

2007 WL 2905352 (Tenn.Cir.Ct.) (Trial Order)
Circuit Court of Tennessee,
Twentieth Judicial District at Nashville.
Davidson County

State of Tennessee, ex rel., Robert E. Cooper, Jr. Attorney General & Reporter, Plaintiff,
v.
Purdue PHARMA L.P., et al., Defendants.

No. 07C1319.
May 8, 2007.

Agreed Final Judgment

Approved for Entry by: for the State of Tennessee, Robert E. Cooper, Jr., B.P.R. No. 10934, Attorney General & Reporter, Meredith Devault, B.P.R. No. 9157, Senior Counsel, Office Of the Attorney General & Reporter, P.O. Box 20207, Nashville, TN 37202, Mary Clement, Director, Division of Consumer Affairs, State of Tennessee.

For Purdue, Robin E. Abrams, Vice President, Associate General Counsel, Purdue Pharma L.P., The Purdue Frederick Company, Purdue Pharma Inc., Tel: 203-588-8477, Fax: 203-588-6204.

W. David Bridgers, Neal and Harwell, PLC, Suite 2000, One Nashville Place, 150 4th Avenue North, Nashville, TN 37219-2498, Tel: 615-244-1713, Fax: 615-726-0573, TN Bar No. 16603.

This Agreed Final Judgment (hereinafter referred to as "Judgment") is entered into between the State of Tennessee and Attorneys General or other entities of the States and Commonwealths of Arizona, Arkansas, California, Connecticut, District of Columbia, Idaho, Illinois, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Montana, Nebraska, Nevada, New Mexico, North Carolina, Ohio, Oregon, Pennsylvania, South Carolina, Texas, Vermont, Virginia, Washington, and Wisconsin (hereinafter referred to as "Signatory Attorneys General"), acting on behalf of their respective states, and pursuant to their respective consumer protection statutes (Tenn. Code Ann. § 47-18-101, *et seq.*, for Tennessee); and Purdue Pharma L.P., *et al.*, (hereinafter referred to as "Purdue").

I. DEFINITIONS

1. The following definitions shall be used in construing this Judgment (hereinafter "Judgment"):
 - A. "Covered Persons" shall mean all officers, employees and all contract or third-party sales representatives, including Medical Liaisons, of Purdue or retained by Purdue having direct responsibility for marketing and promoting OxyContin to Health Care Professionals.
 - B. "Effective Date" shall mean the date on which Purdue receives a copy of this Judgment, duly executed by Purdue and by the Signatory Attorney General and filed with the Court.
 - C. "FDA Guidances for Industry" shall mean documents published by the United States Department of Health and Human Services, Food and Drug Administration ("FDA") that represent the FDA's current recommendations on a topic.

D. "Health Care Professional" or "Health Care Professionals" shall mean any person or persons duly licensed by relevant federal and/or state law to prescribe Schedule II pharmaceutical products, as well as duly licensed pharmacists, nurses and other licensed health professionals.

E. "Off-Label Promotion" shall mean the marketing and promotion of an Off-Label Use. Off-Label Promotion shall not mean discussion of the abuse and diversion of OxyContin that is not inconsistent with the Package Insert.

F. "Off-Label Use" shall mean any use inconsistent with the "Indications and Usage" section of the Package Insert.

G. "OxyContin" shall mean any controlled-release drug distributed by Purdue which contains oxycodone as an active pharmaceutical ingredient.

H. "Package Insert" shall mean the FDA approved label (as described in 21 C.F.R. §§ 201.56 and 57) for OxyContin, including all modifications to the label theretofore approved by the FDA.

I. "Parties" shall mean Purdue and the Signatory Attorneys General.

J. "Purdue" shall mean Purdue Pharma Inc., Purdue Pharma L.P., The Purdue Frederick Company, Inc (d/b/a The Purdue Frederick Company), and all of their United States affiliates, subsidiaries, predecessors, successors, parents and assigns, who manufacture, sell, distribute and/or promote OxyContin.

K. "Remuneration" shall mean any gift, fee, or payment, exceeding twenty-five dollars (\$25.00) in value, provided by Purdue directly or indirectly in connection with marketing or promotion of OxyContin.

L. "Signatory Attorney General" shall mean the Attorney General, or his or her designee, who has agreed to this Judgment.

M. "Subject Matter of this Judgment" shall mean the investigation under the State Consumer Protection Laws of Purdue's promotional and marketing practices regarding OxyContin.

II. COMPLIANCE PROVISIONS

Accordingly, pursuant to *Tenn. Code Ann. § 47-18-108(b)(2)*, it is hereby agreed by Purdue that:

2. In the promotion and marketing of OxyContin, Purdue shall not make any written or oral claim that is false, misleading or deceptive.
3. In the promotion and marketing of OxyContin, Purdue shall not market or promote OxyContin in a manner that is, directly or indirectly, inconsistent with the "Indication and Usage" section of the Package Insert for OxyContin. Further, Purdue shall, consistent with the Package Insert, or as otherwise permitted by the FDA, not promote or market OxyContin in a manner that: (a) avoids or minimizes the fact that OxyContin is indicated for moderate to severe pain when a continuous around-the-clock analgesic is needed for an extended period of time; or (b) avoids, minimizes, or is inconsistent with individualizing treatment using a plan of pain management, such as outlined by the World Health Organization, the Agency for Healthcare Research and Quality (formerly known as the Agency for HealthCare Policy and Research), the Federation of State Medical Boards Model Guidelines or the American Pain Society, as referenced in the Package Insert.

4. In the promotion and marketing of OxyContin, Purdue shall provide "fair balance" statements, as defined in 21 C.F.R. §202.1 as may be amended or supplemented, or as appearing in FDA Guidances for Industry from time to time, regarding contraindications and adverse events, including but not limited to statements regarding OxyContin's potential for abuse, addiction, or physical dependence as set forth in the Package Insert.
5. In the promotion and marketing of OxyContin, Purdue shall not make misrepresentations with respect to OxyContin's potential for abuse, addiction, or physical dependence as set forth in the Package Insert. Further to this general prohibition on misrepresentations, Purdue, in the promotion and marketing of OxyContin, shall not represent, except as may be set forth in the Package Insert, that: a) OxyContin is "nonaddictive" or "virtually nonaddictive"; b) addiction to OxyContin occurs in "less than 1%" of patients being treated with OxyContin; or c) OxyContin's potential for abuse, addiction or physical dependence differs from any other Schedule II opioid analgesic.
6. In the promotion and marketing of OxyContin, Purdue shall not make any written or oral promotional claim of safety or effectiveness for Off-Label Uses of OxyContin in a manner that violates the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA"), and accompanying regulations as may be amended or supplemented, or as appearing in FDA Guidances for Industry from time to time.
7. Except upon a request for such information without solicitation by Purdue to make the request, Purdue shall not provide to Health Care Professionals written materials describing the Off-Label Use of OxyContin that have not appeared in a scientific or medical journal or reference publication or any portion thereof. Purdue shall maintain records for three (3) years of the identity of all Health Care Professionals to whom such materials relating to the Off-Label Use of OxyContin have been provided. "Scientific or medical journal" is a publication whose articles are published in accordance with regular peer-reviewed procedures; that uses experts to review or provide comment on proposed articles; and that is not in the form of a special supplement that has been funded in whole or in part by one or more manufacturers. "Reference publication" is a publication that has no common ownership or other corporate affiliation with a pharmaceutical or medical device manufacturer; that has not been written, edited, excerpted, or published specifically for, or at the request of, such a manufacturer; and that has not been edited or significantly influenced by such a manufacturer.
 8. A. When Purdue provides an individual or entity with any educational grant, research grant, or other similar Remuneration relating to OxyContin, Purdue shall obtain the recipient's agreement: (i) to clearly and conspicuously disclose the existence of said funding or Remuneration to the readers of any resulting letter, study, research or other materials which was supported by said funding or Remuneration, and (ii) to refund said funding or Remuneration if such disclosure is not made.
 - B. Purdue shall require that a recipient of any Remuneration from Purdue for the promotion of OxyContin agree: (i) to clearly and conspicuously disclose the existence, nature and purpose of the Remuneration to the participants in any educational event at which the recipient discusses an Off-Label Use of OxyContin, and (ii) to refund said Remuneration if such disclosure is not made.
 - C. Purdue shall itself clearly and conspicuously disclose the existence of any grant or other form of Remuneration that it has provided for the publication of a letter, study, research or other material relating to OxyContin when Purdue disseminates or refers to said letter, study, research or other material in communications with Health Care Professionals.
9. Purdue shall comply with all applicable Accreditation Council for Continuing Medical Education ("ACCME") Guidelines.

10. Purdue shall comply with paragraphs 2, 3, 4, 5, 7 and 8 of the Pharmaceutical Research and Manufacturers of America Code (effective on July 1, 2002) with respect to payments, gifts and other compensation to Health Care Professionals regarding OxyContin.

11. In the promotion and marketing of OxyContin, Purdue shall not misrepresent the existence, non-existence, or findings of any medical or scientific evidence, including anecdotal evidence, relating to Off-Label Uses of OxyContin. Purdue shall not provide any information that is misleading or lacking in fair balance, as defined in 21 C.F.R. § 202.1, as may be amended or supplemented, or as appearing in FDA Guidances for Industry from time to time, in any discussion of the Off-Label Uses of OxyContin.

12. Purdue shall not sponsor or fund any educational events where Purdue has knowledge at the time the decision for sponsorship or funding is made that a speaker will recommend the Off-Label Use of OxyContin. Further, Purdue shall not promote or fund Health Care Professionals' attendance at educational events where Purdue has knowledge, at the time of said promotion, that Off-Label Use of OxyContin will be recommended or encouraged.

13. Purdue shall, no later than thirty (30) business days after the Effective Date of this Judgment, establish, implement and follow an OxyContin abuse and diversion detection program consisting of internal procedures designed to identify potential abuse or diversion of OxyContin in certain settings (the "OxyContin Abuse and Diversion Detection Program"). The OxyContin Abuse and Diversion Detection Program will apply to Purdue employees and contract or third-party sales representatives, including Medical Liaisons, who contact practicing Health Care Professionals in person or by telephone for the purpose of promoting OxyContin. That Program directs those persons to report to the Office of the General Counsel situations, including, but not limited to the following examples, to the extent that such information or activities are observed or learned of by them: a) an apparent pattern of an excessive number of patients for the practice type, such as long lines of patients waiting to be seen, waiting rooms filled to standing-room-only capacity, or patient-prescriber interactions that are exceedingly brief or non-existent; b) an atypical pattern of prescribing techniques or locations, such as repeated prescribing from an automobile, or repeated prescribing at atypical times, such as after usual office hours when the Health Care Professional is not on call; c) information from a highly credible source or several sources (e.g., pharmacists, law enforcement, other health care workers) that a Health Care Professional or their patients are abusing or diverting medications; d) sudden, unexplained changes in prescribing or dispensing patterns that are not accounted for by changes in patient numbers or practice type; e) a Health Care Professional who has a disproportionate number of patients who pay for office visits and dispensed medications with cash; f) multiple allegations that individuals from a particular practice have overdosed; or g) unauthorized individuals signing prescriptions or dispensing controlled substances. Upon identification of potential abuse or diversion involving a Health Care Professional with whom Purdue employees or its contract or third-party sales representatives, including Medical Liaisons, interact, Purdue will conduct an internal inquiry which will include but not be limited to a review of the Health Care Professional's prescribing history, to the extent such history is available and relevant, and shall take such further steps as may be appropriate based on the facts and circumstances, which may include ceasing to promote Purdue products to the particular Health Care Professional, providing further education to the Health Care Professional about appropriate use of opioids, or providing notice of such potential abuse or diversion to appropriate medical, regulatory or law enforcement authorities. Purdue's obligations under this Section shall expire ten (10) years following the Effective Date of this Judgment or three months from the date on which the last of Purdue's patents covering OxyContin expires, whichever is earlier, but in no event shall be earlier than seven (7) years following the Effective Date of this Judgment.

14. Purdue shall implement and maintain a training and education program with respect to the OxyContin Abuse and Diversion Detection Program, and shall require all Purdue employees and contract or third-party sales representatives, including Medical Liaisons, who contact practicing Health Care Professionals in person or by telephone for the purpose of promoting OxyContin to complete the training and education program no later than thirty (30) business days after the Effective Date of this Judgment. Further, Purdue shall require those Purdue employees and contract or third-party sales representatives, including Medical Liaisons, who contact practicing Health Care Professionals in person or by telephone

for the purpose of promoting OxyContin to complete the training and education program before being allowed to market or promote OxyContin. Purdue's obligations under this Section shall expire ten (10) years following the Effective Date of this Judgment or three months from the date on which the last of Purdue's patents covering OxyContin expires, whichever is earlier, but in no event shall be earlier than seven (7) years following the Effective Date of this Judgment.

15. Within 90 days of the Effective Date of this Judgment, Purdue shall provide to each Health Care Professional whom Covered Persons contact, written, non-branded educational information related to detecting and preventing abuse and diversion of opioid analgesics. To the extent that Purdue concludes that a specific Health Care Professional needs repeated exposure to such non-branded educational materials, Purdue will provide those materials. Purdue's obligations under this Section will remain in effect for ten (10) years following the Effective Date of this Judgment.

16. Purdue shall continue to review news media stories addressing the abuse or diversion of OxyContin and undertake appropriate measures as reasonable under the circumstances to address abuse and diversion so identified, including but not limited to, (i) correcting misinformation, (ii) offering non-branded educational materials to local substance abuse prevention and treatment initiatives, or (iii) directing Health Care Professionals to Purdue's Medical Services group for fair and balanced information on appropriate use of opioid analgesics, prevention and detection of abuse and diversion. Purdue's obligations under this Section shall expire ten (10) years following the Effective Date of this Judgment or three months from the date on which the last of Purdue's patents covering OxyContin expires, whichever is earlier, but in no event shall be earlier than seven (7) years following the Effective Date of this Judgment.

17. No sales incentive (bonus) program for sales of OxyContin shall allow incentive credit to be earned for a Health Care Professional who has been identified through the OxyContin Abuse and Diversion Detection Program as one upon whom sales representatives shall not call. In addition, Purdue shall not employ a compensation structure for persons involved in marketing or promoting OxyContin that is based exclusively on the volume of OxyContin sales.

18. For a period often (10) years following the Effective Date of this Judgment, Purdue's performance evaluation of persons involved in marketing or promoting OxyContin shall meaningfully take into account that sales persons inform Health Care Professionals to whom the sales persons promote OxyContin about its potential for abuse and diversion, and how to minimize those risks; failure to do so shall be considered as a basis for disciplinary action, including, but not limited to censure, probation and termination.

19. In its promotion and marketing of OxyContin, Purdue shall not misrepresent, in any written or oral claim relating to OxyContin, that its sales, medical or research personnel have experience or credentials or are engaging in research activities if they do not in fact possess such credentials or experience, or are not engaging in such activities.

20. All material used in promoting OxyContin, regardless of format (audio, internet, video, print) and whether directed primarily to patients or to Health Care Professionals, shall, not inconsistent with the Package Insert, contain only information that is truthful, balanced, accurately communicated, and not minimize the risk of abuse, addiction or physical dependence associated with the use of OxyContin.

21. Purdue shall not provide samples of OxyContin to Health Care Professionals.

22. The obligations of Purdue under this Judgment shall be prospective only. No Signatory Attorney General shall institute any proceeding or take any action against Purdue under its State Consumer Protection Laws or any similar state authority, or under this Judgment, based on Purdue's prior promotional or marketing practices for OxyContin.

23. Nothing in this Judgment shall require Purdue to:

(a) take an action that is prohibited by the FDCA, the Controlled Substances Act or any regulation promulgated thereunder, or by FDA or the Drug Enforcement Administration;

(b) fail to take an action that is required by the FDCA, the Controlled Substances Act or any regulation promulgated thereunder, or by FDA or the Drug Enforcement Administration;

(c) refrain from dissemination of safety information concerning OxyContin; or

(d) refrain from making any written or oral promotional claim which is the same or substantially the same as the language permitted by FDA under the OxyContin Package Insert and which accurately portrays the data or other information referenced in the OxyContin Package Insert.

24. Purdue shall:

(a) to the extent necessary for compliance with this Judgment, no later than ninety (90) days after the Effective Date of this Judgment, institute compliance procedures which are designed to begin training currently employed Covered Persons on the contents of this Judgment, and about how to comply with this Judgment;

(b) submit to the Attorney General (per the Notice below), no later than one hundred and twenty (120) days after the Effective Date of this Judgment, a written description of such training;

(c) submit to the Attorney General (per the Notice below), one (1) year after the Effective Date of this Judgment, a written affirmation setting forth Purdue's compliance with this paragraph;

(d) for a period of three (3) years from the Effective Date of this Judgment, Purdue shall advise in writing all Covered Persons of the requirements of Paragraphs 2 through 23 of this Judgment;

(e) beginning one (1) year after the Effective Date of this Judgment, for a period of three (3) years, produce and provide on an annual basis to the Attorney General on the anniversary of the Effective Date of this Judgment a report containing basic statistics on Purdue's Abuse and Diversion Detection Program including, but not limited to, statistics on the number of reports, the number of investigations, and a summary of the results, including the number of "Do Not Call" determinations, but shall not include the names of any specific Health Care Professionals; and

(f) upon written request, the Attorney General may obtain state-specific information as described in subsection (e). In addition, Purdue agrees to accept service of a civil investigative demand or similar process by the Attorney General requesting the names of any specific Health Care Professionals described in subsection (e). The Attorney General in receipt of such information shall not disclose it except as provided by law.

III. PAYMENT TO THE STATES

25. No later than thirty (30) days after the Effective Date of this Judgment, Purdue shall pay nineteen million five hundred thousand U.S. dollars (\$19,500,000.00), to be paid by Purdue to the States by electronic fund transfer made payable to the Oregon Department of Justice (as instructed by that Office) which shall divide and distribute these funds as designated by and in the sole discretion of the Signatory Attorneys General as part of the consideration for the termination of their respective investigations under the State Consumer Protection Laws regarding the Subject Matter of this Judgment. The funds received by the State of Tennessee under Section II, Payment to the States of this Judgment (\$719,500.00) shall be distributed and paid as follows:

(A) Pursuant to *Tenn. Code Ann. § 47-18-108(a)(5)* and *§ 47-18-108(b)(4)*, Four Hundred Thousand Dollars (\$400,000.00) shall be paid to the State of Tennessee, Attorney General for attorneys' fees and costs of investigation,

prosecution and monitoring for compliance of this matter, which may be used for consumer protection purposes at the sole discretion of the Attorney General. Court costs shall be paid out of portion of Tennessee's award.

(B) Pursuant to [Tenn. Code Ann. § 47-18-108\(b\)\(3\)](#), One Hundred Seventy-Five Thousand Seven Hundred Fifty Dollars (\$175,750.00) shall be paid to the State of Tennessee's General Fund.

(C) One Hundred Forty-Three Thousand Seven Hundred Fifty Dollars (\$143,750.00) shall be paid to the State of Tennessee to fund a consumer education project(s) selected at the sole discretion of the Director of the Division of Consumer Affairs or to fund investigations and/or litigation pursuant to the Tennessee Consumer Protection Act of 1977 selected at the sole discretion of the Director of the Division of Consumer Affairs.

(D) Any other or additional sums received by the State of Tennessee shall be paid the State of Tennessee, Attorney General which may be used for consumer protection purposes at the sole discretion of the Attorney General.

(E) If the entire amount anticipated by the State of Tennessee is not received, any monies received shall first be attributed to attorneys' fees pursuant to paragraph (A), next to the payment to the General Fund pursuant to paragraph (B) and finally to consumer education funding pursuant to paragraph (C).

IV. GENERAL PROVISIONS

26. This Judgment shall be governed by the laws of the State of Tennessee.

27. This Judgment is entered into by the Parties as their own free and voluntary act and with full knowledge and understanding of the nature of the proceedings and the obligations and duties imposed by this Judgment.

28. Nothing in this Judgment constitutes any agreement by the Parties concerning the characterization of the amounts paid pursuant to this Judgment for purposes of the Internal Revenue Code or any state tax laws, or the resolution of any other matters.

29. This Judgment does not constitute an approval by the Attorney General of any of Purdue's business practices, including its promotional or marketing practices, and Purdue shall make no representation or claim to the contrary.

30. Purdue expressly waives ten day notice of the Attorney General's intention to file an action pursuant to [Tenn. Code Ann. § 47-18-108\(a\)\(2\)](#).

31. Nothing in this Judgment shall be construed to waive any claims of Sovereign Immunity the State may have in any action or proceeding.

32. This Judgment may only be enforced by the parties hereto.

33. Purdue, by signing this Judgment, waives service of process and voluntarily submits to the jurisdiction of this Court.

V. REPRESENTATIONS AND WARRANTIES

30. Purdue warrants and represents that it and its predecessors, successors and assigns manufactured, sold and promoted OxyContin. Purdue further acknowledges that it is a proper party to this Judgment. Purdue further warrants and represents that the individuals signing this Judgment on behalf of Purdue is are doing so in their official capacity and

are fully authorized by Purdue to enter into this Judgment and to legally bind Purdue to all of the terms and conditions of the Judgment.

31. Each of the Parties represents and warrants that it negotiated the terms of this Judgment in good faith.

32. Each of the Signatory Attorneys General warrants and represents that he or she is signing this Judgment in his or her official capacity, and that he or she is fully authorized by his or her state to enter into this Judgment, including but not limited to the authority to grant the release contained in Paragraphs 34 and 35 of this Judgment, and to legally bind the state to all of the terms and conditions of this Judgment.

33. Purdue acknowledges and agrees that the Attorney General has relied on all of the representations and warranties set forth in this Judgment and that, if any representation is proved false, unfair, deceptive, misleading, or inaccurate in any material respect, the Attorney General has the right to seek any relief or remedy afforded by law or equity in the state.

VI. RELEASE

34. Based on his inquiry into Purdue's promotion of OxyContin, the Tennessee Attorney General has concluded that this Judgment is the appropriate resolution of any alleged violations of the State Consumer Protection Laws. The Attorney General acknowledges by his execution hereof that this Judgment terminates Tennessee's inquiry and that of the other Signatory Attorneys General under the State Consumer Protection Laws into Purdue's promotion of OxyContin prior to the Effective Date of this Judgment.

35. In consideration of the Compliance Provisions, payments, undertakings, and acknowledgments provided for in this Judgment, and conditioned on Purdue's making full payment of the amount specified in Paragraph 25, and subject to the limitations and exceptions set forth in Paragraph 36, the State releases and forever discharges, to the fullest extent permitted by law, Purdue and its past and present officers, directors, shareholders, employees, co-promoters, affiliates, parents, subsidiaries, predecessors, assigns, and successors (collectively, the "Releasees"), of and from any and all civil causes of action, claims, damages, costs, attorney's fees, or penalties that the Attorney General could have asserted against the Releasees under the State Consumer Protection Law, Tenn. Code Ann. § 47-18-101, *et. seq.*, by reason of any conduct that has occurred at any time up to and including the Effective Date of this Judgment relating to or based upon the Subject Matter of this Judgment ("Released Claims").

36. The Released Claims set forth in Paragraph 35 specifically do not include the following claims:

- (a) private rights of action by consumers, provided, however, that this Judgment does not create or give rise to any such private right of action of any kind;
- (b) claims relating to Best Price, Average Wholesale Price or Wholesale Acquisition Cost reporting practices or Medicaid fraud or Abuse;
- (c) claims of antitrust, environmental or tax liability;
- (d) claims for property damage;
- (e) claims to enforce the terms and conditions of this Judgment; and
- (f) any state or federal criminal liability that any person or entity, including Releasees, has or may have to the State

VII. NO ADMISSION OF LIABILITY

37. This Judgment does not constitute an admission by Purdue for any purpose, of any fact or of a violation of any state law, rule, or regulation, nor does this Judgment constitute evidence of any liability, fault, or wrongdoing, by Purdue nor does Purdue's agreement in this Judgment not to engage in certain conduct constitute an admission that Purdue has ever engaged in such conduct. Purdue enters into this Judgment for the purpose of resolving the concerns of the Attorney General regarding Purdue's promotional and marketing practices regarding OxyContin. Purdue does not admit any violation of the State Consumer Protection Laws and does not admit any wrongdoing that could have been alleged by the Attorney General.

38. This Judgment shall not be construed or used as a waiver or any limitation of any defense otherwise available to Purdue. This Judgment is made without trial or adjudication of any issue of fact or law or finding of liability of any kind. Nothing in this Judgment, including this paragraph, shall be construed to limit or to restrict Purdue's right to use this Judgment to assert and maintain the defenses of res judicata, collateral estoppel, payment, compromise and settlement, accord and satisfaction, or any other legal or equitable defenses in any pending or future legal or administrative action or proceeding.

VIII. DISPUTES REGARDING COMPLIANCE

39. For the purposes of resolving disputes with respect to compliance with this Judgment, should the Attorney General have legally sufficient cause (which shall include, at a minimum, a reasonable basis to believe that Purdue has violated a provision of this Judgment) to object to any promotional or marketing practices relating to OxyContin subsequent to the Effective Date of this Judgment, then the Attorney General shall notify Purdue in writing of the specific objection, identify with particularity the provisions of this Judgment and/or the State Consumer Protection Laws that the practice appears to violate, and give Purdue thirty (30) business days to respond to the notification; provided, however, that the Attorney General may take any action upon notice to Purdue where the Attorney General concludes that, because of the specific practice, a threat to the health or safety of the public requires immediate action.

40. Upon receipt of written notice and within the thirty (30) business-day period, Purdue shall provide a good faith written response to the Attorney General's objection. The response shall include an affidavit containing either:

a. A statement explaining why Purdue believes it is in compliance with the Judgment; or

b. A detailed explanation of how the alleged violation[s] occurred; and

i. A statement that the alleged breach has been cured and how it has been cured; or

ii. A statement that the alleged breach cannot be reasonably cured within thirty (30) business days from receipt of the notice, but (1) Purdue has begun to take corrective action to cure the alleged breach; (2) Purdue is pursuing such corrective action with reasonable and due diligence; and (3) Purdue has provided the Attorney General with a detailed and reasonable time table for curing the alleged breach.

41. Nothing herein shall prevent the Attorney General from agreeing in writing to provide Purdue with additional time beyond the thirty (30) business-day period to respond to the notice.

42. Nothing herein shall be construed to exonerate any failure to comply with any provision of this Judgment after the date of entry or to compromise the authority of the Signatory Attorney General to initiate a proceeding for failure to

comply. Further, nothing in this subsection shall be construed to limit the authority of the Signatory Attorney General to protect the interests of the State.

43. The Signatory Attorney General represents that he will seek enforcement of the provisions of this Judgment with due regard for fairness and, in so doing, shall take into account efforts that Purdue has taken to cure any claimed violation of this Judgment.

44. Upon giving Purdue thirty (30) business days to respond to the notification described in Paragraph 39 above, the Attorney General shall be permitted to request and Purdue shall produce relevant, non-privileged, non-work-product records and documents in the possession, custody or control of Purdue that relate to Purdue's compliance with each provision of this Judgment as to which legally sufficient cause has been shown.

IX. MODIFICATION OF CERTAIN OPERATIONAL PROVISIONS

45. Any party to this Judgment may petition the Court for modification on thirty (30) days' notice to all other parties to this Judgment. Purdue may petition for modification if it believes that the facts and circumstances that led to the Attorney General's action against Purdue have changed in any material respect. The parties by stipulation may agree to a modification of this Judgment, which agreement shall be presented to this Court for consideration; provided that the parties may jointly agree to a modification only by a written instrument signed by or on behalf of both Purdue and the Attorney General. If Purdue wishes to seek a stipulation for a modification from the State, it shall send a written request for agreement to such modification to the Attorney General at least 30 days prior to filing a motion with the Court for such modification. Within 30 days of receipt from Purdue of a written request for agreement to modify, the Attorney General shall notify Purdue in writing if the Attorney General agrees to the requested modification. The Attorney General shall not unreasonably withhold his consent to the modification.

X. PENALTIES FOR FAILURE TO COMPLY

46. The State may assert any claim that Purdue has violated this Judgment in a separate civil action to enforce this Judgment, or to seek any other relief afforded by law. In any such action or proceeding, relevant evidence of conduct that occurred before the Effective Date shall be admissible on any material issue, including alleged willfulness, intent, knowledge, or breach, to the extent permitted by law. By this Paragraph, Purdue does not waive any evidentiary objection or any other objection it may have as permitted by law to the admissibility of any such evidence.

47. Purdue understands and acknowledges that pursuant to the provisions of the Tennessee Consumer Protection Act, Tenn. Code Ann. § 47-18-108(c), any knowing violation of the terms of this Order shall be punishable by civil penalties of not more than Two Thousand Dollars (\$2,000.00) for each violation, in addition to any other appropriate sanctions including but not limited to contempt sanctions and the imposition of attorneys' fees and civil penalties. Purdue understands that upon execution and filing of this Order, any subsequent failure to comply with the terms hereof is a *prima facie* evidence of a violation of the Tennessee Consumer Protection Act.

XI. COMPLIANCE WITH ALL LAWS

48. Except as expressly provided in this Judgment, nothing in this Judgment shall be construed as:

(a) relieving Purdue of its obligation to comply with all state laws, regulations or rules, or granting permission to engage in any acts or practices prohibited by such law, regulation or rule; or

(b) limiting or expanding in any way any right the State may otherwise have to obtain information, documents or testimony from Purdue pursuant to any state law, regulation or rule, or any right Purdue may otherwise have to oppose

any subpoena, civil investigative demand, motion, or other procedure issued, served, filed, or otherwise employed by the State pursuant to any such state law, regulation, or rule.

XII. NOTICES

49. Any notices required to be sent to the State or to Purdue by this Judgment shall be sent by overnight United States mail. The documents shall be sent to the following addresses:

For the State of Tennessee:

Deputy Attorney General

Division of Consumer Advocate and Protection

State of Tennessee Office of the Attorney General & Reporter

P.O. Box 20207

Nashville, TN 37202

For Purdue:

Vice President, Associate General Counsel

Purdue Pharma L.P.

One Stamford Forum

201 Tresser Boulevard

Stamford, CT 06901-3431

XIII. COURT COSTS

50. Pursuant to *Tenn. Code Ann. § 47-18-116*, any filing fees assessed against Defendants, shall be paid from the State of Tennessee Attorney General's portion of its monetary recovery in this action.

XIII. SIGNATURES

APPROVED FOR ENTRY BY:

FOR THE STATE OF TENNESSEE

<<signature>>

ROBERT E. COOPER, JR., B.P.R. No. 10934

ATTORNEY GENERAL & REPORTER

<<signature>>

MEREDITH DEVAULT, B.P.R. No. 9157

SENIOR COUNSEL

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MARY CLEMENT, DIRECTOR

DIVISION OF CONSUMER AFFAIRS

STATE OF TENNESSEE

DATE: 4-26-07

FOR PURDUE

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Date: May 3, 2007.

APPROVED FOR ENTRY ON THIS 6th DAY OF MAY, ENTERED IN ACCORDANCE WITH TENNESSEE
RULE OF CIVIL PROCEDURE 58.

IT IS SO ORDERED.

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CIRCUIT COURT JUDGE