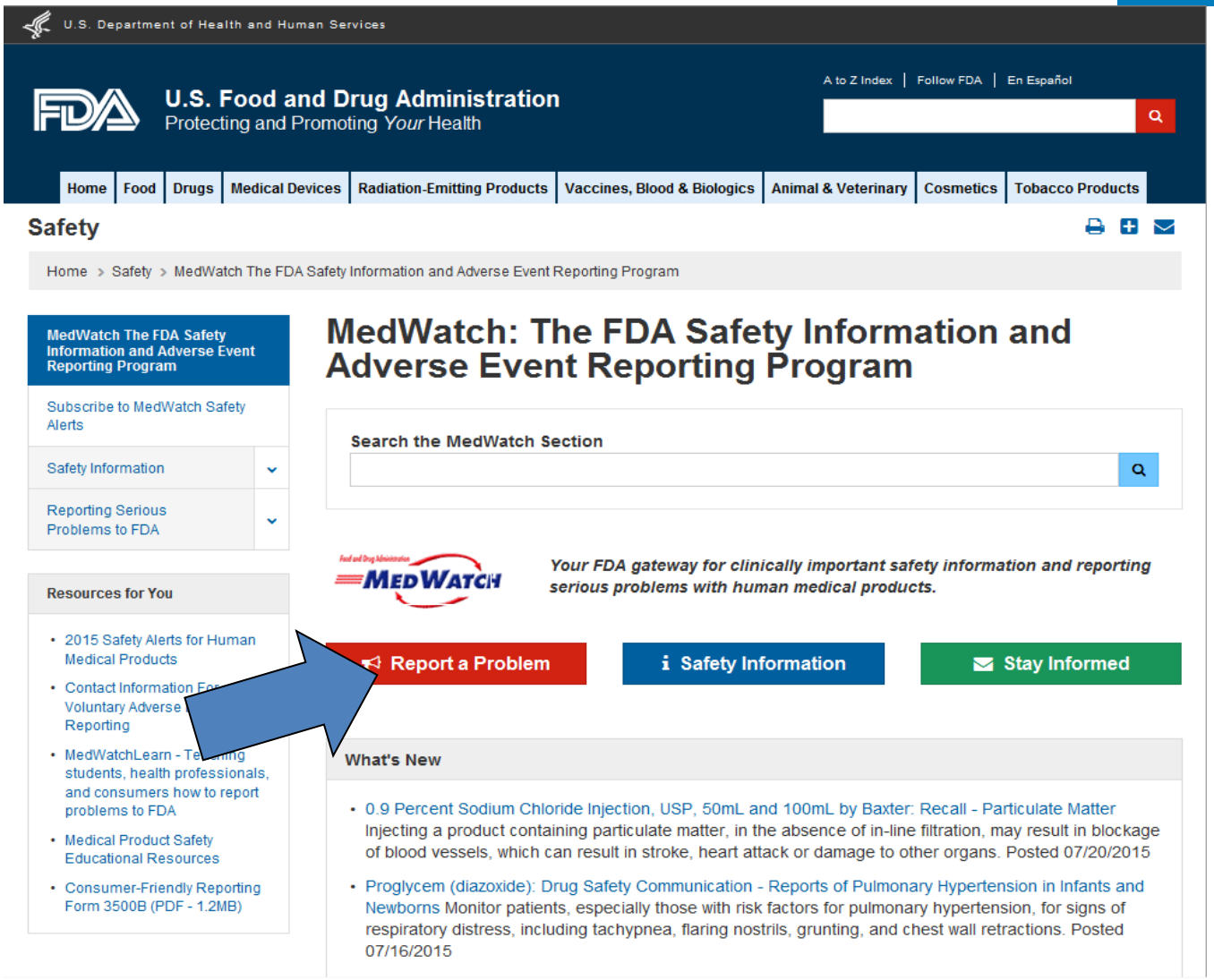
Any event that:

- Is fatal
- Is life-threatening
- Is permanently disabling
- Requires/prolongs hospitalization
- Causes a birth defect
- Requires intervention to prevent permanent impairment or damage
- Potentially cause harm or near miss

MedWatch- How do I report?

- Online
- Mail/Fax
- By Phone

1-800-332-1088



www.fda.gov/medwatch

MedWatch - Safety Info OUT

Staying Informed:
Information Delivered
to You

Subscribe to
MedWatch
Email
Twitter
RSS feeds

www.fda.gov/medwatch

Challenge Question 1

What is MedWatch?

A. A way to send information to FDA on problems with medical products
B. A way to receive safety information from FDA
C. Both A and B

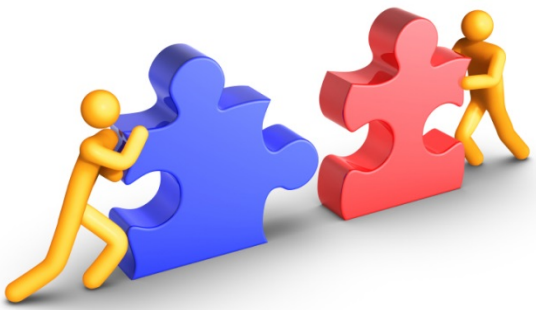
Engaging with FDA- FDA Advisory Committees

- 50 committees and panels to obtain independent expert advice
- Membership types
  - Academician/Practitioner
  - Consumer Representative
  - Industry Representative
  - Patient Representative
- Open Public Hearing

- *http://www.fda.gov/AdvisoryCommittees/default.htm*

Challenge Question 2

- Which of the following are ways to collaborate and engage with the FDA?
  A. Report a product problem to MedWatch
  B. Participation in Advisory Committee Meetings
  C. FDA Bad Ad Program
  D. All of the above



BadAd@fda.gov

BadAd

FOOD AND DRUG ADMINISTRATION FDA

FDA's Bad Ad Program

Empowering HCPs to Recognize and Report False or Misleading Drug Promotion

Office of Prescription Drug Promotion (OPDP)
United States Food & Drug Administration

Objectives

- Discuss FDA's role in regulating prescription drug promotion and advertising
- Recognize 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
- Describe 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.

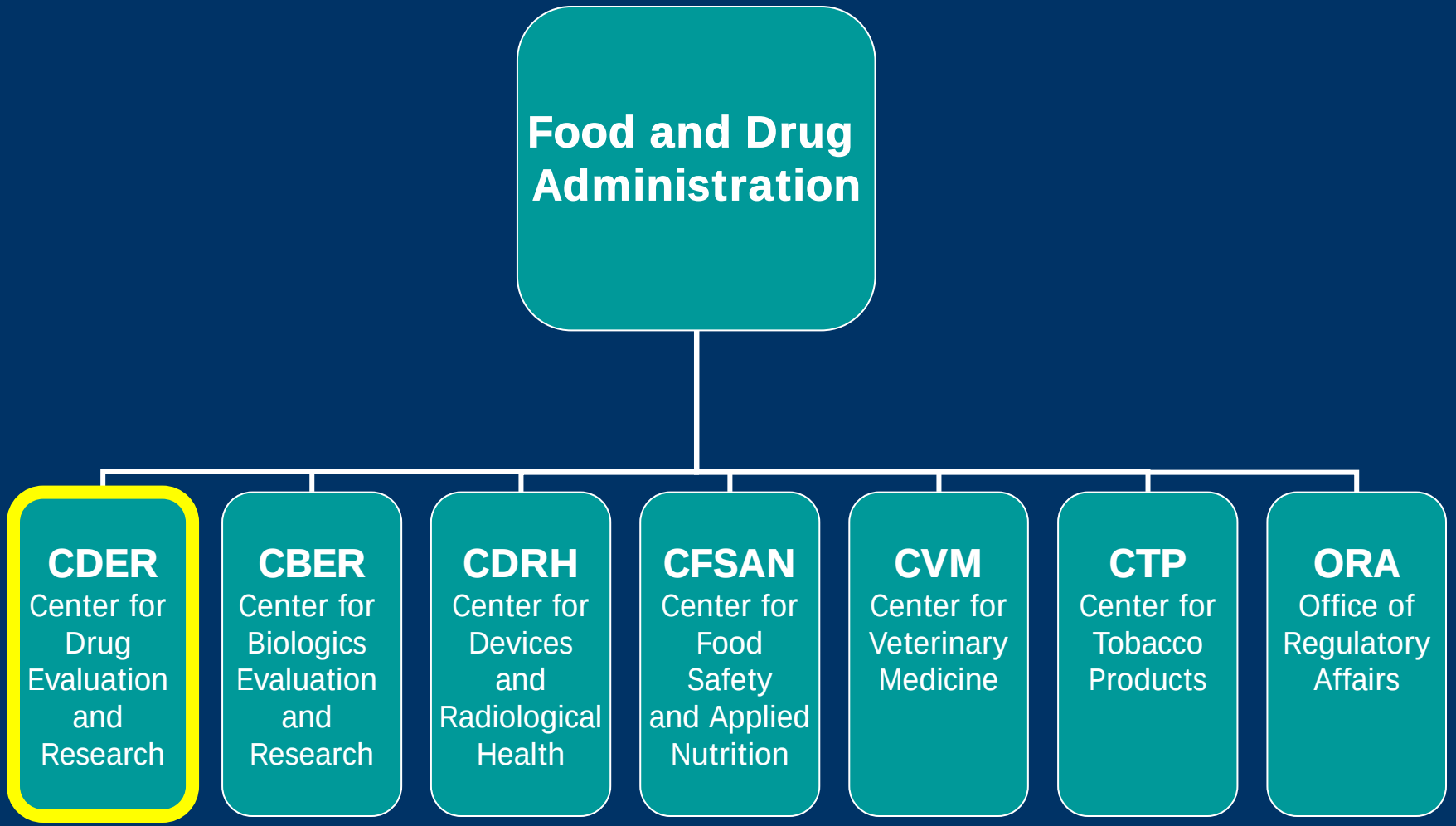
FDA U.S. FOOD & DRUG ADMINISTRATION

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 U.S. FOOD & DRUG ADMINISTRATION

FDA Structure



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.

Challenge Question #3

- Which of the following statements is true?
  A. FDA approves promotional materials
  B. The pharma industry spends the majority of its advertising budget on direct-to-consumer (DTC) advertising
  C. FDA can ban DTC advertising
  D. None of the above

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 label

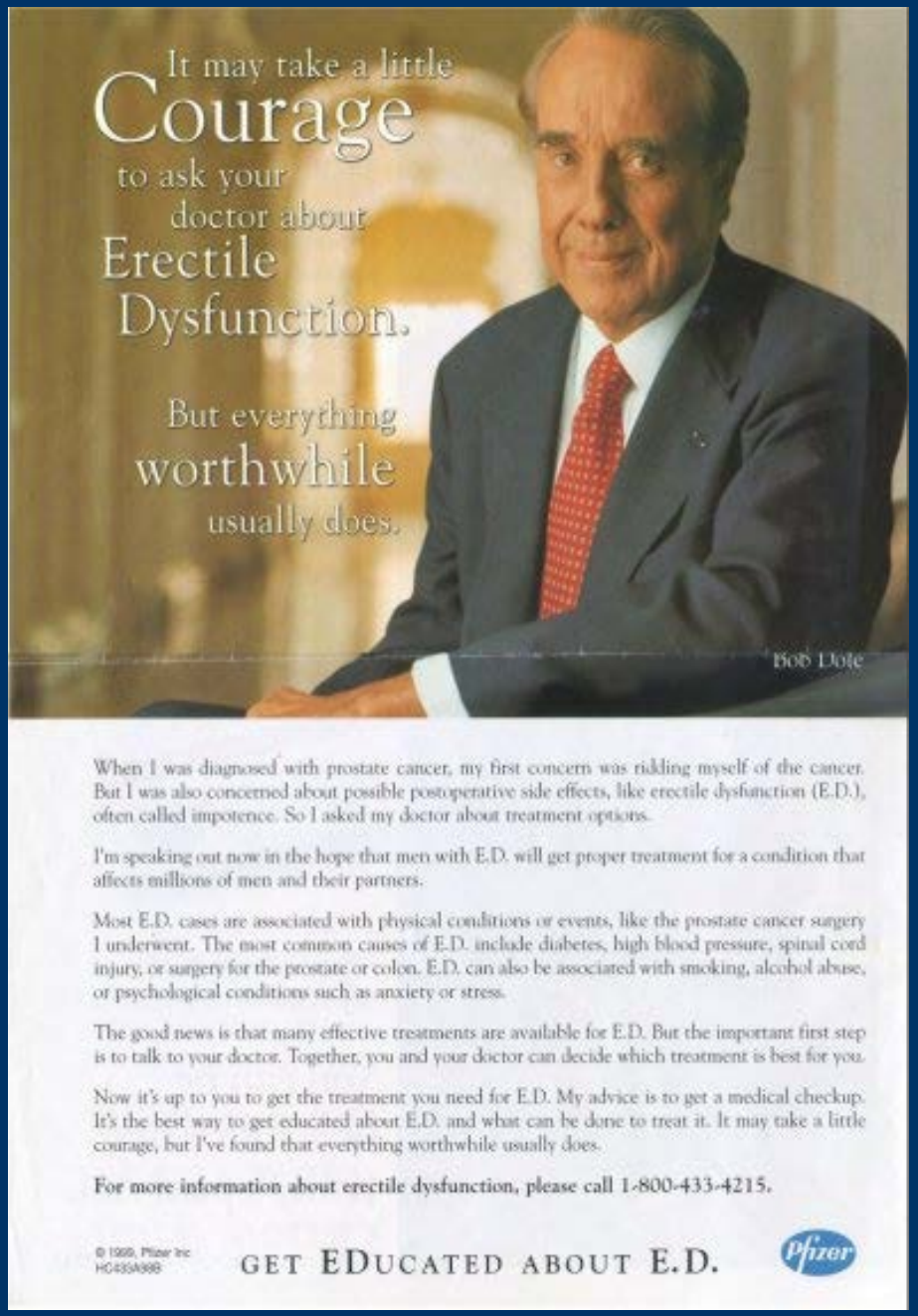
Categories of Promotional Materials

Help-Seeking
Institutional
Reminder

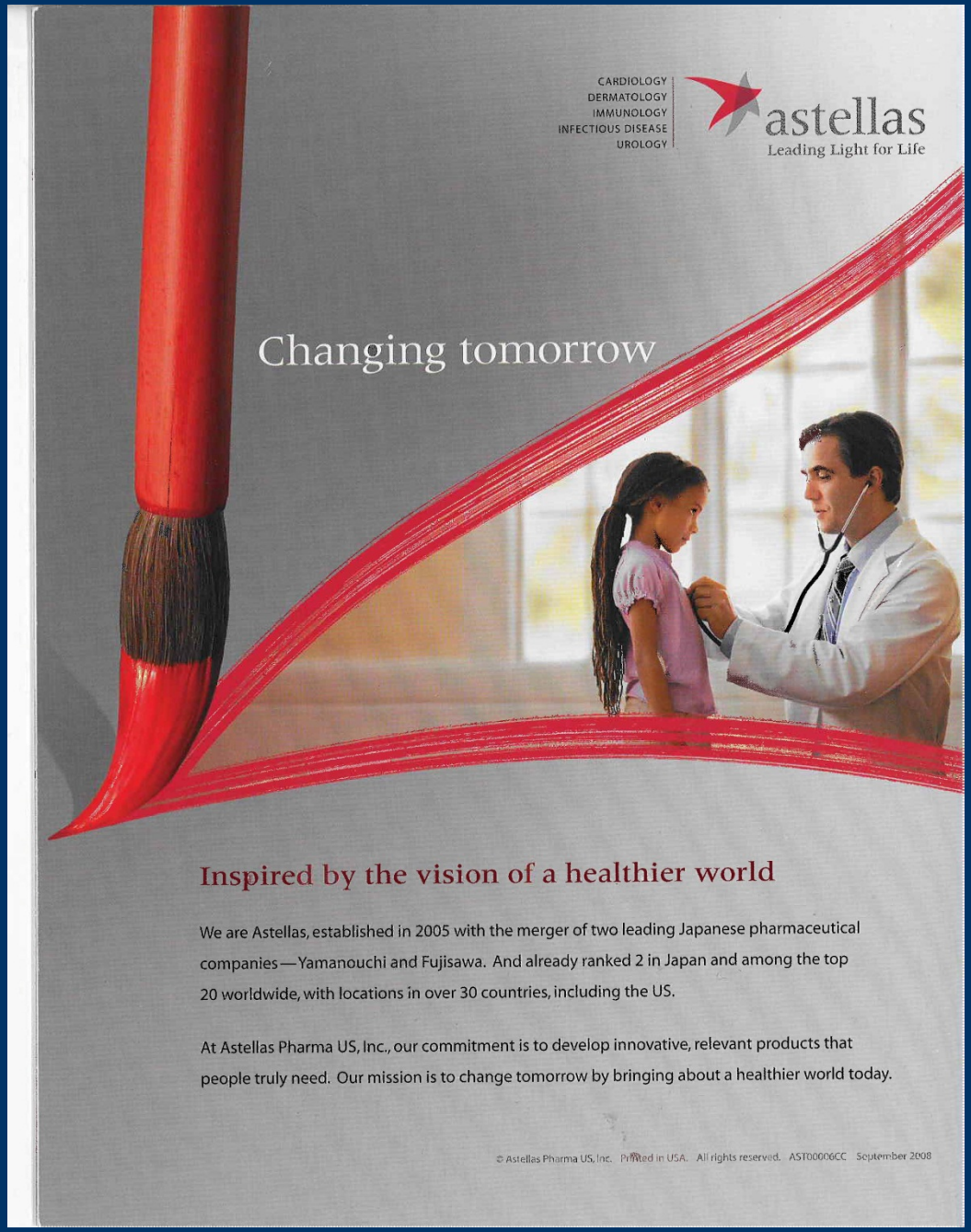
Full Product

⇦ Cannot make any representations about a specific product

Help-Seeking Ad



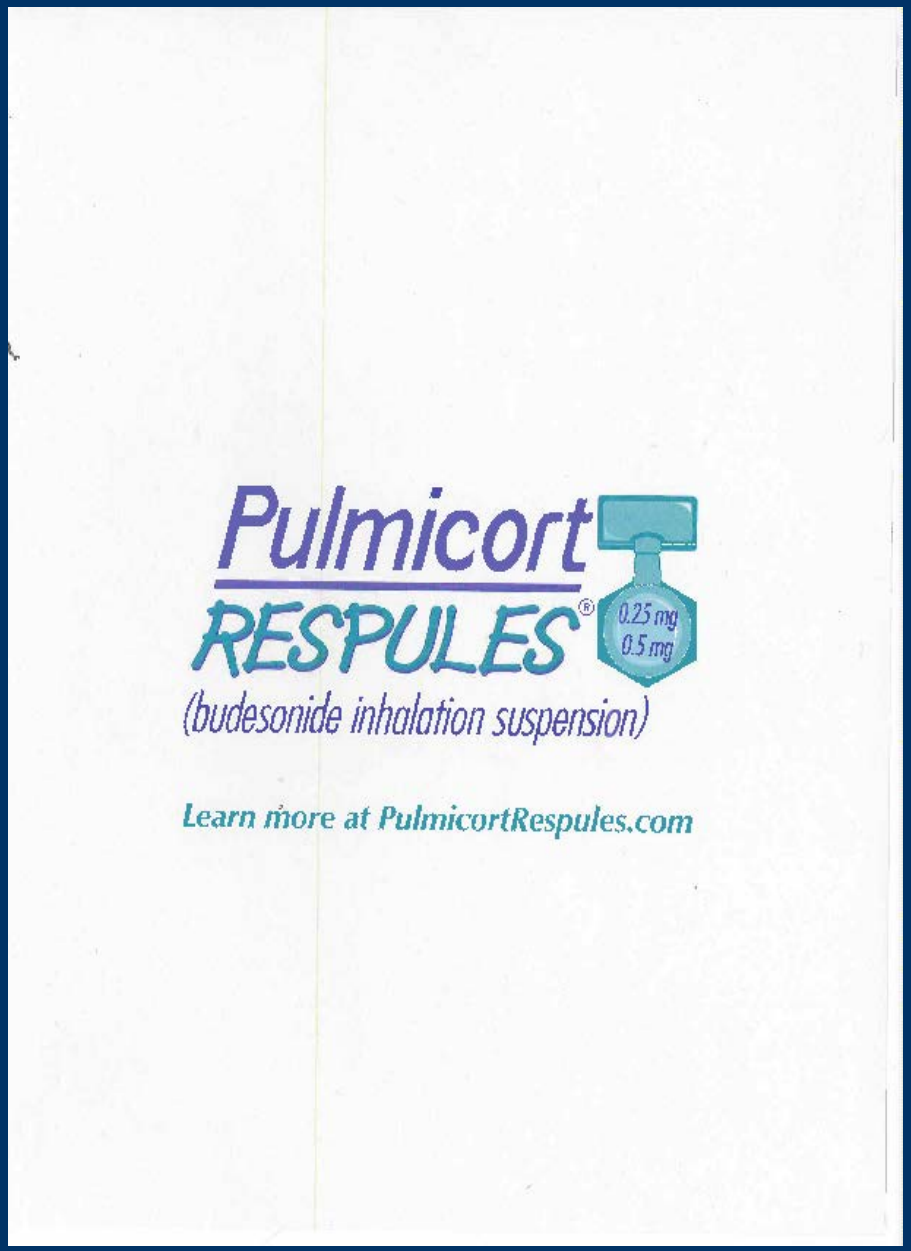
Institutional Ad



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

Reminder Ad


Pulmicort
RESPULES®
0.25 mg
0.5 mg
(budesonide inhalation suspension)
Learn more at PulmicortRespules.com

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

Full Product Claim DTC Ad

Product Claim
DTC Ad
Brief Summary

ACTONEL® (AK-toh-nel)
Tablets Patient Information

ACTONEL (risedronate sodium tablets) 5 mg and ACTONEL (risedronate sodium tablets) 35 mg for Osteoporosis

Read this information carefully before you start to use your medicine. Read the information you get every time you get more medicine. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment. If you have any questions or are not sure about something, ask your healthcare provider or pharmacist.

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

ACTONEL may cause problems in your stomach and esophagus (the tube that connects the mouth and the stomach), such as trouble swallowing (dysphagia), heartburn (esophagitis), and ulcers (see "What are the possible side effects of ACTONEL?").

You must follow the instructions exactly for ACTONEL to work and to lower the chance of serious side effects (see "How should I take ACTONEL?").

What is ACTONEL?

ACTONEL is a prescription medicine used:

- to prevent and treat osteoporosis in postmenopausal women (see "What is osteoporosis?").
- to prevent and treat osteoporosis in men and women that is caused by treatment with steroid medicines such as prednisone.
- to treat Paget's disease of bone (osteitis deformans). The treatment for Paget's disease is very different than for osteoporosis and uses a different type of ACTONEL. This leaflet does not cover using ACTONEL for Paget's disease. If you have Paget's disease, ask your healthcare provider how to use ACTONEL.

ACTONEL may reverse bone loss by stopping more loss of bone and increasing bone mass in most people who take it, even though they won't be able to see or feel a difference. ACTONEL helps lower the risk of breaking bones (fractures). Your healthcare provider may measure the thickness (density) of your bones or do other tests to check your progress.

See the end of this leaflet for information about osteoporosis.

Who should not take ACTONEL?

Do not take ACTONEL if you:

- have low blood calcium (hypocalcemia).
- cannot sit or stand up for 30 minutes.
- have kidneys that work poorly.
- have an allergy to ACTONEL. The active ingredient in ACTONEL is risedronate sodium (see the end of this leaflet for a list of all the ingredients in ACTONEL).

Tell your doctor before using ACTONEL if:

- you are pregnant. We do not know if ACTONEL can harm your unborn child.
- you are breast-feeding. We do not know if ACTONEL can pass through your milk and if it can harm your baby. You will need to decide whether to stop breast-feeding 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-a-Week):

- Take ACTONEL first thing in the morning before you eat or drink anything except plain water.
- Take ACTONEL while you are sitting or standing up.
- Take ACTONEL with 6 to 8 ounces (about 1 cup) of plain water. Do **not** take it with any other drink besides plain water. Do not take it with coffee, tea, juice, or milk or other dairy drinks.
- Swallow ACTONEL whole. Do not chew the tablet or keep it in your mouth to melt or dissolve.
- After taking ACTONEL you must wait at least 30 minutes **BEFORE**:
  - lying down. You may sit, stand, or do normal activities like read the newspaper or take a walk.
  - eating or drinking anything except plain water.
  - you take vitamins, calcium, or antacids. Take vitamins, calcium, and antacids at a different time of the day from when you take ACTONEL.
- Keep taking ACTONEL for as long as your healthcare provider tells you.
- For ACTONEL to treat your osteoporosis or keep you from getting osteoporosis, you have to take it as often and in the way it is prescribed.
- Your healthcare provider may tell you to take calcium and vitamin D supplements and to exercise.

What is my ACTONEL schedule?

If your doctor has prescribed **ACTONEL 5 mg daily (a yellow tablet):**

- Take 1 ACTONEL 5-mg tablet every day in the morning.
- If you forget to take your ACTONEL 5 mg in the morning, do **not** take it later in the day. Take only 1 ACTONEL 5-mg tablet the next morning and continue your usual schedule of 1 tablet a day. Do **not** take 2 tablets on the same day.

If your doctor has prescribed **ACTONEL 35 mg Once-a-Week (an orange tablet):**

- Choose 1 day of the week that you will remember and that best fits your schedule to take your ACTONEL 35 mg. Every week, take 1 ACTONEL 35-mg tablet in the morning on your chosen day.
- If you forget to take your ACTONEL 35 mg in the morning, do **not** take it later in the day. Take only 1 ACTONEL 35-mg tablet the next morning and continue your usual schedule of 1 tablet on your chosen day of the week. Do **not** take 2 tablets on the same day.

What should I avoid while taking ACTONEL?

- Do not eat or drink anything except water before you take ACTONEL and for at least 30 minutes after you take it.
- Do not lie down for at least 30 minutes after you take ACTONEL.
- Foods and some vitamin supplements and medicines can stop your body from absorbing (using) ACTONEL. Therefore, do not take the following products at or near the time you take ACTONEL: food, milk, calcium supplements, or calcium-, aluminum-, or magnesium-containing medicines, such as antacids (see "How should I take ACTONEL?").

What are the possible side effects of ACTONEL?

Stop taking ACTONEL and tell your healthcare provider right away if:

- **swallowing is difficult or painful.**
- **you have chest pain.**
- **you have very bad heartburn and it doesn't get better.**

ACTONEL may cause:

- pain or trouble swallowing (dysphagia).
- heartburn (esophagitis).
- ulcers in your stomach and esophagus (the tube that connects the mouth and the stomach).

For patients with osteoporosis, the overall occurrence of side effects with ACTONEL was similar to placebo (sugar pill) and most were either mild or moderate. The most common side effects with ACTONEL include back pain, joint pain, upset stomach, abdominal (stomach area) pain, constipation, diarrhea, gas, and headache. Tell your healthcare provider if you have pain or discomfort in your stomach or esophagus.

These are not all the possible side effects of ACTONEL. You can ask your healthcare provider or pharmacist about other side effects.

What is osteoporosis?

Osteoporosis is a disease that causes bones to become thinner. Thin bones can break easily. Most people think of their bones as being solid like a rock. Actually, bone is living tissue, just like other parts of the body—your heart, brain, or skin, for example. Bone just happens to be a harder type of tissue. Bone is always changing. Your body keeps your bones strong and healthy by replacing old bone with new bone.

Osteoporosis causes the body to remove more bone than it replaces. This means that bones get weaker. Weak bones are more likely to break. Osteoporosis is a bone disease that is quite common, especially in older women. However, young people and men can develop osteoporosis, too. Osteoporosis can be prevented, and with proper therapy it can be treated.

How can osteoporosis affect me?

- You may not have any pain or other symptoms when osteoporosis begins.
- You are more likely to break (fracture) a bone especially if you fall because osteoporosis makes your bones weaker. You are most likely to break a bone in your back (spine), wrist, or hip.
- You may "shrink" (get shorter).
- You may get a "hump" (curve) in your back.
- You may have bad back pain that makes you stop some activities.

Who is at risk for osteoporosis?

Many things put people at risk for osteoporosis. The following people have a higher chance of getting osteoporosis:

Women who:

- are going through or who are past menopause ("the change").
- are white (Caucasian) or Asian.

People who:

- are thin.
- have family members with osteoporosis.
- do not get enough calcium or vitamin D.
- do not exercise.
- smoke.
- drink alcohol often.
- take bone-thinning medicines (like prednisone or other corticosteroids) for a long time.

General information about ACTONEL

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use ACTONEL for a condition for which it was not prescribed. Do not give ACTONEL to other people, even if they have the same symptoms you have. It may harm them.

What if I have other questions about ACTONEL?

This leaflet summarizes the most important information about ACTONEL for osteoporosis. If you have more questions about ACTONEL, ask your healthcare provider or pharmacist. They can give you information written for healthcare professionals. For more information, call 1-877-**ACTONEL** (toll-free) or visit our Web site at www.actonel.com.

What are the ingredients of ACTONEL?

ACTONEL (active ingredient): risedronate sodium.

ACTONEL (inactive ingredients): crospovidone, ferric oxide red (35-mg tablets only), ferric oxide yellow, hydroxypropyl cellulose, hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, silicon dioxide, and titanium dioxide.

ACTONEL® is marketed by:
Procter & Gamble Pharmaceuticals
Cincinnati, OH 45202
and
Aventis Pharmaceuticals Inc.
Kansas City, MO 64137

MAY 2002

Actonel
(risedronate sodium tablets)

 Printed in USA ACT-JA-15924-1 0905-6507

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

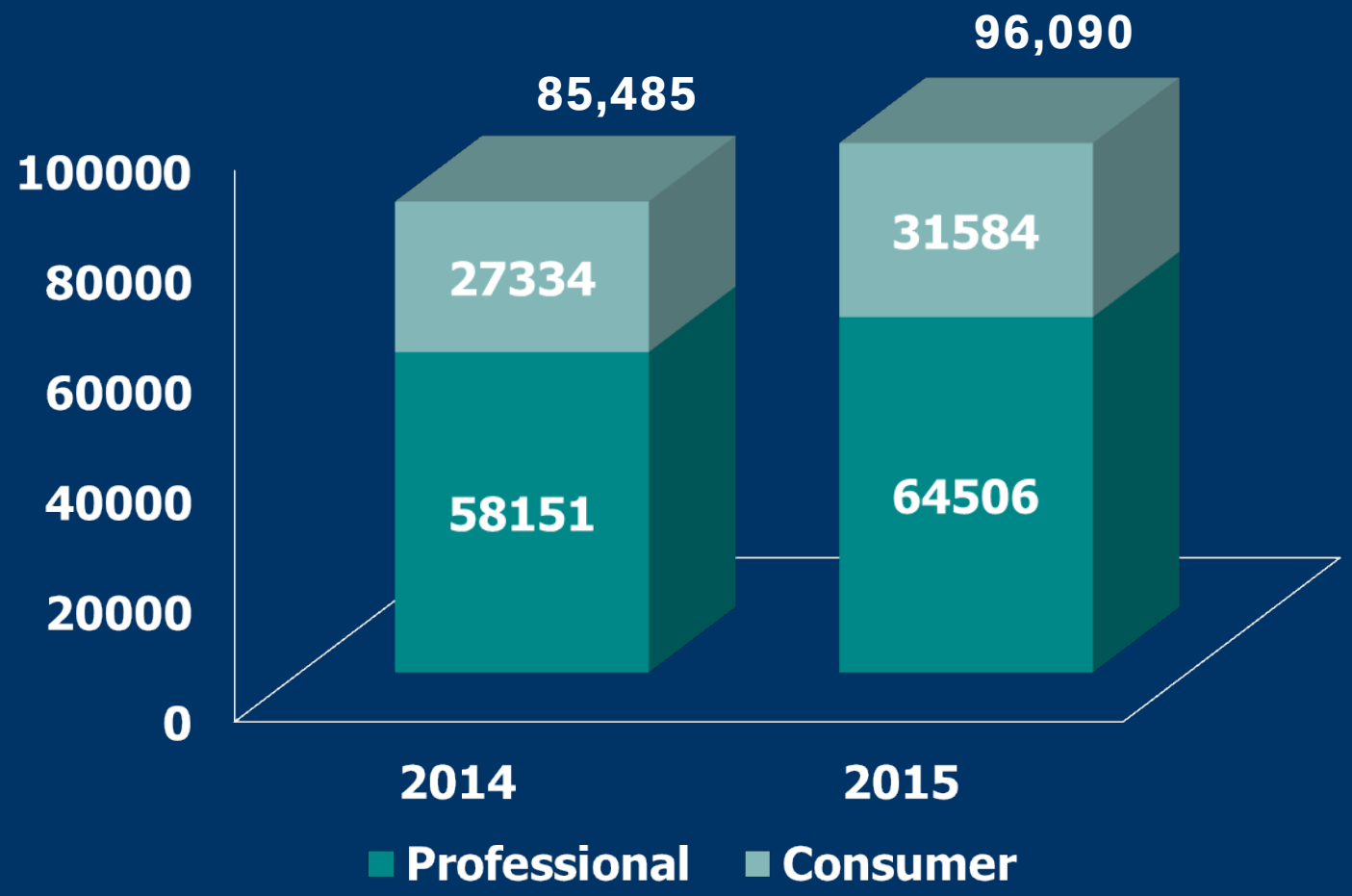
Adequate Provision

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

Challenge Question #4

- How many promotional pieces did OPDP receive in 2015?
  A. 5,000
  B. 15,000
  C. 55,000
  D. 95,000

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

- 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

- 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:
    - 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 **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 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)

Enforcement Example: Derma-Smoothe (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.

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Pediatric Atopic Dermatitis

- Diseases We Treat Main
- Scalp Psoriasis
- Eczema/Atopic Dermatitis
- Pediatric Atopic Dermatitis
- Itchy Ears
- Non-Prescription Products For:
  - Excessive Sweating
  - Oily Skin, Oily Hair
  - Dry Itchy Skin

Derma-Smoothe/FS® (Body Oil)

(fluocinolone acetonide oil), 0.01%

Severe and All Over

3 mos.

and

NO

Adrenal Suppression!

ONLINE STORE >>
Non-Prescription Products

Derma-Smoothe/FS® (Body Oil)

(fluocinolone acetonide oil), 0.01%

The only product for patients 3 months and older that can be used when their eczema is severe and all over!

Go Beyond the Itch!!

- ✓The refined peanut oil vehicle repairs the skin barrier function by driving moisture into the skin, which is the key to treating the disease.
- ✓The only corticosteroid that does not cause adrenal suppression, even when used over 90% of the body!
- ✓Patient cost is only $45.00 for a full course of treatment!

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