



August 6, 2014

MADIGAN JOINS \$35 MILLION SETTLEMENT WITH PFIZER***Madigan & 41 Attorneys General Reach Settlement Over Illegal Marketing of Kidney Transplant Drug Rapamune***

Chicago — Attorney General Lisa Madigan today announced a national \$35 million settlement with Pfizer Inc. for illegally marketing a drug designed to prevent kidney transplant rejection for use in non-kidney transplant patients.

Madigan and 41 other states joining the settlement allege the drug's manufacturer, former Wyeth Pharmaceuticals which was purchased by Pfizer in 2009, illegally marketed Rapamune for uses not approved by the U.S. Food and Drug Administration (FDA). The company allegedly marketed the drug in illegal combinations with other transplant medications and for treating non-kidney transplant patients after surgery. The states also allege Wyeth offered financial incentives to doctors and hospitals to prescribe Rapamune for such unapproved uses.

"Promoting drugs for unapproved uses is a potentially deadly practice that can threaten patients' lives. The FDA needs to determine that drugs are safe for a specific treatment before they are prescribed," Madigan said.

The settlement requires Pfizer to ensure that its marketing and promotional practices do not unlawfully promote Rapamune or any Pfizer product. Specifically, Pfizer must not:

- Make false, misleading, or deceptive claims regarding its products;
- Compare the safety or efficacy of a Pfizer product to another product when that claim is not supported by substantial evidence as defined by federal law and regulations;
- Promote any Pfizer product for unapproved uses;
- Provide incentive compensation for sales that may be attributable to unapproved uses of any Pfizer product;
- Affirmatively seek the inclusion of Rapamune in hospital protocols or standing orders unless Rapamune has been approved by the FDA for the indication for which it is to be included in the protocol or standing order;
- Disseminate information describing any unapproved use of Rapamune unless such information and materials comply with applicable FDA regulations and the recommended actions in FDA Guidances for Industry; or
- Seek to influence the prescribing of Rapamune in hospitals or transplant centers in any manner (including through funding clinical trials) that does not comply with the federal anti-kickback statute.

Illinois will receive more than \$1.3 million under the settlement. Joining Madigan in reaching today's settlement were attorneys general from the following states: Alabama, Arizona, Arkansas, California, Colorado, Delaware, District of Columbia, Florida, Georgia, Hawaii, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, South Dakota, Tennessee, Texas, Utah, Virginia, Washington and Wisconsin.

-30-

[Return to August 2014 Press Releases](#)