

DuaneMorris

FDA Regulation of Promotion & Advertising

Part 2: Direct-to-Consumer Ads

ComplianceOnline Seminar

November 6-7, 2014

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Overview

- Only U.S. and New Zealand allow Direct-to-Consumer (DTC) for regulated medical products
- DTC advertisements -- three types
 - *Product claim ads:* name a drug and the condition it treats, and talk about both its benefits and risks.
 - *Reminder ads:* give the drug's name, but not the drug's uses.
 - *Help-seeking ads:* These describe a disease or condition, but don't recommend or suggest specific drugs.
 - FDA – a “true” help seeking ad is not considered a drug ad and thus not subject to agency jurisdiction (but FTC could assert jurisdiction)

DTC Ads – Providing Risk Information

- *Print ads* – “Brief Summary”
- *Broadcast ads* – “major statement” -- allowed to include only the most important risk information – “*major side effects and contraindications*” if make “*adequate provision*” for disseminating the approved or permitted package labeling
 - fail to make adequate provision, then you would need a brief summary in the broadcast ad [*not desirable*]
 - source: 21 CFR 202.1(e)(1)

DTC – Broadcast Ads

DTC – Broadcast Ads – Risk Information

- *Broadcast ads* – “major statement” -- allowed to include only the most important risk information – “*major side effects and contraindications*” if make “*adequate provision*” for disseminating the approved or permitted package labeling
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Making “Adequate Provision”

- **Broadcast DTC ads – ways to make “adequate provision” for a drug's prescribing information – typically may include:**
 - a health care professional (for example, a doctor)
 - a toll-free telephone number
 - the current issue of a magazine that contains a print ad
 - however, that print ad must contain the entire approved prescribing info, not just a “brief” summary
 - a Web site address
- **Guidance on “Adequate Provision” – found in 1999 Consumer-Directed Broadcast Advertisements**

6 *[Hot link]*

Adequate Provision – A Comprehensive Way

- **Guidance – has an approach that is “comprehensive”**
 - Toll-free telephone # -- upon calling,
 - Choice of having risk info read to you or full info mailed timely (within 2 business days for receipt in 4-6 days)
 - reading – can be via prerecorded prompts
 - “Print ad” approach – aimed in part at people that don’t want to be identified or lack access to internet
 - include a toll-free # and how to get full labeling (because the print ad only requires a brief summary)
 - be careful to choose publications of adequate circulation and availability

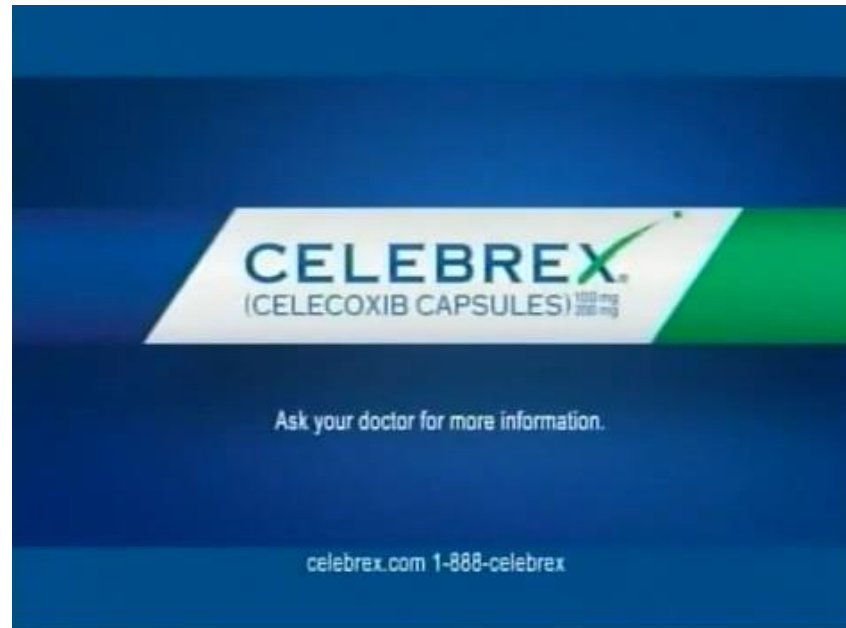
Adequate Provision ...

- Website address -- for full labeling
- HCPs – such as docs and pharmacists -- as source – of “additional product info”
- **Celebrex TV ad: appeared from 23 to 33 seconds**



Adequate Provision ... Celebrex

- At very end ... appeared for a couple seconds, but on YouTube, so can't know how long it ran in reality



- But, was 2 minutes after “Golf”

DTC Broadcast Ads – “Major Statement”

- **FDAAA – 2007 – the “major statement” must be in “clear, conspicuous and neutral manner”**
 - 30 months to establish standards via regulation
- **Proposed regulations on standards for assessing major statement – March 29, 2010 – 75 Fed. Reg. 15376**
- **Technical distinction**
 - 502(n) – applies solely to TV or radio broadcast
 - 202.1(e)(1) – applies to TV, radio or “telephone communication systems”
 - proposed rule – makes the distinction

DTC Broadcast Ads – “Major Statement” ...

- **Proposed 2010 Rule -- “Clear, Conspicuous & Neutral” Manner**
 - Still pending; but, is binding on FDA as an advisory opinion
 - **Four Criteria:**
 - Information is presented in language that is readily understandable by consumers;
 - Audio information is understandable in terms of the volume, articulation, and pacing used;
 - Textual information is placed appropriately and is presented against a contrasting background for sufficient duration and in a size and style of font that allows the information to be read easily; and
 - No distracting representations exist -- such as statements, text, images, sound, or any combination thereof -- that detract from the communication of the major statement.

DTC Broadcast Ads – “Major Statement” ...

- **4 Criteria – “clear, conspicuous and neutral”**
 - Seen as consistent with 2009 FDA Draft Guidance on [Presenting Risk Information in Prescription Drug and Medical Device Promotion](#) [*Hot link*]
- **5th Criterion:**
 - FDA considered requiring that the major statement in a TV ad appear in both the video and audio parts of the presentation
 - not in proposed rule

DTC – Broadcast – FDAAA Review -- § 503B

- **FDAAA – 2007 – Added Section 503B of the Act**
 - FDA may require submission of the ad (and story boards, scripts, etc.) not later than 45 days before dissemination
 - FDA may recommend changes
 - necessary to protect the “consumer good and well being,” or
 - consistent with the prescribing info for the drug
 - FDA may recommend that specific info on efficacy of drug in certain patient groups be added (e.g., elderly, pediatrics, ethnic)
 - No authority to require changes, except:
 - may require info on a “serious risk” (in labeling) if ad would otherwise be false or misleading without it
 - date of approval if within 2 years of original approval date

Pre-Dissemination Review of TV ads

- **Draft Guidance – March 2012**
 - [Direct-to-Consumer Television Advertisements--FDAAA DTC Television Ad Pre-Dissemination Review Program](#) [*Hot link*]
- **Six categories**
 - 1 – *initial* ad ever for a drug or initial ad for a new or expanded approved indication of the drug
 - 2 – *all* ads for drugs with REMS involving elements to assure safe use (ETASU)
 - 3 – *all* ads for Schedule II controlled substances
 - 4 – *first* ad following a safety labeling update that affects the boxed warning, Contraindications, or Warnings & Precautions

Pre-Dissemination Review of TV ads ...

- **Six categories ...**
 - **5** – first ad for a sponsor after receiving an enforcement letter (warning or untitled) for that drug that either cites a TV ad or causes a TV ad to be discontinued because the ad contains violations similar to what was cited in the enforcement letter
 - **6** – any TV ad otherwise identified by FDA as subject to pre-dissemination review
- **Notice process**
 - **Categories 1, 4, 5, and 6** – either in approval letter (1, 4), enforcement letter (5) or other letter (6)
 - **Already approved drugs – Categories 1, 2, and 3** – F.R. notice

Pre-Dissemination Review of TV ads ...

- **Contents of submission – detailed**
 - Cover letter
 - Annotated storyboard –to show which references support which claims –
 - citing approved labeling
 - or, if not in approved labeling, other references
 - Current approved labeling
 - Verification that persons in ads are either real patients – including spokespersons -- or real health care providers (HCP)
 - Verification of translation of foreign videos
 - Complete copy of final video (in acceptable format)

Pre-Dissemination Review of TV ads ...

- **Acceptable formats:**
 - MPEG-2-HD (High Definition Video)
 - WMV-HD (High Definition Video)
 - DVD-VR or DVD+VR
 - DVD-Video or Mini-DVD
 - CD-R or CD-RW or VHS
- **Review –**
 - FDA has 45 days prior to planned dissemination; if it will be late, it will inform sponsor
 - if FDA is late, and you disseminate, FDA will stop review

Pre-Dissemination Review of TV ads ...

- **Disseminating an ad in violation of 503B – is a “prohibited act” under § 301(kk) of the Act**
 - failure to submit at all
 - disseminate before end of 45-day period
 - failure to incorporate required additions to ad as per Section 503B(e) – such as serious risks in labeling or approval dates
- **Civil monetary penalties – FDAAA revised § 303** so that any person who disseminates or causes another party to disseminate a false or misleading DTC ad shall be liable for a civil penalty of up to \$250,000 for the first violation, and up to \$500,000 for subsequent violations in a 3 year period.

DTC Ads – Civil Monetary Penalties

- **CMP law does not distinguish between TV and print/radio ads**
- **Factors**
 - whether submitted under §503B or §736A (advisory review)
 - whether disseminated before end of 45-day period
 - whether they incorporated any comments
 - whether they stopped disseminating after getting CMP notice
 - whether they had it reviewed by qualified regulatory, medical and legal reviewers before dissemination
 - any prior CMPs in last year
 - scope and extent of remedial action(s)

DTC – Print Ad Requirements

DTC Print Ads and Risk Information

- *Print ads* – “Brief Summary”
- Draft Guidance -- 2004 -- [Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements \(PDF - 192KB\) \[Hot Link\]](#)
- 2007 FDAAA statement – all DTC print ads must include this statement:
 - "You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [MedWatch](#), or call 1-800-FDA-1088."

2004 Draft Guidance on DTC Print Ad

Brief Summary

- **“Each specific side effect and contraindication” -- must be disclosed in the brief summary**
 - Side effects, warnings, precautions, contraindications, important notes, etc.
 - Problem – lay readers often cannot follow the detailed brief summaries using all the risk info from the approved labeling
- **Guidance approach – some options**
 - present all the risk info from the approved full prescribing info
 - use any approved patient labeling
 - use “Highlights” labeling (then subject to a proposed rule; now finalized)

Draft Guidance -- DTC Print Ad Brief Summary ...

- Include a statement that it is not full prescribing info and provide way (phone or web) to get P.I.
- **Option 1** -- Approved full *patient* labeling –
 - be careful to ensure that it is not too narrow as to certain serious or frequent risks
 - include the following from the approved *professional* labeling
 - Contraindications – all
 - Warnings – all
 - Precautions – major precautions, including any that are SAEs, or steps to avoid those SAEs
 - Adverse reactions – 3 to 5 most likely to impact quality of life or drug therapy compliance

Draft Guidance -- DTC Print Ad Brief Summary ...

- **Option 2** -- Approved patient labeling, less non-risk info, plus the following from the approved professional labeling
 - Contraindications – all
 - Warnings – all
 - Precautions – major precautions, including any that are SAEs, or steps to avoid those SAEs
 - Adverse reactions – 3 to 5 most likely to impact quality of life or drug therapy compliance
- **Option 3** – “Highlights” Labeling – Risk information (e.g., Boxed Warning, Contraindications, Warnings/Precautions, Most Common Adverse Reactions)

DTC – Product Print Ad – Let’s Review

1 **Arbitraer**
(misvastatium) 100mg tablets

2 **Help Relieve Seasonal Allergy Symptoms**

3 **Arbitraer** is a prescription medicine that helps control seasonal allergy symptoms, like runny nose, sneezing, and itchy, watery eyes. By taking **Arbitraer**, **once a day** you can relieve your allergy symptoms for up to 24 hours.

4 You may begin to experience relief of allergy symptoms 2 hours after taking **Arbitraer**.

You may experience headaches, cold symptoms, coughing, or backaches while using **Arbitraer**.

5 **Arbitraer** is for use in adults 18 and older. **Arbitraer** is not for use in children.

6 You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1800-FDA-1088

7 See reverse for important information about Arbitraer.

8 Ask your doctor if **Arbitraer** is right for you.

9 **ACE**
Pharmaceuticals
800-555-5555 www.arbitraer.com

This advertisement is entirely fictional—no connection between "Arbitraer (misvastatium)" and any real company or product is intended, expressed, or implied.

DTC -- Product Print Ad – Let's Review ...

- Brand name/established name

1 Product claim ads must identify the drug's brand and generic names. The ad correctly mentions the fictional drug's brand name, Arbitraer, and its generic name, misvastatium.



- At least one approved use

2 Product claim ads must accurately state an FDA-approved use for the drug. In addition, the ad may not make a claim that is not supported by substantial evidence or substantial clinical experience. This ad appropriately states that Arbitraer is approved to treat seasonal allergy symptoms.



DTC -- Product Print Ad – Let’s Review ...

- Prescription use –

3

Product claim ads should say that the drug is given by prescription only. This ad appropriately states that Arbitraer is a prescription drug.



3

Allergy Symptoms
 Arbitraer is a prescription medicine that helps control seasonal allergy symptoms, like runny nose, sneezing, and itchy, watery eyes. By taking Arbitraer, once a day you can relieve your allergy

- “Fair balance”

4

This ad provides the required “fair balance” of information about the risks and benefits of Arbitraer. The ad as a whole does not put more emphasis on the drug’s benefits than its risks.




4

Arbitraer, once a day you can relieve your allergy symptoms for up to 24 hours.
 You may begin to experience relief of allergy symptoms 2 hours after taking **Arbitraer**.
 You may experience headaches, cold symptoms, coughing, or backaches while using **Arbitraer**.

DTC -- Product Print Ad – Let's Review ...

- Age use; Accurate graphic depictions

5 The man on the beach who is pictured in the ad is in the approved age range for users of the drug. The ad also reinforces this point by stating that Arbitraer is for adults 18 and older and is not for use in children.



coughing, or wackches while using Arbitraer.
Arbitraer is for use in adults 18 and older. Arbitraer is not for use in children.

- FDAAA required Medwatch statement

6 As required by the Food and Drug Amendments Act of 2007, print ads must include the statement "You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch, or call 1-800-FDA-1088."



You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1800 FDA-1088

DTC -- Product Print Ad – Let's Review ...

- **Brief Summary**

7

Print ads must include a "brief summary" of all the risks listed in the drug's FDA-approved prescribing information. The "brief summary" contains one or more pages of important information about a drug's risks. The "brief summary" usually follows the part of the ad that displays colorful images and graphics.

[View the Brief Summary \(23Kb\)](#)



7

[See reverse for important information about Arbitraer.](#)

– provided on next slide

DTC -- Product Print Ad – Let’s Review ...

- Brief Summary ...

ACE

Pharmaceuticals

IMPORTANT INFORMATION ABOUT

Arbitraer®
(misvastatium)
100 mg tablets

Brief Summary (For full Prescribing Information and Patient Information, refer to package insert.)

WHAT IS ARBITRAER?

Arbitraer is a prescription drug called an antihistamine. Arbitraer is used to treat seasonal allergy symptoms, such as runny nose, sneezing, itchy nose or throat, and itchy, watery, or red eyes.

WHO IS ARBITRAER FOR?

Arbitraer is for use in adults 18 years of age and older.

Arbitraer is not for use in children. Arbitraer has not been tested in children under the age of 18 years.

WHAT SHOULD I KNOW ABOUT TAKING ARBITRAER WITH OTHER DRUGS?

- Taken with some other drugs, Arbitraer may change the way those other drugs work. Tell your doctor or pharmacist if you are taking erythromycin or ketoconazole in addition to Arbitraer
- Do not take Arbitraer within 30 minutes of taking an antacid that contains aluminum and magnesium (such as Tums® or Maalox®)

WHAT ARE THE MOST COMMON SIDE EFFECTS OF ARBITRAER?

Side effects of Arbitraer include:

- Headache
- Cold
- Coughing
- Backache

This listing of side effects is not complete. Your doctor or pharmacist can discuss with you a more complete list of side effects that may occur when taking Arbitraer.

HOW SHOULD I TAKE ARBITRAER?

Do:

- Take Arbitraer as your doctor tells you to
- Take Arbitraer with or without food
- Talk to your doctor or pharmacist before starting any new drugs

Don't:

- Take Arbitraer within 30 minutes of taking an antacid that contains aluminum and magnesium (such as Tums® or Maalox®)
- Give Arbitraer to other people. It may harm them, even if your problems are the same

WHERE SHOULD I GO FOR MORE INFORMATION ABOUT ARBITRAER?

- Talk to your healthcare provider
- Go to www.Arbitraer.com or call 1-800-555-5555

ACE

Pharmaceuticals

Arbitraer® is a registered trademark of ACE Pharmaceuticals

DTC -- Product Print Ad – Let's Review ...

- See your doctor ...

8 The ad directs the reader to seek a doctor's advice about taking Arbitraer. The drug company has included this statement as a way to ensure that a consumer will not think he or she is qualified to make the prescribing decision.




- For more info ...

9 Product claim ads may provide sources of further information, such as a website and toll-free telephone number.



DTC – Print Reminder Ad – Let's Review

The Ad:



1 *Ask Your Doctor About*

2 **Arbitraer**
(misvastatium)

This advertisement is a purely editorial-use connection between "Arbitraer (misvastatium)" and any real company or product is intended, expressed, or implied.

DTC – Print Reminder Ad – Let’s Review ...

- Just about the drug – no suggestions about uses

1 The ad does not describe or name the condition the drug treats or make dosage recommendations. Notice that neither allergies nor any allergy symptoms are mentioned or pictured.



- Brand and established name

2 Reminder ads must identify the drug's brand name (if it has one) and its generic name. The ad correctly mentions the fictional drug's brand name, Arbitraer, and its generic name, misvastatium.



DTC -- Print Ad – “Help Seeking” -- Review

The Ad:

1

2

Runny Nose?
Sneezing?
Itchy, Watery
eyes?

You may be suffering from
Seasonal Allergies

3 There is help.
Ask your healthcare provider for more information.

4


drug co.

This advertisement is entirely fictional. No connection between "Aldimex" (generic name) and any real company or product is intended, expressed, or implied.

DTC -- Print Ad – *Help Seeking* – Review ...

- No specific drug

1 The image in this ad identifies a person who may have seasonal allergy symptoms. The ad does not show an image of a specific drug.



- Says a malady, but no specific treatment

2 This help-seeking ad identifies seasonal allergy symptoms without identifying a possible drug treatment.



DTC -- Print Ad – *Help Seeking* – Review ...

- Talks about getting help, but no specifics

3

This and any help-seeking ad may recommend that readers seek the advice of their healthcare provider.

3

There is help.
Ask your healthcare provider for more information.

- Gives info on where to seek more info and can say the company (although not done here)

4

While this ad may not name a drug, it may identify the company sponsoring the ad and provide a telephone number to call or a website to visit for more information.

4

This advertisement is entirely fictional; no connection between "Artiflex (generic name)" and any real company or product is intended, expressed, or implied.

drug co.

DTC – Print Product Ad – What’s Wrong?

- 6 errors (at least)

Arbitraer
(misvastatium) 100mg tablets

**Makes breathing easier
... immediately**

Arbitraer will help
control your asthma symptoms

5 out of 6 seasonal allergy
sufferers agree ...

Arbitraer is the best!

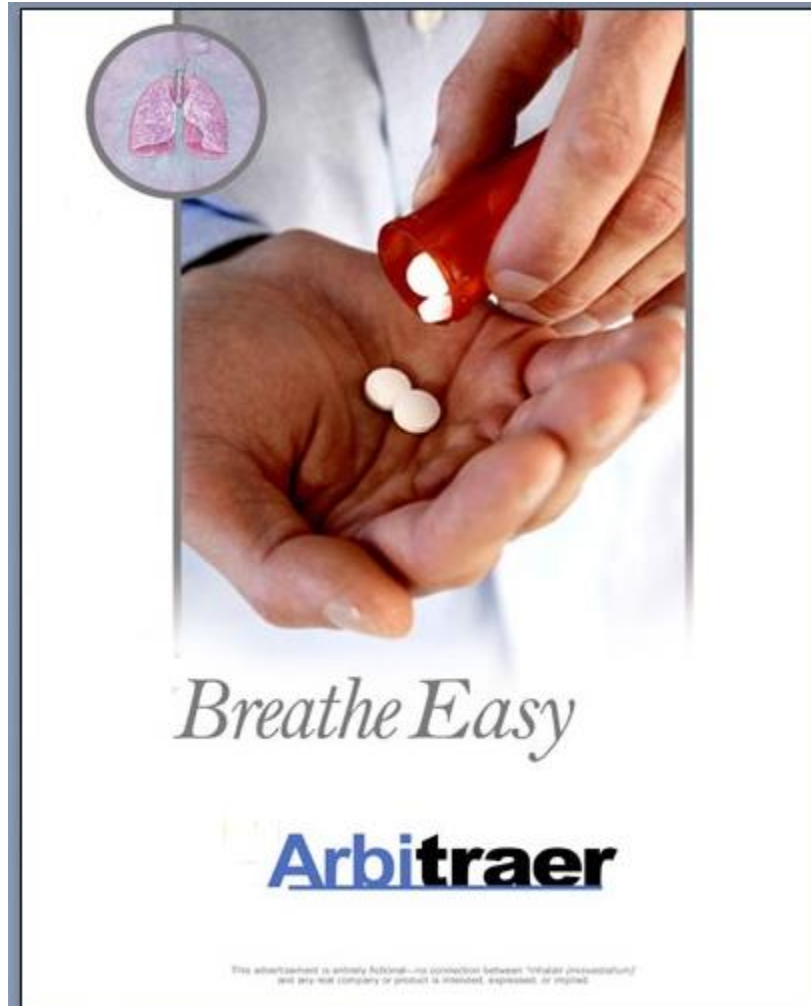
ACE
Pharmaceuticals

Side effects include coughing and
headaches.

This advertisement is entirely fictional—no connection between "Arbitraer"
and any real company or product is intended, approved, or implied.

DTC – Print Reminder Ad – What’s Wrong?

- 3 errors -



DTC – Print – *Help Seeking* – What’s Wrong?

- At least 2 errors – How could you “fix”?

Runny Nose?
Sneezing?
Itchy, Watery
eyes?

You may be suffering from
Seasonal Allergies

There is help. There is Artbitraer.
Ask your healthcare provider to prescribe Artbitraer.

drug co. 800-555-5555

This advertisement is entirely fictional—no connection between Artbitraer (misspelled) and any real company or product is intended, expressed, or implied.

As a “Help Seeking”
Ad?

or

As a Product Ad?

DTC Ads – Telephone Drug Advertisements

Telephone Advertisements

- **Occur when you call the sponsor and they provide you with information that is not a reminder ad**
 - thus, is an “unintentional ad”
- **1999 Guidance on DTC Advertisements – discusses from an “adequate provision” basis**
 - Mailing info
 - Shifting to a recorded risks or reading the risks
- **Telephone communications -- will be discussed in greater detail later on Disseminating Information**

DTC Ads – Restricted Devices

DTC -- Devices

- **No guidances**
 - 2004 – draft guidance issued – but withdrawn in 9/2012
- **No separate statutory requirements such as 503B for drugs**
- **No regulatory duty to submit devices ads – distinguish 21 CFR 314.81 for drugs**
- **Much less common than with drugs**

DTC – “Help Seeking” and “Disease Awareness” Ads – Issues

Draft Guidance -- 2004

- "Help-Seeking" and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms *[Hot link]*
- If truly a disease communication claim, not subject to FDA jurisdiction

What's a Disease Awareness Communication?

- **Discusses disease or health condition**
- **If DTC**
 - advises audience to “see your doctor”
 - Should discourage self-diagnosis or treatment
- **If HCP-aimed, encourages HCP to know signs & symptoms of disease or provides info to aid in diagnosing disease**
- **Do NOT mention a specific drug or device**
- **Do NOT include any representation as to a specific drug or device (e.g., picture)**

When Might You Step Over The “Ad” Line?

- **“Bundling”** -- (my term) – a disease awareness ad with a reminder ad for a drug (that happens to treat the disease)
 - cited in 2004 Draft Guidance
 - “perceptual similarity” between ads can make worse
 - thematic, graphic, visual and other presentation elements
 - temporal or physical proximity
 - must be “perceptually distinct”

End of Part 2 – DTC Ads