Pharmaceutical Industry's Ad Guidelines Draw Fire

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 further 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 August at an American Legislative Exchange Council meeting in Dallas. They call for pharmaceutical manufacturers to educate physicians and other health care providers about new drugs before advertising them to consumers.

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DR. FRIST

"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.

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

▶ DTC ads should be balanced, and discuss both the benefits and risks of the medication. The information 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.

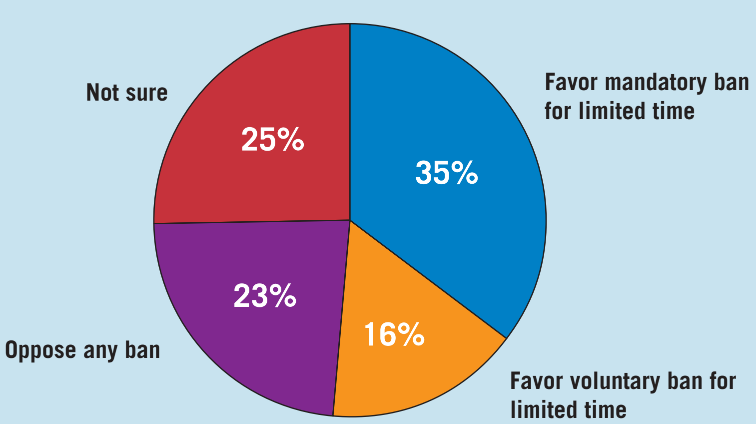
▶ Ads that identify a product by name should include the product's indications as well as its risks and benefits. This means no more ads that just give the name of the medication and tell what it's for, Mr. Tauzin said.

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 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

Psychiatric Residents Increasing

The number of psychiatric residents is increasing modestly, according to a resident census conducted by the American Psychiatric Association. As of Aug. 30, the total number of psychiatric residents had increased 1.6% over the previous year. U.S. medical graduates increased 4%, and women residents were up 5.5%, the census showed. Psychosomatic medicine, a new psychiatric subspecialty, had 60% female fellows. The top three most popular subspecialties were child and adolescent psychiatry, addiction psychiatry, and forensic psychiatry; all subspecialties had increasing numbers of fellows except for geriatric psychiatry. Geographically, the highest concentration of residents was in New York state, followed by California.

Data on Youth Suicide Attempts

About 900,000 children aged 12-17 planned to commit suicide during their worst or most recent episode of major depression, according to data from the Substance Abuse and Mental Health Services Administration. Of those who planned suicide, 712,000 attempted it. The report, which was compiled using data from the 2004 National Survey on Drug Use and Health, defined a "major depressive episode" as a period of at least 2 weeks in which a person experienced a depressed mood or loss of interest or pleasure in daily activities, and had at least five of nine symptoms of depression listed in the DSM-IV. "Suicide is a preventable tragedy," said Charles Curie, the SAMHSA administrator. "It is a thief that sets no boundaries and seeks victims of all ages."

Public Health Unpreparedness

Many local public health agencies are ill-prepared to learn about and respond to naturally occurring outbreaks of deadly infectious diseases or acts of bioterrorism, a test by the RAND Corporation has found. To conduct the test, researchers posed as local physicians who were reporting fictitious cases of botulism, anthrax, smallpox, bubonic plague, and other diseases to 19 public health agencies in 18 states nationwide. (Agency directors agreed in advance to participate in the test, but did not tell their staff members.) In one case, after listening to a description of the classic symptoms of bubonic plague, a public health worker advised the caller not to worry because no similar cases had been reported. Another caller who reported a botulism case was told: "You're right; it does sound like botulism. I wouldn't worry too much if I were you." The article appears in the Aug. 30 online edition of Health Affairs.

Drug Abuse Counseling Protocol

SAMHSA has issued a new Treatment Improvement Protocol designed to help substance abuse counselors working with clients in the criminal justice system. The guidelines, known as TIP 44, provide information on screening, assessments, treatment services, and follow-up services for people in various criminal justice settings. For example, they note that in the pretrial setting, treatment professionals need to be careful not to coerce clients into waiving due process rights. The guidelines also explain that in-prison drug abuse treatment followed by community-based continuing care has been credited with reducing short-term recidivism and relapse rates. The guidelines are available online at www.samhsa.gov/news/newsreleases/TIP%2044-CJA.pdf.

Part B Premiums on the Rise

Medicare Part B monthly premiums will be $88.50 in 2006, an increase of $10.30 from the current $78.20 premium, the Centers for Medicare and Medicaid Services reported. The agency cited continued rapid growth in the intensity and use of Part B services as the main reason for the increase. "This growth is seen in physician office visits, lab tests, minor procedures, and physician-administered drugs. It also includes rapid growth in hospital outpatient services," CMS said in a statement. They also said that "part of the premium increase is necessary to increase assets that, for accounting purposes, are held in the Part B trust fund." Though premiums are rising, most Medicare beneficiaries will see significantly lower out-of-pocket health care costs in 2006 because of the savings in drug costs from the new Medicare prescription drug benefit, the agency contends.

Employer Health Coverage Declines

The percentage of businesses offering health insurance to employees has declined over the past 5 years as the cost of providing insurance benefits outpaces inflation and wage growth, according to the 2005 Annual Employer Health Benefits Survey released by the Kaiser Family Foundation and Health Research and Educational Trust. The survey found that three of five firms (60%) offered coverage to workers in 2005, a decrease from 69% in 2000 and 66% in 2003. "The drop stems almost entirely from fewer small businesses offering health benefits, as nearly all businesses (98%) with 200 or more workers offer such benefits," the news release stated. The survey found that 20% of employers that offer health insurance currently provide a high-deductible health plan option. Very large companies—those with 5,000 or more employees—are significantly more likely than smaller ones to offer a high-deductible plan option, with 33% offering such an option in 2005. High-deductible health plans are defined in the survey as plans with at least a $1,000 deductible for single coverage or at least a $2,000 deductible for family coverage. In the meantime, relatively few workers are enrolled in "consumer-driven" plans, despite their growing availability.

—Joyce Frieden with staff reports