Skeptics Scorn Drug Industry's Ad Guidelines

The voluntary rules on direct-to-consumer marketing were called 'a meaningless attempt to fool people.'

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 PhRMA chief, former congressman Billy Tauzin, cites the drug companies' pledge to educate health care professionals before launching DTC campaigns.

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 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 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.

Clinical Trials Must Include More Blacks to Improve Their Care

BY NANCY WALSH
New York Bureau

NEW YORK — Racial disparities in access to health care will disappear only when adequate and representative samples of minorities participate in clinical trials, Winston Price, M.D., said at the annual meeting of the National Medical Association.

That disparities in delivery of health care exist is not in question. The Institute of Medicine report "Unequal Treatment: Confronting Racial and Ethnic Disparities in Healthcare" revealed the extent of the problem, showing disparities even after adjustment for factors such as insurance coverage and socioeconomic status.

But a widespread mistrust of the U.S. health care system among minorities—not least because of past abuses such as the Tuskegee Syphilis Study, in which blacks went untreated for many years despite the availability of effective therapy—has led to an unwillingness among African Americans to participate in the clinical trials that might directly benefit their own health.

An increasing understanding of genetic differences and racial differences in response to medications now makes it imperative that minorities be included and their needs addressed in the drug development process, said Dr. Price of the State University of New York Health Science Center, Brooklyn.

The experience with BiDil, a fixed-dose combination of isosorbide dinitrate and hydralazine approved specifically for the treatment of heart failure in black patients, shows it can be done.

"You had 1,050 African Americans who enrolled in the study, and the attrition rate was zero," Dr. Price, who is also president of the NMA, said in a press briefing. "Every single one stayed with that study until completion. The drug was approved by the Food and Drug Administration on June 23, not because it was the right thing to do but because it was pure science and evidence based. All we're asking for is parity."

Other model programs also are demonstrating that blacks can be recruited successfully, Christopher L. Edwards, Ph.D., said at the briefing.

Programs that are successful tend to be well entrenched in the community; they have significant outreach and education and strong, ongoing relationships with local organizations such as churches and fraternities, Dr. Edwards said.

They do not pressure potential study participants, but, rather, provide information and allow patients to process the information at home and respond to the investigators when they are ready, he said.

Successful investigators are available to the community not only when recruiting; they are able to articulate the tangible benefits of participation, not only for patients themselves but also for future generations.

Dr. Edwards' program in the department of psychiatry at Duke University Medical Center, Durham, N.C., is an excellent example.

"We make ourselves available for interviews on television, religious radio, and pop radio. In one creative marketing plan, we placed advertisements for one of our genetic studies on the side of 20 city buses, and have seen a significant number of patients responding," he said.

The overall strategy of information dissemination is to go where the patients are, and not to rely on them to come to us, he said. "With the bus advertisements, the demographic we were recruiting was reliant on public transportation," Dr. Edwards added. And the advertisements provided phone numbers, not e-mail addresses or Web sites, because the latter obviously would not be particularly helpful for a population that doesn't own computers.

'We placed ads for one of our genetic studies on the side of 20 city buses, and [had a good response].'

DR. EDWARDS

In the Duke program, the relevant stakeholders are at the table when recruiting programs are being designed. "If we are recruiting college students, we had students who sat on review panels and advisory boards to give us guidance as to what they would respond to, how, and in what setting," Dr. Edwards said.

Another panel member, Rahn K. Bailey, M.D., said that throughout his career he has been interested in issues such as differences in drug metabolism between African Americans and other patients. For example, about 40% of black patients are slow or intermediate metabolizers of many psychiatric medications, said Dr. Bailey of the department of psychiatry and human behavior, University of Texas, Houston, and chair of the NMA psychiatry and behavioral sciences section.

Because of this, black patients tend to experience more toxicity, and efficacy may be compromised, he said.

"It's not surprising to me now that many of my patients over the years have had great difficulty getting better, relapsed a lot quicker, come back to the hospital frequently, and ended up in the legal system because of clinical issues that were not addressed medically," Dr. Bailey said.

"In psychiatry it's as if we did all our studies on inpatients and none on outpatients, or in suburban communities rather than inner cities. The distinctions are apparent and actually affect medical decision making, he said, adding that these issues also are relevant in cardiovascular medicine, neurology, ob.gyn., and other areas of medicine.

Audience member William Lawson, M.D., brought up the work of Surgeon General David Satcher, M.D., Ph.D., in his 1999 report "Mental Health: A Report of the Surgeon General." One of the points made in this report was that virtually all psychiatric studies done in the United States included primarily white males, so almost all the available psychiatric drugs had less than 1% African American participation, said Dr. Lawson, chair of psychiatry, Howard University, Washington.

"And the consequences have been awful. For example, once the second-generation antipsychotic medications came on the market it became clear that the risk of obesity, diabetes, and metabolic syndrome was much more of a problem for African Americans and Hispanics than for whites. We don't want to improve the mental health of our patients at the expense of giving them complications that can be lethal," Dr. Lawson said. ■