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An Introduction to the Regulation of Prescription Drug Promotion: The Role of FDA

Kathryn J. Aikin, Ph.D.
Division of Drug Marketing, Advertising and Communications
Office of Medical Policy
Center for Drug Evaluation and Research, FDA

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Presentation Overview

- Introduction to FDA and DDMAC
- Regulatory authority
- Regulatory requirements
- Evolution of Direct-to-Consumer advertising
- Advertising examples
- DDMAC enforcement, policy, advisory, surveillance and research programs
An Introduction to FDA and DDMAC
Agencies and Offices within Department of Health and Human Services

- OS – Office of the Secretary
- ACF - Administration for Children & Families
- AoA - Administration on Aging
- AHRQ - Agency for Healthcare Research & Quality
- ATSDR - Agency for Toxic Substances & Disease
- CDC - Centers for Disease Control & Prevention
- CMS - Centers for Medicare & Medicaid Services
- FDA - Food & Drug Administration
- HRSA - Health Resources & Services Administration
- IHS - Indian Health Service
- NIH - National Institutes of Health
- OIG - Office of Inspector General
- SAMHSA - Substance Abuse & Mental Health Services Administration
What does FDA do?

FDA is responsible for:

- protecting the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products, medical devices, our nation’s food supply, cosmetics, dietary supplements, and products that give off radiation
- regulating tobacco products
- advancing the public health by helping to speed product innovations
- helping the public get the accurate, science-based information they need to use medicines and foods to improve their health
DDMAC’s Mission

- Protect the public health by assuring prescription drug information is truthful, balanced, and accurately communicated

- To guard against false and misleading advertising and promotion through comprehensive surveillance, enforcement, and educational programs
DDMAC’s Role

- Surveillance and enforcement
- Advice to industry/within FDA
- Guidances and policy development
- Research
FDA’s Regulatory Authority Regarding Promotion
Federal Food, Drug and Cosmetic Act

- Prescription drug promotion must...
  - Not be false or misleading
  - Have fair balance
  - Be consistent with the approved product labeling, or the package insert (PI)
  - Only include claims substantiated by adequate and well-controlled clinical studies
False, Lacking in Fair Balance or Otherwise Misleading

“Contains a representation or suggestion, not approved or permitted for use in the labeling, that a drug is better, more effective…safer, has fewer, or less incidence of, or less serious side effects or contraindications than has been demonstrated by substantial evidence…whether or not such representations are made by comparison with other drugs or treatments, and whether or not such a representation or suggestion is made directly or through use of published or unpublished literature, quotations or references.” (21 CFR 202.1 (e)(5)(i))

“Contains a drug comparison that represents or suggests that a drug is safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective … by substantial evidence or substantial clinical experience.” (21 CFR 202.1 (e)(5)(ii))
What Does this Mean?

- Accurately communicate indication(s) including context for any claim
  - Limitations on indication(s)
  - Relevant patient population
  - Concomitant therapies/treatments
  - Likelihood of benefit(s)
- Communicate most important risks in a manner reasonably comparable to benefits (presentation and language)
- Cannot omit important information
  - In plain language → Ads must communicate an accurate and balanced picture of the drug product
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
Sec. 901 of Title IX of FDAAA contains a number of provisions related to DTC advertising:

- Prereview of DTC TV ads (adds § 503B to FDCA)
- Clear, conspicuous, and neutral manner major statement requirement (amends § 502(n) of FDCA)
- Civil monetary penalties for violative DTC ads (amends § 303 of FDCA)
- Report on DTC advertising

Sec. 906 of Title IX - Statement for Inclusion in DTC Drug Ads
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
  - DDMAC receives >70K submissions per year
Clarification to Some Beliefs

- **Preapproval or preclearance**
  - Law prohibits requiring preapproval of any ad except under “extraordinary circumstances”

- **Types of Reviews**
  - **Enforcement**
    - Review process for materials already in use
      - Submitted materials
      - Monitoring program
  - **Advisory comments**
    - When requested by sponsors
      - Launches, TV ads, other materials
    - Pre-submission
      - Accelerated approval (subparts E and H)
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
  - Accompanied by a “Brief Summary” of the approved product label
- Broadcast (e.g., TV, radio, telephone communication systems)
  - Accompanied by a “Brief Summary” of the approved product label OR discloses the most important risk information and makes “Adequate Provision” for disseminating the approved product label
Advertising: FDA versus FTC

- FDA – created in 1906
  - Prescription drugs (human and animal)
  - Restricted medical devices
  - Biologics
  - Vaccines
  - Tobacco *new*

- FTC – created in 1914
  - Over-the-counter drugs
  - Unrestricted medical devices
  - Dietary supplements
  - Consumer package goods
  - Tobacco
Why regulate prescription drug advertisements?
Falling out hair prematurely grey can be cured by taking Capsuloids.

Look at this picture of the skin and you can plainly see how the hair grows, also that nothing rubbed on the skin or hair can ever get down to enter the roots. The hair can be made to grow firm again and the colour restored only through the roots, and by taking Capsuloids.

Dose.—3 or 3 just before each meal, three times daily.

18, Stanbridge Road,
Putney, S.W.

Gentlemen,—I cannot thank you enough for sending me your little Hair booklet, for that caused me to try Capsuloids for my hair, which was falling out so rapidly that I feared I would lose it altogether; and so much had fallen out that I had been using a wig for six weeks.

I enclose my photograph, which I have just had taken, so that you may see how splendid my hair now is.

My hair was formerly of a very light colour, and it was considered very beautiful, and it is now even more beautiful, for it is almost golden—that is, a richer colour.

If Capsuloids were a guinea a box I would not be without them. I have taken many boxes, but I am repaid a thousandfold.

Gratefully yours,
Mrs. F. Otto Passmore.

Science and the microscope have proved that when a certain peculiar germ settles in the growing cells in the tips of the hair-roots, those roots become weakened and stop carrying up the colour from the blood corpuscles to the hair, and often become loose, so that the hair falls out.

We guarantee that Capsuloids will kill those Germs, we guarantee that Capsuloids will then restore the Hair.

Capsuloids contain those wonderful little blood corpuscles extracted from the purest fresh blood, specially treated, and enclosed in little gelatine covers. They agree with the weakest stomachs. They produce millions of new red corpuscles which kill the germs, strengthen the roots, and make them grow firm again, supply more colour, which the roots carry up to the hair, and make the hair once more grow luxuriantly.

Send for free hair booklet and copy of what the "Lancet" says.

Sold everywhere at the reduced price of 2/6 per box, or sent post free by the Capsuloid Co., Ltd., 31, Snow Hill, London, E.C. (S. & W.). Special free sample given when three boxes are ordered, larger sample with six, if this Coupon is enclosed.
CARBOLIC SMOKE BALL

WILL POSITIVELY CURE

OFFICERS

CARRIE S. HALLMAN, KENTUCKY
MRS. J. WILLEY, OHIO
MRS. J. B. BLACK, PENNSYLVANIA
MRS. J. W. DOUGLAS, NEW YORK
MRS. B. J. SMITH, GEORGIA
LUCY WILLS, ALABAMA

£100 REWARD

CARBOLIC SMOKE BALL CO.

INFLUENZA,

£1000 IS DEPOSITED

THE CARBOLIC SMOKE BALL,

INFLUENZA

£1000 IS DEPOSITED

THE CARBOLIC SMOKE BALL. CO., 27, PRINCES ST., HANOVER SQ., LONDON, W.
Categories of Promotional Materials

- Help-Seeking/
- Disease Awareness
- Institutional
- Reminder

Product Claim

Cannot make any representations about a specific product - requires no balance
Types of Prescription Drug Advertising

- Help Seeking/Disease Awareness - discussion of disease
- Reminder - names the drug but does not include indication, dosage recommendations, or any other non-permitted representations about the drug
- Product Claim - must include information about the drug in “brief summary”
Regulatory Requirements
In Brief Summary: Risk Disclosure for Print Ads

- Print ads need information “in brief summary” about risks and effectiveness
  - Risk presentations comparably prominent to effectiveness presentations as “fair balance”
- Regulations require that print ads must address all risk concepts
  - Draft Guidance provides alternatives to traditional “brief summary” for DTC print ads
    - Approved PPI
    - Consumer friendly version of risks from Highlights
ONCAZIL (strodacazil)

This summary contains important information about ONCAZIL. Read it carefully before you start taking ONCAZIL.

It is not intended to replace the advice of your doctor. Read this information carefully before you start taking ONCAZIL. Ask your doctor or pharmacist if you do not understand any of this information or if you want to know more about ONCAZIL.

Uses
ONCAZIL is used to treat asthma in adults and children as young as 12 years.

ONCAZIL is not used to treat asthma in children younger than 12 years.

ONCAZIL has been studied to reduce the number of asthma attacks in adults with asthma who take other asthma medicines.

ONCAZIL is not the same as a fast-acting inhaler that you take during an asthma attack.

Dosage
ONCAZIL should be taken as a maintenance therapy to control asthma.

How to take ONCAZIL
ONCAZIL should be taken at least 1 hour before an asthma attack.

Missed dose
If you miss a dose, take it as soon as you remember. If it is already time for your next dose, skip the missed dose and continue with your regular dose. Do not take a double dose.

Precautions
ONCAZIL should be used with caution in patients with a history of heart disease, including heart failure.

Side Effects
ONCAZIL may cause side effects such as dizziness, headache, and tiredness.

Other Side Effects
ONCAZIL may cause other side effects such as nausea, vomiting, and diarrhea.

Storage
Store ONCAZIL at room temperature (59-86°F or 15-30°C).

Laurylamine
ONCAZIL contains laurylamine, which is a possible cigarette smoke and exposure to ONCAZIL may cause an allergic reaction.

Food and Medicines You May Be Taking
ONCAZIL may interact with other medicines you are taking, including antacids, antihistamines, and bronchodilators.

Other Things to Tell the Doctor
ONCAZIL may interact with other medicines you are taking, including antacids, antihistamines, and bronchodilators.

What to Do in the Case of an Overdose
If you take more than the prescribed amount of ONCAZIL, contact your doctor or pharmacist immediately.

Rx only
10 mg tablets

KAM Laboratories
1155 N. Main St.
Los Angeles, CA 90012

www.oncazil.com

1-800-ONCAZIL
Most Important Risks

- “Fair balance” for print ads
- Specific risk disclosure requirement for broadcast ads; likely to include:
  - Contraindications (relevant to patients)
  - Major warnings, especially if boxed or bolded
  - Significant precautions/drug interactions
  - Frequent side effects
Additional Considerations

- Reasonably comparable communication of risks
  - Consumer-friendly language for both benefits and risk (readability)
  - Prominence of presentation
- Necessary context for claims/risks
- What’s needed for informed discussion with health care professional
Specific Disclosure Requirements

- Food, Drug, & Cosmetic Act (502(n)):
  - Prescription drug ads must include “information in brief summary relating to side effects, contraindications, and effectiveness”
  - Act left specifics to regulations
“Brief Summary”

- Regulations: “Brief summary” information must include “each specific side effect and contraindication”
  - meaning, all risk concepts
- Typical compliance: reprinting risk-related sections of product labeling
  - but, verbatim reprinting not required
“Brief Summary”: Print vs. Broadcast

- Print: little or no flexibility to reduce required information
- Broadcast: media limitations implicitly acknowledged through provision of alternative means of disseminating additional information
Broadcast Advertisement

Requirements

- *Must* have information about “major side effects and contraindications”
  - in audio, or audio plus visual
- PLUS can *either*:
  - present brief summary, or
  - make “adequate provision” for disseminating product labeling
Broadcast Advertisement Guidance

- Takes advantage of regulatory flexibility
- Reinforces requirements that ads:
  - must be truthful and not misleading
    - communicate Rx status of product
  - communicate product’s indication
  - communicate most important risk information
Clarifies “Adequate Provision” for DTC Ads

- One possible, multi-faceted approach to reach *diverse audience* with required product information
  - toll-free phone number for information to be mailed or read
  - concurrently available print information
  - internet address
  - reference to health care provider as source of more product information
Clarification to Some Beliefs

- No laws or regulations ever prohibited promoting prescription drugs to consumers (in general or for specific products or drug classes)

- Regulatory focus is on the content of the materials NOT their general existence or the amount of promotion
2008 Promotional Spending: Professional versus Consumer

82% Professional
18% Consumer

# of Final Promotional Pieces Submitted (2253s) 2003 - 2009

Mixed | Consumer | Professional | Total

2003: 4,423 | 6,099 | 29,575 | 40,097
2004: 6,877 | 8,417 | 37,526 | 52,851
2005: 6,223 | 9,285 | 39,153 | 54,661
2006: 10,917 | 14,456 | 45,712 | 71,085
2007: 14,970 | 15,998 | 45,663 | 76,631
2008: 10,917 | 14,456 | 45,712 | 71,085
2009: 14,970 | 15,998 | 45,663 | 76,631

2003-2009 Total: 76,631
The Evolution of Direct-to-Consumer Prescription Drug Advertising
If the law allowed ads to be directed to consumers, why didn’t we see them until relatively recently?
Evolution of Direct-to-Consumer (DTC) Advertising

- Up to 1980s: consumer communications controlled through “learned intermediary”
- 1980’s: First DTC ads and fallout
  --1983-1985: FDA voluntary moratorium
  --1985: moratorium lifted, regulations provide “sufficient safeguards to protect consumers”
- 1990s: increase in print ads
- Mid 1990s: broadcast ads enter mix
Why did DTC become important?

- Consumer empowerment
  - desire for more involvement in own care
  - consumers actively seeking information
- Aging baby-boomer population
  - caring for selves, children, parents
- Managed Care
- Sponsors’ marketing strategy
Early Broadcast Environment: Before 1996

- Static -- sponsor uncertainty regarding requirement for “brief summary”
- “Adequate provision” for providing labeling always allowed
  - Adequate provision not defined in regulation
- Major risks required to be disclosed regardless of path chosen
Result:

A broadcast environment dominated by reminder advertising
Risk Disclosure for Broadcast Ads

- Broadcast ads need:
  - **most important** risks disclosed in ad itself in audio or audio and video: aka, the “major statement”
  - AND
  - access to either **all** risks or “adequate provision” for disseminating product labeling (PI)
Addressing “Adequate Provision”

- How to reach diverse group of consumers?
  - sponsors had some suggestions
  - 1997 draft guidance; 1999 final guidance
    - reference to health care provider
    - print ads/brochures
    - telephone contact number
    - internet site
- Reinforces underlying requirements
- Encourages consumer-friendly information
Examples of Direct-to-Consumer Advertising
Examples of DTC Promotion

- Help-Seeking
  - disease discussion … “see your doctor”… consistently encouraged, important for under-diagnosed, under-treated health conditions
  - not drug ads, so not covered by FD&C Act
  - draft guidance clarifies FDA’s position on these types of ads
“At first I didn’t want to get up for work. Then I didn’t want to get up at all. My doctor said I was depressed... Then I learned that treatment can help.

Now, I’m feeling better.”

About 1 in 6 Americans will experience depression in their lifetimes. Depression is a condition that can affect people’s jobs, families, and lives. But there is hope. Treatment is available—psychological therapy and antidepressant medicines are among the options that can help relieve depression. In fact, it has been shown that most people who receive treatment improve. Through patient education and research and development of drug therapies, Pfizer is helping millions of people realize that depression can be overcome.

If you’d like to learn more about depression, please call your doctor. For free, confidential brochures about depression, its symptoms, and its treatment, please call 1-888-549-9422. www.depression-info.com

Life is our life’s work. Pfizer
Examples of DTC Promotion

- Reminder ads/labeling
  - exempted from risk disclosure requirements
  - includes product name, but no representations beyond dosage form, packaging, price info
  - not allowed for products with boxed warnings
Examples of DTC Promotion

- **Product claim**
  - claims or representations trigger disclosure requirements for accuracy and balance
- **risk disclosure requirements**
  - **Body of promotional piece**
    - Usually the most serious risks and most common adverse events
  - **Brief summary or full product labeling must be included**
    - “brief summary” for print ads
    - “adequate provision” for broadcast ads
    - full product labeling for promotional labeling
Oversight Program for DTC

- Voluntary Compliance
  - Advisory comments
  - Guidance documents
  - Educational efforts
    - Outreach
    - Website
- Comprehensive surveillance and enforcement program
Continuing Evolution of DTC

- Major Guidance Development
  - Broadcast ads (“Adequate Provision”) (1997 & 1999)
  - Brief Summary Alternatives (2004)
  - Help-Seeking Communications (2004)
  - Presentation of Risk Information (2009)
- FDAAA – Title IX (Sept 2007)
  - First law to specifically address DTC
DDMAC Regulatory Enforcement
Enforcement

- Untitled letters (Notice of Violation/NOV)
- Warning letters
- Injunction/consent decree
- Seizures
- Criminal action
- Civil monetary penalties
Common Violations

- Inadequate communication of risk info
  - Missing content
  - Presentation (minimization, comparability)
- Misleading communication of indication
  - Promoting beyond the indicated population or beyond the indication of the drug
- Misleading product efficacy claims
  - Overstatement of efficacy
Examples of Violative Advertisements
Now available!
A complete line of Bupropion ER (SR).
AB Rated to Wellbutrin SR® *

▲ 100 mg, 150 mg and 200 mg tablets
▲ 60, 100 and 500 count bottles

Look for the new Zyban® equivalent — Coming Soon!

SAN DO Z

Eon Labs

Eon Labs
“Reminder Ad” for Bupropriion ER

- NOV issued for this “impermissible reminder ad”
- "Reminder advertisements. . . are not permitted for a prescription drug product whose labeling contains a boxed warning relating to a serious hazard associated with the use of the drug product."
- Labeling contains a boxed warning
- Ad fails to present brief summary
Viagra “Reminder” TV Ad

- Makes representations about Viagra
- Approved indication not presented
- No risk information, no adequate provision
- Overstates efficacy of product
Lenticular Magnet for Trileptal
Trileptal - Magnet

- Omission of indication and risk information
  - Effectiveness claims presented, but indication and risk are not
    - (Included on back of magnet—as a practical matter, this information is not communicated)
    - Magnet is designed to adhere to magnet surfaces—once displayed, content on back is not visible
- Encourages use in circumstances other than those for which shown to be safe and effective
  - Implies drug is indicated for generalized seizures
    - Full indication is not presented on front of magnet
    - Especially problematic in the view where only generalized seizures claim is visible
THERE CAN BE LIFE WITH RELIEF

The most common side effects associated with OxyContin® are:
- constipation, nausea, vomiting, diarrhea, abdominal pain
- dizziness, headache, dry mouth, sweating, flushing

OxyContin® is contraindicated in patients with
- known hypersensitivity to codeine or
- patients who are taking MAO inhibitors.

Please see the Contraindications section in the package insert.

Purdue is committed to maintaining the
- highest standards of marketing practices in the industry while continuing to advance the proper treatment of pain in America. If Purdue’s marketing and sales practices fail to meet these standards, we urge you to contact us at
- 1-888-600-9211.

OxyContin®
(OXYCODONE HCl CONTROLLED-RELEASE) TABLETS
IT WORKS

Please read brief summary of prescribing information
Including boxed warning on reverse side.

Copyright 2003 Purdue Pharma L.P., Stamford, CT 06901-3523
A7827 - PUB-6995710
OxyContin Journal Ad

- No risk information from the boxed warning (e.g., abuse liability and potentially fatal risks due to formulation) included in the body of the ads
- Minimization of other risk information
- Broadening of Indication/Failure to communicate limitations on indication
- Serious public health concerns
- Corrective advertisement requested
Corrective Advertisements
2005 WL

**Overstatement of Efficacy** – there is no evidence that Enbrel provides complete clearing of the psoriasis as demonstrated by the models

- “tell psoriasis where to get off – Enbrel”
- the super mentions, “results may vary” which is not sufficient
- unsubstantiated claim: “Enbrel is a breakthrough” when no significant advantage has been shown over drugs for this condition
- misleading onset claim: “dramatically clear skin fast” (consumers may not interpret this as 2 months)

**Misleading Communication of the Limits to the Indication**

- broadens the indication – this drug is indicated for moderate to severe psoriasis

**Minimization of Risk**

- the major statement is minimized by distracting visuals, fast-paced graphics/supers
Yaz TV Ad

- Broadening of indication
  - Symptoms in these ads are commonly seen in women with PMS, which is a disorder that is less serious and more common condition than PMDD
  - Acne: PI – Yaz treats moderate acne only
- Overstatement of efficacy
  - “Goodbye to you” and kicking away balloons —PI says that patients experienced a decrease (improvement) in PMDD symptoms, not elimination of symptoms
  - Acne: Again, elimination of symptoms—clear skin, goodbye to you, balloons disappearing
- Minimization of risk
  - Distracting visuals
  - Numerous scene changes
  - Background music
DDMAC Policy Development, Advice and Surveillance Programs
Policy Development

- Draft Guidance on Presentation of Risk Information
- Research on Brief Summary leading to revised draft guidance
- Future areas for guidance development
  - e.g., Internet guidance including social media
- Implementation of FDAAA provisions
Advice to Industry

- Provide comments on DRAFT promotional materials (VOLUNTARY in most cases)
  - Launch materials for new drugs or new indications
  - Direct-to-consumer (DTC) broadcast ads
  - Non-launch materials

- Pre-submission required for certain drugs (e.g., Subpart H/Subpart E “accelerated approval”)

- Technical assistance on Social Science research studies
Advice within FDA

Provide consultation on:

- Draft labeling
- Cartons and product labels
- Medication Guides
- Patient Package Inserts (PPIs)
- Dear Healthcare Provider letters
- Pharmacoeconomics, health-related patient-reported outcome protocols
- Social Science research studies
Surveillance

- Review materials submitted to DDMAC at the time of initial dissemination (Form 2253)

- Conferences

- Complaints
  - Healthcare professionals
  - Consumers
  - Competitors
DDMAC Research Program
Research Focus

- Informed Decision Making
- Risk Communication
- Enforcement
OMB Information Collections
Flow of Federal Register Notices for Public Comment

**Peer Review**
- Program office sends the draft 60-day FR notice to PRA analyst
- PRA analyst reviews draft 60-day FR notice
- Corrected draft 60-day FR notice returned to PRA analyst

**RIHSC Review**
- If PRA analyst makes changes to the draft 60-day FR notice, it is returned to the program office for revisions
- 60-day FR notice forwarded to RES for publication
- 60-day notice published in FR; program office sends ICR (supporting statement, attachments and form 83-I) to PRA analyst for review

**If no comments are received on the 60-day FR notice**
- PRA analyst prepares 30-day FR notice
- Program office sends response to comments to PRA analyst
- PRA analyst uploads the ICR into HHS’s tracking system
- PRA analyst notifies HHS of the 30-day FR notice publication
- HHS forwards ICR to OMB
- OMB has 60 days to take action on the information collection. OMB may APPROVE, APPROVE WITH CONDITIONS or DISAPPROVE

**If comments are received on the 60-day FR notice**
- PRA analyst prepares 30-day FR notice
- Program office sends response to comments to PRA analyst
- PRA analyst forwards 30-day notice to OCC
- If OCC review is requested by program office, the PRA analyst forwards 30-day notice to OCC
- 30-day FR notice forwarded to RES
- 30-day notice published in Federal Register

**60 day comment period**
**30 day comment period**
Informed Decision Making Studies

- Impact of Distraction on Consumer Understanding of Risk and Benefit Information in Direct-to-Consumer Prescription Drug Broadcast Advertisements*
- Drug Risk/Benefit Analysis in Variations of Display Pages of Print Direct-to-Consumer Prescription Drug Advertisements
- Presentation of Quantitative Information about Benefits and Risks in DTC Ads
- Toll-Free Number for Reporting Side Effects in DTC Television Ads

*With Nancy Ostrove, (FDA, Office of the Commissioner) and Scott Douglas (HHS, Office of the Assistant Secretary for Planning and Evaluation)
Informed Decision Making Studies, continued

- Disease Awareness Information in Branded Promotional Material
- Examination of Online Direct-to-Consumer Promotion
- Focus Groups to Investigate Consumer and Physician Beliefs about Direct-to-Consumer (DTC) Advertising
Risk Communication Studies

- Variations in the Brief Summary in Direct-to-Consumer (DTC) Print Advertisements for Prescription Drugs: Use, Content and Format
- Experimental Study of Format Variations in the Brief Summary of Direct-to-Consumer (DTC) Print Advertisements
- Impact of Incentives Embedded in Direct-to-Consumer Prescription Drug Print Advertisements on Consumer Perceptions of Product Risks and Benefits
Enforcement Studies

- Copy Testing of individual advertisements
Questions?
Online DDMAC Information

- DDMAC home page: http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm
  - Phone number: (301) 796-1200
  - Fax numbers: (301) 847-8444 and (301) 847-8445
  - My contact info: kathryn.aikin at fda.hhs.gov