Press Releases

December 13, 2017

MADIGAN ANNOUNCES $12 MILLION MULTISTATE SETTLEMENT WITH MEDTRONIC

Chicago — Attorney General Lisa Madigan today announced a $12 million settlement with a company that manufactures a device used primarily in spinal surgeries. The settlement with Medtronic Sofamor Danek, Inc. and Medtronic Sofamor Danek USA, Inc. (Medtronic) resolves allegations that the company misled consumers about the safety of its Infuse® Bone Graft Device.

According to Madigan's complaint, Medtronic used deceptive company-sponsored scientific literature to make false and misleading claims about Infuse's safety, effectiveness and quality. The false marketing created an artificial demand for Infuse in a range of fusion surgeries. The company's fraudulent conduct was the subject of a 16-month investigation by the U.S. Senate Finance Committee.

"Medtronic misled the public in order to sell more of its bone graft devices, without regard for patients' safety," Madigan said. "This settlement ensures the company's marketing is accurate and complies with federal regulations."

Joining Madigan in announcing the settlement were the attorneys general of California, Massachusetts, Oregon and Washington. Under the settlement, Illinois will receive $2.4 million. The judgment is subject to court approval.

The settlement also requires Medtronic to ensure its marketing and promotional practices do not unlawfully promote Infuse. In particular, Medtronic shall:

- Make clinical trial data relating to Infuse publically available through the government-run website ClinicalTrials.gov;
- Refrain from making false, misleading or deceptive claims regarding Infuse;
- Use information about clinical trials relating to Infuse for promotional purposes in a manner that is truthful, non-misleading, accurate, fairly balanced, consistent with approved labeling, appropriately substantiated by objective evidence, does not contain overreaching messaging, and compliant with FDA regulations;
- Disseminate published medical journal articles reporting on clinical trials relating to Infuse only if they are truthful, scientifically and medically valid, when considered with supplemental materials not misleading, and disclose any Medtronic sponsorship of the clinical trials if applicable;
- Contractually require medical journal article authors to comply with authorship standards, acknowledge Medtronic sponsorship, and comply with conflict of interest disclosure standards in medical journal articles reporting on Medtronic-sponsored trials of Infuse where Medtronic approved the release of clinical trial data;
- Comply with applicable federal regulations relating to the reporting for clinical trials of Infuse; and,
- Comply with applicable federal regulations relating to the disclosure to FDA of information regarding Medtronic's financial relationships with investigators for Medtronic-sponsored clinical trials of Infuse.

Assistant Attorney General E. Paige Boggs handled the case for Madigan's Consumer Fraud Bureau.

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