Making Drug Ads Add up: PhRMA Voluntary Guidelines Address Clarity and Accuracy, Not Spending

Stephen Barlas

With pharmacy benefit managers under intense pressure to reduce drug costs for health plans, nothing would help more than if physicians were to prescribe the most cost-effective medications for their patients. That doesn’t happen all the time, though—and physicians aren’t necessarily at fault. Physicians today often encounter patients who demand glitzy new medications, very expensive ones that they might have seen advertised on television or in a magazine, even though the older alternatives might be the better choice, at least as the first step in treatment.

The federal government might not care if only private health plans were suffering from ad-induced, new drug price sticker shock. However, with the new Medicare outpatient benefit about to begin and with Medicaid drug costs shooting through the roof, Congress and the Department of Health and Human Services are rattling their sabers. And some of the rules set by the Food and Drug Administration (FDA) on direct-to-consumer (DTC) drug advertising may be trimmed in the future as a result.

It is with this prospect in mind that Pharmaceutical Research and Manufacturers of America (PhRMA), the brand-name trade association, issued voluntary guidelines on DTC advertising in July. If the guidelines are implemented faithfully, they will quiet some of the complaints about opaque television and magazine drug ads, which are difficult to decipher and, in some cases, have been less than candid about adverse effects. Honest, truthful, clear ads will also warn some consumers to avoid using drugs that they might otherwise press their physicians to prescribe. Yet as long as drug ads do not have to provide some information about their cost-benefit compared with other drugs in the same category, consumers will still demand—and physicians will still prescribe—budget-busting drugs for no good reason.

Just to pick on rofecoxib (Vioxx®) for a minute. If the FDA’s rules on drug advertising had forced Merck to do a per-dosage cost comparison between Vioxx® and aspirin and ibuprofen, for example, and then compare the advantages and disadvantages of each drug, initial sales of Vioxx® would not have taken off as they did.

PhRMA’s guidelines go part of the way toward addressing public concerns. For example, they state that DTC television advertising that identifies a product by name should clearly state the health conditions for which the medication is approved and the major risks associated with the drug being advertised. That would eliminate the confusion, at least in my mind, caused by the ad for the erectile dysfunction drug Levitra® (vardenafil, Bayer/GlaxoSmithKline) showing a man throwing a football through a tire. The ad had to be explained to me. A clear statement of a drug’s major risks would address the complaints that consumers had with respect to Vioxx® and antidepressants, two recent examples of drugs and classes whose side effects were not clearly disclosed.

But the drug industry is probably going to have to go further than that. Just making sure that ads for erectile dysfunction drugs are not shown on prime time TV programs (e.g., sporting events for which young boys and girls make up a significant percentage of the audience) and that the ads are not obtuse does not solve the problem of drug costs.

This is the problem that most concerns people like Senate Majority Leader Bill Frist (R-Tenn.), a physician in his “other life.” He has proposed that drug companies voluntarily refrain from airing and publishing DTC ads for the first two years in which a new drug is on the market. This suggestion was decidedly not part of the PhRMA voluntary guidelines.

“Used appropriately, direct-to-consumer advertising can empower patients without inflating need or distorting medical realities,” Senator Frist says. “But research evidence indicates that this blitz in direct marketing has unwittingly led to inappropriate prescribing, which most importantly can compromise patient safety and care.”

He has asked the Government Accountability Office to analyze the FDA’s oversight of prescription drug advertising, the pharmaceutical industry’s spending on such advertising, and the potential impact on utilization, health care spending, and patient education and awareness. The FDA is already looking over its shoulder. The agency announced that it would schedule public workshops this fall aimed at determining whether its DTC rules need to be changed. In addition, just to let Dr. Frist and others know that it isn’t planning to fall sleep at the wheel in the meantime, the FDA wrote to Pfizer and Actelion Pharmaceuticals at the end of July, a few days after the PhRMA guidelines were unveiled, to order them to immediately cease disseminating certain promotional materials that were considered misleading.

The agency said that Pfizer’s print ad for linezolid, an anti-infective agent marketed as Zyvox®, violated federal regulations because it made unsubstantiated claims of superiority over another product; it lacked fair balance; it broadened the indication for the medication; and it omitted important risk information associated with use of the drug. A Pfizer spokeswoman says that the company has made changes in the ad, has submitted them to the FDA, and was waiting to hear whether the changes were acceptable. In the future, one would expect that Pfizer, Actelion, and other drug companies would not even need to receive warning letters. That is the hoped-for effect of the PhRMA guidelines.