

**IN THE COURT OF COMMON PLEAS
FRANKLIN COUNTY, OHIO**

STATE OF OHIO, *ex rel.*
MICHAEL DEWINE,
ATTORNEY GENERAL

Plaintiff,

V.

WYETH PHARMACEUTICALS INC.

Defendant.

CASE NO.: 14 CVH - 008143

JUDGE: REECE

AGREED ENTRY AND
FINAL JUDGMENT FOR

RECEIVED
ATTORNEY GENERAL OF OHIO

AUG 11 2014

CONSUMER PROTECTION SECTION
PUBLIC INSPECTION FILE

Plaintiff, State of Ohio, acting by and through Attorney General Michael DeWine, has brought this action against Wyeth Pharmaceuticals Inc. (“Wyeth”) pursuant to the various provisions of Ohio’s Consumer Sales Practices Act, R.C. 1345.01 *et seq.* 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. The Parties have consented to the entry of this Agreed Entry and Final Judgment Order (“Order”) for the purposes of settlement only, without any admission by any party, and without trial or finding of any issue of fact or law. Pfizer, as parent of Wyeth, agrees to be bound by the terms of this Order.

PARTIES

1. The State of Ohio, *ex rel.* Michael DeWine, Attorney General (“Attorney General”), by and through his Consumer Protection Section is the Plaintiff in this case. The Section is charged with, among other things, the responsibility of enforcing the Consumer Sales Practices Act, R.C. 1345.01 *et seq.* (“Consumer Sales Practices Act”).

2. Wyeth and Pfizer do business in the State of Ohio. Wyeth is a wholly owned subsidiary of Pfizer, with executive offices are located at 235 East 42nd Street, New York, New

York 10017. At all times relevant hereto, Wyeth and Pfizer, engaged in trade affecting consumers, within the meaning of the Consumer Sales Practices Act, in the State of Ohio, including, but not limited to Franklin County.

NOW THEREFORE, IT IS HEREBY ORDERED, ADJUDGED AND DECREED 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 Order shall be governed by the laws of the State of Ohio.

1.3 Entry of this Order 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 Order.

1.5 Pfizer is willing to enter into this Order 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 Order 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 Order.¹

1.7 Pfizer is entering into this Order 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

¹ This agreement is entered into pursuant to and subject to the State Consumer Protection laws cited in footnote 6.

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 Order under those laws. No part of this Order, 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 by any third party to any court for any purpose.

1.8 This Order 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 Order. This Order 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 Order.

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

1.10 No part of this Order 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 Order.

1.11 This Order (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 Order 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 Order 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 Order, 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 Order:

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 Order.

2.3 “Effective Date” shall mean the date on which a copy of this Order, duly executed by Pfizer and by the Signatory Attorney General, is approved by, and becomes an Order 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, 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/order. 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 Ohio, or his/her authorized designee, who has agreed to this Order.

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.

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.

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. 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).

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 Order, including, but not limited to, ensuring that all Promotional Speakers' Promotional Materials and Promotional Media for Rapamune® comply with Pfizer's obligations in this Order.

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 Order, 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 Order.

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 Order.

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 Order 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 Order, 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. The payment to the Attorney General under this paragraph shall be \$984,812.97.

5. RELEASE

5.1 By its execution of this Order, the State of Ohio 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 Ohio 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 Order, 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 Ohio.
- (b) any civil or administrative liability that any person and/or entity, including Released Parties, has or may have to the State of Ohio 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 Ohio arising from the purchase of a Pfizer Product.

- (c) any liability under the State of Ohio'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 Order shall relieve Pfizer of the obligations it maintains under any other Order or agreement relating to any Pfizer Product.

6. DISPUTE RESOLUTION

6.1 For the purposes of resolving disputes with respect to compliance with this Order, 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 Order subsequent to the Effective Date of this Order, then such Attorney General shall notify Pfizer in writing of the specific objection, identify with particularity the provision of this Order 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 Order, 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 Order 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 Order in a separate civil action to enforce compliance with this Order, 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 Order.

7.2 The acceptance of this Order by the Attorney General of Ohio shall not be deemed approval by the Attorney General of Ohio or the state of Ohio 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 Attorney General of Ohio or any other governmental unit of the state of Ohio has approved, sanctioned or authorized any practice, act, advertisement, or conduct of Pfizer.

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

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

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

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

Wyeth Pharmaceuticals Inc. / 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

Attorney General of Ohio:

The Attorney General of Ohio
Attn: Section Chief
Consumer Protection Section
30 East Broad Street, 14th Floor
Columbus, Ohio 43215

7.8 To the extent that any provision of this Order 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 Order.

SO ORDERED, ADJUDGED AND DECREED.

APPROVED AND AGREED TO BY:

PLAINTIFF

Michael DeWine
Attorney General of the State of Ohio

By: /s/ Michael S. Ziegler
Michael S. Ziegler (0042206)
Assistant Attorney General
Attorney for Plaintiff State of Ohio,
ex rel. Michael DeWine Attorney General
Office of the Ohio Attorney General
Consumer Protection Section
30 East Broad Street, 14th Floor
Columbus, Ohio 43215
614/466-3980
614/466-8898 (facsimile)
michael.ziegler@ohioattorneygeneral.gov

Date: August 4, 2014

DEFENDANT

Wyeth Pharmaceuticals Inc.,

By: /s/ Margaret M. Madden, per written authorization, by Michael S. Ziegler
Margaret M. Madden
Vice President and Assistant General Counsel
Pfizer Inc

Date: 07/31/14

For Pfizer Inc, as Current Parent of Wyeth Pharmaceuticals Inc.,

By: /s/ Margaret M. Madden, per written authorization, by Michael S. Ziegler
Margaret M. Madden
Vice President and Assistant General Counsel
Pfizer Inc

Date: 07/31/14

For Wyeth Pharmaceuticals Inc. and Pfizer Inc,

By: /s/ Joshua S. Levy, per written authorization, by Michael S. Ziegler
Joshua S. Levy
Ropes & Gray LLP
Prudential Tower, 800 Boylston Street
Boston, MA 02199

Counsel for Defendant Wyeth Pharmaceuticals Inc. and Pfizer Inc

Date: 08/01/14

Approved as to form:

By: /s/ Matthew D. Golish, per written authorization, by Michael S. Ziegler

Matthew D. Golish (0071586)
Supreme Court ID Number
Gonzalez Saggio & Harlan LLP
526 Superior Avenue
Suite 620
Cleveland, Ohio 44114
Phone 216-771-9300
Fax 216-771-9307
mathew_golish@gshllp.com

Attorney for Defendant Wyeth Pharmaceuticals Inc. and Pfizer Inc

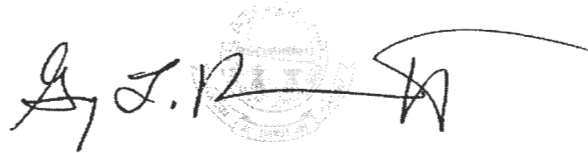
Date: August 1, 2014

***** Pursuant to the Court's Fourth Amended Administrative Order issued December 20, 2013, the party submitting a proposed order/entry shall, after the order/entry has been signed by the Judge and e-Filed, print out a copy of the same and mail it to all non-registered parties on the case. *****

Franklin County Court of Common Pleas

Date: 08-08-2014
Case Title: OHIO STATE -VS- WYETH PHARMACEUTICALS INC
Case Number: 14CV008143
Type: JUDGMENT ENTRY

It Is So Ordered.

A handwritten signature in black ink, appearing to read "G. L. Reece, II", is written over a faint, circular official seal of the Franklin County Court of Common Pleas. The signature is fluid and cursive, with a long horizontal stroke extending to the right.

/s/ Judge Guy L. Reece, II