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Meghan E. Stoppel, #23685
Assistant Attorney General
Office of the Kansas Attorney General
120 SW 10th Avenue, 2nd Floor
Topeka, Kansas 66612
Ph: (785) 296-3751
Fax: (785) 291-3699
meghan.stoppel@ag.ks.gov

IN THE DISTRICT COURT OF SHAWNEE COUNTY, KANSAS

Division 1

STATE OF KANSAS, *ex rel.*)
DEREK SCHMIDT, Attorney General,)
)
Plaintiff,)
)
v.)
)
WYETH)
PHARMACEUTICALS INC.,)
)
Defendant.)

Case No. 2014 CV 777

(Pursuant to K.S.A. Chapter 60)

JOURNAL ENTRY OF CONSENT JUDGMENT

NOW on this 6 day of August, 2014, Plaintiff's Journal Entry of Consent Judgment comes before the Court pursuant to K.S.A. 50-632(b). The Plaintiff, State of Kansas, *ex rel.* Derek Schmidt, Attorney General, appears by and through Meghan E. Stoppel, Assistant Attorney General. Defendant Wyeth Pharmaceuticals Inc. (hereinafter "Wyeth") and Pfizer Inc ("Pfizer"), as current parent of Defendant Wyeth, appear by and through the undersigned counsel.

WHEREUPON the Parties advise the Court that they have stipulated and agreed to the following:

PARTIES, JURISDICTION AND VENUE

1. Derek Schmidt is the duly elected, qualified and acting Attorney General for the State of Kansas.

2. The Attorney General's authority to bring this action is derived from the statutory and common law of the State of Kansas, specifically the Kansas Consumer Protection Act, K.S.A. 50-623 *et seq.*

3. Venue is proper under K.S.A. 50-638 in the Third Judicial District of Kansas (Shawnee County).

4. At all times relevant hereto, Wyeth engaged in "consumer transactions" in Kansas, as defined by K.S.A. 50-624(c).

5. In October 2009, Pfizer Inc ("Pfizer") acquired Wyeth, and Wyeth became a wholly owned subsidiary of Pfizer. Pfizer represents that the conduct at issue occurred prior to this acquisition. Plaintiff, by its counsel, and Pfizer, by its counsel, have agreed to the entry of this Consent Judgment ("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 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, pursuant to the Kansas Consumer Protection Act, K.S.A. 50-623 *et seq.*

1.2 The terms of this Judgment shall be governed by the laws of the State of Kansas.

1.3 Entry of this 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 Judgment.

1.5 Pfizer is willing to enter into this 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 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 Judgment.¹

1.7 Pfizer is entering into this 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 or wrongdoing, all of which Pfizer expressly denies. Pfizer does not admit any violation of the State Consumer Protection Laws set forth in footnote 6, and does not admit any wrongdoing that was or could have been alleged by any Attorney General before the date of the Judgment under those laws. No part of this 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 This agreement is entered into pursuant to and subject to the State Consumer Protection laws cited in footnote 6.

1.8 This 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 Judgment. This 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 Judgment.

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

1.10 No part of this 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 Judgment.

1.11 This 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 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 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 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 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 Judgment.

2.3 “Effective Date” shall mean the date on which a copy of this Judgment, duly executed by Pfizer and by the Signatory Attorney General, is approved by, and becomes a 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 staff representing Alabama, Arizona, Arkansas, California, Colorado, Delaware, District of Columbia,

Florida, Georgia², Hawaii³, 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, Utah⁴, Virginia, Washington, and Wisconsin.

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 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 "Attorneys 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 Utah, the Utah Division of Consumer Protection is charged with administering and enforcing the Consumer Sales Practices Act, the statute relevant to this judgment. References to the "States," "Parties," or "Attorneys General," with respect to Utah, refers to the Utah Division of Consumer Protection.

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.⁵

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.

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.

⁵ Pfizer represents that in January 2011, Pfizer withdrew the sales force responsible for marketing Rapamune®.

2.25 “Signatory Attorney General” shall mean the Attorney General of Kansas, or his/her authorized designee, who has agreed to this Judgment.

2.26 “State Consumer Protection Laws” shall mean the consumer protection laws cited in footnote 6 under which the Attorneys General have conducted the investigation.⁶

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.

⁶ ALABAMA – Alabama Deceptive Trade Practices Act § 8-19-1 *et seq.* (2002); ARIZONA - Consumer Fraud Act, A.R.S. §44-1521 *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. Stat. 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 – 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, NJSA 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).

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.

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 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 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 years from the Effective Date of this 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 years from the Effective Date of this 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 years from the Effective Date of this 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 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 30 days after the Effective Date of this 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 Judgment, the State of Kansas 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 Kansas Attorney General 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 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 Kansas.
- (b) any civil or administrative liability that any person and/or entity, including Released Parties, has or may have to the State of Kansas 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 Kansas arising from the purchase of a Pfizer Product.

- (c) any liability under the State of Kansas'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 Judgment shall relieve Pfizer of the obligations it maintains under any other 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 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 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 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 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 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 Judgment in a separate civil action to enforce compliance with this 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 Judgment.

7.2 The acceptance of this Judgment by the Kansas Attorney General shall not be deemed approval by the Kansas Attorney General 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 Kansas Attorney General or any other governmental unit of the

State of Kansas has approved, sanctioned or authorized any practice, act, advertisement, or conduct of Pfizer.

7.3 Any failure by any party to this Judgment to insist upon the strict performance by any other party of any of the provisions of this Judgment shall not be deemed a waiver of any of the provisions of this 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 Judgment.

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

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

7.6 This 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 Judgment shall be provided to the following via email and Overnight Mail:

For Pfizer Inc:
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

For Office of the Kansas Attorney General:
Office of the Kansas Attorney General
Consumer Protection/Antitrust Division
c/o Meghan E. Stoppel
120 SW 10th Ave., 2nd Floor
Topeka, Kansas 66612-1597
meghan.stoppel@ag.ks.gov

7.8 To the extent that any provision of this 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 Judgment.

IT IS THEREFORE ORDERED, ADJUDGED AND DECREED that the stipulations and agreements of the Parties contained herein are adopted and approved as the findings of fact and conclusions of law of the Court and any monies owed hereunder by Defendant immediately become a Judgment upon filing.

IT IS FURTHER ORDERED, ADJUDGED AND DECREED that pursuant to the Kansas Consumer Protection Act and the provisions of K.S.A. 50-632(b), the Court hereby approves the terms of this Judgment and adopts the same as the Order of the Court.

IT IS SO ORDERED.


DISTRICT COURT JUDGE


JOINTLY APPROVED AND
SUBMITTED FOR ENTRY:

FOR PLAINTIFF, STATE OF KANSAS



Derek Schmidt, KS #17781
Attorney General
Office of the Kansas Attorney General
120 SW 10th Ave., 2nd Floor
Topeka, Kansas 66612-1597
Phone: (785) 296-2215

Date: 8/6/2014



Meghan E. Stoppel, KS #23685
Assistant Attorney General
Office of the Kansas Attorney General
120 SW 10th Ave., 2nd Floor
Topeka, Kansas 66612-1597
Phone: (785) 296-3751
Fax: (785) 291-3699

Date: 8/6/14

FOR PFIZER INC

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

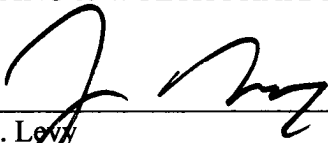
Date: 7/31/14

FOR WYETH PHARMACEUTICALS INC.

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

Date: 7/31/14

FOR PFIZER INC & WYETH PHARMACEUTICALS INC.

By: 
Joshua S. Levy
Ropes & Gray LLP
Prudential Tower, 800 Boylston Street
Boston, MA 02199

Date: 8-1-14

LOCAL COUNSEL FOR PFIZER INC & WYETH PHARMACEUTICALS INC.

By: Taylor Fields

Date: 8/1/14

Taylor Fields, KS# 77913
Fields & Brown, LLC
1100 Main, Suite 1600
Kansas City, Missouri 64105
Phone: (816) 474-1700
Fax: (816)421-6239
tfields@fieldsandbrown.com