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Drug industry issues ethics code for consumer advertising

By Thomas Ginsberg; INQUIRER STAFF WRITER

Under pressure from physicians and politicians, the pharmaceutical industry issued its first ethics code today for consumer advertising, including a vow to limit ads for conditions like sexual dysfunction.

The guidelines, however, are strictly voluntary and contain only vague self-enforcement mechanisms. They also lack explicit bans demanded by a variety of critics, including a call by Senate Majority Leader Bill Frist (R., Tenn.) for a moratorium on advertising a drug for two years after it is launched.

As a result it was unclear whether the code would meet its primary goal: preempting Congressional legislation to tighten control over the \$4 billion drug-ad business, long criticized by health groups.

There was no immediate reaction from Frist or other drug-industry critics, including Sen. Charles Grassley (R., Iowa) and Sen. Edward Kennedy (D., Mass.).

Sidney Wolfe, director of health research at the advocacy group Public Citizen, said in a statement that the "guidelines are a meaningless attempt to fool people into believing the guidelines are stronger than they really are."

Doug Wood, a Washington-based attorney specializing in pharmaceutical advertising, said political pressure has grown so intense that forestalling legislation may require a "real change in behavior in the marketplace," not just a set of guidelines.

Still, the guidelines may represent a small victory for the industry which, until now, had failed to persuade its members to adopt a single code for advertising.

The pharmaceutical industry spent an estimated \$4 billion last year on direct-to-consumer advertising, known as DTC, according to TNS Media Intelligence, a monitoring group.

The huge DTC expenditure has also been a windfall for the advertising industry, which in turn has become a powerful ally of the drug industry on Capitol Hill, according to Wood, chairman of the Global Advertising Lawyers Alliance, a trade group.

The push for DTC restrictions grew last year after safety scandals involving antidepressants and pain-relievers, in particular Merck & Co. Inc.'s recall of Vioxx, one of the most heavily advertised drugs of all time. The Food and Drug Administration has stepped up scrutiny of ads but it can only request, not compel, companies to change their ads.

In its announcement, the industry's leading U.S. trade group, the Pharmaceutical Research Manufacturers of America, said companies can become "signatories" to the principles by promising publicly to follow them.

Among the principles, signatory companies should pick the timing or placement of ads "to avoid audiences that are not age-appropriate for the messages involved." It says companies should try to limit adult-oriented ads to TV programs or publications whose audience is at least 80 percent adult.

The provision refers to ads for erectile dysfunction drugs like Viagra and Cialis. At least one legislator, Rep. James Moran (D., Va.) has introduced a bill to ban such TV ads from 6 a.m. to 10 p.m. Instead of a ban, the group leaves discretion to individual companies.

The group also said a drug company "should submit all new direct-to-consumer television advertisements to the FDA before releasing them for broadcast."

This provision varies only slightly from current FDA rules, under which regulators may ask to see ads only in certain cases. Legislation proposed by Grassley would mandate pre-approval of ads by the FDA.

Another provision calls on signatory companies to "spend an appropriate amount of time to educate health professionals about new medicines or new therapeutic indications before beginning the first direct-to-consumer campaign."

In deflecting the two-year moratorium call from Frist, the group asserted that "a single uniform waiting period" could have the "unintended consequence of denying patients important information about new medicines, even after health care professionals have been well educated."