

**STATEMENT
OF
THE HONORABLE BART STUPAK
SUBCOMMITTEE ON
OVERSIGHT AND INVESTIGATIONS
“DIRECT-TO-CONSUMER ADVERTISING: MARKETING,
EDUCATION, OR DECEPTION?”**

MAY 8, 2008

Nearly ten years ago, the U.S. Food and Drug Administration (FDA) relaxed its rules related to direct-to-consumer (DTC) advertisements for prescription pharmaceutical products. Since then, spending on DTC ads has increased from about \$1.1 billion in 1997 to about \$4.2 billion in 2005. This nearly 300 percent increase in DTC ad spending dwarfs the 86 percent spending increase in advertisements to physicians and the 103 percent spending increase in research and development over the same period.

The pharmaceutical industry insists that DTC ads are mainly an educational endeavor designed to educate consumers about new products. Research shows that some DTC advertising result in patients seeing their doctor and discussing previously undiagnosed conditions.

We must acknowledge that DTC ads are also designed to market and sell these products. Research has shown that DTC advertising may result in advertised drugs being prescribed when a similar, less-expensive drug may have been just as appropriate. Every \$1 spent on DTC advertising results in up to a \$6 increase in sales, and one study demonstrated that every \$1,000 spent in DTC advertisements resulted in 24 new prescriptions.

The purpose of the hearing is to examine the potentially misleading and deceptive tactics used in direct-to-consumer (DTC) advertisements (ads) for prescription pharmaceutical products. Our hearing today will examine three specific television advertisements: ads for Lipitor featuring Mr. Robert Jarvik, “Food and Family” ads for Vytorin, and “cancer fatigue” or “quality of life” ads for Procrit.

Pfizer’s Lipitor ads featured Mr. Robert Jarvik, an individual who has never held a license to practice medicine and has never been allowed to prescribe a medication. For his participation in these ads, he was paid \$1.35 million dollars; however, none of his ads indicates that he was compensated for his appearance. In addition, Mr. Jarvik states, in one of these ads, that he himself takes Lipitor, yet he admitted in an interview that he didn’t begin taking Lipitor until a few months after he began filming his commercials. These ads are in violation of the American Medical Association’s guidelines concerning the involvement of health professionals

in DTC advertisements. Mr. Jarvik's ads helped maintain Lipitor's position as the most prescribed anti-cholesterol "statin" drug. [Run Lipitor Ad]

Merck and Schering-Plough's ads for Vytorin resulted in \$5 billion dollars in sales in 2007. However, while these ads peppered the airwaves, the release of an important study examining Vytorin's ability to stop cholesterol build-up was delayed and suppressed by the companies. Significant, valuable results from this study were delayed for two years, while Vytorin was continuously marketed to consumers.

We now know that Vytorin has no effect on cholesterol build-up - however, this information came to us about two years too late. Many consumers may not have taken Vytorin had they been aware of the study results, especially since a less expensive, equally effective generic drug, Zocor, was already available. In addition, taxpayer dollars may have been needlessly spent on Vytorin through Medicare Part D as the drug was marketed to consumers while the company sat on its study results. [Run Vytorin Ad]

Johnson & Johnson's Procrit was approved by FDA to treat chemotherapy- and dialysis-induced anemia. Yet for seven years, it was marketed directly to consumers for the treatment of "cancer fatigue" in order to improve the "quality of life" for patients. This was clearly an instance of off-label marketing—a practice that is prohibited by FDA. Not only did the company advertise the drug, but FDA did nothing to stop them. [Run Procrit Ad]

These are three examples of drug companies acting improperly. Our goal today is to expose the deceptive and misleading aspects of each of these television ad campaigns, but also those of DTC ads in general. We also intend to explore better practices for DTC marketing.

Both the Lipitor ads with Mr. Jarvik and the Vytorin "Food & Family" ads were voluntarily withdrawn shortly after our Subcommittee began investigating DTC ads in January of this year. However, American consumers should not have to rely on the oversight function of Congress to make sure drug companies tell the truth in their advertisement campaigns. It is likely that DTC ads will continue, and pharmaceutical companies may continue using the same questionable practices that were used in these three ad campaigns.

The FDA's Division of Drug Marketing, Advertising, and Communications (DDMAC) is responsible for regulating DTC ads. Drug companies are required to submit copies of their ads at the same time that they are disseminated, but no preclearance is yet required. If a DTC ad is found to be in violation of FDA regulations, FDA can issue written letters for serious violations, which may lead to regulatory action by FDA. However, if a company refuses to comply, FDA cannot impose fines except through an administrative hearing.

Today we will hear from several witnesses, including the three pharmaceutical companies responsible for the Jarvik, "Food & Family," and "cancer fatigue" campaigns. We will also hear from the Kaiser Family Foundation about the effects of DTC ads, the American Medical Association regarding their policy on the portrayal of health professionals in DTC ads, and the Government Accountability Office concerning FDA's role in regulating DTC ads. We will also hear from Dr. Ruth Day from Duke University who will provide an overview of research on how

people understand and remember information in drug ads and how to improve their ability to do so. We will learn some of the techniques used in broadcast advertisements that affect how consumers process the information in DTC ads. This information may reveal that it's not simply a matter of what is said in a DTC advertisement, but more importantly, what people take away from it.

The United States is only one of two countries that allows DTC ads. Pharmaceutical companies should consider it a privilege to be allowed to air DTC ads in this country. As with all privileges, there comes responsibility, and we should make sure that pharmaceutical companies conduct themselves responsibly. The Food and Drug Administration shares the responsibility to make certain that drugs are marketed responsibly to consumers. I also believe that Congress shares this responsibility, and I intend to make certain that our Committee ensures that pharmaceuticals market their products properly.

I believe that Congress needs to decide whether the U.S. should continue to be one of two countries in the world that allow DTC ads, and if we continue to allow such advertising, whether any further limits to DTC ads should be required. If the three ads that we will discuss today are indicative of typical DTC ad campaigns, it appears that we need to enforce significant restrictions on DTC ads to protect American consumers from manipulative commercials designed to mislead and deceive for the profit of pharmaceutical companies.

I look forward to the testimony of each witness today, and it is my sincere hope that today's hearing will lead to a better understanding of the effects of DTC advertisements and their proper role in our health care system.