Press Releases

July 15, 2009

MADIGAN REACHES AGREEMENT WITH MERCK, SCHERING-PLOUGH JOINT VENTURE FOR DELAYING DISCLOSURE OF NEGATIVE DRUG STUDY RESULTS

Companies Deceptively Marketed Cholesterol-Lowering Drug as More Effective Than Generic Equivalent

Chicago — Attorney General Lisa Madigan, along with 35 other Attorneys General, today announced a $5.4 million agreement with Merck & Co. Inc, Schering-Plough Corp., and a joint venture of the two companies, MSP Singapore Company, LLC., to resolve an investigation into the companies' lengthy delay in releasing negative results from a clinical trial that showed that the companies' brand-name cholesterol-reducing drug was no more effective than a generic equivalent.

"The pharmaceutical manufacturers failed to properly and fully inform consumers about how their brand-name cholesterol-lowering drug performed in a clinical trial," Madigan said. "This settlement will protect patients by ensuring that the companies' marketing reflects the true results of any scientific trial in a timely fashion."

Madigan's investigation focused on allegations that the companies engaged in unfair and deceptive practices after failing to promptly report unsatisfactory results from a clinical trial about the health effects of Vytorin®, a cholesterol-lowering drug which was found to be no more effective in reducing plaque in carotid arteries than a cheaper, generic cholesterol-lowering equivalent. At the end of the clinical trial in May 2006, the companies promoted Vytorin® in consumer advertising campaigns as more effective than other cholesterol-lowering medications, a claim that was contrary to the clinical trial's results. Trial managers allegedly waited nearly two years, until January 2008, to report the negative trial results and another four months to produce the complete results of the study. Throughout that lengthy time period, the companies allegedly continued to promote Vytorin® as a more effective cholesterol-lowering drug than its counterparts.

As a result of the investigation conducted by the Attorneys General, the settlement mandates that the companies:

- Obtain pre-approval from the U.S. Food and Drug Administration (FDA) for all direct-to-consumer television advertisements;
- Comply with FDA suggestions to modify drug advertising;
- Register clinical trials and post their results;
- Prohibit ghost writing of articles;
- Reduce conflicts of interest for members of Data Safety Monitoring Boards that ensure the safety of participants in clinical trials; and
- Comply with detailed rules prohibiting the deceptive use of clinical trials.

In addition to agreeing to these requirements, the companies agreed to pay the states' investigation costs. For its work on this investigation, Illinois will receive $200,000 of the $5.4 million.

Attorneys General from the District of Columbia and the following states also participated in today's agreement: Arizona, Arkansas, California, Colorado, Delaware, Florida, Hawaii, Idaho, Iowa, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Mississippi, Missouri, Montana, Nebraska, New Jersey, Nevada, New Mexico, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Vermont, West Virginia, Washington, and Wisconsin.

Bureau Chief James Kole, Supervising Assistant Attorney General Ryan Tyrrell Lipinski, and Drs. Arnold Widen and Babs Waldman handled the matter for Madigan's Consumer Fraud Bureau.

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