

<p>DISTRICT COURT, CITY AND COUNTY OF DENVER, COLORADO 1437 Bannock Street Denver, CO 80202</p> <hr/> <p>STATE OF COLORADO, ex rel. JOHN W. SUTHERS, ATTORNEY GENERAL</p> <p>Plaintiff,</p> <p>v.</p> <p>WYETH PHARMACEUTICALS INC.</p> <p>Defendant.</p>	<p style="text-align: center;">▲ COURT USE ONLY ▲</p>
<p>JOHN W. SUTHERS, Attorney General JAY B. SIMONSON, 24077* First Assistant Attorney General Ralph L. Carr Judicial Center 1300 Broadway, 7th Floor Denver, CO 80203 Telephone: 720-508-6000 FAX: 720-508-6040 *Counsel of Record</p>	<p>Case No. Div:</p>
<p>COMPLAINT</p>	

1. Plaintiff, State of Colorado, by and through John W. Suthers, Attorney General of the State of Colorado, (“Attorney General” or “State”) brings this action against Defendant WYETH PHARMACEUTICALS INC. (“Defendant or Wyeth”) for violations of the Colorado Consumer Protection Act (“CCPA”), §§ 6-1-101 et seq., C.R.S. (2014).

2. The Attorney General brings this action pursuant to the CCPA, in the public interest, to protect the public's health, safety and welfare and pursuant to his general statutory and common law authority powers and duties pursuant to CCPA, C.R.S. §§ 6-1-103 . The Attorney General has reason to believe that the above-named Defendant has violated and/or is continuing to violate the CCPA. The Attorney General also has reason to believe that this action is in the public interest.

3. Upon interest and belief, the State of Colorado alleges as follows:

JURISDICTION AND VENUE

4. This Court has jurisdiction over Wyeth pursuant to CCPA, C.R.S. §§ 6-1-103 and 6-1-110 because Wyeth has transacted business within the State of Colorado at all times relevant to this Complaint.

5. Venue for this action properly lies in Denver County, Colorado, pursuant to C.R.S. § 6-1-103 because Wyeth transacts business in Denver County, Colorado.

PARTIES

6. Plaintiff, State of Colorado, ex rel. John W. Suthers, Attorney General, is charged with enforcing the CCPA, which prohibits unfair or deceptive acts or practices affecting the conduct of any trade or commerce. Pursuant to the CCPA, C.R.S. § 6-1-105, the Attorney General may initiate civil law enforcement proceedings in the name of the State to enjoin violations of the CCPA and to secure such equitable and other relief as may be appropriate in each case.

7. Defendant WYETH PHARMACEUTICALS INC. is a wholly owned

subsidiary of Pfizer Inc, a Delaware corporation with its principal place of business at 235 East 42nd Street, New York, NY 10017. At all relevant times, Wyeth did business in Colorado selling and promoting the prescription drug Rapamune®.

COMMERCE

8. In the course of advertising, soliciting, selling, promoting and distributing the prescription drug Rapamune®, Wyeth has engaged in a course of trade or commerce that violates C.R.S. § 6-1-105(1)(e) and (u).

9. Wyeth was, at all times relative hereto, engaged in trade or commerce in the State of Colorado by developing, manufacturing, promoting, selling, and distributing the prescription drug Rapamune®.

BACKGROUND

10. With certain limited exceptions not relevant here, a drug may not be distributed in interstate commerce without FDA approval.

11. To gain FDA approval, data from adequate and well-controlled clinical trials must demonstrate that the drug is safe and effective for a particular use.

12. As part of the approval process, the FDA must approve the drug's labeling which is required to set forth detailed information about the drug, including the approved medical conditions of use, dosages, and patient populations(s).

13. Once the FDA has found a drug to be safe and effective for a particular use and approved it for that use, doctors are free to exercise their medical judgment to prescribe the drug for other, unapproved (or "off-label") uses. However,

manufacturers are proscribed by federal law from promoting the drug for off-label uses.

14. Rapamune (sirolimus) is an immunosuppressant drug that was approved by the FDA in 1999 as an “adjunct” drug in combination with cyclosporine and steroids to prevent rejection of the transplanted kidney. It is not approved for use by any other type of organ transplant patient. Nor is it approved for combination with other drugs.

15. Rapamune is only approved as “de-novo” treatment – meaning for use immediately after a transplant. It is not approved for “conversion” - meaning switching to another immunosuppressant sometime after the transplant.

16. In 2002, FDA required a “black box warning” to be added to Rapamune’s labeling. This warning informed prescribers and patients that Rapamune use by liver transplant patients is associated with serious risks, including graft loss and death.

17. In 2003, FDA required another “black box warning” be added to Rapamune’s labeling. This time, to caution that Rapamune use by lung transplant patients is associated with serious risks, including death.

18. In 2007, another warning was added regarding a serious side effect called proteinuria (protein in urine).

19. 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.

ALLEGATIONS RELATING TO DEFENDANT’S MARKETING AND PROMOTION OF RAPAMUNE

20. Despite Rapamune’s limited 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.

21. Wyeth also promoted Rapamune off-label using a “conversion” protocol (switching a patient to Rapamune after de novo use of a different transplant rejection drug).

22. Wyeth also promoted Rapamune off-label for use after kidney transplant in combination with drugs other than indicated in the product’s FDA approved labeling.

VIOLATIONS OF LAW: COLORADO CONSUMER PROTECTION ACT, §§ 6-1-101 et seq

23. Plaintiff realleges and incorporates by reference herein each and every allegation contained in the preceding Paragraphs 1 through 22.

24. Defendant, in the course of engaging in the development, manufacture, promotion, sales, and interstate distribution of the prescription drug Rapamune®, has engaged in a course of trade or commerce which constitutes deceptive, or

misleading practices, and is therefore unlawful under the CCPA by making representations about Rapamune® when Defendant knew the representations were not true.

25. Defendant, in the course of marketing, promoting, selling, and distributing the prescription drug Rapamune®, has engaged in a course of trade or commerce which constitutes deceptive, or misleading practices, and is therefore unlawful under C.R.S. §6-1-105(e) by representing that Rapamune® has characteristics, uses, and benefits that it does not have.

26. Defendant, in the course of marketing, promoting, selling, and distributing the prescription drug Rapamune®, has engaged in a course of trade or commerce which constitutes deceptive, or misleading practices, and is therefore unlawful under C.R.S. §6-1-105(u) by failing to disclose material information concerning its product that was known at the time of sale and such failure was intended to induce consumers to buy the product.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, State of Colorado, respectfully request that this Court:

A. Permanently enjoin and restrain Defendant, its agents, employees, and all other persons and entities, corporate or otherwise, in active concert or participation with any of them, from engaging in deceptive or misleading conduct, acts, or practices which violate the Colorado Consumer Protection Act in the promotion and

marketing of its prescription drug Rapamune®, pursuant to C.R.S. § 6-1-105(1)(e) ;

B. Order Defendant to pay civil penalties of up to \$2,000 for each and every violation of the CCPA, pursuant to C.R.S. § 6-1-112(1)(a);

C. A judgment in an amount to be determined at trial for disgorgement, or other equitable relief pursuant to § 6-1-110(1).

D. Order Defendant to pay all costs for the prosecution and investigation of this action, pursuant to § 6-1-113(4), C.R.S. (2014); and

E. Grant Plaintiff such other and further relief as the Court deems equitable and proper.

Dated this 6th day of August, 2014.

Respectfully submitted,

FOR THE STATE OF COLORADO

JOHN W. SUTHERS
Attorney General

/s/ Jay B. Simonson
JAY B. SIMONSON, 24077*
First Assistant Attorney General
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