



PRESS RELEASE

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COLORADO ATTORNEY GENERAL REACHES \$35 MILLION SETTLEMENT WITH PFIZER CONCERNING RAPAMUNE®

42 State Attorneys General Allege Pfizer's Off-Label Marketing Violated FDA Warning

DENVER —The [Colorado Attorney General's Office](#) joined 41 other state attorneys general today in announcing a consumer protection settlement with [Pfizer, Inc.](#), parent company of Wyeth Pharmaceuticals, Inc. totaling \$35 million of which Colorado will receive \$649,029. The agreement settles allegations that [Wyeth](#) unlawfully promoted Rapamune, an immunosuppressive drug used to prevent organ rejection after kidney transplant surgery. The Attorney General's Complaint alleges that Wyeth unlawfully engaged in off-label marketing of Rapamune for uses for which it was not approved.

In 2002, the Food and Drug Administration (FDA) required a “black box warning” to be added to Rapamune’s labeling warning prescribers and patients that Rapamune use by liver transplant patients is associated with serious risks, including graft loss and death. Then in 2003, the FDA required another “black box warning” to caution that Rapamune use by lung transplant patients is associated with serious risks, including death. Another warning was added to the labeling in 2007 regarding a serious side effect called proteinuria (protein in urine). In June, 2009, yet another warning was added based on the results of a Wyeth study that suggested that liver transplant patients prescribed Rapamune experience “significantly higher” organ rejection than patients treated with alternative immunosuppressant drugs.

Despite Rapamune’s limited FDA approval for use in kidney (renal) transplant only, and despite black box warnings relating to use in lung and liver transplants, Wyeth promoted Rapamune off-label for non-renal transplants patients such as liver, heart, pancreas, islet (pancreas cells) and lung transplant patients, according to the Complaint.

Under the terms of the Consent Judgment, Pfizer shall not:

- Make, or cause to be made, any written or oral claim that is false, misleading, or deceptive regarding any Pfizer product;
- Make any claim comparing the safety or efficacy of a Pfizer product to another product when that claim is not supported by substantial evidence;
- Promote any Pfizer product for off-label uses;
- Pay financial incentives for sales attributable to the off-label uses of any Pfizer product;
- 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.

The complaint was filed today in Denver District Court. In addition to Colorado, Alabama, Arizona, Arkansas, California, Delaware, District of Columbia, Florida, Georgia, Hawaii, Illinois, 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 also participated in the settlement.

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