

Some Drug Ads Don't "Ad" Up

by Stephen Barlas



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When the House and Senate take up a Medicare prescription drug bill this year, there is one thing you can be sure of: members of Congress will propose all sorts of amendments meant to rein in pharmaceutical expenditures—and not just for Medicare recipients. It happened when Medicare bills landed on both floors in 2002. It will happen again in 2003.

One of those amendments, undoubtedly, will aim to crack down on drug company advertising on television and in magazines. Last year, Representative Frank Pallone (D-NJ) and Senator Debbie Stabenow (D-MI) introduced a bill that would have prevented drug companies from claiming a tax deduction for advertising that was larger than the company's expenditures on research and development (R&D). Don't expect to see that amendment in 2003, though, because the General Accounting Office (GAO) published a report in November 2002 that shattered the premise behind the amendment—the premise being that drug companies are spending more on advertising than on R&D. Actually, the reverse is true. The figures for 2001 were \$30.3 billion spent on R&D, and \$19.1 billion spent on promotional activities, of which \$2.7 billion was used for direct-to-consumer advertising.

Although the GAO report undermines the Pallone/Stabenow amendment, it does provide plenty of fodder for anyone

who might suggest that direct-to-consumer advertising has gotten slightly out of hand. The problem isn't that spending on direct-to-consumer advertising increased 145% between 1997 and 2001—or that most of that spending was concentrated on about 50 drugs, for which the number of prescriptions increased by 25% in 2001, in contrast to 4% for other drugs. These kinds of statistics on the "top 50" advertised drugs would be totally unobjectionable if the drugs themselves were superior in terms of efficacy and side effects and if their ads were fair and honest. In too many cases, however, neither is true.

I've had some personal experience in this area. I used to get sinus infections all the time. My physician gave me a sample of, and a prescription for, Flonase[®] Nasal Spray (fluticasone propionate, manufactured by Glaxo Wellcome, now GlaxoSmithKline). Heck, it sounded like a good idea. I had been seeing television and magazine ads everywhere for Flonase[®] when it first arrived on the market. It was new; therefore, I thought it must work. This drug was expensive: \$40 for a couple of ounces that lasted a couple of weeks. I didn't have insurance coverage for drugs, but I thought I'd give it a try.

Flonase[®] never worked for me. Eventually, I started taking Safeway's brand of antihistamines at a cost of \$4 for two weeks. I take two every morning year-round. I haven't had a sinus infection since. Imagine my annoyance, then, when I saw in the GAO report that one of the "poster children" for inaccurate advertising was none other than, you guessed it, Flonase[®].

Between 1999 and 2000, the Food and Drug Administration (FDA) had sent

four regulatory letters to Glaxo Wellcome, including one warning letter, which was a more serious matter compared with the three "untitled" letters. What were the untitled letters about? The FDA said that the company had made unsubstantiated efficacy claims for Flonase[®]. The warning letter concerned its failure to disclose information about risks and major side effects. The FDA sent four letters because each time that Glaxo Wellcome received one, it discarded its current ad, redesigned it—again including inaccurate information—and put it back on the airwaves or in the magazines, at which point the FDA was forced to send the next regulatory letter. Recently, a GlaxoSmithKline spokesperson did not respond to a request for comment on the GAO report.

The FDA also sent four successive letters to Pfizer with concerns about its ads for Lipitor[®] (atorvastatin), a cholesterol-lowering drug.

In many instances, inaccurate drug company ads have already completed their media "run" by the time an FDA regulatory letter hits the company's inbox. In 2002, it took the FDA's Office of General Counsel between 13 and 55 days to approve a regulatory letter to a drug company after it received a request to do so from the FDA's division of drug marketing, advertising, and communications. Of all direct-to-consumer ads, 32% appear on television for less than two months.

So don't expect to hear a lot of congressional rhetoric this year about how much drug companies spend on television advertising. Complaints about quantity are out. Complaints about quality are definitely in. ■