U.S. Drugmakers, Under Criticism, Set Voluntary Curbs on Ads

Aug. 2 (Bloomberg) -- Drugmakers will make a voluntary pledge today to comply with federal advertising rules to fend off threats by Congress to curb their annual $4.01 billion consumer marketing campaigns, an industry consultant said.

In an announcement in Dallas today, members of the Pharmaceutical Research and Manufacturers of America are likely to state that companies will strictly adhere to requirements that direct-to-consumer ads explicitly describe all of a drug's health risks. The companies also will agree only to make claims based on substantial scientific evidence as required by the Food and Drug Administration.

The public vow is part of a strategy by Billy Tauzin, the new head of the industry trade group and a former Louisiana congressman, to counter charges that the industry is spending too much money on advertising and pushing pills that have turned out to be dangerous.

"I am not expecting the PhRMA guidelines to go beyond what the FDA already requires," said Wayne Pine, a former FDA spokesman and drug marketing consultant with APCO Worldwide, a Washington-based consulting firm. In making a public pledge "the industry is clearly trying to deal with the comments made by members of Congress that direct-to-consumer advertising may have gone too far."

Television and print ads, for example, helped promote the wide use of Vioxx, a $2.5-billion-a-year seller before Merck & Co. withdrew the product drug in September, acknowledging that the prescription painkiller was associated with a risk of heart disease.

Free Drugs
Drugmakers increased spending on consumer advertising in the U.S. 22 percent last year to $4.01 billion, according to industry consultant IMS Health Inc.

In today's press conference announcing the voluntary guidelines the companies also will agree to publicize information about discounted and free drugs that drugmakers already offer to low-income patients, Pine said. The ads will promote a telephone hotline PhRMA recently created to advise people how to access the discount programs, he said.

The adoption of the guidelines and the agreement to promote the drug discount plans comes less than seven months after Tauzin took over the pharmaceutical industry group with the goal of changing the industry's image. He said in an interview July 25 that the new advertising guidelines are part of his new strategy.

"He is not only trying to put a better face on the industry," said Daniel Troy, a Sidley Austin Brown & Wood LLP partner, who resigned last year as FDA chief counsel, in a telephone interview. "He is trying to modify behavior."

Cancer Survivor
Tauzin said he has been telling chief executives that their companies must exhibit "social consciousness" to avoid increased regulation. Tauzin, 62, is a recent survivor of intestinal cancer. He said he is using that experience to persuade company CEOs to be more conscious of the needs of patients.

"This is an attitude that I am impressing on the board," Tauzin said in the interview. "They didn't hire me to take instructions. They hired me to lead them."

Tauzin had to get agreement from a board that includes leaders of three members of the Dow Jones Industrial Average, Pfizer Inc., Merck & Co. and Johnson & Johnson.

"The fact that he was able to bring a number of companies together in agreement on the principles is an enormous first step," said Brian Henry, a spokesman for New York-based Bristol-Myers Squibb Co.
The industry's voluntary guidelines also will call for making certain television ads "targeted for audience and age appropriateness," according to a tentative version posted July 21 on the trade group's Web site.

Pines, who has written several books on drug advertising to consumers, said in an interview July 29 that this language is a reference to the sexually suggestive ads for erectile dysfunction medicines, several of which attracted criticism when they ran during this past year's Super Bowl.

It's too soon to say whether the new language means the companies will end Super Bowl ads for impotence drugs, said Dan Collins a spokesman for Eli Lilly & Co., which jointly markets with Icos Corp. one of the medicines, Cialis.

Michal Fishman, a spokeswoman for Viagra marketer Pfizer Inc., said the company intends to comply with the guidelines. She could not say yet whether that would apply to Viagra ads during the Super Bowl.

Officials at Bayer AG, which sells Levitra, didn't return calls seeking comment.

The new guidelines are intended to counter complaints so that this kind of promotion can continue, said Jack Caufee, a researcher with the Washington-based American Enterprise Institute, a group dedicated to limited government, in a telephone interview.

Innocuous

"The principles look pretty innocuous," Caufee said. "They are things that the industry would have wanted to do anyway. The critics will jump in right away about what the guidelines don't address."

Senate Majority Leader Bill Frist on July 1 asked drugmakers for a voluntary moratorium on consumers advertising of medicines within their first two years on the market. Frist and others have said that a two-year delay would allow doctors to become more familiar with a new drug before patients, as a result of seeing ads, begin clamoring for the product.

"I look forward to reviewing the industry's complete and final recommendations and examining areas where improvements may be needed," said Frist, a Tennessee Republican who is also a heart surgeon, in a statement July 21.

GAO Report

Frist also said he still is waiting to see results of a study he requested on direct-to-consumer advertising of drugs from Congress's investigative arm, the Government Accountability Office.

So far only Bristol-Myers Squibb, maker of the Plavix heart drug, said it would delay direct-to-consumer advertising for the first 12 months after their introduction.

Senators Ron Wyden, an Oregon Democrat, and John Sununu, a New Hampshire Republican, in May introduced legislation that would increase payments back to the Medicaid program for drugs advertised directly to consumers. If enacted, the proposal would reduce profits for drugmakers from sales through one of the largest U.S. health insurers, the state and federal programs for the poor.

The FDA now regulates drug advertising by sending letters to companies, citing cases where the agency feels an ad doesn't include enough information on potential risks of a drug or exaggerates how effective a treatment is.

The FDA lost a 2002 Supreme Court case about an agency attempt to limit what pharmacies specializing in compounding drugs could tell their customers. The Washington Legal Foundation, a watchdog group for regulator agencies, has said repeatedly that this case shows how the First Amendment limits the FDA's ability to regulate drug advertising.

Only the U.S. and New Zealand allow drugmakers to promote medicines directly to consumers, said Boston University health policy professor Alan Sager.

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