JOHN J. HOFFMAN
ACTING ATTORNEY GENERAL OF NEW JERSEY
Division of Law
124 Halsey Street - 5th Floor
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Attorney for Plaintiffs

By: Natalie A. Serock (040892010)
Deputy Attorney General
(973) 648-3070

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

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Attorney for Plaintiffs

By: Natalie Serock (040892009)
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A True Copy
Sue Regan
SUE REGAN
Deputy Clerk of Superior Court

CLERK OF SUPERIOR COURT
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MERCER COUNTY
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DEPUTY CLERK OF SUPERIOR COURT

SUPERIOR COURT OF NEW JERSEY
CHANCERY DIVISION, MERCER COUNTY
DOCKET NO. MER-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,

Defendant.

Civil Action

FINAL CONSENT JUDGMENT

Plaintiffs 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, (collectively, "Plaintiffs"), have filed a Complaint for a permanent injunction and other relief in this matter pursuant to the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1 et seq. ("CFA"), alleging that Defendant Wyeth Pharmaceuticals Inc. (hereinafter "Wyeth") committed violations of the aforementioned Act. Pfizer Inc ("Pfizer") acquired Wyeth in October 2009, and Wyeth became a wholly owned subsidiary of Pfizer. Pfizer represents that the conduct at issue occurred prior to this acquisition. Plaintiffs, by its counsel, and Pfizer, by its counsel, have agreed to the entry of

this Final Consent Judgment ("Consent Judgment") by the Court without trial or adjudication of any issue of fact or law, and without finding or admission of wrongdoing or liability of any kind. Pfizer, as parent of Wyeth, agrees to be bound by the terms of this Consent Judgment.

IT IS HEREBY ORDERED THAT:

1. FINDINGS

1.1 This Court has jurisdiction over the subject matter of this lawsuit and over all Parties.

1.2 The terms of this Consent Judgment shall be governed by the laws of the State of New Jersey.

1.3 Entry of this Consent Judgment is in the public interest and reflects a negotiated agreement among the Parties.

1.4 The Parties have agreed to resolve the issues resulting from the Covered Conduct by entering into this Consent Judgment.

1.5 Pfizer is willing to enter into this Consent Judgment regarding the Covered Conduct in order to resolve the Attorneys General's concerns under the State Consumer Protection Laws as to the matters addressed in this Consent Judgment and thereby avoid significant expense, inconvenience, and uncertainty.

1.6 The Parties have agreed to resolve the issues raised by the Covered Conduct by entering into this Consent Judgment.[1]

1.7 Pfizer is entering into this Consent Judgment solely for the purpose of settlement, and nothing contained herein may be taken as or construed to be an admission or concession of any violation of law, rule, or regulation, or of any other matter of fact or law, or of any liability

[1] This agreement is entered into pursuant to and subject to the State Consumer Protection laws cited in footnote 7.

or wrongdoing, all of which Pfizer expressly denies. Pfizer does not admit any violation of the State Consumer Protection Laws set forth in footnote 7, and does not admit any wrongdoing that was or could have been alleged by any Attorney General before the date of the Consent Judgment under those laws. No part of this Consent Judgment, including its statements and commitments, shall constitute evidence of any liability, fault, or wrongdoing by Pfizer. This document and its contents are not intended for use by any third party for any purpose, including submission to any court for any purpose.

1.8 This Consent Judgment shall not be construed or used as a waiver or limitation of any defense otherwise available to Pfizer in any action, or of Pfizer's right to defend itself from, or make any arguments in, any private individual, regulatory, governmental, or class claims or suits relating to the subject matter or terms of this Consent Judgment. This Consent Judgment is made without trial or adjudication of any issue of fact or law or finding of liability of any kind. Notwithstanding the foregoing, a State may file an action to enforce the terms of this Consent Judgment.

1.9 It is the intent of the Parties that this Consent Judgment not be admissible in other cases or binding on Pfizer in any respect other than in connection with the enforcement of this Consent Judgment.

1.10 No part of this Consent Judgment shall create a private cause of action or confer any right to any third party for violation of any federal or state statute except that a State may file an action to enforce the terms of this Consent Judgment.

1.11 This Consent Judgment (or any portion thereof) shall in no way be construed to prohibit Pfizer from making representations with respect to any Pfizer Product that are required

under Federal law or regulations or in Food and Drug Administration ("FDA") approved Labeling.

1.12 Nothing in this Consent Judgment shall require Pfizer to:

(a) take any action that is prohibited by the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq. ("FDCA") or any regulation promulgated thereunder, or by the FDA; or

(b) fail to take any action that is required by the FDCA or any regulation promulgated thereunder, or by the FDA. Any written or oral Promotional claim subject to this Consent Judgment which is the same, or materially the same, as the language required or agreed to by the Director of the Office of Prescription Drug Promotion, the Director of the Advertising and Promotional Labeling Branch, the Director of the Center for Drug Evaluation and Research, or the Director of the Center for Biologics Evaluation and Research, or their authorized designees in writing shall not constitute a violation of this Consent Judgment, unless facts are or become known to Pfizer that cause the claim to be false, misleading, or deceptive.

2. DEFINITIONS

The following definitions shall be used in construing this Consent Judgment:

2.1 "Clearly and Conspicuously" shall mean a disclosure in size, color, contrast, font, and location that is readily noticeable, readable and understandable and is presented in proximity to all information necessary to prevent it from being misleading or deceptive. A statement may not contradict or be inconsistent with any other information with which it is presented. If a statement modifies, explains, or clarifies other information or is necessary to prevent other information from being misleading or deceptive, then the statement must be presented in close

proximity to that information, in a manner that is readily noticeable, readable, and understandable, and it must not be obscured in any manner.

2.2 "Covered Conduct" shall mean Wyeth's Promotional and marketing practices, and dissemination of information and remuneration to HCPs regarding the prescription drug Rapamune® through the Effective Date of the Consent Judgment.

2.3 "Effective Date" shall mean the date on which a copy of this Consent Judgment, duly executed by Pfizer and by the Signatory Attorney General, is approved by, and becomes a Consent Judgment of the Court.

2.4 "FDA Guidances for Industry" shall mean final documents issued by the FDA pursuant to 21 U.S.C. §371(h) that represent the FDA's current thinking on a topic.

2.5 "Health Care Professional" or "HCP" shall mean any physician or other health care practitioner, who is licensed to provide health care services or to prescribe pharmaceutical products.

2.6 "Healthcare Organization" shall mean an entity, public or private, that is intended and incentivized to tie patient care to quality metrics and value models and includes organizations such as payors, Health Maintenance Organizations (HMO), Long Term Care (LTC) pharmacy providers, Pharmacy Benefit Management (PBM), Integrated Delivery Networks (IDN), Accountable Care Organizations (ACO), and hospital formulary committees.

2.7 "Labeling" shall mean all FDA-approved labels and other written, printed, or graphic matter (a) upon any article or any of its containers or wrappers, or (b) accompanying such article.

2.8 "Medical Information Response" shall mean a non-Promotional, scientific communication to address Unsolicited Requests for medical information from HCPs.

2.9 "Medical Outcome Specialists" shall mean Pfizer personnel who work with Healthcare Organizations that determine the drugs to be placed on a formulary.

2.10 "Multistate Executive Committee" shall mean the Attorneys General and their staffs representing California, Florida, Illinois, Maryland, New York, North Carolina, Oregon, Pennsylvania, and Texas.

2.11 "Multistate Working Group" shall mean the Attorneys General and their staffs representing Alabama, Arizona, Arkansas, California, Colorado, Delaware, District of Columbia, Florida, Georgia[2], Hawaii[3], Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Hampshire, New Jersey[4], New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, South Dakota, Tennessee, Texas, Utah[5], Virginia, Washington, and Wisconsin.

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[2] With regard to Georgia, the Administrator of the Fair Business Practices Act, appointed pursuant to O.C.G.A. § 10-1-395, is statutorily authorized to undertake consumer protection functions for the State of Georgia. References to the "States," "Parties," or "Attorneys General," with respect to Georgia, include the Administrator of the Fair Business Practices Act.

[3] Hawaii is being represented on this matter by its Office of Consumer Protection, an agency which is not part of the state Attorney General's Office, but which is statutorily authorized to undertake consumer protection functions, including legal representation of the State of Hawaii. For simplicity, the entire group will be referred to as the "Attorney General," and such designation, as it includes Hawaii, refers to the Executive Director of the State of Hawaii Office of Consumer Protection.

[4] With regard to New Jersey, the Attorney General, pursuant to *N.J.S.A.* 52:17A-4, is charged with the responsibility of enforcing the Consumer Fraud Act, *N.J.S.A.* 56:8-1 *et seq.* ("CFA"). The Director of the New Jersey Division of Consumer Affairs, pursuant to *N.J.S.A.* 52:17B-124, is charged with the responsibility of administering the CFA. References to the "States," "Parties," or "Attorneys General," with respect to New Jersey, includes the Director of the New Jersey Division of Consumer Affairs.

[5] With regard to Utah, the Utah Division of Consumer Protection is charged with administering and enforcing the Consumer Sales Practices Act, the statute relevant to this Consent Judgment. References to the "States," "Parties," or "Attorneys General," with respect to Utah, refers to the Utah Division of Consumer Protection.

2.12 "Off-Label" shall mean a use related to an indication that was not approved by the FDA or information that was not contained in the FDA label at the time information regarding such use was communicated.

2.13 "Parties" shall mean Wyeth, Pfizer, and the Signatory Attorney General.

2.14 "Pfizer" shall mean Pfizer Inc and its wholly owned subsidiary, Wyeth Pharmaceuticals Inc., including all of its subsidiaries and divisions, predecessors, successors, and assigns doing business in the United States.

2.15 "Pfizer Marketing" shall mean Pfizer personnel responsible for marketing Rapamune in the United States.

2.16 "Pfizer Medical" shall mean Pfizer personnel assigned to the Pfizer medical organization, including those personnel assigned to Pfizer's Medication Information Department ("USMI") or any successor group performing the same functions as the USMI.

2.17 "Pfizer Product" or "Product" shall mean any FDA-approved prescription drug or biological product manufactured, distributed, sold, marketed or Promoted by Pfizer in the United States.

2.18 "Pfizer Sales" shall mean the Pfizer sales force, if any, responsible for United States Rapamune sales, including, but not limited to, the field force and all management personnel such as district managers, regional managers, vice president(s) over sales, and president over sales.[6]

2.19 "Promotional," "Promoting," or "Promote" shall mean representations about a Pfizer Product and other practices intended to increase sales or that attempt to influence prescribing practices of HCPs, including direct-to-consumer.

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[6] Pfizer represents that in January 2011, Pfizer withdrew the sales force responsible for marketing Rapamune®.

2.20 "Promotional Materials" shall mean any item used to Promote Rapamune.

2.21 "Promotional Media" shall mean Promotional Materials in any media format for use in speaker programs.

2.22 "Promotional Speaker" shall mean an HCP speaker engaged by Pfizer to Promote Rapamune.

2.23 "Rapamune" shall mean all Pfizer immunosuppressant Products that contain sirolimus or any other Pfizer Product that is currently approved by the FDA as prophylactic for solid organ rejection after transplant surgery.

2.24 "Reprints Containing Off-Label Information" shall mean articles or reprints from a scientific or medical journal, as defined in 21 C.F.R. 99.3(j), or reference publication, as defined in 21 C.F.R. 99.3(i), describing an Off-Label use of Rapamune.

2.25 "Signatory Attorney General" shall mean the Attorney General of the State of New Jersey, or his authorized designee, who has agreed to this Consent Judgment.

2.26 "State Consumer Protection Laws" shall mean the consumer protection laws cited in footnote 7 under which the Attorneys General have conducted the investigation.[7]

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[7] ALABAMA—Alabama Deceptive Trade Practices Act § 8-19-1 et seq. (2002); ARIZONA – Consumer Fraud Act, A.R.S. §44-1521 et seq.; 1521 et seq.; ARKANSAS – Arkansas Deceptive Trade Practices Act, Ark. Code Ann. § 4-88-101, et seq.; CALIFORNIA – Bus. & Prof Code §§ 17200 et seq. and 17500 et seq.; COLORADO – Colorado Consumer Protection Act, Colo. Rev. Stat. § 6-1-101 et seq.; DELAWARE – Delaware Consumer Fraud Act, Del. CODE ANN. tit. 6, §§ 2511 to 2527; DISTRICT OF COLUMBIA, District of Columbia Consumer Protection Procedures Act, D.C. Code §§ 28-3901 et seq.; FLORIDA – Florida Deceptive and Unfair Trade Practices Act, Part II, Chapter 501, Florida Statutes, 501.201 et. seq.; GEORGIA - Fair Business Practices Act, O.C.G.A. Sections 10-1-390 et seq.; HAWAII – Uniform Deceptive Trade Practice Act, Haw. Rev. Stat. Chpt. 481A and Haw. Rev. State. Chpt. 480; ILLINOIS – Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/2 et seq.; INDIANA- Ind. Code §§ 24-5-0.5-0.1 et seq.; IOWA - Iowa Consumer Fraud Act, Iowa Code Section 714.16; KANSAS - Kansas Consumer Protection Act, K.S.A. 50-623 et seq.; KENTUCKY – Kentucky Consumer Protection Act, KRS Ch. 367.110, et seq.; LOUISIANA – Unfair Trade-Practices and Consumer Protection Law, LSA-R.S. 51:1401, et seq.; MAINE – Unfair Trade Practices Act, 5 M.R.S.A. § 207 et seq.; MARYLAND - Maryland Consumer Protection Act, Md. Code Ann., Com. Law §§ 13-101 et seq.; MASSACHUSETTS – Mass. Gen. Laws c. 93A, §§ 2 and 4; MICHIGAN – Michigan Consumer Protection Act, MCL § 445.901 et seq.; MINNESOTA - Minnesota Deceptive Trade Practices Act, Minn. Stat. §§ 325D.43-48; Minnesota False Advertising Act, Minn. Stat. § 325F.67; Minnesota Consumer Fraud Act, Minn. Stat. §§ 325F.68-70; Minnesota Deceptive Trade Practices Against Senior Citizens or Disabled Persons Act, Minn. Stat. § 325F.71.; MISSISSIPPI - Mississippi Consumer Protection Act, Miss. Code Ann.§ 75-24-1, et seq.; MISSOURI – Missouri Merchandising Practices Act, Mo. Rev. Stat. §§ 407.010 et seq.; NEBRASKA –

2.27 "Unsolicited Request" shall mean a request for information regarding Rapamune communicated to an agent of Pfizer that has not been prompted by or on behalf of Pfizer.

2.28 "Wyeth" shall mean Wyeth Pharmaceuticals Inc., a wholly owned subsidiary of Pfizer Inc.

2.29 Any reference to a written document shall mean a physical paper copy of the document, an electronic version of the document, or electronic access to such document.

3. COMPLIANCE PROVISIONS

IT IS FURTHER ORDERED, ADJUDGED AND DECREED THAT:

Promotional Activities

3.1 Pfizer shall not make, or cause to be made, any written or oral claim that is false, misleading, or deceptive regarding any Pfizer Product.

3.2 Pfizer shall not make any claim comparing 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.

Consumer Protection Act, Neb. Rev. Stat. §§ 59-1601 et seq. and Uniform Deceptive Trade Practices Act, Neb. Rev. Stat. §§ 87-301 et seq.; NEVADA – Deceptive Trade Practices Act, Nevada Revised Statutes 598.0903 et seq.; NEW HAMPSHIRE - New Hampshire Consumer Protection Act, RSA 358-A; NEW JERSEY – New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1 et seq.; NEW MEXICO – NMSA 1978, § 57-12-1 et seq.; NEW YORK – General Business Law Art. 22-A, §§ 349-50, and Executive Law § 63(12); NORTH CAROLINA – North Carolina Unfair and Deceptive Trade Practices Act, N.C.G.S. 75-1.1, et seq.; NORTH DAKOTA – Unlawful Sales or Advertising Practices, N.D. Cent. Code § 51-15-02 et seq.; OHIO – Ohio Consumer Sales Practices Act, R.C. 1345.01, et seq.; OKLAHOMA – Oklahoma Consumer Protection Act 15 O.S. §§ 751 et seq.; OREGON – Oregon Unlawful Trade Practices Act, Or. Rev. Stat. § 646.605 et seq.; PENNSYLVANIA – Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 P.S. 201-1 et seq.; SOUTH DAKOTA – South Dakota Deceptive Trade Practices and Consumer Protection, SDCL ch. 37-24; TENNESSEE – Tennessee Consumer Protection Act, Tenn. Code Ann. 47-18-101 et seq.; TEXAS – Texas Deceptive Trade Practices-Consumer Protection Act, Tex. Bus. And Com. Code 17.41, et seq.; UTAH - Consumer Sales Practices Act, Utah Code Ann. §§ 13-11-1 et seq.; VIRGINIA-Virginia Consumer Protection Act, Va Code Ann. §59.1-196 et seq.; WASHINGTON – Unfair Business Practices/Consumer Protection Act, RCW §§ 19.86 et seq.; WISCONSIN – Wis. Stat. § 100.182 et seq. (Fraudulent Drug Advertising Representations).

3.3 Pfizer shall not Promote Rapamune to an HCP who practices in a specialty that is unlikely to prescribe for a use in Rapamune's FDA approved Labeling.

3.4 Pfizer shall not make any written or oral Promotional claim of safety or effectiveness for any Pfizer Product in a manner that violates the FDCA, accompanying regulations, or voluntary agreements with FDA, as interpreted by the FDA in a writing by the Director of the Center for Drug Evaluation at the FDA.

3.5 Pfizer shall not Promote any Pfizer Product for Off-Label uses.

3.6 Pfizer shall not make any claim that contradicts or minimizes a precaution, warning, or adverse reaction that is described in product Labeling for Rapamune.

3.7 In Promotional Materials, Pfizer shall Clearly and Conspicuously disclose all material facts regarding the following: the risks associated with Rapamune as set forth in the products' FDA-approved Labeling; information in any boxed warning; and facts about the negative consequences and side effects that can result from use of Rapamune. Pfizer shall present information about effectiveness and risk in a balanced manner. Whenever Pfizer knows or has reason to believe the current Labeling does not reflect the efficacy or risks of Rapamune, Pfizer shall promptly notify the Food and Drug Administration.

3.8 Pfizer shall not 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.

3.9 Pfizer shall require that all Promotional Speakers comply with Pfizer's obligations in paragraphs 3.1 through 3.8, 3.24, and 3.28 of this Consent Judgment, including, but not limited to, ensuring that all Promotional Speakers' Promotional Materials and Promotional Media for Rapamune comply with Pfizer's obligations in this Consent Judgment.

3.10 Pfizer shall notify its sales force promptly of any warning letter received from the FDA which affects the conduct of any sales representative in Promoting the relevant Pfizer Product and shall promptly provide a detailed explanation of the effect of the letter on the Promotion of Pfizer Products.

Financial Incentives to Pfizer Sales, Medical Outcome Specialists, and/or Pfizer Marketing

3.11 Pfizer's financial incentives shall be designed to ensure that Pfizer Sales, Medical Outcome Specialists, and/or Pfizer Marketing are not motivated to engage in improper Promoting, selling, and marketing of Rapamune.

3.12 Pfizer's financial incentives shall not include mechanisms to provide incentive compensation for sales that may be attributable to the Off-Label uses of any Pfizer Product.

3.13 For six (6) years from the Effective Date of this Consent Judgment, Pfizer shall continue to implement measures whereby sales goals, if any, for Rapamune can be met without including Off-Label prescriptions.

Dissemination and Exchange of Medical Information

The following provisions shall be effective for six (6) years from the Effective Date of this Consent Judgment.

3.14 Pfizer shall not knowingly disseminate any Medical Information Response, including one that describes any Off-Label use of Rapamune, that makes any false, misleading, or deceptive representation regarding Rapamune or any false, misleading, or deceptive statement concerning a competing product.

3.15 Pfizer Sales, Pfizer Marketing, and Medical Outcomes Specialists shall not develop the medical content of Medical Information Responses regarding Rapamune. Notwithstanding the foregoing, Medical Outcomes Specialists may assist in the development of pharmacoeconomic content of Medical Information Responses.

3.16 Medical Information Responses to Unsolicited Requests for Off-Label information regarding Rapamune may be disseminated only by Pfizer Medical.

3.17 Pfizer Medical shall have ultimate responsibility for developing and approving all Medical Information Responses regarding Rapamune. Additional approvals may be provided by Pfizer's legal department. Pfizer shall not distribute any such materials unless:

(a) clinically relevant information is included in these materials to provide scientific balance;

(b) data in these materials are presented in an unbiased, non-Promotional manner; and

(c) these materials are clearly distinguishable from sales aids and other Promotional Materials.

Responses to Unsolicited Requests for Off-Label Information

The following provisions shall be effective for six (6) years from the Effective Date of this Consent Judgment.

3.18 If Pfizer elects to respond to an Unsolicited Request for Off-Label information Pfizer Medical shall provide specific, accurate, objective, and scientifically balanced responses. Any such response shall not Promote Rapamune for any Off-Label use(s).

3.19 Any written Pfizer response to an Unsolicited Request for Off-Label information regarding Rapamune shall be a Medical Information Response and shall include:

(a) a copy of the FDA-required Labeling, if any, for the product (e.g., FDA- approved package insert and, if the response is for a consumer, FDA-approved patient labeling);

(b) a prominent statement notifying the recipient that the FDA has not approved or cleared the product as safe and effective for the Off-Label use addressed in the accompanying materials;

(c) a prominent statement disclosing the indication(s) for which FDA has approved or cleared the product;

(d) a prominent statement providing all important safety information including, if applicable, any boxed warning for the product;

(e) non-biased information or data relating to the particular Off-Label use that is the subject of the request, including applicable data that are not supportive or that cast doubt on the safety or efficacy of that use; and

(f) a comprehensive list of references for all of the information disseminated in the response (e.g., a bibliography of publications in peer-reviewed medical journals or in medical or scientific texts; citations for data on file, for summary documents, or for abstracts).

3.20 Pfizer Sales, Pfizer Marketing, and Medical Outcome Specialists may respond orally to an Unsolicited Request for Off-Label information regarding Rapamune only by offering to request on behalf of the HCP that a Medical Information Response be sent to the HCP in follow up or by offering to put the HCP in touch with Pfizer Medical. Notwithstanding the foregoing, Medical Outcomes Specialists may respond to inquiries related to pharmacoeconomics or health outcomes from formulary decision makers or the groups responsible for the management of health benefits within Healthcare Organizations, but not prescribers unless employed or engaged by a Healthcare Organization in a role connected to formulary decisions or the management of health benefits.

3.21 Information distributed by USMI in response to an Unsolicited Request for Off-Label information shall be:

(a) provided only to the individual making the request;

(b) tailored to answer only the specific Off-Label question(s) asked;

(c) scientific in nature; and

(d) unaccompanied by other material or information that is Promotional in nature or tone.

Reprints

3.22 Pfizer shall not disseminate any information describing any Off-Label use of any Pfizer Product if such use has been submitted to the FDA for approval and the FDA has either advised Pfizer that it refuses to approve such application or that FDA-identified deficiencies must be resolved before approval can be granted unless Pfizer has first Clearly and Conspicuously disclosed to the recipient of the information that the FDA has issued such advice. Pfizer may disclose to any recipient of such information whether the information was presented to the FDA prior to the FDA's issuance of such advice regarding the Off-Label use.

3.23 Pfizer shall not disseminate information describing any Off-Label or unapproved use of Rapamune unless such information and materials comply with applicable FDA regulations and the recommended actions in FDA Guidances for Industry.

Reprints Containing Off-Label Information

3.24 Pfizer Medical shall be responsible for the identification, selection, approval and dissemination of Reprints Containing Off-Label Information regarding Rapamune.

3.25 Reprints Containing Off-Label Information regarding Rapamune:

(a) shall be accompanied by the FDA approved Labeling for the product and contain a disclosure in a prominent location, which would include the first page or as a cover page where practicable, indicating that this article discusses Off-Label information; and

(b) shall not be referred to or used in a Promotional manner.

3.26 Reprints Containing Off-Label Information regarding Rapamune may only be disseminated by Pfizer Medical to HCPs. Notwithstanding the foregoing, Medical Outcomes Specialists may disseminate reprints relating to pharmacoeconomics or health outcomes to formulary decision makers or the groups responsible for the management of health benefits within Healthcare Organizations, but not prescribers unless employed or engaged by a Healthcare Organization in a role connected to formulary decisions or the management of health benefits.

3.27 Nothing in this Consent Judgment shall preclude Pfizer from disseminating reprints which have only an incidental reference to Off-Label information. If reprints have an incidental reference to Off-Label information, such reprints shall not be subject to the requirements of Section 3.23 and such incidental reference to Off-Label information shall not be referred to or used in a Promotional manner as prohibited by Section 3.25(b).

3.28 Pfizer shall maintain a disclosure program which allows for the anonymous disclosure of compliance policy violations and contains a no retaliation policy.

Clinical Research

3.29 Pfizer shall report clinical research regarding Rapamune in an accurate, objective and balanced manner, and as required by applicable law. For all Pfizer-sponsored clinical trials and to the extent permitted by the National Library of Medicine, Pfizer shall register clinical trials and submit clinical trial results to the federal clinical trial registry and results data bank regarding Rapamune on the publicly accessible NIH website (www.clinicaltrials.gov) as required by the FDA Amendments Act of 2007, Public Law No. 110-85, 121 Stat 823, and any accompanying regulations that may be promulgated pursuant to that Act.

3.30 When presenting information about a clinical study regarding Rapamune in any Promotional materials, Pfizer shall not do any of the following:

(a) present information or conclusions from a study that is inadequate in design, scope, or conduct to furnish significant support for such information or conclusions;

(b) use the concept of statistical significance to support a claim that has not been demonstrated to have clinical significance or validity or fails to reveal the range of variations around the cited average results;

(c) use statistical analyses and techniques on a retrospective basis to discover and cite findings not soundly supported by the study, or to suggest scientific validity and rigor for data from the study, the design or protocol of which is not amenable to formal statistical evaluations;

(d) present the information in a way that implies that the study represents larger or more general experience with the drug than it actually does;

(e) use statistics on numbers of patients, or counts of results or side effects, derived from pooling data from various insignificant or dissimilar studies in a way that suggests either that such statistics are valid if they are not or that they are derived from large or significant studies supporting favorable conclusions when such is not the case. If any results derived from pooling data are presented, Pfizer shall disclose the method of pooling;

(f) use tables or graphs to distort or misrepresent the relationships, trends, differences, or changes among the variables or products studied; or

(g) use reports or statements represented to be statistical analyses, interpretations, or evaluations that are inconsistent with or violate the established principles of statistical theory, methodology, applied practice and inference, or that are derived

from clinical studies the design, data, or conduct of which substantially invalidate the application of statistical analyses, interpretation, or evaluation.

3.31 Pfizer shall not 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 (codified at 42 U.S.C. § 1320a-7b).

4. PAYMENT

4.1 No later than thirty (30) days after the Effective Date of this Consent Judgment, Pfizer shall pay a total amount of Thirty-Five Million Dollars ($35,000,000.00) to be divided and paid by Pfizer directly to each Signatory Attorney General of the Multistate Working Group in an amount to be designated by and in the sole discretion of the Multistate Executive Committee. Said payment shall be used by the States as attorneys' fees and other costs of investigation and litigation, or to be placed in, or applied to, the consumer protection enforcement fund, including future consumer protection enforcement, consumer education, litigation or local consumer aid fund or revolving fund, used to defray the costs of the inquiry leading hereto, or for any lawful purpose, at the sole discretion of each Signatory Attorney General. The Parties acknowledge that the payment described herein is not a fine, penalty, or payment in lieu thereof.

5. RELEASE

5.1 By its execution of this Consent Judgment, the State of New Jersey releases Pfizer and all of its past and present, subsidiaries and divisions, predecessors, successors, and assigns (collectively, the "Released Parties") from the following: all civil claims, causes of action, damages, restitution, fines, costs, and penalties that the Attorney General of the State of New Jersey has asserted or could have asserted against the Released Parties under the above-cited consumer protection statutes resulting from the Covered Conduct up to and including the Effective Date.

5.2 Notwithstanding any term of this Consent Judgment, specifically reserved and excluded from the release in Paragraph 5.1 as to any entity or person, including Released Parties, are any and all of the following:

(a) any criminal liability that any person and/or entity, including Released Parties, has or may have to the State of New Jersey.

(b) any civil or administrative liability that any person and/or entity, including Released Parties, has or may have to the State of New Jersey not expressly covered by the release in Paragraph 5.1 above, including, but not limited to, any and all of the following claims:

(i) state or federal antitrust violations;

(ii) claims involving "best price," "average wholesale price," "wholesale acquisition cost," or any reporting practices;

(iii) Medicaid claims, including, but not limited to, federal Medicaid drug rebate statute violations, Medicaid fraud or abuse, and/or kickback violations related to any State's Medicaid program;

(iv) state false claims violations; and

(v) actions of state program payors of the State of New Jersey arising from the purchase of a Pfizer Product.

(c) any liability under the State of New Jersey's above-cited consumer protection laws which any person and/or entity, including Released Parties, has or may have to individual consumers.

5.3 Nothing contained in this Consent Judgment shall relieve Pfizer of the obligations it maintains under any other Consent Judgment or agreement relating to any Pfizer Product.

6. DISPUTE RESOLUTION

6.1 For the purposes of resolving disputes with respect to compliance with this Consent Judgment, should any of the Signatory Attorneys General have a reasonable basis to believe that Pfizer has engaged in a practice that violates a provision of this Consent Judgment subsequent to the Effective Date of this Judgment, then such Attorney General shall notify Pfizer in writing of the specific objection, identify with particularity the provision of this Consent Judgment that the practice appears to violate, and give Pfizer thirty (30) days to respond to the notification; provided, however, that a Signatory Attorney General may take any action if the Signatory Attorney General concludes that, because of the specific practice, a threat to the health or safety of the public requires immediate action. Upon receipt of written notice, Pfizer shall provide a good-faith written response to the Attorney General notification, containing either a statement explaining why Pfizer believes it is in compliance with the Consent Judgment, or a detailed explanation of how the alleged violation occurred and a statement explaining how Pfizer intends to remedy the alleged breach. Nothing in this section shall be interpreted to limit the state's Civil Investigative Demand ("CID") or investigative subpoena authority, to the extent such authority exists under applicable law, and Pfizer reserves all of its rights in responding to a CID or investigative subpoena issued pursuant to such authority.

6.2 Upon giving Pfizer thirty (30) days to respond to the notification described above, the Signatory Attorney General shall also be permitted reasonable access to inspect and copy relevant, non-privileged, non-work product records and documents in the possession, custody, or control of Pfizer that relate to Pfizer's compliance with each provision of this Consent Judgment pursuant to that State's CID or investigative subpoena authority. If the Signatory Attorney General makes or requests copies of any documents during the course of that inspection, the Signatory Attorney General will provide a list of those documents to Pfizer.

6.3 The State may assert any claim that Pfizer has violated this Consent Judgment in a separate civil action to enforce compliance with this Consent Judgment, or may seek any other relief afforded by law, but only after providing Pfizer an opportunity to respond to the notification described in paragraph 6.1 above; provided, however, that a Signatory Attorney General may take any action if the Signatory Attorney General concludes that, because of the specific practice, a threat to the health or safety of the public requires immediate action.

7. GENERAL PROVISIONS

7.1 Pfizer shall not cause or encourage third parties, nor knowingly permit third parties acting on its behalf, to engage in practices from which Pfizer is prohibited by this Consent Judgment.

7.2 The acceptance of this Consent Judgment by the State of New Jersey shall not be deemed approval by the State of New Jersey of any of Pfizer's advertising or business practices. Further, neither Pfizer nor anyone acting on its behalf shall state or imply, or cause to be stated or implied, that the State of New Jersey or any other governmental unit of the State of New Jersey has approved, sanctioned or authorized any practice, act, advertisement, or conduct of Pfizer.

7.3 Any failure by any party to this Consent Judgment to insist upon the strict performance by any other party of any of the provisions of this Consent Judgment shall not be deemed a waiver of any of the provisions of this Consent Judgment, and such party, notwithstanding such failure, shall have the right thereafter to insist upon the specific performance of any and all of the provisions of this Consent Judgment.

7.4 This Consent Judgment represents the full and complete terms of the settlement entered into by the Parties hereto. In any action undertaken by the Parties, no prior versions of

this Consent Judgment and no prior versions of any of its terms that were not entered by the Court in this Consent Judgment, may be introduced for any purpose whatsoever.

7.5 This Court retains jurisdiction of this Consent Judgment and the Parties hereto for the purpose of enforcing and modifying this Consent Judgment and for the purpose of granting such additional relief as may be necessary and appropriate.

7.6 This Consent Judgment may be executed in counterparts, and a facsimile or .pdf signature shall be deemed to be, and shall have the same force and effect as, an original signature.

7.7 All Notices under this Consent Judgment shall be provided to the following via email and Overnight Mail:

Joshua S. Levy
ROPES & GRAY LLP
Prudential Tower, 800 Boylston Street
Boston, MA 02199-3600
joshua.levy@ropesgray.com

Margaret M. Madden
Vice President and Assistant General Counsel
Pfizer Inc
235 East 42nd Street New York,
NY 10017
margaret.m.madden@Pfizer.com

7.8 To the extent that any provision of this Consent Judgment obligates Pfizer to change any policy(ies) or procedure(s) and to the extent not already accomplished, Pfizer shall implement the policy(ies) or procedure(s) as soon as reasonably practicable, but no later than 120 days after the Effective Date of this Consent Judgment.

IT IS ON THE 6th **DAY OF** August **2014 SO ORDERED, ADJUDGED AND DECREED.**

HON.
PAUL INNES, P.J.Ch.

JOINTLY APPROVED AND
SUBMITTED FOR ENTRY

FOR PLAINTIFFS:

JOHN J. HOFFMAN
ACTING ATTORNEY GENERAL OF NEW JERSEY

By: Natalie Serock Date: 8/5/14

Natalie Serock
Deputy Attorney General
124 Halsey Street, 5th Floor
Newark, New Jersey 07101
973-648-3070

FOR PFIZER INC

By: _____ Date: 7/31/14

Margaret M. Madden
Vice President and Assistant General Counsel
Pfizer Inc

FOR WYETH PHARMACEUTICALS INC.

By: _____ Date: 7/31/14

Margaret M. Madden
Vice President and Assistant General Counsel
Pfizer Inc

FOR PFIZER INC AND WYETH PHARMACEUTICALS INC.

By: _____ Date: 8.1.14

Joshua S. Levy
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