Drug Industry DTC Ad Guidelines Draw Criticism

BY JOYCE FRIEDEN
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New voluntary guidelines for direct-to-consumer prescription drug advertising released by the Pharmaceutical Research and Manufacturers of America have drawn criticism from politicians and consumer groups who say they don't go far enough.

"While I wish the PhRMA guidelines would have gone farther and proposed a moratorium on DTC [direct to consumer] advertising of newly approved drugs, I hope individual pharmaceutical manufacturers will seriously consider such a measure," Senate Majority Leader Bill Frist, M.D. (R-Tenn.) said in a statement. Sidney Wolfe, M.D., director of the Public Citizen Health Research Group, called the PhRMA announcement "a meaningless attempt to fool people into believing the guidelines are stronger than they really are."

The guidelines were released in Dallas in early August at a meeting of the American Legislative Exchange Council.

Among other things, the guidelines call for pharmaceutical manufacturers to educate physicians and other health care providers about new drugs before advertising them to consumers.

"The centerpiece is the notion that the companies are committing an appropriate amount of time to educate health care professionals about new medications and new indications … to make sure physicians and other providers know about the medicines and benefits before," direct-to-consumer advertising campaigns are undertaken, Billy Tauzin, CEO of PhRMA and a former congressman from Louisiana, said at a press conference sponsored by PhRMA.

The length of time the companies will take to educate physicians will depend on several factors, including whether the drug is a life-saving one and how complex the risk-benefit profile is, Mr. Tauzin said. "We are also committed to continuing to educate health care professionals as additional info about a medication is obtained from all sources, even after medication has begun being marketed."

Other provisions of the voluntary guidelines, which 23 companies have signed onto, include:

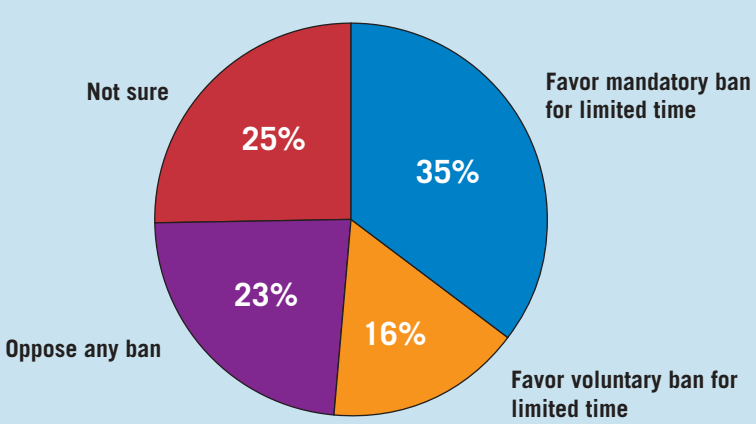
- ▶ DTC ads should be balanced, and discuss both the benefits and the risks of the medication. The information in the ads should be presented in "clear, understandable language, without distraction from the content."
- ▶ Ads should be targeted to avoid audiences that are not age-appropriate. For example, Karen Katen, president of Pfizer Human Health, said that her company would not run a television advertisement for Viagra (sildenafil) during the Super Bowl, when young children may be watching.
- ▶ Companies should submit new DTC print and television advertisements to the FDA before releasing them. PhRMA board chair Bill Weldon said this does not mean that companies would submit an ad to the FDA on Tuesday and then run it on Wednesday. "The intent is to make sure that FDA has been able to comment on any programs prior to advertising," said Mr. Weldon, who is also chairman and CEO of Johnson & Johnson.
- ▶ Ads that identify a product by name should include the product's indications as well as its risks and benefits. This means no more ads that just give the name of the medication and tell what it's for, Mr. Tauzin said.

PhRMA also will convene an independent board in about a year to get outside opinion on whether the companies are following the guidelines. The panel will include experts in health care, broadcasting, and other relevant disciplines. The panel's report "will be made public, and also made available to the FDA," Mr. Tauzin said. ■

The voluntary guidelines are available at www.phrma.org/publications/policy//admin/2005-08-02.1194.pdf.

DATA WATCH

Most People Support Restrictions on Direct-to-Consumer Advertising of New Drugs



Note: Based on a nationwide survey of 2,207 adults conducted July 6-8, 2005.
Percentages do not add to 100% because of rounding.
Source: The Wall Street Journal Online/Harris Interactive

KEVIN FOLEY, RESEARCH

POLICY & PRACTICE

Merck Loses First Vioxx Lawsuit

A jury in Texas last month awarded $253 million to the widow of a man who died after taking Vioxx (rofecoxib). The plaintiff charged that the drug maker Merck & Co. failed to warn physicians about the danger posed by Vioxx, that the drug was improperly designed, and that the company's negligence caused the death of the plaintiff's husband, Robert Ernst. Merck executives plan to appeal the verdict on the grounds that the jury was allowed to hear testimony that was both irrelevant and not based on reliable science, the company said. "While we are disappointed with the verdict, this decision should be put in its appropriate context," Kenneth C. Frazier, Merck's senior vice president and general counsel, said in a statement. "This is the first of many trials. Each case has a different set of facts. Regardless of the outcome in this single case, the fact remains that plaintiffs have a significant legal burden in proving causation." The award included $24 million in actual damages and $229 million in punitive damages. But the punitive damages could be reduced to about $2 million, according to Merck, since punitive damages are limited under Texas law.

Drug Acquisition Program Delay

Physicians who plan to participate in the Medicare Competitive Acquisition Program (CAP) for Part B Drugs and Biologicals will have to wait an extra 6 months for the launch of the program. Under CAP, as currently envisioned by Medicare, physicians would obtain drugs from a vendor and the vendor would be responsible for billing Medicare and collecting coinsurance or deductibles from patients. Officials at the Centers for Medicare and Medicaid Services announced last month that the agency is suspending the current CAP vendor bidding process. The bids had been scheduled to be due Aug. 5, but CMS officials are putting that process on hold to "more fully review public comments" and make clarifications to the bidding process. CMS officials expect to publish a final rule on CAP in late 2005, and bidding will open for all vendors again after the rule is published. If everything proceeds on schedule, drugs could be first delivered under the program by July 2006.

SEGRA Development Partnership

AstraZeneca and Schering AG are partnering for research and development in the area of Selective Glucocorticoid Receptor Agonists (SEGRAs). The two companies are planning to collaborate until the end of phase I clinical trials aimed at identifying novel SEGRAs. The 3-year agreement gives AstraZeneca an exclusive, worldwide license to develop and market compounds for rheumatoid and respiratory diseases. Schering AG, which has an advanced collection of identified SEGRAs, will have the exclusive, worldwide license for all other indications. Schering will also receive upfront fees, with both companies retaining rights to future payments and royalties. The full financial terms of the agreement were not made public.

Bones 101

The U.S. Bone and Joint Decade, an organization aimed at increasing awareness of musculoskeletal conditions, is launching a pilot project this fall on bone health and osteoporosis education. The program will include 1-hour educational sessions aimed at men and women in their mid-50s and 60s, to be held at public libraries and health clubs in at least six locations around the United States. Appropriately, the program's working title is "Fit to a T," as in the T scores commonly used to gauge a person's bone density and susceptibility to fragility fracture. Participants will learn how to discuss their bone health with their physician and also how to assess their living environment for falling risk.

Spine Care Recognition

The National Committee for Quality Assurance (NCQA) is planning to launch a new physician recognition program late next year that will focus on quality care for patients with chronic back pain. The diagnosis and treatment of back pain are highly variable in the United States. While some patients never receive standard interventions, others undergo unnecessary diagnostic imaging and surgery, according to the NCQA. The organization has already convened a 15-member spine care advisory committee charged with providing advice on appropriate, evidence-based performance measures. The committee is made up of clinical researchers from different specialty areas, employers, health plans, and disability insurers. "In many cases, back pain is treated with unnecessary surgery that still leaves the patient in pain," NCQA President Margaret E. O'Kane said in a statement. "This program will steer people to doctors who not only know how to diagnose back problems, but who also explain the pros and cons of treatment options, help them manage their condition and get well again."

Clinician's Guide to Alcoholism

Physicians have a new tool to help them identify and care for patients with heavy drinking and alcohol use disorders, About 3 in 10 U.S. adults drink at levels that increase their risk for physical, mental health, and social problems; of these heavy drinkers, about 1 in 4 currently has alcohol dependence problems that often go undetected in medical and mental health care settings. The National Institute on Alcohol Abuse and Alcoholism recently released a new guide called "Helping Patients Who Drink Too Much: A Clinician's Guide," which offers guidance for conducting brief interventions and managing patient care. If a patient drinks heavily (five or more drinks in a day for men or four or more for women), the guide shows physicians how to look for symptoms of alcohol abuse or dependence. The guide is at www.niaaa.nih.gov.

—Mary Ellen Schneider