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By: Natalie A. Serock (040892010)
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SUPERIOR COURT OF NEW JERSEY
CHANCERY DIVISION,
MERCER COUNTY
DOCKET NO. C-60-14

JOHN J. HOFFMAN, Acting Attorney General of the State of New Jersey, and STEVE C. LEE, Acting Director of the New Jersey Division of Consumer Affairs,

Plaintiffs,

v.

WYETH PHARMACEUTICALS INC.,

Defendants.

Civil Action

COMPLAINT

1. Plaintiffs, John J. Hoffman, Acting Attorney General of the State of New Jersey ("Attorney General"), with offices located at 124 Halsey Street, Fifth Floor, Newark, New Jersey, and Steve C. Lee, Acting Director of the New Jersey Division of Consumer Affairs ("Director"), with offices located at 124 Halsey Street, Seventh Floor, Newark, New Jersey (collectively, "Plaintiffs") bring this action against Wyeth Pharmaceuticals Inc. ("Defendant" or "Wyeth"), for violating the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1 et seq. ("CFA"),

by among other things: (1) in its advertising, offering for sale and/or selling the prescription drug Rapamune®, making representations about the drug that Defendant knew were not true; and (2) in its advertising, offering for sale and/or selling the prescription drug Rapamune®, representing that the drug has sponsorship, approval, characteristics, ingredients, uses, benefits, quantities or qualities that it does not have.

2. This Complaint is being filed concurrently with a Final Consent Judgment.

JURISDICTION AND VENUE

3. This Court has jurisdiction over the subject matter of this action and over the Defendant pursuant to the CFA, N.J.S.A. 56:8-1 et seq. Venue is proper pursuant to R. 4:3-2 because Mercer County is a county in which the Defendant has advertised and/or conducted business.

PARTIES

4. The Attorney General is charged with enforcing the CFA. The Director is charged with administering the CFA on behalf of the Attorney General. By this action, the Attorney General and the Director seek injunctive and other relief for violations of the CFA, pursuant to N.J.S.A. 56:8-8, 8-11, 8-13, and 8-19, against Defendant for engaging in unconscionable commercial practices and misrepresentations in connection with the advertising, offer for sale and/or sale of its prescription drug Rapamune®.

5. Wyeth is a wholly owned subsidiary of Pfizer, Inc., a Delaware corporation with its principal place of business at 235 East 42nd Street, New York, New York 10017. At all

relevant times, Wyeth has marketed, promoted, distributed, offered for sale and sold the prescription drug Rapamune® to consumers throughout the United States, including New Jersey.

GENERAL ALLEGATIONS

6. With certain limited exceptions not relevant here, a drug may not be distributed in interstate commerce without approval from the Food and Drug Administration ("FDA").

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

8. 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.

9. 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 uses ("Off-Label Uses"). However, manufacturers are proscribed by federal law from promoting the drug for off-label uses.

10. The FDA approved Wyeth's Rapamune® (sirolimus) as an "adjunct" drug in combination with cyclosporine and steroids to prevent rejection of the transplanted kidney. The FDA did not approve Rapamune® for use by any other type of organ transplant patient nor is it approved for combination with other drugs.

11. The FDA only approved Rapamune® as "de-novo" treatment – meaning for use immediately after a transplant ("De-Novo Treatment"). The FDA did not approve Rapamune®

for "conversion" treatment – meaning switching to another immunosuppressant sometime after the transplant ("Conversion Treatment").

12. In 2002, the 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.

13. In 2003, the FDA required another "black box warning" be added to Rapamune's® labeling. This warning informed prescribers and patients that Rapamune® use by lung transplant patients is associated with serious risks, including death.

14. In 2007, the FDA required a third "black box warning" be added to Rapamune's® labeling. This warning informed prescribers and patients that Rapamune® use can cause a serious side effect known as proteinuria (protein in urine).

15. In June 2009, the FDA required a fourth "black box warning" be added to Rapamune's® labeling. This warning was added based on the results of a Wyeth study that suggested that liver transplant patients who are prescribed Rapamune® experience "significantly higher" organ rejection than patients treated with alternative immunosuppressant drugs.

16. Despite the fact that the FDA only approved Rapamune for use in kidney/renal transplants, and despite the FDA required "black box warnings" relating to Rapamune® use in lung and liver transplants, Wyeth continued to promote Rapamune® for use by patients who had liver, heart, pancreas, islet (pancreas cells) and lung transplants.

17. Moreover, despite the fact that the FDA only approved Rapamune® for De-Novo Treatment, Wyeth marketed Rapamune® for Conversion Treatment, meaning that a patient could

be switched to Rapamune® after use of a different transplant rejection drug immediately after a transplant.

18. Additionally, Wyeth promoted Rapamune® off-label for use after kidney transplant in combination with other drugs other than indicated in the Rapamune's® FDA-approved labeling.

COUNT I

VIOLATION OF THE CFA BY DEFENDANT UNCONSCIONABLE COMMERCIAL PRACTICES)

19. Plaintiffs repeat and reallege the allegations contained in paragraphs 1 through 18 as if more fully set forth herein.

20. The CFA, N.J.S.A. 56:8-2, prohibits:

> The act use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or knowing[] concealment, suppression or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise . . .

21. Defendant, in the course of marketing, promoting, selling and distributing the prescription drug Rapamune® has engaged in the advertisement or sale of merchandise through unconscionable commercial practices in violation of the CFA, specifically by making representations about Rapamune®, when Defendant knew the representations were not true.

COUNT II

VIOLATION OF THE CFA BY DEFENDANT (MISREPRESENTATIONS)

22. Plaintiffs repeat and reallege the allegations contained in paragraphs 1 through 21 as is more fully set forth herein.

23. Defendant, in the course of marketing, promoting, selling, and distributing the prescription drug Rapamune® has engaged in the advertisement or sale of merchandise through misrepresentations in violation of the CFA, specifically by representing that Rapamune® has sponsorship, approval, characteristics, ingredients, uses, benefits, quantities, or qualities that it does not have.

PRAYER FOR RELIEF

WHEREFORE, based on the foregoing allegations, Plaintiffs respectfully request that the Court enter judgment against Defendant:

(a) Finding that the acts of Defendant constitute unlawful practices in violation of the CFA, N.J.S.A. 56:8-1 et seq.;

(b) Permanently enjoining Defendant and its owners, officers, directors, shareholders, members, founder, managers, agents, servants, employees, representatives, corporations, independent contractors, subsidiaries, affiliates, successors, assigns and all other entities or persons directly under its control, to cease and desist from engaging in or continuing to engage in, or doing any acts or practices in violation of the CFA, N.J.S.A. 56:8-1 et seq., including, but not limited to, the acts and practices alleged in the Complaint;

(c) Directing Defendant to restore to any affected person, whether or not named in this Complaint, any money or real or personal property acquired by means of any practice alleged herein to be unlawful and found to be unlawful, as authorized by the CFA, N.J.S.A. 56:8-8;

(d) Assessing the maximum statutory civil penalties against Defendant for each and every violation of the CFA, in accordance with the CFA, N.J.S.A. 56:8-13;

(e) Directing the assessment of costs and fees, including attorneys' fees, against Defendant for the use of the State of New Jersey, as authorized by the CFA, N.J.S.A. 56:8-11 and N.J.S.A. 56:8-19; and

(f) Granting such other relief as the interest of justice may require.

JOHN J. HOFFMAN
ACTING ATTORNEY GENERAL OF NEW JERSEY
Attorney for Plaintiffs

By: Natalie Serock
Natalie A. Serock
Deputy Attorney General

Dated: August 6, 2014
Newark, New Jersey

RULE 4:5-1 CERTIFICATION

I certify, to the best of my information and belief, that the matter in controversy in this action involving the aforementioned violations of the CFA, is not the subject of any other action pending in any other court of this State. I further certify, to the best of my information and belief, that the matter in controversy in this action is not the subject of a pending arbitration proceeding in this State, nor is any other action or arbitration proceeding contemplated. I also certify that there is no other party who should be joined in this action at this time.

JOHN J. HOFFMAN
ACTING ATTORNEY GENERAL OF NEW JERSEY
Attorney for Plaintiffs

By: Natalie Serock
Natalie A. Serock
Deputy Attorney General

Dated: August 6, 2014
Newark, New Jersey

RULE 1:38-7(c) CERTIFICATION OF COMPLIANCE

I certify that confidential personal identifiers have been redacted from documents now submitted to the court, and will be redacted from all documents submitted in the future in accordance with Rule 1:38-7(b).

JOHN J. HOFFMAN
ACTING ATTORNEY GENERAL OF NEW JERSEY
Attorney for Plaintiffs

By: Natalie Serock
Natalie A. Serock
Deputy Attorney General

Dated: August 6, 2014
Newark, New Jersey

DESIGNATION OF TRIAL COUNSEL

Pursuant to R. 4:25-4, Deputy Attorney General Natalie A. Serock is hereby designated as trial counsel for the Plaintiffs in this action.

JOHN J. HOFFMAN
ACTING ATTORNEY GENERAL OF NEW JERSEY
Attorney for Plaintiffs

By: Natalie Serock
Natalie A. Serock
Deputy Attorney General

Dated: August 6, 2014
Newark, New Jersey