



U.S. Food and Drug Administration

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**United States Food & Drug Administration**  
U.S. Department of Health and Human Services



***The Bad Ad Program***

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**FDA - Drug Information Webinar**  
**April 28, 2011**



# Objectives

1. Learn about FDA's role in regulating prescription drug promotion and advertising, as well as the role that physicians and other healthcare professionals can play in ensuring that prescription drug promotion and advertising is truthful and not misleading.
2. Learn how to better identify misleading prescription drug promotion and advertising by reviewing specific types of violative prescription drug promotion (i.e. Overstatement of Efficacy, Minimization of Risk, Off-label Promotion).
3. Learn how to effectively report misleading prescription drug promotion to the FDA through the Bad Ad Program.

# FDA's Mission – part 1

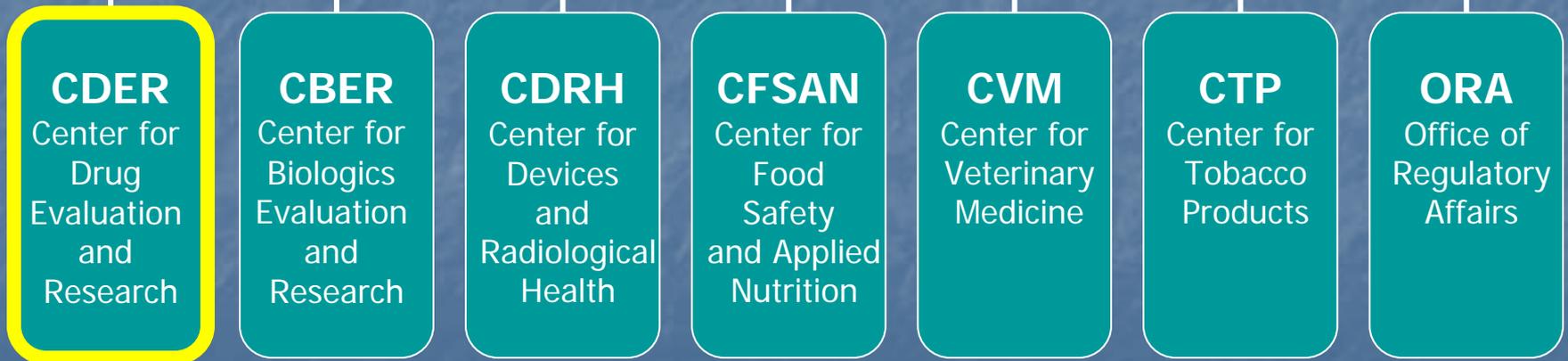
- The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation, and by regulating the manufacture, marketing, and distribution 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 Antimicrobial Products
- Division of Botanical Products
- Division of Anesthesia and Analgesia Products
- Division of Metabolism and Endocrinology 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 Drug Marketing, Advertising, and Communications (DDMAC)

- To protect the public health by assuring 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.

# What Does DDMAC Regulate?

- Written and printed 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
- Oral Presentations made by representatives of the company which include:
  - Sales Reps
  - Hired Spokespeople
  - Medical Science Liaisons

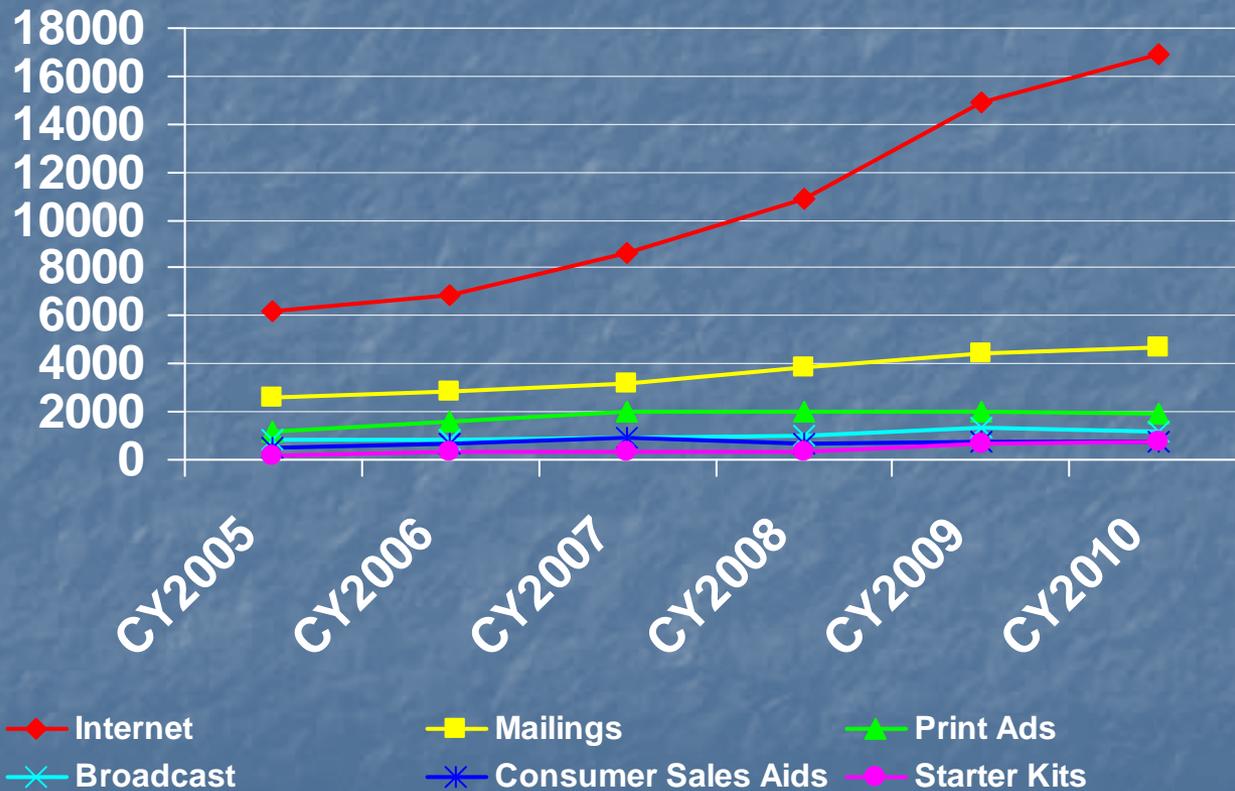
# Advertising Misconceptions

- 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”

# Total # of promotional pieces



# Direct-to-Consumer Drug Advertising Trends



# What does DDMAC do?

- Advice to industry
- Advice within FDA
- Guidances and Policy Development
- Research
- **Surveillance and Enforcement**



# Limitations to Surveillance

- DDMAC's normal surveillance activities include:
  - Monitor drug promotions sent to us
  - Monitor Medical Convention Exhibit Halls
  - Review complaints submitted by Industry Competitors
- However, these surveillance activities do not allow us to monitor certain types of drug promotion that occur in places such as physician offices and industry-sponsored dinner and lunch programs. These types of promotion include:
  - Verbal statements from drug reps or company-paid speakers
  - Home-made promotional materials not submitted to FDA

That's why we developed the **Bad Ad Program**

# The Bad Ad Program

Created to provide HCPs an easy way to report misleading promotion that occurs in field based settings, e.g. offices and dinner programs.

Created by 2 former sales representatives with 11 years combined selling experience

# What is the Bad Ad Program?

- The Bad Ad Program is 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.
- When HCPs recognize misleading drug promotion, they can help put a stop to it by reporting it to FDA:
  - Call
    - **877-RX-DDMAC (877-793-3622)**
  - Email
    - **BadAd@fda.gov**

# What are the most common problems with promotion?

- Omitting or downplaying of risk information
  - Example: Presenting efficacy information but no risk information
- Overstating the effectiveness
  - Example: "Drug X delivers rapid results in 3 days." However, clinical trials for Drug X showed results at 12 weeks, not 3 days.
- Promoting unapproved uses
  - Example: Company rep tells you a drug is effective for a use that is not in the FDA approved PI
- Misleading drug comparisons
  - Example: Drug X is more effective than Drug Y, when there is not substantial evidence to support this claim
    - Substantial Evidence is a higher level of evidence than that used in traditional evidence-based medicine

# What should I do if I see misleading drug promotion?

- Any health care professional can report a potentially misleading promotion to DDMAC by:
  - sending an e-mail to **BadAd@fda.gov** or
  - calling **877-RX-DDMAC (877-793-3622)**
- Reports can be submitted anonymously by health care professionals. However, FDA encourages professionals to include contact information so that DDMAC officials can follow-up if necessary for more information.

# What will DDMAC do with my complaint?

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

# What will happen if I report misleading promotion to DDMAC?

- Contribution to ongoing DDMAC surveillance activities
- Untitled letters (Notice of Violation/NOV)
- Warning letters
- Injunction/consent decree
- Seizures
- Criminal action

# Examples of Enforcement Actions

- Byetta (exenatide) – *Convention*
- Provigil (modafinil) – *P&T committee*
- Seroqueul (quetiapine) – *Office*
- Aricept (donepezil)– *TV ad*
- Derma-Smoothie/FS (fluocinolone acetonide) – *Website*



# Enforcement Examples: Byetta (exenatide)

- DDMAC and sales rep interaction at commercial exhibit hall during 91st Endocrine Society's Annual Meeting (ENDO)

## Overstatement of Efficacy

- Sales Rep Stated:
  - "Byetta had a positive effect on cholesterol and triglyceride levels and because of this effect, 'cardiovascular benefits' are associated with the use of Byetta."

# Enforcement Examples: Byetta (exenatide)

## Broadening of Indication/Promotion of Unapproved Use

- Sales Rep Stated:
  - “Although Byetta is not indicated for use by itself because it was not FDA approved this way and the FDA requires additional studies, Byetta can be used by itself.”
  - “There might be managed care, like Medicare or Medicaid issues when prescribing Byetta alone, but there are ways to deal with that.”

# Enforcement Examples: Provigil (modafinil)

- Promotional piece distributed on behalf of company at the Maryland Health and Mental Hygiene's P&T committee meeting in 2006.

## Broadening of indication/Omission of risk

- Approved Indication:
  - To improve wakefulness in patients with excessive sleepiness associated with narcolepsy, obstructive sleep apnea/hypopnea syndrome, and shift work sleep disorder (SWSD)

# Enforcement Examples: Provigil (modafinil)

## Risk Information for Provigil

- *Warning:* Patients with abnormal sleepiness who take Provigil should be advised that their level of wakefulness may not return to normal. Patients with excessive sleepiness, including those taking Provigil, should be frequently reassessed for their degree of sleepiness and if appropriate, advised to avoid driving or any other potentially dangerous activity.
- *Precaution:* Patients should be cautioned about operating an automobile or other hazardous machinery until they are reasonably certain that Provigil therapy will not adversely affect their ability to engage in such activities.

# The Utility of Provigil (modafinil) in the Medical and Psychiatric Population

Harry Kerasidis M.D.

Provigil (modafinil) is categorized as a stimulant medication. It is unique in its pharmacologic effect and mechanism of action.

## Sleep Disorder Related Fatigue

- Sleep Disorder Related Fatigue is the sleepiness, inattentiveness, and psychological changes resulting from disordered sleep.
- Forty million Americans suffer from a chronic sleep disorder. This translates into 17% of the workforce, working in a chronically fatigued state.
- 20% of all adults report impairing sleepiness a few days a week or more. More commonly in shift-workers (30%)
- Corporate America is losing \$18 billion each year to lost productivity due to Sleep Disorder Fatigue.
- Nearly 1/3 of all fatal-to-the-driver heavy trucking accidents are due to driver fatigue. For every driver lost, an average of 4 innocent bystanders are also lost.

Provigil (modafinil) has FDA indications for the following disorders that result in Sleep Disorder Fatigue:

- **Narcolepsy**, a genetic disorder of primary daytime sleepiness affecting 1 of every 2500 individuals.
- **Persistent hypersomnolence in treated obstructive sleep apnea.** Obstructive sleep apnea affects 5% of the population. About 15% of these individuals have persistent daytime sleepiness even when the apnea is treated.
- **Shift Work Sleep Disorder**, excessive sleepiness that persists in individuals engaging in shift work despite attempts to alleviate this symptom.
  - Up to 24 million Americans work irregular shift schedules.
  - Approximately 25% of night/rotating shift workers meet criteria for SWSD resulting in increased risks of motor vehicle accidents, work related accidents and errors, and clinically significant impairment in social and occupational function.

Provigil (modafinil) has utility in the treatment of other sleep disorders that cause excessive daytime sleepiness including idiopathic hypersomnolence syndrome, delayed sleep phase syndrome, and, paradoxically, some cases of insomnia.

Provigil (modafinil) also has utility in the treatment of other neurologic and psychiatric disorders associated with fatigue, sleepiness, or inattentiveness:

#### Multiple Sclerosis Related Fatigue

- MS affects about 300,000 Americans. 10-20% of these individuals suffer from chronic fatigue. Provigil (modafinil) is very effective in relieving the fatigue related to MS

#### Parkinson's Disease Related Fatigue

- Parkinson's and the medications used to treat Parkinson's Disease often results in daytime sleepiness, which often can be offset with the use of Provigil (modafinil)

#### Chronic Fatigue Syndrome Fibromyalgia, & chronic pain conditions

- The fatigue related to CFS and Fibromyalgia often responds to Provigil (modafinil). Many of the medications used to treat these conditions also lead to impairing daytime sleepiness which often can be offset by Provigil (modafinil).

#### Attention Deficit Disorder

- Affects approximately 5% of the pediatric population, and 2-3% of the adult population.
- Double blind placebo controlled studies have shown significant improvements in multiple cognitive measures in this population without the risks attendant to the traditional stimulants used to treat this condition.

#### Depression

- In a retrospective case series, modafinil was found to augment actions of antidepressants, especially in patients with residual tiredness or fatigue. Clinical experience supports this published finding.

**Provigil (modafinil) is a unique medication with proven efficacy, safety, utility and versatility; and low potential for abuse, dependence and diversion.**

# Enforcement Examples: Seroquel (quetiapine)

- An AstraZeneca sales rep made an sales call to a physician's office promoting Seroquel & Seroquel XR in 2008.

## Promotion of Unapproved Use

- The sales rep proactively provided the physician with information about Seroquel & Seroquel XR effectiveness in treating MDD in the form of oral statements and a mailing. The physician had not requested information on the drug's use in MDD patients.
  - Neither drug was approved to treat MDD at the time of the sales call.
- Mailing included a "disclaimer" stating that AZ does not recommend the use of either drug in any other manner than as described in the enclosed PI.
  - However, this was insufficient to mitigate the promotion of an unapproved use

# Enforcement Examples: Aricept (donepezil)

- DDMAC sent an enforcement letter to Esai regarding two TV ads that aired in 2009.
- Let's view one of the TV ads to see if you can identify the misleading aspect of this promotion.

# Enforcement Examples: Aricept (donepezil)

Efficacy of Aricept was measured through ADAS-cog:

- Cognitive subscale of the Alzheimer's Disease Assessment Scale measured from 0 to 70
- Multi-item instrument that examines selected aspects of cognitive performance, including elements of memory, orientation, attention, reasoning, language, and praxis.
- Higher scores indicate greater cognitive impairment



# Enforcement Examples: Aricept (donepezil)

## Overstatement of Efficacy

- In clinical trials, the mean differences in the ADAS-cog (0 to 70 scale) change scores compared to placebo were:
  - 5 mg/day = -2.8 units
  - 10 mg/day = - 3.1 units

# Enforcement Examples: Aricept (donepezil)

## Overstatement of Efficacy

- The totality of the claims and presentations misleadingly overstate the efficacy of Aricept
- These presentations imply that, as a result of Aricept treatment, patients' cognitive and daily functioning will be restored to normal

# Enforcement Examples: Derma-Smoothie/FS (fluocinolone acetonide)

- Warning Letter issued in December 2010 was the first enforcement resulting from a Bad Ad program complaint.
- Bad Ad complaint on the Derma-Smoothie website which:
  - Overstated efficacy
  - Omitted/Minimized risk
  - Presented Unsubstantiated Superiority claims
  - Broadened the indication

# Enforcement Examples: Derma-Smoothe/FS (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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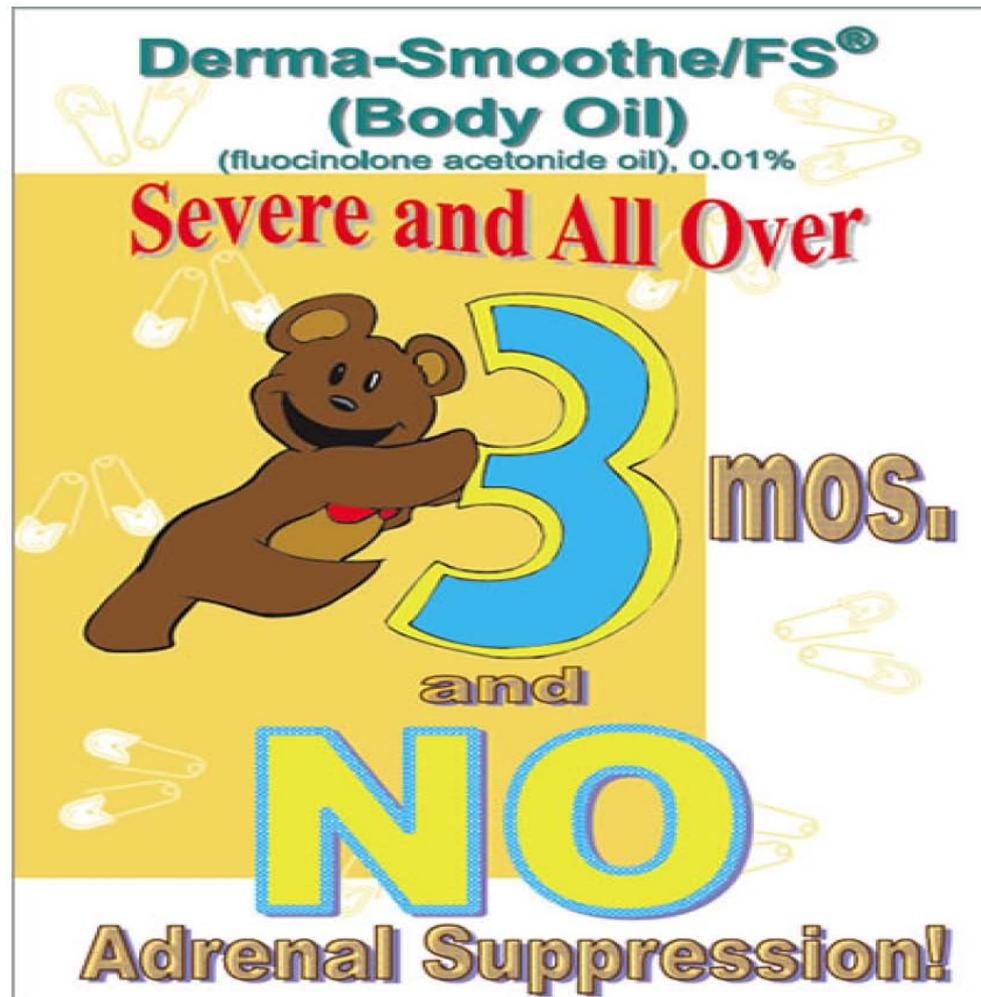


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# Recognize and Report Misleading Promotion

- Phone: 877-RX-DDMAC  
(877-793-3622)
- E-Mail: [BadAd@fda.gov](mailto:BadAd@fda.gov)
- For additional information, call DDMAC's Main Number at (301) 796-1200 or visit the website for Bad Ad: [www.fda.gov/badad](http://www.fda.gov/badad)
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