DISTRICT COURT, DENVER CITY AND COUNTY, COLORADO 1437 Bannock Street Denver, Colorado 80202 STATE OF COLORADO, ex rel. JOHN W. SUTHERS, ATTORNEY GENERAL, Plaintiff, v. Pfizer Inc, Defendant.	▲ **COURT USE ONLY** ▲
Attorneys for Plaintiff: JOHN W. SUTHERS Attorney General JAY B. SIMONSON, 24077* First Assistant Attorney General 1525 Sherman Street, 5th Floor Denver, CO 80203 (303) 866-5079 (303) 866-4916 Fax *Counsel of Record	Case No.:
FINAL CONSENT JUDGMENT	

Plaintiff, THE PEOPLE OF THE STATE OF COLORADO, by John Suthers, Attorney General of the State of Colorado, has filed a Complaint for a permanent injunction and other relief in this matter pursuant to the Colorado Consumer Protection Act § 6-1-101 et. seq. C.R.S. 2010, alleging that Pfizer Inc ("Pfizer") committed violations of the aforementioned Act.

Plaintiff, by its counsel, and Pfizer, by its counsel, have agreed to the entry of this Final Judgment and Consent Decree ("Final Consent Judgment") by the Court without trial or adjudication of any issue of fact or law or finding of wrongdoing or liability of any kind.

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 Final Consent Judgment shall be governed by the laws of the State of Colorado.

1.3 Entry of this Final 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 involving the prescription drugs Zyvox® and Lyrica® by entering into this Final Consent Judgment.

1.5 Pfizer is willing to enter into this Final 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 Final 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 Final Consent Judgment.[1]

A. Pfizer is entering into this Final 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 or wrongdoing, all of which Pfizer expressly denies. Pfizer does not admit any

[1] This agreement is entered into pursuant to and subject to the State Consumer Protection laws cited in footnote 3.

violation of the State Consumer Protection Laws set forth in footnote 3, and does not admit any wrongdoing that was or could have been alleged by any Attorney General before the date of the Final Consent Judgment under those laws. No part of this Final 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.

B. This Final 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 Final Consent Judgment. This Final 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 Final Consent Judgment.

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

D. No part of this Final 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 Final Consent Judgment.

1.7 This Final 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.

1.8 Nothing in this Final Consent Judgment shall require Pfizer to:

(a) take any action that is prohibited by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301 *et seq*. ("FFDCA") 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 Final 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 Final 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 Final 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 Pfizer's Promotional and marketing practices, sampling practices, and dissemination of information and remuneration to HCPs regarding the prescription drugs Zyvox® and Lyrica® through the Effective Date of the Final Consent Judgment.

2.3 "Effective Date" shall mean the date on which a copy of this Final Consent Judgment, duly executed by Pfizer and by the Signatory Attorney General, is approved by, and becomes a final 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 (HM), 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 "Lyrica®" shall mean all Pfizer Products that are FDA-approved drug formulations containing pregabalin.

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

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

2.11 "Multistate Executive Committee" shall mean the Attorneys General and their staffs representing Arizona, Illinois, Maryland, New Jersey, Pennsylvania, South Carolina, and Texas.

2.12 "Multistate Working Group" shall mean the Attorneys General and their staff representing Alabama, Arizona, Arkansas, California, Colorado, Delaware, District of Columbia, Florida, Hawaii, Idaho, Illinois, Indiana, Kansas, Kentucky, Maryland, Michigan, Montana, Nebraska, Nevada, New Jersey, New Mexico, North Carolina, Ohio, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Vermont, Virginia, Washington, and Wisconsin.[2]

2.13 "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.

2.14 "Parties" shall mean Pfizer and the Signatory Attorney General.

[2] 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.

2.15 “Pfizer Inc” or “Pfizer” shall mean Pfizer Inc, including all of its affiliates over which it has a controlling interest, subsidiaries and divisions, predecessors, successors, and assigns doing business in the United States.

2.16 “Pfizer Marketing” shall mean Pfizer personnel responsible for marketing Zyvox® or Lyrica® in the United States.

2.17 “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.

2.18 “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.

2.19 “Pfizer Sales” shall mean the Pfizer sales force responsible for U.S. Zyvox® or Lyrica® sales, including, but not limited to, the field force and all management personnel such as district managers, regional managers, and vicepresident over sales, and president over sales.

2.20 “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.

2.21 “Promotional Materials” shall mean any item used to Promote Zyvox® or Lyrica®

2.22 “Promotional Media” shall mean Promotional Materials in any media format for use in speaker programs.

2.23 "Promotional Speaker" shall mean an HCP speaker engaged by Pfizer to Promote Zyvox® or Lyrica®.

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 Zyvox® or Lyrica®.

2.25 "Signatory Attorney General" shall mean the Attorney General of Colorado, or his/her authorized designee, who has agreed to this Final Consent Judgment.

2.26 "State Consumer Protection Laws" shall mean the consumer protection laws cited in footnote 3 under which the Attorneys General have conducted the investigation.[3]

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

---

[3] ALABAMA – *Alabama Deceptive Trade Practices Act* § 8-19-1 *et. seq.* (2002); ARIZONA – *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 2536; 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*.; HAWAII – *Uniform Deceptive Trade Practice Act*, Haw. Rev. Stat. Chpt. 481A and Haw. Rev. Stat.Chpt. 480 [501.201 *et seq.*]; IDAHO – *Consumer Protection Act*, Idaho Code Section 48-601 *et seq.*; ILLINOIS – *Consumer Fraud and Deceptive Business Practices Act*, 815 ILCS 505/2 *et seq*.; INDIANA – *Deceptive Consumer Sales Act*, I.C. §24-5-0.5 *et seq*.; KANSAS - *Kansas Consumer Protection Act*, K.S.A. 50-623 et seq. KENTUCKY – *Kentucky Consumer Protection Act*, KRS Ch. 367.110, *et seq*.; MARYLAND - *Maryland Consumer Protection Act*, Md. Code Ann., Com. Law §§ 13-101 *et seq*.; MICHIGAN – *Michigan Consumer Protection Act*, MCL § 445.901 *et seq*.; MONTANA – Montana Code Annotated 30-14-101 *et seq*.; NEBRASKA – *Uniform Deceptive Trade Practices Act*, NRS §§ 87-301 *et seq*.; NEVADA – Deceptive Trade Practices Act, Nevada Revised Statutes 598.0903 *et seq*.; NEW JERSEY – *New Jersey Consumer Fraud Act*, NJSA 56:8-1 *et seq*.; NEW MEXICO – NMSA 1978, § 57-12-1 *et seq*.; NORTH CAROLINA – North Carolina Unfair and Deceptive Trade Practices Act, N.C.G.S. 75-1.1, *et seq*.; OHIO – *Ohio Consumer Sales Practices Act*, R.C. 1345.01, *et seq*.; PENNSYLVANIA – *Pennsylvania Unfair Trade Practices and Consumer Protection Law*, 73 P.S. 201-1 *et seq*.; RHODE ISLAND – *Rhode Island Deceptive Trade Practices Act*, Rhode Island General laws § 6-13.1-1 *et seq.* ; SOUTH CAROLINA – *South Carolina Unfair Trade Practices Act*, sections 39-5-10 *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*.; VERMONT – *Consumer Fraud Act*, 9 V.S.A. §§ 2451 *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*.; WEST VIRGINIA – *West Virginia Consumer Credit and Protection Act*, W. Va. Code § 46A-1101 *et seq.;* WISCONSIN – Wis. Stat. § 100.18 (Fraudulent Representations).

2.28 "Zyvox®" shall mean all Pfizer Products that are FDA-approved drug formulations containing linezolid.

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 FDA-approved Pfizer Product, including, but not limited to, any false, misleading, or deceptive claim when comparing the efficacy or safety of Zyvox® to vancomycin.

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 Zyvox® or Lyrica® to an HCP who practices in a specialty that is unlikely to prescribe for a use in Zyvox®'s or Lyrica®'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 present patient profiles/types based on selected symptoms of the FDA-approved indication(s) when Promoting Zyvox® or Lyrica® for six years from the Effective Date of this Judgment, unless:

A. Zyvox®'s or Lyrica®'s specific FDA-approved indication(s) is/are stated Clearly and Conspicuously in the same spread (e.g. on the same page or on a facing page) in any Promotional Materials that reference the selected symptoms;

B. Promotional Materials have a statement indicating that prescribers should take into consideration the full range of a patient's symptoms and other relevant information before making a treatment decision.

3.7 Pfizer shall not make any claim that contradicts or minimizes a precaution, warning, or adverse reaction that is described in product Labeling for Zyvox® or Lyrica®.

3.8 In Promotional Materials, Pfizer shall Clearly and Conspicuously disclose all material facts regarding the following: the risks associated with Zyvox® or Lyrica® 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 Zyvox® or Lyrica®. 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 Zyvox® or Lyrica®, Pfizer shall promptly notify the Food and Drug Administration.

3.9 Pfizer shall not affirmatively seek the inclusion of Zyvox® or Lyrica® in hospital protocols or standing orders unless Zyvox® or Lyrica® has been approved by the FDA for the indication for which it is to be included in the protocol or standing order.

3.10 Pfizer shall require that all Promotional Speakers comply with Pfizer's obligations in paragraphs 3.1 through 3.8, 3.26, and 3.33 of this Final Consent Judgment, including, but not limited to, ensuring that all Promotional Speakers' Promotional Materials and Promotional Media for Zyvox® and Lyrica® comply with Pfizer's obligations in this Final Consent Judgment.

3.11 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 Marketing

3.12 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 Zyvox® or Lyrica®.

3.13 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.

3.14 For six years from the Effective Date of this Final Consent Judgment, Pfizer shall continue to implement measures whereby sales goals for Zyvox® or Lyrica® can be met without including Off-Label prescriptions.

3.15 For six years from the Effective Date of this Final Consent Judgment, Pfizer shall not award prizes or other incentives to its sales force as rewards for the Off-Label sale or use of any FDA-approved Pfizer Product.

Dissemination and Exchange of Medical Information

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

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

3.17 Pfizer Sales, Pfizer Marketing, and Medical Outcomes Specialists shall not develop the medical content of Medical Information Responses regarding Zyvox® or Lyrica®. Notwithstanding the foregoing, Medical Outcomes Specialists may assist in the development of pharmacoeconomic content of Medical Information Responses.

3.18 Medical Information Responses to Unsolicited Requests for Off-Label information regarding Zyvox® or Lyrica® may be disseminated only by Pfizer Medical.

3.19 Pfizer Medical shall have ultimate responsibility for developing and approving all Medical Information Responses regarding Zyvox® or Lyrica®. 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 Final Consent Judgment.

3.20 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 Zyvox® or Lyrica® for any Off-Label use(s).

3.21 Any written Pfizer response to an Unsolicited Request for Off-Label information regarding Zyvox® or Lyrica® 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).

3.22 Pfizer Sales, Pfizer Marketing, and Medical Outcome Specialists may respond orally to an Unsolicited Request for Off-Label information regarding Zyvox® or Lyrica® 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.

3.23 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

3.24 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.

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

3.26 Reprints Containing Off-Label Information

A. Pfizer Medical shall be responsible for the identification, selection, approval and dissemination of Reprints Containing Off-Label Information regarding Zyvox® or Lyrica®.

B. Reprints Containing Off-Label Information regarding Zyvox® or Lyrica®:

(i) 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 the article may discuss Off-Label information; and

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

C. Reprints Containing Off-Label Information regarding Zyvox® or Lyrica® 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 Final 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 3.24 and such incidental reference to Off-Label information shall not be referred to or used in a Promotional manner as prohibited by Section 3.26. B.ii.

Product Samples

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

3.28 Pfizer shall only provide samples of Zyvox® or Lyrica® to those HCPs who have specialties that customarily treat patients who have diseases for which treatment with Zyvox® or Lyrica® would be consistent with that product's FDA- approved Labeling.

3.29 Pfizer shall not disseminate samples of Zyvox® or Lyrica® with the intent of increasing Off-Label prescribing.

Sales Force Monitoring

3.30 Pfizer shall maintain a compliance program consistent with its Corporate Integrity Agreement signed on August 31, 2009 that includes a chief compliance officer; a compliance committee; a written code of conduct; written policies and procedures; education and training initiatives; a disclosure program that allows for confidential disclosure and investigation of potential compliance violations and appropriate disciplinary procedures; and regular internal auditing procedures. The compliance program shall include a sales force monitoring program designed to directly and indirectly observe the appropriateness of the sales force's interactions with HCPs and to identify potential Off-Label Promotional activities. The sales force monitoring program shall also include a Promotional speaker monitoring program, direct field observations of the sales force, and the monitoring and review of other records related to the sales force's interactions with HCPs. Pfizer's sales force monitoring program shall also include a centralized electronic system to be used by the sales force in connection with the detailing of HCPs that is consistent with the Corporate Integrity Agreement signed on August 31, 2009. The centralized electronic system shall include a detailing system that allows for and does not discourage the entry of free text summaries of interactions with HCPs. This paragraph shall be effective until December 31, 2014.

3.31 Pfizer shall maintain a disclosure program which allows for the anonymous disclosure of compliance policy violations and contains a nonretaliation policy.

Clinical Research

3.32 Pfizer shall report clinical research regarding Zyvox® and Lyrica® 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 Zyvox® and Lyrica® 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.

3.33 When presenting information about a clinical study regarding Zyvox® or Lyrica® 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.

4. PAYMENT

4.1 No later than 30 days after the Effective Date of this Final Consent Judgment, Pfizer shall pay a total amount of Forty-Two Million Nine Hundred Thousand Dollars ($42,900,000.00) 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, at the sole discretion of each Signatory Attorney General. Colorado's allotted share shall be held in trust by the Colorado Attorney General to be used first for reimbursement of the State's actual costs and attorney fees and, second, to be held along with any interest thereon, in trust by the Attorney General for future consumer education, consumer fraud, or antitrust enforcement actions. 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 Final Consent Judgment, the State of Colorado releases Pfizer and all of its past and present affiliates over which it has a controlling interest, 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 Colorado 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 Final 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 Colorado.

B. Any civil or administrative liability that any person and/or entity, including Released Parties, has or may have to the State of Colorado 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 Colorado arising from the purchase of a Pfizer Product.

C. Any liability under the State of Colorado'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 Final Consent Judgment shall relieve Pfizer of the obligations it maintains under any other judgment or 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 Final 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 Final Consent Judgment subsequent to the Effective Date of this Final Consent Judgment, then such Attorney General shall notify Pfizer in writing of the specific objection, identify with particularity the provision of this Final 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 Final 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 Final 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 Final Consent Judgment in a separate civil action to enforce compliance with this Final 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 Final Consent Judgment.

7.2 The acceptance of this Final Consent Judgment by the State of Colorado shall not be deemed approval by the State of Colorado 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 State of Colorado or any other governmental unit of the State of Colorado has approved, sanctioned or authorized any practice, act, advertisement, or conduct of Pfizer.

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

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

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

7.6 This Final 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 Final 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

Gary F. Giampetruzzi
Vice President and Assistant General Counsel, Head of Government Investigations
Pfizer Inc
150/2/04
150 East 42nd Street
New York, NY 10017
Gary.Giampetruzzi@Pfizer.com

7.8 To the extent that any provision of this Final 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 Final Consent Judgment.

IT IS SO ORDERED, ADJUDGED AND DECREED.

_____

Presiding Judge

JOINTLY APPROVED AND
SUBMITTED FOR ENTRY

PLAINTIFF, THE STATE OF COLORADO

By: */s/ Mark T. Bailey* Date: December 8, 2012

MARK T. BAILEY, 36861*
Assistant Attorney General
Consumer Fraud Unit
(303)866-4059
mark.bailey@state.co.us

JOHN SUTHERS
Colorado Attorney General

FOR DEFENDANT PFIZER INC

By: */s/ Joshua S. Levy* Date: December 5, 2012

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

By: */s/ Ross B. Galin* Date: December 3, 2012

Ross B. Galin
O'Melveny & Myers LLP
Times Square Tower, 7 Times Square
New York, NY 10036