FDA Considers Tightening Regulations for Direct-to-Consumer Advertising

In August, the Pharmaceutical Researchers and Manufacturers of America (PhRMA) sought to curb growing public criticism over its consumer advertising practices by releasing voluntary advertising guidelines. The document stated that drug advertising should serve the public health by “increasing awareness about diseases” and “educating patients about treatment options.”

The voluntary PhRMA guidelines are viewed by some as an attempt to placate the U.S. Food and Drug Administration, which is considering tighter regulations on consumer drug advertising. In November, the agency held a 2-day hearing to solicit input from consumer advocates and the drug industry on how to proceed.

Current guidelines, put in place in 1997, allow drug companies to advertise directly to consumers if such ads balance supposed benefits with possible risks. Drug companies must submit advertisements for FDA review only at the time of airing; the FDA has no power to force companies to preclear advertising, although some choose to do so. If the agency deems that an advertisement does not comply with regulations, it sends warning letters proposing changes to the ad. However, because the FDA guidelines are not full-blown regulations, the agency does not have the power to fine or otherwise sanction drug companies for running misleading ads.

Beginning in January 2006, the United States will be the only country that allows direct-to-consumer drug advertising for pharmaceuticals. (New Zealand allows such ads through the end of 2005.)

Consumer groups want Congress to grant the FDA the power to fine companies that run misleading advertisements. And many are skeptical of the sincerity of PhRMA’s new guidelines, citing past statements that undermine the notion that the drug companies see advertising as anything more than a means to boost its profits. “The ultimate goal of [direct-to-consumer] advertising is to stimulate consumers to ask their doctors about the advertised drugs, and then … get the prescription,” two drug advertising executives wrote in 1998 in Medical Marketing and Media, a newsletter for their trade.

“They sell medical products just like any other products … just like toys and cars and deodorant. The goal is to make us want them,” said Diana Zuckerman, Ph.D., director of the National Research Center for Women and Families, at the November hearing.

Recent statistics seem to support her claim. In 2000 and 2001, Merck spent $296 million rolling out its new (and ultimately ill-fated) arthritis drug Vioxx (rofecoxib), the largest amount spent on advertising for any drug in that period. The trade magazine Advertising Age rewarded Merck by naming Vioxx one of the top new “megabrands” that is, consumer recognition of the product was widespread. In 2003, the Kaiser Family Foundation published a report claiming that for every $1 spent on promotion, drug companies gained $4.20 in revenue. That same year, PhRMA said its members spent $25 billion on promotion, including advertising and free samples for physicians, and $33 billion on what the industry categorized as research.

But social scientists and other observers remain divided over the impact on consumer behavior of direct-to-consumer advertising, which first appeared as print advertisements in the mid-1980s and on radio and TV in 1997. An FDA study of public and physician attitudes toward the ads produced equivocal results. Only 4% of consumers in the survey said that a drug ad prompted them to visit a physician, and the survey “did not find strong support” for the claim that ads led patients to expect a prescription. About half of the physicians in the survey reported feeling at least some pressure to prescribe a drug that a patient saw advertised.

Balancing Risks

However, 65% of physicians felt that TV ads, in particular, led patients to overestimate a drug’s benefits and underestimate its risks, a concern that surfaced repeatedly during the FDA hearing. Joe Cranston, M.D., scientific director for the American Medical Association, said that there is “good evidence” that television ads lack balance in presenting risks and benefits, a requirement of current FDA regulations. In 2003, Duke University’s Ruth Day, Ph.D., a social scientist, analyzed 29 television drug ads and concluded that risk information received fewer sentences and was conveyed with more difficult-to-comprehend words. Also, viewers recalled advertised benefits much more easily than they recalled possible risks.

Day and others at the meeting said that positive images shown during the typical voiceover recitation of side effects—for instance, a mother bending to tie her grandchild’s shoe in an ad for an arthritis drug—undermine any risk message. The FDA, for its part, is just starting to study such communications issues. “It’s difficult to precisely define what is ‘fair and balanced,’” said Kathryn Aikin, Ph.D., a social science analyst in the FDA’s Division of Drug Marketing, Advertising, and Communications.
“But people are starting to research [the issue], which is great to see.”

However, the drug industry points to the vagueness of current FDA regulations. “Using personal judgment rather than social science to decide what ‘in compliance’ means … has led to a lack of predictability” in how the FDA will enforce advertising regulations, said Peter Pitts, Ph.D., director of the Center for Medicines in the Public Interest, a think tank with some industry funding. “The FDA needs a solid benchmark study, a quantitative project” to judge whether ads are balanced. “Where are the metrics?” he asked.

**Ad Delays**

During the hearing, consumer advocates repeatedly pointed to the Vioxx campaign as an example of how advertising new drugs can harm patients. A study published in *The Lancet* in February 2005 reported that the drug caused serious cardiovascular problems in 140,000 people in the United States during its 5-year reign as arthritis drug of choice.

Consumers Union, publisher of *Consumer Reports*, was among the groups calling for either an outright ban on consumer advertising or, at the least, a 2- or 3-year moratorium on advertising for new drugs following their FDA approval. “Given accelerated approval and a streamlined approach [to drug approval] at the FDA, we often don’t know how safe drugs are” when first released, said William Vaughn, senior policy analyst at Consumers Union. In its new guidelines, PhRMA urges member companies to delay consumer advertising on new drugs until they spend “an appropriate amount of time” educating physicians about the product. The guidelines, however, leave plenty of wiggle room: “Establishing a single uniform waiting period for all companies and all medicines could have the unintended consequence of denying patients important information about new medicines, even after health care professionals have been well educated.”

For cancer drugs, the moratorium may not be the best solution, said Greg Abel, M.D., a hematologist–oncologist at the Dana-Farber Cancer Institute in Boston. “I’m not sure a 1-year or 2-year moratorium is helpful to cancer patients. That’s longer than the expected survival” for many patients, he said. “Cancer patients are the most vulnerable to misleading ads,” he added. “Ads for chemotherapy should have a higher level of scrutiny.”

The PhRMA guidelines also call for companies to submit all ads to the FDA prior to broadcast. Current regulations require companies to submit ads only at the time of broadcast, for the FDA to review at its discretion.

During his presentation at the hearing, Pfizer’s president of U.S. pharmaceuticals, Pat Kelly, focused mainly on advertising’s ability to educate the public about undertreated conditions. “It’s a powerful argument, but one where Pfizer and others undercut themselves with overzealous use of promotional, not educational, messages,” James Gardner, from the online marketing firm One to One Interactive, said during the hearing. Plastering NASCAR racers with Viagra slogans “is hard to defend from an educational perspective,” he said.

Kelly noted that Pfizer has earmarked a media budget equivalent to a “major brand” for health education advertising and other materials discussing conditions, not products. He also said that the company will “strictly limit” advertising in the first 6 months after a drug’s launch. PhRMA itself has created an office of accountability to publicly distribute company advertising policies and to respond to comments from consumers and physicians. Meanwhile, Bristol-Myers Squibb announced that it will not advertise new drugs for a year after FDA approval. “The [advertising guidelines] recognize that consumer advertising must be used with care,” said Scott Lassman, J.D., assistant general counsel for PhRMA. “Drugs aren’t like lightbulbs or toothpaste.” Twenty-six of PhRMA’s 33 member companies have agreed to follow the guidelines.

Whether such statements placate the FDA will be known in the first half of next year, when the agency is expected to release revised consumer advertising regulations.

---

**—Brian Vastag**

© Oxford University Press 2005. DOI: 10.1093/jnci/dji457