Chapter

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What are the rules for promoting medications to consumers in the U.S.?

The U.S. and New Zealand are the only two countries that allow the direct-to-consumer (DTC) advertising of prescription medications. The promotion of over-the-counter (OTC) products and dietary supplements to consumers is allowed in this country and in other countries.

The rules and regulations in the U.S. for DTC advertising are different for prescription medicines, OTC drugs, and dietary supplements. The rules are also somewhat different for print and broadcast promotions.

What are the current regulations?

Two federal agencies are responsible for overseeing this promotion, and these agencies use different standards to distinguish truthful advertising from false or misleading advertising. These agencies are the FDA and the Federal Trade Commission (FTC).

The regulation of advertising, including drug advertising, must not violate the First Amendment right of free speech guaranteed by the U.S. Constitution. The concept of First Amendment protection for religious and political speech is well recognized. The Supreme Court has ruled that truthful commercial speech such as advertising, as long as it is not false or misleading, also is entitled to protection under the Constitution.

Public safety is the primary reason for regulatory restrictions on medication promotion. Drug advertising that overemphasizes product benefits and downplays the medication's potential harms may present a significant public health concern.

The regulations for prescription drug advertising require ads to contain "fair balance" information, whether for DTC promotions or ads targeting the medical professions. In the past, this meant that print ads would have to appear with the text of a drug's professional product labeling, or a brief summary of the professional label. This essentially prohibited television or radio advertising of medications to consumers because all the label information would have to be read on the radio or appear on the TV screen.

In the late 1990s, the FDA opened the door for DTC television and radio broadcast advertising by allowing the use of a "major statement" of


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medication risks instead of the professional product label. The advertisement, either print or broadcast, has to direct the consumer to a medication's professional product label printed in a magazine or manufacturer's Web site.

From the consumers' perspective, the problem with the current interpretation of the regulations is that professional product labels are not written for them. This information is written in dense technical jargon in small type, and it assumes the reader is a health professional. The FDA has never written regulations directly addressing DTC prescription medication advertising. Instead, the agency has applied the regulations that govern direct-to-professional advertising to DTC advertising.

The regulatory oversight of OTC medication promotion is the responsibility of the FTC. The FTC standards for OTC drug promotion require advertising to be truthful and non-deceptive, require the advertiser to have evidence to back up their claims, and require that the ads cannot be unfair. The evidence standard requires "competent and reliable scientific evidence." The FDA's standard for "substantial evidence" is technically and legally much stricter.

What is the FDA's role?

The FDA is responsible for overseeing all prescription medication advertising in the U.S. This regulatory responsibility resides with the FDA's Division of Drug Marketing, Advertising, and Communications (DDMAC). This small organization operates with limited resources but has the enormous task of ensuring truthful, balanced and accurate communication of prescription medication information and advertising.

DDMAC regulates all print and broadcast prescription medication advertising targeting both consumers and health professionals. When DDMAC finds that a company is distributing false or misleading advertising in violation of laws and regulations, a Notice of Violation or Warning Letter may be issued to that company. These notices can be found on the FDA's Web site, at www.fda.gov/ICECI/enforcementactions/warningletters/default.htm.

In cases of repeated advertising violations, DDMAC can require companies to distribute correctional advertisements, though this option is rarely used. Newly enacted legislation will give DDMAC the authority to review DTC ads prior to their dissemination to ensure accuracy and fair balance.

What is the argument for and against DTC advertising?

Before discussing the pros and cons of DTC advertising, it must be noted that DTC advertising should not be analyzed in isolation. DTC and direct-to-professional promotions are two parts of a carefully planned marketing strategy for prescription medications.

One of the main arguments for DTC advertising is that it is educational for consumers. Proponents of DTC prescription medication advertising, primarily pharmaceutical manufacturers, maintain that medication advertising gives consumers the information they need to make informed decisions about their treatment options.

Another argument put forth by those in favor of DTC advertising is that it drives consumers to consult their physicians with questions about the advertised medications. It is argued that previously undetected health problems may be found at these appointments.

Opponents of DTC advertising argue that an important educational message about the safety and effectiveness of prescription medications can not be communicated in a 30- or 60-second television or radio advertisement. The dictionary defines the purpose of advertising as calling attention to a product by emphasizing its desirable qualities and to arouse a desire to buy the product.

In the view of opponents, the sole purpose of DTC advertising is to sell. Advertising is one-sided and does not allow for fully informed decisions about medications. This risks needless adverse drug reactions and substantial economic harm to individuals and the health-care system because costly medications may be prescribed when less expensive, safer, and more effective alternatives are available.

What is the experience?

DCT advertising has been a remarkable economic success for the pharmaceutical industry. The top four most frequently prescribed prescription drugs in the U.S. in 2007 also were among the top drugs in terms of spending on DTC advertising: atorvastatin (Lipitor), montelukast (Singulair), escitalopram (Lexapro) and esomeprazole (Nexium). They accounted for sales approaching $16 billion in 2007.

The power of advertising is evident from noting that atorvastatin is a cholesterol-lowering statin drug. There is now a less-expensive generic version of simvastatin (Zocor) available to lower cholesterol. The biggest market for Singulair is to treat hayfever, but it may be less effective for this use than OTC loratadine (Claritin). Escitalopram, an antidepressant, and esomeprazole, used for stomach acid reflux, have the same chemical structures as older drugs citalopram (Celexa), and OTC omeprazole (Prilosec), respectively.

A 2002 survey by the American Association for Retired People of 1,250 persons age 45 or older reported that 91 percent had seen a commercial ad for a medication on TV. Of them, 19 percent subsequently asked for the advertised medication, and 11 percent had received a prescription.

DTC advertising has grown from slightly less than $1 billion in 1996 to over $4 billion spent in 2005. DTC advertising is a very good investment

for manufacturers. Every dollar spent on DTC advertising results in a sales increase of as much as $6, according to a Congressional estimate.

Many of the most heavily advertised medications may not be that important therapeutically. COX-2 drugs including rofecoxib (Vioxx), valdecoxib (Bextra), and celecoxib (Celebrex) were heavily promoted as safer drugs for arthritis and pain with a lower risk of GI tract toxicity, ulcers and hemorrhage than older drugs known as non-steroidal anti-inflammatory drugs (NSAIDs). Rofecoxib and valdecoxib were removed from the market because of unacceptable heart risks. A national survey of COX-2 prescribing found 63 percent of the growth in the use of these drugs was in patients who could have used older, less expensive NSAIDs.

Key messages

- ✓ Promotion of prescription medications is regulated.
- ✓ DTC advertising generates strong patient demand, which physicians have difficulty controlling.
- ✓ DTC advertising appears to increase the sale of newer, more costly medications when less expensive, equally effective older drugs are available.
- ✓ The U.S. is one of just two countries in the world which allow DTC advertising of prescription medications.
- ✓ Promotion of OTC medications is less restricted than promotion of prescription medications.