Press Releases

October 22, 2008

MADIGAN, 33 AGs REACH $60 MILLION SETTLEMENT WITH PFIZER

Agreement Concludes Investigation Into Improper Marketing of Pain Relievers

Chicago—Attorney General Lisa Madigan announced today that she has reached a $60 million settlement with Pfizer Inc., resolving a five-year investigation into the allegedly improper marketing for Bextra and Celebrex. The settlement, which includes 33 other Attorneys General, requires Pfizer to significantly restrict its promotional practices and will protect consumers from deceptive and misleading marketing tactics that obscure a medication's negative health effects.

"Pfizer's misleading claims and deceptive actions put consumers' health at risk," said Madigan, who was one of the leaders of the multi-state investigation. "This settlement should send a strong message to the pharmaceutical industry that we won't tolerate deceptive and dangerous marketing promotions and tactics."

In a complaint filed today along with the settlement agreement, Madigan and the other states alleged that Pfizer engaged in unfair and deceptive practices in marketing its second-generation pain reliever, Bextra, for unapproved "off-label" uses, including acute and surgical pain. While physicians may prescribe drugs for any uses, the law clearly prohibits pharmaceutical manufacturers from marketing their products for off-label uses.

The multi-state investigation initially began in 2003 in an effort to determine whether Pfizer had misrepresented that its first-generation pain reliever, Celebrex, was safer and more effective than traditional non-steroidal anti-inflammatory drugs (NSAIDS), such as Ibuprofen and naproxen. As the investigation proceeded, Madigan's office and the other states became concerned about Pfizer's marketing and promotion of it second-generation pain reliever, Bextra. The investigation concluded that Pfizer engaged in an aggressive, deceptive and unlawful campaign to promote Bextra "off label" for uses that had been expressly rejected by the U.S. Food and Drug Administration (FDA).

In 2001, the FDA rejected Pfizer's application to prescribe Bextra for acute and surgical pain symptoms due to concerns about its negative side effects. Studies have shown that drugs like Bextra increase the risk of heart attacks and strokes. Bextra is also known to cause a serious and sometimes fatal skin condition. Despite the FDA's rejection, Pfizer allegedly continued to aggressively market Bextra for acute and surgical pain.

As part of the settlement, Pfizer will cease the following conduct in all subsequent drug promotion and marketing campaigns:

- The "ghost writing" of articles and studies by medical practitioners paid by Pfizer;
- Failing to adequately disclose conflicts of interest for Pfizer promotional speakers when these consultants also speak at supposedly independent Continuing Medical Education sessions;
- Distributing samples to doctors with the intent to encourage off-label prescribing;
- Distributing information to doctors about an off-label use when the FDA has rejected the off-label use, unless Pfizer clearly discloses that (1) FDA rejected the use and (2) the FDA's reason for rejecting the use;
- Distributing off-label studies and articles in a promotional manner to doctors;
- Providing incentives to sales staff to increase off-label prescribing;
- Promoting the off label use of drugs for inclusion in hospital standing orders and protocols;
- Using "mentorships" to pay physicians for time spent with Pfizer sales reps;
- Using grants to encourage use of Pfizer products;

- Using sales personnel to make grant decisions that are supposedly unrelated to promotions and marketing; and
- Using patient testimonials to misrepresent a drug's effectiveness.

The settlement also requires that Pfizer submit all "direct-to-consumer" (DTC) television drug advertisements to the FDA for approval and comply with any FDA comments before running the advertisements. For any new pain relief drugs, Pfizer also must delay DTC advertising for up to 18 months if the FDA recommends this delay. Additionally, the settlement generally prohibits Pfizer from deceptive and misleading advertising or promotion of any Pfizer drug, requires Pfizer to register all clinical trials and results, and mandates that Pfizer ensure that all participants in sponsored clinical trials have provided adequate informed consent. Finally, as part of this settlement agreement, Illinois will receive $3 million exclusively for future consumer education and enforcement actions.

The Attorneys General of the following states also participated in today's settlement: Alaska, Arizona, Arkansas, California, Connecticut, Florida, District of Columbia, Idaho, Iowa, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Montana, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Vermont, Washington and Wisconsin.

Bureau Chief James Kole and Assistant Attorneys General Ryan Tyrrell Lipinski and Sean Morales-Doyle are handling the case for Madigan's Consumer Protection Division.

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