Press Releases

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ATTORNEY GENERAL MADIGAN AND 42 ATTORNEYS GENERAL REACH $33 MILLION SETTLEMENT WITH JOHNSON & JOHNSON OVER MISREPRESENTATION OF DRUG QUALITY

Chicago — Attorney General Lisa Madigan and 42 other attorneys general today announced they have reached a $33 million settlement with Johnson & Johnson and its subsidiary over misrepresentations it made about manufacturing practices of well-known, over-the-counter (OTC) drugs that resulted in recalls of products manufactured between 2009 and 2011, including children's medicines.

McNeil-PPC, Inc., a wholly-owned subsidiary of Johnson & Johnson that manufactured the OTC drugs between 2009 and 2011 and which is now a part of Johnson & Johnson Consumer Inc., represented that it complied with federal Good Manufacturing Practices (cGMP) even though the Federal Drug Administration (FDA) found that some McNeil manufacturing facilities did not comply between 2009 and 2011. This meant some of the OTC drugs were not manufactured, processed, packed or held in conformance with the cGMP mandates. In addition, between May 2009 and April 2010, there were reports of foreign material, particulate matter or contamination in some of the OTC drugs.

"Johnson & Johnson's disregard for proper manufacturing practices of children's medications was unacceptable," Madigan said. "This settlement will shed light on this failure and serve as a reminder for all companies to follow the manufacturing processes required by law."

The company's alleged quality control lapses led to the recall of many common medications, including Tylenol, Motrin, Benadryl, St. Joseph Aspirin, Sudafed, Pepcid, Mylanta, Rolaids, Zyrtec, and Zyrtec Eye Drops.

The complaint filed today alleges Johnson & Johnson acting through McNeil violated state consumer protection laws by (1) misrepresenting the cGMP compliance and the quality of their OTC drugs, and (2) representing that the OTC drugs had sponsorship, approval, characteristics, ingredients, uses, benefits, quantities or qualities that they did not have. The complaint further alleges McNeil delivered certain batches of OTC drugs for state commerce that failed to comply with federal standards, and as such, were deemed adulterated.

The settlement agreement requires Johnson & Johnson Consumer Inc. to ensure that its marketing and promotional practices do not unlawfully promote OTC drug products. Specifically, the company shall not:

- Represent on its websites that Johnson & Johnson OTC drug product facilities meet cGMP as outlined by the FDA if the company has had a recall of OTC drug products within the prior 12 months;
- Fail to follow its internal standard operating polices regarding whether to open a Corrective Action/Preventive Action plan (CAPA) during the manufacture of an OTC drug; and
- Fail to provide information to participating attorneys general within 60 days of a written request regarding the identity of wholesalers or warehouses to which any OTC drugs that were subject to a recall were distributed in their state.

Joining Madigan in the settlement are attorneys general from: Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Hawaii, Idaho, Indiana, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New Jersey, New York, North Carolina, North Dakota, Ohio, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Vermont, Virginia, Washington, West Virginia, Wisconsin and the District of Columbia.

The settlement was handled by Assistant Attorney General Paige Boggs in Madigan's Consumer Protection Bureau.

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