



February 9 , 2009

MADIGAN REACHES SETTLEMENT WITH BAYER FOR VIOLATING 2007 AGREEMENT TO CEASE DECEPTIVE MARKETING PRACTICES

Pharmaceutical Manufacturer Must Submit Ads for FDA Approval, Fund \$20 Million Corrective Ad Campaign

Chicago—Attorney General Lisa Madigan today reached a settlement with Bayer Corporation based on allegations the company violated a 2007 agreement by using misleading advertising to market its oral contraceptive, Yaz.

"This settlement reflects the continual monitoring my office performs to ensure that the pharmaceutical industry is not using deceptive marketing and advertising practices," Madigan said. "When defendants violate their agreements, we will pursue action in the best interests of the state."

The new terms, which Madigan helped craft with the Oregon and California Attorneys General and the U.S. Food and Drug Administration's (FDA), require Bayer to submit all future Yaz television commercials to the FDA for approval prior to airing, to comply with all the FDA's recommended changes to the advertising, and to clearly and conspicuously disclose the symptoms for which the FDA has approved the advertised medications.

Madigan filed the settlement agreement in Sangamon County Circuit Court today. This dispute arose when the FDA sent a letter to Bayer, expressing concern that Bayer was advertising Yaz with misleading statements indicating the drug could be used to treat unapproved symptoms, including the relatively common premenstrual syndrome (PMS). The FDA's letter also warned Bayer that its marketing campaign inappropriately suggested that Yaz is approved for the treatment of mild acne. In fact, Yaz has been approved by the FDA for use *only* for the treatment of symptoms of premenstrual dysphoric syndrome (PMDS) when oral contraception is also indicated, and/or the treatment of moderate acne vulgaris when oral contraception is also indicated.

Today's settlement resolves allegations that Bayer's 2008 marketing of Yaz violated its 2007 agreement. The 2007 agreement was based on allegations that Bayer used deceptive advertising to market Baycol, a cholesterol-lowering drug, and failed to disclose Baycol's safety risks. In addition to requiring FDA approval of Yaz advertising, today's settlement requires that Bayer conduct a \$20 million corrective advertising program to remedy misinformation from the misleading Yaz advertisements.

"This is a great example of collaboration between the FDA and state Attorneys General," said Tom Abrams, director of the FDA's Division of Drug Marketing, Advertising and Communications. "By working together, we can achieve excellent results and double our efforts to clean up misleading advertising in the marketplace. This significantly benefits the public by ensuring that consumers are not misled about information relating to their health."

Madigan was joined in the settlement by the Attorneys General of Arizona, Arkansas, California, Connecticut, Delaware, Florida, Idaho, Iowa, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Mississippi, Montana, Nevada, North Carolina, Ohio, Oregon, Pennsylvania, South Dakota, Tennessee, Texas, Washington and Wisconsin.

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