**IN THE IOWA DISTRICT COURT FOR POLK COUNTY**

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| **STATE OF IOWA ex rel THOMAS J. MILLER, ATTORNEY GENERAL OF IOWA,** | ) | |
| **Plaintiff,** | ) | **Equity No.** EQCE 076903 |
| **vs.** | ) | |
| **WYETH PHARMACEUTICALS INC.** | ) | |
| **Defendant.** | ) | |

## PETITION

1. Plaintiff, the State of Iowa, ex rel. Attorney General Thomas J. Miller ("Attorney General" or "State"), brings this action against Defendant WYETH PHARMACEUTICALS INC. ("Defendant or Wyeth") for violating Iowa Consumer Fraud Act, Iowa Code § 714.16.

2. The Attorney General brings this action pursuant to the Iowa Consumer Fraud Act, in the public interest, to protect the public's health, safety, and welfare and under his authority pursuant to Iowa Code § 714.16. The Attorney General has reason to believe that the above-named Defendant has violated and/or is continuing to violate the Iowa Consumer Fraud Act. The Attorney General also has reason to believe that this action is in the public interest.

3. Upon information and belief, the State of Iowa alleges as follows:

## JURISDICTION AND VENUE

4. This Court has jurisdiction over Wyeth pursuant to Iowa Code § 714.16 because Wyeth has transacted business within the State of Iowa at all times relevant to this Petition.

5. Venue for this action properly lies in Polk County, Iowa, pursuant to Iowa Code § 714.16(10), because Wyeth transacts business in Polk County, Iowa and/or some of the transactions out of which this action arose occurred in Polk County, Iowa.

## PARTIES

6. Plaintiff, State of Iowa ex rel. Thomas J. Miller, Attorney General, is charged with enforcing the Iowa Consumer Fraud Act, which prohibits unfair or deceptive acts or practices. Pursuant to the Iowa Consumer Fraud Act, the Attorney General may initiate civil law enforcement proceedings in the name of the State to enjoin violations of the Iowa Consumer Fraud Act 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 Texas selling and promoting the prescription drug Rapamune®.

## BACKGROUND

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

9. 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.

10. 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).

11. 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.

12. 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.

13. 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.

14. 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.

15. 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.

16. In 2007, another warning was added regarding a serious side effect called

proteinuria (protein in urine).

17. 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

18. 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.

19. 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).

20. 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.

21. This Petition for injunctive relief has not been presented to, or denied by, any other judge of the district court.

22. Pursuant to Iowa R. Civ. P. 1.207, no security is required of the State.

## VIOLATIONS OF LAW: IOWA CONSUMER FRAUD ACT

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 unfair, deceptive, or misleading practices, which are unlawful under the Iowa Consumer Fraud Act, Iowa Code § 714.16(2) 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 unfair, deceptive, or misleading practices, which are unlawful under Iowa Consumer Fraud Act, Iowa Code § 714.16(2), by representing that Rapamune® has sponsorship, approval, characteristics, ingredients, uses, benefits, quantities, or qualities that it does not have.

## PRAYER FOR RELIEF

WHEREFORE, Plaintiff, State of Iowa, 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 unfair, deceptive or misleading conduct, acts, or practices which violate the Iowa Consumer Fraud Act in the promotion and marketing of its prescription drug Rapamune®, pursuant to Iowa Code § 714.16(7);

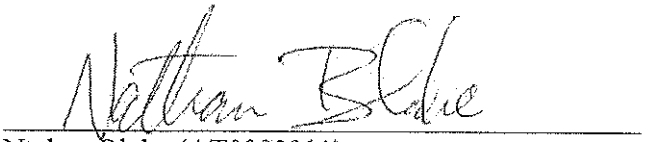
B. Order Defendant to pay civil penalties of up to $40,000 for each and every violation of the Iowa Consumer Fraud Act, pursuant to Iowa Code § 714.16(7);

C. Order Defendant to pay all costs for the prosecution and investigation of this action, pursuant to Iowa Code § 714.16(11); and

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

Respectfully submitted,

THOMAS J. MILLER
IOWA ATTORNEY GENERAL



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