

A dose of honesty in prescription drug ads

By Alison Bass | June 2, 2008

LAST MONTH, a congressional committee held a hearing to examine the extent to which drug companies run misleading ads about their products. The committee spotlighted TV commercials for three drugs - the cholesterol-lowering drugs Lipitor and Vytorin, and the antianemia drug Procrit - and it raised concerns that the makers of these drugs had, in the words of Representative Bart Stupak of Michigan, aired "manipulative commercials designed to mislead and deceive" consumers.

Stupak, a Democrat who is chairman of the Energy and Commerce Subcommittee on Oversight and Investigations, called for new restrictions on direct-to-consumer ads and questioned whether pharmaceutical companies should be allowed to do such advertising at all. The United States is one of only two countries that permit those ads. Stupak's comments received little media coverage, possibly because Republican members of the panel kept questioning why the issue merited congressional attention.

Here's why it does. Little more than a year ago, my 83-year-old father was told he had a low red blood cell count, which could explain why he had been feeling tired lately. His doctor prescribed a high dosage of Procrit and my father started taking injections of the drug. He had no idea that high doses of Procrit and other erythropoiesis-stimulating agents can cause an increased risk of heart failure in patients with kidney problems, which he has had. Nor did he know that in March 2007, the Food and Drug Administration required black box warnings be added to the label of these drugs detailing the risks of taking them.

Five days after his first Procrit injection, my father had a mild heart attack - his chest felt constricted and he was having trouble breathing. My mother rushed him to the hospital, where doctors put two stents in one artery and used angioplasty to blow the other artery open. Yet even after his heart attack, my father continued to take Procrit at dosages higher than recommended by the FDA.

Why? Because that's what his doctor told him to do and he had seen and read nothing to caution him otherwise. To the contrary, print and television ads and labeling information for patients implied that Procrit could reduce fatigue and weakness in people with anemia.

Indeed, for seven years, Johnson & Johnson, which sold Procrit, aired TV commercials showing exhausted senior citizens suddenly revived after taking the drug. Similar claims were made on the labels for Procrit and another erythropoiesis-stimulating agent,

Aranesp, even though both drugs were approved by the FDA only for their ability to reduce the need for blood transfusions.

While the Procrit TV ads were ostensibly targeted at cancer patients who develop severe anemia as the consequence of chemotherapy, the commercials seemed designed for a much broader audience.

As Dr. Otis Brawley, professor of hematology and oncology at the Winship Cancer Institute, told a FDA advisory panel meeting last year: "I think one of the most important issues here is that most doctors and most patients think that this drug has been approved because it improved quality of life. There is a lot of sleight of hand here with how this drug is used, what the drug is used for."

Johnson & Johnson took its Procrit commercials off the air in 2005, but did not change the erroneous labeling information until March 2007.

Until recently, Johnson & Johnson and Amgen, the maker of Aranesp and another erythropoiesis-stimulating agent, Epogen, also offered doctors millions of dollars in rebates for prescribing their drugs. Is it any surprise that all three became blockbuster drugs, with combined sales of nearly \$14 billion in 2006?

At the congressional hearing in May, Stupak and Dingell pointed to the misleading Procrit ads as evidence of the need for more stringent oversight of drug advertising. But their message was repeatedly undercut by four Republican legislators, all of whom, it's worth noting, have received thousands of dollars in campaign contributions from drug companies, including the ones on the hot seat in May. At the hearing, the drug company representatives were quick to note that the ads under scrutiny - for Vytarin and Lipitor as well as Procrit - are no longer on the air.

That may be so, but Johnson & Johnson was just called to task for airing another TV commercial touting the benefits of a drug-coated stent that it makes. In an article in the New England Journal of Medicine, several cardiologists called the stent ads "potentially deceptive" because they focus "almost exclusively" on the device's benefits and neglect to spell out its risks. Sound familiar?

Alison Bass is author of "Side Effects: A Prosecutor, a Whistleblower, and A Bestselling Antidepressant on Trial." ■

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