

An Overview of Direct-to-Consumer Prescription Drug Promotion

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Risk Communication Advisory Committee
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DTC an Evergreen Issue

- May 8, 2008 Hearing
 - House Energy & Commerce Subcommittee on Oversight and Investigations
 - Testimony from researchers, AMA, GAO, Merck/Schering-Plough, Ortho Biotech, Pfizer
 - Web cast and prepared testimony at:
http://energycommerce.house.gov/cmte_mtgs/110-oi-hrg.050808.DTC.shtml

Regulatory Oversight

- Oversight of drug promotion is split
 - 1962 Kefauver-Harris amendments to Federal Food, Drug, and Cosmetic Act (FFDC Act)
 - agreement with Federal Trade Commission
- FTC has primary jurisdiction over OTC drug advertising
- FDA has primary jurisdiction over Rx drug labeling **and** advertising; also over OTC drug labeling

Background Facts - 1

- Until FDAAA, the FFDC Act did not distinguish between advertising to health care professionals and advertising to patients or consumers
- Currently, implementing regulations (21 CFR 202.1) do not distinguish between advertising to health care professionals and advertising to patients or consumers

That is, the underlying rules historically have been the same regardless of audience

Background Facts - 2

- Promotion directed toward consumers was never prohibited – practice changed
- FFDC Act generally prohibits any requirement for preclearance of advertising
 - except in “extraordinary circumstances”
- FFDC Act requires advertisements to include “information in brief summary” about product risks and benefits

Classes of Promotional Materials - 1

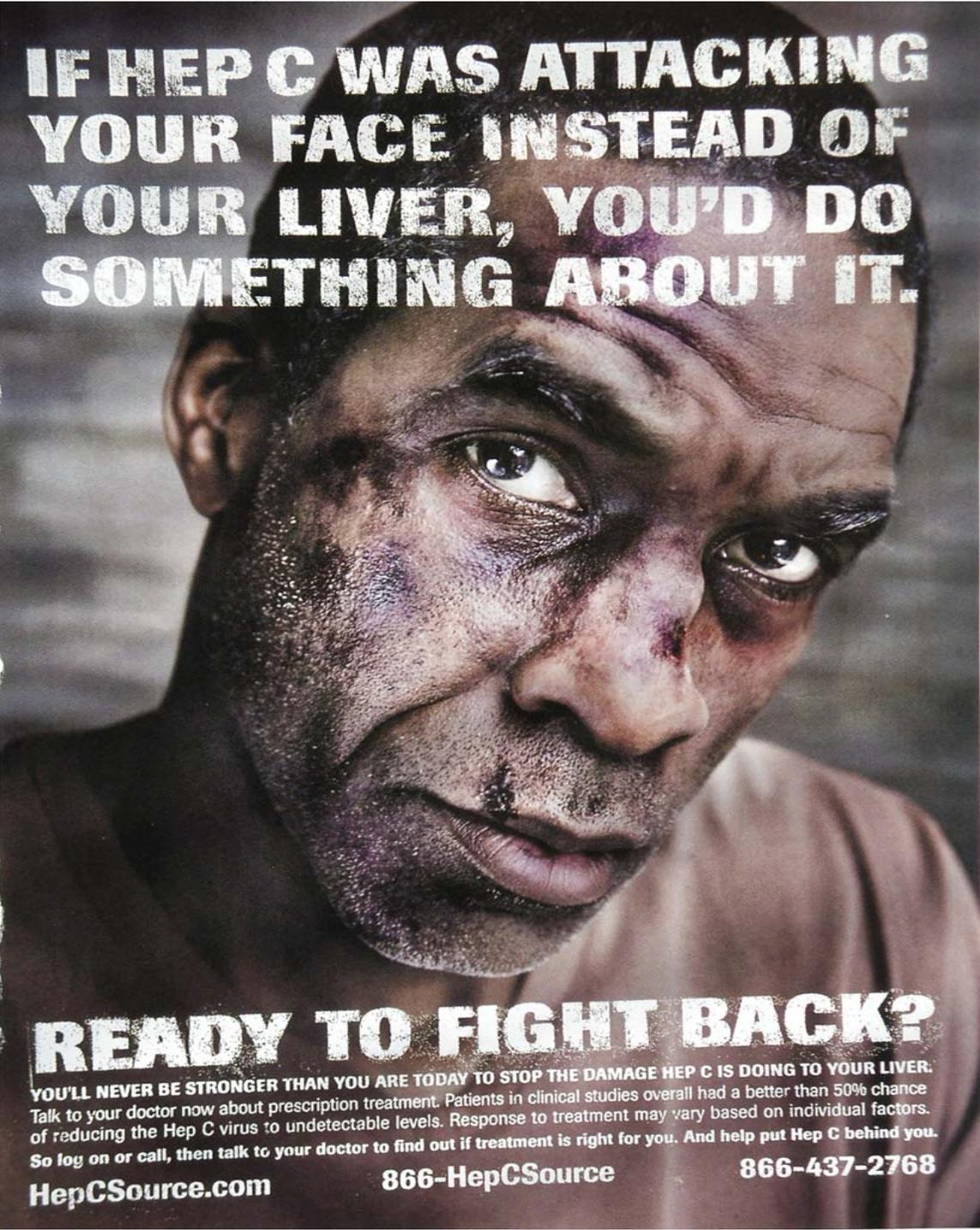
- Different classes of promotional materials
- Labeling (of the promotional variety)
 - brochures, mailing pieces, literature, detail aids, price lists, calendars, and "similar pieces of printed, audio, or visual matter descriptive of a drug," and references (e.g., PDR)

Classes of Promotional Materials - 2

- Advertisements
 - in journals, magazines, newspapers, other periodicals or through broadcast media (TV, radio, telephone communications systems)
- Different types of advertisements have different regulatory implications

Help-Seeking Advertisements

- "See your doctor," disease oriented
- **Not** drug ads
- If done properly, FDA does not regulate
 - regulated by Federal Trade Commission



**IF HEP C WAS ATTACKING
YOUR FACE INSTEAD OF
YOUR LIVER, YOU'D DO
SOMETHING ABOUT IT.**

READY TO FIGHT BACK?

YOU'LL NEVER BE STRONGER THAN YOU ARE TODAY TO STOP THE DAMAGE HEP C IS DOING TO YOUR LIVER.
Talk to your doctor now about prescription treatment. Patients in clinical studies overall had a better than 50% chance
of reducing the Hep C virus to undetectable levels. Response to treatment may vary based on individual factors.
So log on or call, then talk to your doctor to find out if treatment is right for you. And help put Hep C behind you.

HepCSource.com

866-HepCSource

866-437-2768

YOU'LL NEVER BE STRONGER THAN YOU ARE TODAY

- ↓ WHAT YOU NEED TO KNOW
- ↓ WHY YOU SHOULD GET TESTED
- ↓ THE IMPORTANCE OF TREATMENT
- ↓ RECOMMENDED RESOURCES



**GET
TREATED**

Think You Have Hep C?

Get tested! You owe it to yourself, your loved ones, your future.

Know You Have Hep C?

Prescription treatment can help reduce the hep C virus until it can't even be detected plus have a positive effect on the liver.

Physician Locator

Use our network of resources to find a specialist in your area.

Información en Español

Respuestas a sus preguntas sobre la hepatitis C



READY TO FIGHT BACK?

THE HEP C ACTION NEWSLETTER

Get hep C information you can use today—including details about hep C treatments and services.

This site is brought to you by **Roche Laboratories Inc.**, committed to hepatitis C research and **treatment**.



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Reminder Advertisements

- Regulations specifically exempt from disclosure requirements
- Focus on name(s) of product
 - designed to remind knowledgeable persons of existence of product
- No representations beyond dosage form and packaging, price information
- Not permitted for drugs with boxed warnings

The advertisement features three distinct scenes. In the top left, a man in a plaid shirt and hat pushes a wheelbarrow full of autumn leaves. In the top right, a man in a dark vest and light trousers walks across a small patch of grass. In the center, a woman wearing a straw hat, glasses, a yellow shirt, and blue overalls sits on a white picket fence. A golden retriever sits beside her, and a large bouquet of red roses is in the foreground.

NORVASC[®]
(amlodipine besylate)

For more information, please visit our
Web site at www.norvasc.com

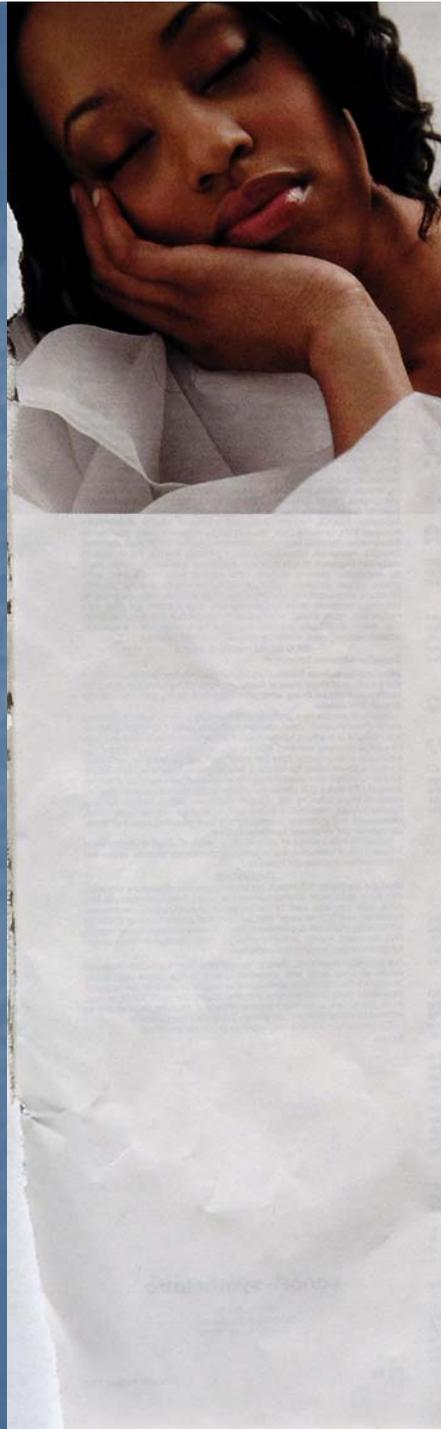
1447266 © 2003, Pfizer Inc.

Product Claim Advertisements

- Communicate benefits **and** risks
- Require
 - name(s) and amount of product in each unit
 - approved use (indication)
 - optionally, other **substantiated** claims
- Risk disclosure
 - requirements vary for print vs broadcast

Part of a product claim ad*

* "brief summary" not shown



The real Ambien® story: It shouldn't keep you up at night.

Recent news reports have focused on rare occurrences of sleepwalking and sleep-related eating in patients who may also be taking AMBIEN. But, it's important to know the facts.

AMBIEN prescribing information has always included these events, known collectively as somnambulism, as possible rare side effects. And, patients who experience certain sleep disorders already have an increased propensity to sleepwalk.

But the fact is that throughout the 14 billion nights of therapy worldwide provided by zolpidem, the active ingredient of AMBIEN, patient safety always has been and will continue to be of paramount importance to the makers of AMBIEN. So we want to remind you of these key safety tips:

- Take the exact dose of AMBIEN prescribed by your healthcare provider.
- Do not take AMBIEN for extended periods or with any other medicines without first talking to your healthcare provider.
- Always take AMBIEN immediately before you go to bed.
- Take AMBIEN only when you can get a full night's sleep before you need to be active again.
- Never take AMBIEN with alcohol.

Sleep well.

About AMBIEN® (zolpidem tartrate) CIV

AMBIEN is indicated for the short-term treatment of insomnia. There is a low occurrence of side effects associated with the short-term use of AMBIEN. The most commonly observed side effects in controlled clinical trials were drowsiness, dizziness and diarrhea. When you first start taking AMBIEN, use caution in the morning when engaging in activities requiring complete alertness until you know how you will react to this medication. In most instances, memory problems can be avoided if you take AMBIEN only when you are able to get a full night's sleep (7 to 8 hours) before you need to be active again. As with any sleep medication, do not use alcohol while you are taking AMBIEN. Prescription sleep aids are often taken for 7 to 10 days – or longer as advised by your doctor. All people taking sleep medicines have some risk of becoming dependent on the medicine.

For more information, talk to your doctor or visit www.FactsAboutAmbien.com

AMBIEN
[ZOLPIDEM TARTRATE] CIV
5 MG & 12.5 MG TABLETS

sanofi aventis
Because health matters

Please see brief summary on the adjacent page.

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Ad Content Requirements

- Can't be false or misleading
 - claimed uses must be consistent with drug labeling
 - claims must be substantiated
- Must present "fair balance" between benefits and risk information
- Can't omit "material" facts

Plain language meaning: Ads must communicate an accurate and balanced picture of the product

Risk Disclosure Depends on Whether Ad or Labeling

- Regulatory distinctions have implications
- Advertisements vs. Labeling
 - “brief summary” vs. full package insert
- Print vs. Broadcast ads
 - generally, print ads require **all** product risks
 - but, 2004 draft guidance offers alternatives

Risk Disclosure Draft Guidance

- Encourages using
 - approved patient “package inserts” or Medication Guides (both labeling written for patients) or
 - translation of new “highlights” section of physician labeling into consumer-friendly language

Example: Use of Medication Guide*

*Type of approved patient labeling

IMPORTANT INFORMATION

WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT VYVANSE?

Vyvanse is a stimulant medicine. The following have been reported with use of stimulant medicines.

1. Heart-related problems:

- sudden death in patients who have heart problems or heart defects
- strokes and heart attack in adults
- increased blood pressure and heart rate

Tell your doctor if you or your child has any heart problems, heart defects, high blood pressure, or a family history of these problems.

Your doctor should check you or your child carefully for heart problems before starting Vyvanse.

Your doctor should check you or your child's blood pressure and heart rate regularly during treatment with Vyvanse.

Call your doctor right away if you or your child has any signs of heart problems such as chest pain, shortness of breath, or lightheaded while taking Vyvanse.

2. Mental (psychiatric) problems:

- new or worse behavior and thought problems
- new or worse aggressive behavior or hostility
- new psychotic symptoms (such as hearing voices, believing things that are not true, or suspicious) or new manic symptoms

Tell your doctor about any mental problems you or your child has, or about a family history of mania, bipolar illness, or depression.

Call your doctor right away if you or your child has any new or worsening mental symptoms or problems while taking Vyvanse, especially seeing or hearing things that are not real, believing things that are not real, or are suspicious.

WHAT IS VYVANSE?

Vyvanse is a central nervous system stimulant prescription medicine. It is used for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD). Vyvanse may help increase attention and decrease impulsiveness and hyperactivity in patients with ADHD. Vyvanse should be used as part of a total treatment program for ADHD that may include counseling or other therapies.

Vyvanse is a federally controlled substance (CII) because it can be abused or lead to dependence. Keep Vyvanse in a safe place to prevent misuse and abuse. Selling or giving away Vyvanse may harm others, and is against the law. Tell your doctor if you or your child has (or has a family history of) ever abused or been dependent on alcohol, prescription medicines or street drugs.

WHO SHOULD NOT TAKE VYVANSE?

Vyvanse should not be taken if you or your child:

- has heart disease or hardening of the arteries
- has moderate to severe high blood pressure
- has hyperthyroidism
- has an eye problem called glaucoma
- is very anxious, tense, or agitated
- has a history of drug abuse
- is taking or has taken within the past 14 days an antidepressant medicine called a monoamine oxidase inhibitor or MAOI.

• is sensitive to, allergic to, or had a reaction to other stimulant medicines.

Vyvanse has not been studied in children less than 6 years old.

Vyvanse is not recommended for use in children less than 3 years old.

Vyvanse may not be right for you or your child. Before starting Vyvanse tell your or your child's doctor about all health conditions (or a family history of) including:

- heart problems, heart defects, high blood pressure
- mental problems including psychosis, mania, bipolar illness, or depression
- eye or thyroid's problems
- eye or kidney problems
- thyroid problems
- seizures or have had an abnormal brain wave test (EEG)

Tell your doctor if you or your child is pregnant, planning to become pregnant, or breastfeeding.

CAN VYVANSE BE TAKEN WITH OTHER MEDICINES?

Tell your doctor about all of the medicines that you or your child takes including prescription and nonprescription medicines, vitamins, and herbal supplements. Vyvanse and some medicines may interact with each other and cause serious side effects.

Sometimes the doses of other medicines will need to be adjusted while taking Vyvanse. Your doctor will decide whether Vyvanse can be taken with other medicines.

Especially tell your doctor if you or your child takes:

- antidepressant medicines including MAOIs
- antipsychotic medicines
- lithium
- blood pressure medicines
- seizure medicines
- narcotic pain medicines



Keep the medicines that you or your child takes. Keep a list of your medicines with you to show your doctor and pharmacist.

Do not start any new medicine while taking Vyvanse without talking to your doctor first.

HOW SHOULD VYVANSE BE TAKEN?

- Take Vyvanse exactly as prescribed. Vyvanse comes in 3 different strength capsules. Your doctor may adjust the dose until it is right for you or your child.
- Take Vyvanse once a day in the morning.
- Vyvanse can be taken with or without food.
- From time to time, your doctor may stop Vyvanse treatment for awhile to check ADHD symptoms.
- Your doctor may do regular checks of the blood, heart, and blood pressure while taking Vyvanse. Children should have their height and weight checked often while taking Vyvanse. Vyvanse treatment may be stopped if a problem is found during these check-ups.
- If you or your child takes too much Vyvanse or overdose, call your doctor or poison control center right away, or get emergency treatment.

WHAT ARE POSSIBLE SIDE EFFECTS OF VYVANSE?

See "What is the most important information I should know about Vyvanse?" for information on reported heart and mental problems.

Other serious side effects include:

- slowing of growth (height and weight) in children
- seizures, mainly in patients with a history of seizures
- eyesight changes or blurred vision

Common side effects include:

- upper belly pain
- decreased appetite
- dryness
- dry mouth
- irritability
- trouble sleeping
- nausea
- sweating
- weight loss

Vyvanse may affect your or your child's ability to drive or do other dangerous activities.

Talk to your doctor if you or your child has side effects that are bothersome or do not go away.

This is not a complete list of possible side effects. Ask your doctor or pharmacist for more information.

HOW SHOULD I STORE VYVANSE?

- Store Vyvanse in a safe place at room temperature, 59 to 86° F (15 to 30° C). Protect from light.
- Keep Vyvanse and all medicines out of the reach of children.

GENERAL INFORMATION ABOUT VYVANSE

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Vyvanse for a condition for which it was not prescribed. Do not give Vyvanse to other people, even if they have the same condition. It may harm them and it is against the law.

This Medication Guide summarizes the most important information about Vyvanse. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about Vyvanse that was written for healthcare professionals. For more information about Vyvanse, please contact Shire US, Inc. at 1-800-628-0386 or visit www.Vyvanse.com.

WHAT ARE THE INGREDIENTS IN VYVANSE?

Active ingredient: lisdexamfetamine dimesylate

Inactive ingredients: microcrystalline cellulose, croscarmellose sodium, and magnesium stearate. The capsule shells contain glycerin, titanium dioxide, and one or more of the following: D&C Red #28, D&C Yellow #10, FD&C Blue #1 and FD&C red #40.

NEED INFORMATION OR HAVE A QUESTION?

This is only a summary of important information. Ask your doctor or pharmacist for complete product information. Go to www.Vyvanse.com, or call 1-800-628-0386.

Manufactured for: Shire US Inc., Wayne, PA 19087. Made in USA.

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This Medication Guide has been approved by the U.S. Food and Drug Administration. 02/07 L34853

What About Broadcast Ads?

- Defined as ads in television, radio, and over telephone communication systems
- Changing broadcast environment changed interpretation of "adequate provision" requirement
 - to give access to approved package insert
- 1999 guidance provided interpretation

Broadcast Risk Disclosure

- Required risk disclosure is
 - all the risks OR
 - the major risks (“major statement”) plus access to approved labeling (“adequate provision”)
- Need to reach diverse audience
 - reference to health care provider
 - print ads/brochures
 - telephone contact number
 - internet site

Enforcement Options

- Letters noting violations
 - no regulatory “clout”
 - high level of voluntary compliance
- Warning Letters
 - regulatory clout
 - prelude to more serious action
 - generally request corrective action
- Seizure, injunction, prosecution
 - threat may result in voluntary consent decree