

Keeping Watch Over Direct-to-Consumer Ads



An anyone who watches TV in the United States is probably familiar with “direct-to-consumer” (DTC) advertising for prescription drugs.

Provided by drug companies, these ads are aimed at a general audience, and not at health care professionals such as doctors, nurses, and pharmacists. The ads are broadcast on TV and radio, and published in magazines and newspapers. They also appear online.

DTC advertising often features celebrity spokespeople, computer generated characters, or actors portraying happy and satisfied patients.

A standout trait of these ads on TV is the narrated list of a drug’s potential side effects. This list is required. Prescription drug makers must provide risk information in any promotion that qualifies as a product-claim advertisement.

Ensuring Balance and Accuracy

The United States is one of the few places in the world that allow DTC advertising. (New Zealand is the only other developed nation that does.)

FDA oversees prescription drug advertising with the Federal Food, Drug, and Cosmetic Act and related regulations.

Through its Division of Drug Marketing, Advertising, and Communications (DDMAC), FDA ensures that all prescription drug promotion provided by drug firms is truthful, balanced, and accurately communicated.

Part of FDA’s Center for Drug Evaluation and Research (CDER), DDMAC

recently hired 12 new reviewers to help evaluate promotional pieces submitted to the agency. With these additional staffers, the division has 28 primary reviewers.

What DTC Advertisers Must Provide

Drug companies are generally required to include all of a drug’s risk information in a product claim ad.

In print ads, this is usually done in a section called the “Brief Summary.” Despite its title, this summary would take many minutes to read or scroll down a TV screen. This is where the long list of side effects in the TV ads comes into play.

Broadcast ads are allowed to include only the most important risk information—as long as the ads tell viewers or listeners how to get the full FDA-approved prescribing information, which describes all of the drug’s risks.

These broadcast ads must give a number of sources that can provide a drug’s prescribing information. These sources 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
- a Web site address

Types of DTC Ads

DTC advertisements come in three forms.

- **Product claim ads:** These name a drug and the condition it treats, and talk about both its benefits and risks.
- **Reminder ads:** They 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.

A Topic of Debate

While DTC advertising has many supporters, it raises concerns for many people.

Proponents say that the ads

- provide useful information to consumers that may result in better health
- can advance public health by encouraging more people to talk with health care professionals about problems, particularly undertreated conditions such as high blood pressure and high cholesterol
- can help remove the stigma associated with diseases that in the past were rarely openly discussed (including erectile dysfunction and depression)
- can remind patients to get their prescriptions refilled and help them adhere to their medication regimens

However, many people are concerned that such promotion

- may contain false or misleading information
- does not provide enough information about the risks and negative effects of the advertised drugs
- may not advance—and may even threaten—the public health
- encourages overuse of prescription drugs
- encourages use of the most costly treatments, instead of less expensive treatments that would be just as satisfactory

FDA's Role

FDA encourages companies that offer DTC advertising to include accurate information in their ads. Through a comprehensive surveillance and enforcement program, the agency ensures that consumers are not misled or deceived by advertisements that violate the law.

New Online Guide for Consumers

FDA recently launched a new Web site: "Be Smart About Prescription Drug Advertising, A Guide for Consumers."

The site is designed to educate consumers about how to view direct to consumer (DTC) advertising, prepare them for discussions with health care providers, and help improve patient understanding and medical care.

The site includes these tips:

- Your health care provider is the best source of information about the right medicines for you.
- Prescription drug advertisements can provide useful information for consumers to work with their health care providers to make wise decisions about treatment.
- If you think a prescription drug ad violates the law, contact FDA's Division of Drug Marketing, Advertising, and Communications (DDMAC).


The online guide also provides the following:

- Interactive example ads – The guide offers example ads for fictitious drugs to illustrate the different requirements for different types of ads. This helps users learn in both a visual and written manner.
- A list of questions to ask – Consumers can print out a list of questions they should ask themselves when they see a prescription drug ad. This can help discussions with their health care providers.
- A site-specific survey – Users can answer the survey by clicking on the "Give us Feedback" tab. This is an opportunity to give FDA feedback about how well the site addresses users' needs.

The Web page also offers information on "The Basics" of drug ads and a question-and-answer section.

Visit "Be Smart About Prescription Drug Advertising, A Guide for Consumers" at www.fda.gov/cder/ethicad/

Much of FDA's compliance and enforcement activity in regard to this type of advertising is focused on ensuring that companies don't minimize the risks of the drug in the ad or overstate its benefits.

In addition, FDA advances and encourages better communication of labeling and promotional information to health professionals and to consumers. 

This article appears on FDA's Consumer Health Information Web page (www.fda.gov/consumer), which

features the latest updates on FDA-regulated products. Sign up for free e-mail subscriptions at www.fda.gov/consumer/consumerenews.html.

For More Information

FDA Division of Drug Marketing, Advertising, and Communications
www.fda.gov/cder/ddmac/

Be Smart About Prescription Drug Advertising, A Guide for Consumers
www.fda.gov/cder/ethicad/background.htm