

IN THE MATTER OF  
WARNER-LAMBERT COMPANY LLC

**ASSURANCE OF VOLUNTARY COMPLIANCE**

This Assurance of Voluntary Compliance (“Assurance”) is entered into between the Attorneys General of Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin and Wyoming (“Signatory Attorneys General”),<sup>1</sup> acting pursuant to their respective consumer protection statutes, and Warner-Lambert Company LLC, successor to Warner-Lambert Company (hereinafter referred to as “Warner-Lambert”).

**I. DEFINITIONS**

1. The following definitions shall be used in construing this Assurance:

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<sup>1</sup> For the purposes of this agreement, when the entire group is referred to as “Signatory Attorneys General,” such designation, as it pertains to CONNECTICUT, shall refer to the Commissioner of the Department of Consumer Protection, who enters this Assurance of Voluntary Compliance pursuant to the Connecticut Unfair Trade Practices Act, Conn. Gen. Stat. Sec. 42-110j, acting by and through his counsel, Richard Blumenthal, Attorney General for the State of Connecticut. The chief legal officer of the DISTRICT OF COLUMBIA is the Corporation Counsel, who for uniformity shall also be referred to as “Attorney General.” With regard to GEORGIA, the Administrator of the Fair Business Practices Act, appointed pursuant to O.C.G.A. Section 10-1-395, is statutorily authorized to undertake consumer protection functions, including the acceptance of Assurances of Voluntary Compliance, for the State of Georgia. The term “Attorneys General” as used herein, as it pertains to Georgia, refers to the Administrator of the Fair Business Practices Act. With regard to HAWAII, Hawaii is represented 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 represent the State of Hawaii in consumer protection actions. Hereafter, when the entire group is referred to as the "States" or "Attorneys General," such designation as it pertains to Hawaii, refers to the Executive Director of the State of Hawaii Office of Consumer Protection. For MONTANA, the acting agency is the Consumer Protection Office.

A. “Signatory Attorney General” shall mean the Attorney General of each state in the Multistate Working Group investigating Neurontin, or his or her designee.

B. “Covered Persons” shall mean all current and future officers, employees and agents of Warner-Lambert having direct responsibility for marketing and promoting Neurontin to prescribers.

C. “Advertising Subaccount” shall mean a subaccount that shall finance the National Advertising Program to be administered by the MSEC.

D. “Compliance Provisions” shall mean Paragraphs 6 through 19 of this Assurance.

E. “Effective Date” shall mean the date on which Warner-Lambert receives a copy of this Assurance, duly executed by Warner-Lambert and by each Signatory Attorney General.

F. “Individual State” and “State” shall mean each Signatory Attorney General who is participating in the Multistate Working Group.

G. “Multistate Working Group” (“MSWG”) shall mean the Attorneys General and their staffs representing the states of Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, and Wyoming.

H. “Multistate Executive Committee” (“MSEC”) shall mean a committee of the MSWG composed of the representatives of the Attorneys General from Florida, New York, Ohio, Oregon, Texas and Vermont.

- I. “National Advertising Program” shall mean a program designed to provide to prescribers information relating to Neurontin and other drugs in the same therapeutic class.
- J. “Neurontin” or the “Product” shall mean gabapentin.
- K. “Off-Label Use” shall mean any indication that has not been approved by the U.S. Food and Drug Administration.
- L. “Parties” shall mean Warner-Lambert and the Individual States.
- M. “Prescriber and Consumer Education Program” shall mean national programs, regional programs, and programs in individual states or in a group of states, funded by the Settlement Fund, relating to prescriber and consumer education regarding drug information, drug marketing, and the conditions for which drugs are prescribed.
- N. “Prescriber and Consumer Education Subaccount” shall mean a subaccount that shall finance the Prescriber and Consumer Education Program.
- O. “Settlement Account” shall mean a new interest bearing account secured and maintained by the State of Oregon used to hold and administer the Settlement Fund.
- P. “Settlement Fund” shall mean the amount of twenty-eight million U.S. dollars (\$28,000,000.00) required to be paid pursuant to this Assurance.
- Q. “Special Committee” shall mean the Attorneys General, or their authorized designees, that comprise the MSEC plus two Attorneys General, or their authorized designees, from the remaining members of the MSWG which shall be selected on a biannual rotating basis, in the first instance by the Attorneys General of the MSEC and thereafter by the Attorneys General represented on the Special Committee.

R. “State Consumer Protection Laws” shall mean the consumer protection laws under which the Attorneys General have conducted their investigation.<sup>2</sup>

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<sup>2</sup> ALABAMA - Deceptive Trade Practices Act, Ala. Code § 8-19-1 *et seq.*; ALASKA – Unfair Trade Practices and Consumer Protection Act, AS 45.50.471 through 45.50.561 *et seq.*; ARIZONA - Consumer Fraud Act, A.R.S. § 44-1521 *et seq.*; 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, C.R.S. §§ 6-1-101 *et seq.*; CONNECTICUT – Connecticut Unfair Trade Practices Act, Conn. Gen. Stat. §42-110 *et seq.*; DELAWARE - Consumer Fraud Act, 6 Del.C. Section 2511, *et seq.*, UDTPA, 6 Del.C. Section 2531, *et seq.*; DISTRICT OF COLUMBIA – Consumer Protection Procedures Act, D.C. Official Code § 28-3901 *et seq.*; FLORIDA - Deceptive and Unfair Trade Practices Act, Fla. Stat. Ch. 501.201 *et seq.*; GEORGIA - Fair Business Practices Act of 1975, O.G.C.A. § 10-1-390 *et seq.*; HAWAII – Haw. Rev. Stat. § 480-2; IDAHO - Consumer Protection Act, Idaho Code § 48-601 *et seq.*; ILLINOIS - Consumer Fraud and Deceptive Business Practices Act, 815 ILCS § 505/1 *et seq.* (2002); INDIANA - Deceptive Consumer Sales Act, Indiana Code 24-5-0.5-1 *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 - Consumer Protection Statute, KRS 367.170; LOUISIANA – LSA-R.S. 51:1401, *et. seq.*; MAINE – Unfair Trade Practices Act, 5 M.R.S.A. section 205-A *et. seq.*; MARYLAND - Consumer Protection Act, Maryland Commercial Law Code Annotated § 13-101 *et seq.*; MASSACHUSETTS - Consumer Protection Act, M.G.L. c. 93A *et seq.*; MICHIGAN - Consumer Protection Act, Mich. Comp. Laws §445.901 *et seq.* (2004); MINNESOTA - Minn. Stat. secs. 8.31; 325F.67; 325F.69; MISSISSIPPI - Consumer Protection Act, Miss. Code Ann. § 75-24-1 *et seq.*; MISSOURI - Missouri Merchandising Practices Act, Missouri Revised Statutes Section 407.010 *et. seq.*; MONTANA - Mont. Code Ann. § 30-14-101 *et seq.*; NEBRASKA - CPA Neb.Rev.Stat.59-1601, *et seq.* (Reissue 1999 & Cum Supp. 2002)) & UDTPA, Neb.Rev.Stat. 87-301 *et. seq.* (Reissue1999 & Cum Supp. 2002); NEVADA - Deceptive Trade Practices Act, Nevada Revised Statutes 598.0903 *et seq.*; NEW HAMPSHIRE – RSA 358-A:2; NEW JERSEY - Consumer Fraud Act, N.J.S.A. 56:8-1 *et seq.*; NEW MEXICO - Unfair Trade Practices Act, NMSA § 57-12-1 *et seq.* (1978); NEW YORK - N.Y. Gen. Bus. Law §§ 349 & 350 and Executive Law § 63(12); NORTH CAROLINA - Unfair and Deceptive Trade Practices Act, N.C.G.S. § 75-1.1 *et seq.*; NORTH DAKOTA - Consumer Fraud and Unlawful Credit Practices N.D.C.C. § 51-15-01 *et seq.*; OHIO - Consumer Sales Practices Act, R.C. § 1345.01 *et seq.*; OKLAHOMA – 15 O.S. sections 751 *et seq.*; OREGON - Unlawful Trade Practices Act, ORS 646.605 to 646.656; PENNSYLVANIA - Unfair Trade Practices and Consumer Protection Law, 73 P.S. § 201-1 *et seq.*; RHODE ISLAND - Unfair Trade Practice and Consumer Protection Act, R.I. Gen. Laws § 6-13.1-1, *et seq.*; SOUTH CAROLINA - Unfair Trade Practices Act, Sections 39-5-10 *et seq.*; SOUTH DAKOTA - SDCL § 37-24-1 through 40 *et seq.*; TENNESSEE - Consumer Protection Act, Tenn. Code Ann. § 47-18-101 *et seq.*, (1977); TEXAS - Deceptive Trade Practices and Consumer Protection Act, Tex. Bus. And Com. Code § 17.41 *et seq.*, (Vernon 2002); UTAH - Consumer Sales Practices Act, §13-11-1 *et seq.*; Truth In Advertising Act, §13-11a-1 *et seq.*; VERMONT - Consumer Fraud Act, 9 V.S.A. § 2451 *et seq.*; VIRGINIA - Virginia Consumer Protection Act, 59.1 -196 *et seq.*; WASHINGTON - Unfair Business Practices/Consumer Protection Act, R.C.W. 19.86 *et seq.*; WEST VIRGINIA - Code Section 46A-1-101 *et seq.*; WISCONSIN - Wis. Stat. § 100.18 (Fraudulent Representations); WYOMING -W.S. §§ 40-12-102 *et seq.*

S. “Subject Matter of this Assurance” shall mean the Signatory Attorneys’ General investigation under the State Consumer Protection Laws of Warner-Lambert’s promotional and marketing practices regarding the Off-Label Use of Neurontin.

T. “Warner-Lambert” shall mean Warner-Lambert Company LLC, its affiliates, subsidiaries, predecessors, successors, parents and assigns who manufacture, sell, distribute and/or promote Neurontin.

## **II. BACKGROUND**

2. Warner-Lambert is in the business of researching, developing, manufacturing, distributing and promoting drugs for use in treating various illnesses and diseases.

3. Neurontin, a prescription drug, is approved by the FDA as safe and effective in adjunctive treatment for epilepsy and in the treatment of post-herpetic neuralgia.

4. The States have concerns that Warner-Lambert Company, the predecessor of Warner-Lambert Company LLC, has engaged in certain promotional and marketing practices for Off-Label Uses of Neurontin, and in particular that those promotional and marketing practices violated the State Consumer Protection Laws.

5. Warner-Lambert does not admit any violation of the State Consumer Protection Laws. Warner-Lambert enters into this Assurance for the purpose of resolving the Signatory Attorneys’ General inquiry into Neurontin promotional and marketing practices, arriving at a complete and total settlement and resolution of any disagreement as to the matters addressed in this Assurance to avoid unnecessary expense, inconvenience, and uncertainty, without admitting any violation of law and without admitting any wrongdoing, and for settlement purposes only.

## **III. COMPLIANCE PROVISIONS**

6. Warner-Lambert shall not make any written or oral claim that is false, misleading or deceptive regarding the Product.

7. Warner-Lambert shall not make any written or oral promotional claim of safety or effectiveness for the Product for Off-Label Uses in a manner that violates the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.* (“FDCA”), and accompanying regulations.

8. Warner-Lambert shall not provide to health care professionals written materials describing the Off-Label Use of the Product that have not appeared in a scientific or medical journal or reference publication or any portion thereof, except upon an independent request for such information, without solicitation by Warner-Lambert to make the request. Warner-Lambert shall maintain records for three years of the identity of all health care professionals to whom such materials relating to the Off-Label Use of the Product have been provided. “Scientific or medical journal” is a publication whose articles are peer-reviewed and 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.

9. A. When Warner-Lambert provides an individual with any educational grant, research grant, or other similar remuneration relating to the Product, Warner-Lambert shall obtain the recipient’s agreement to clearly and conspicuously disclose the existence of said remuneration to the readers of any letter, study, research or other materials which was funded by said remuneration, and to refund said remuneration if such disclosure is not made.

B. Warner-Lambert shall require that a recipient of any remuneration from Warner-Lambert relating to the promotion of the Product agree to clearly and conspicuously disclose, both

orally and in writing as part of any prepared presentation materials, 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 the Product, and to refund said remuneration if such disclosure is not made.

C. Warner-Lambert 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 the Product when Warner-Lambert disseminates or refers to said letter, study, research or other material in communications with health care professionals.

10. In addition to the requirements set forth in paragraphs 6 - 19 herein, Warner-Lambert shall comply with the relevant Accreditation Council for Continuing Medical Education Guidelines with respect to participation in educational events relating to the Product.

11. Warner-Lambert shall not misrepresent the nature of any promotional, educational or research event relating to the Product.

12. In addition to the requirements set forth in paragraphs 6 - 19 herein, Warner-Lambert 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 remuneration to health care providers regarding the Product.

13. Warner-Lambert shall not misrepresent the existence, non-existence, or findings of any medical or scientific evidence, including anecdotal evidence, relating to Off-Label Uses of the Product. In any discussion of the Off-Label Uses of the Product, any information provided by Warner-Lambert shall not be misleading or lacking in fair balance, as defined in 21 CFR §202.1.

14. Warner-Lambert shall not misrepresent, in any written or oral claim relating to the Product that its sales, medical or technical 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.

15. Warner-Lambert shall comply with the federal anti-kickback statute, 42 U.S.C. §1320a7, with respect to its relationship with any physician or other health care provider relating to the Product.

16. If Warner-Lambert provides information about the Product to Drugdex or any other reference compendium, the information shall not be misleading or lacking in fair balance, as defined in 21 CFR §202.1.

17. The obligations of Warner-Lambert under this Assurance shall be prospective only. No Signatory Attorney General shall institute any proceeding or take any action against Warner-Lambert under its State Consumer Protection Laws or any similar state authority, or under this Assurance, based on Warner-Lambert's prior promotional or marketing practices for Neurontin.

18. Nothing in this Assurance shall require Warner-Lambert to:

(a) take an action that is prohibited by the FDCA or any regulation promulgated thereunder, or by FDA; or

(b) fail to take an action that is required by the FDCA or any regulation promulgated thereunder, or by FDA. Any written or oral promotional claim subject to this Assurance which is the same or substantially the same as the language prescribed by FDA in the Neurontin package insert, and which accurately portrays the data or other information referenced in the Neurontin package insert, shall not constitute a violation of this Assurance.

19. Warner-Lambert shall:

(a) within 90 days after the Effective Date of this Assurance, institute compliance procedures which are designed to begin training those Warner-Lambert officers and employees



whose responsibilities or duties include compliance with this Assurance, about how to comply with this Assurance;

(b) submit to each Signatory Attorney General, within 120 days after the Effective Date of this Assurance, a written description of such training; and

(c) submit to each Signatory Attorney General, one year after the Effective Date of this Assurance, a written affirmation setting forth Warner-Lambert's compliance with this paragraph.

(d) for a period of three (3) years from the Effective Date of this Assurance, Warner-Lambert shall provide a copy of Paragraphs 6 through 18 of this Assurance to all current and future officers, employees and agents having direct responsibility for marketing and promoting the Product ("Covered Persons").

#### **IV. SETTLEMENT FUND**

20. Within thirty days of the Effective Date of this Assurance, Warner-Lambert shall pay the amount of twenty-eight million U.S. dollars (\$28,000,000.00) (the "Settlement Fund") to the States by electronic funds transfer, or certified or cashier's check, made payable to the Oregon Department of Justice and shall be tendered to the State of Oregon to be held in a new interest bearing account (the "Settlement Account"), created for the benefit of the Multistate Working Group ("MSWG"), the monies of which shall be used for the purposes delineated in Paragraphs 20 through 32 pursuant to the terms of this Assurance, and shall be administered pursuant to the Order attached as Exhibit A (the "Order"). Warner-Lambert and the Signatory Attorneys General stipulate that the Oregon Attorney General shall submit the Order to the Marion County Circuit Court concurrently with the submission

of this Assurance.<sup>3</sup> The Settlement Fund, and interest generated therefrom, shall not be commingled with other funds, and shall be administered pursuant to the Order.

21. Upon payment of the Settlement Fund in the manner prescribed in Paragraph 20 of this Assurance, and upon further payment to the Signatory Attorneys General as prescribed in Paragraph 33, Warner-Lambert shall (a) be fully divested of any interest in, or ownership of, the monies paid and all interest in the monies, and any subsequent interest or income derived therefrom shall inure entirely to the benefit of MSWG, pursuant to the terms of this Assurance; (b) have no further obligation to make any payment to the Signatory Attorneys General, pursuant to this Assurance; (c) have no control over, responsibility for or input as to the disbursement of any funds or designation of any funds; and (d) have no further obligation to the Signatory Attorneys General, pursuant to Paragraph 20 and Paragraph 33 of this Assurance.

**V. DISBURSEMENT OF PAYMENTS:  
NATIONAL ADVERTISING PROGRAM**

22. A portion of the Settlement Fund, in the amount of six million U.S. dollars (\$6,000,000.00), shall be paid from the Settlement Account for use by the MSEC to develop the National Advertising Program on behalf of the MSWG. The fund subaccount that shall finance the National Advertising Program shall be known as the Advertising Subaccount. Such fund shall be administered by the MSEC.

23. The National Advertising Program shall provide information to prescribers regarding Neurontin and other drugs in the same therapeutic class, including, but not limited to, by placing advertisements in medical journals.

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<sup>3</sup> Warner-Lambert and the Signatory Attorneys General further stipulate that the Signatory Attorneys General may substitute Exhibit A with the Order signed and entered by the Marion County Circuit Court upon said Court's approval.

24. The MSEC may retain experts and other vendors, including advertising agencies, from the monies in the Advertising Subaccount to assist in the drafting, design and implementation of the National Advertising Program on behalf of the MSWG.

25. Any advertisement or other public communication regarding Neurontin prepared in connection with the National Advertising Program shall not be misleading or lacking in fair balance, as defined in 21 CFR §202.1.

26. At the conclusion of the National Advertising Program, as determined by the MSEC, any portion of the monies provided for in Paragraph 20 of this Assurance that are not expended in the National Advertising Program, pursuant to Paragraphs 22 through 25, shall be transferred to the Prescriber and Consumer Education Subaccount created pursuant to Paragraphs 27 - 29, below.

**VI. DISBURSEMENT OF PAYMENTS:  
PRESCRIBER AND CONSUMER EDUCATION GRANTS**

27. A portion of the Settlement Fund, in the amount of twenty-one million U.S. dollars (\$21,000,000.00), shall be paid from the Settlement Account for use by the MSWG in funding national programs, regional programs, or programs in individual states or in a group of states, relating to prescriber and consumer education regarding drug information, drug marketing, and the conditions for which drugs are prescribed (“Prescriber and Consumer Education Program”). The Settlement Fund subaccount that shall finance the Prescriber and Consumer Education Program shall be known as the Prescriber and Consumer Education Subaccount, and shall be administered by the Special Committee on behalf of the MSWG.

28. The Prescriber and Consumer Education Program shall make grants available to Individual States or a group of States, or to other governmental entities, academic institutions, or not-for-profit organizations that have current section 501(c)(3) status from the Internal Revenue Service and have expertise and experience in health-related or consumer protection issues, approved by the

Special Committee for the purpose of funding programs designed to educate prescribers and/or consumers relating to drug information, drug marketing, and the conditions for which drugs are prescribed.

29. The Special Committee may retain experts and other vendors from the monies in the Prescriber and Consumer Education Subaccount to assist in developing the criteria for grant applications as well as in reviewing any grant application. The Special Committee shall require in any contract with a grantee of the Prescriber and Consumer Education Program that the grantee possess, with respect to any representation made in a public communication produced in connection with said grant, substantial evidence or substantial clinical experience that substantiates the representation.

**VIII. DISBURSEMENT OF PAYMENTS:  
EVALUATION AND ADMINISTRATION OF ADVERTISING SUBACCOUNT AND  
PRESCRIBER AND CONSUMER EDUCATION SUBACCOUNT**

30. No Individual Signatory Attorney General shall have any claim to the funds in the Advertising Subaccount. Distributions from the Advertising Subaccount shall be made at the discretion of the MSEC, and solely for the purposes outlined in this Assurance.

31. No Individual Signatory Attorney General shall have any claim to the funds in the Prescriber and Consumer Education Subaccount. Distributions from the Prescriber and Consumer Education Subaccount shall be made at the discretion of the Special Committee and solely for the purposes outlined in this Assurance.

32. A portion of the Settlement Fund, in the amount of one million U.S. dollars (\$1,000,000.00), shall be paid from the Settlement Account into a subaccount created for purposes of evaluating the effectiveness of the National Advertising Program and the Prescriber and Consumer Education Program and of grantees' compliance with the requirements of the Prescriber and Consumer Education Program (the "Evaluation Subaccount"). Funds in the Evaluation Subaccount shall be

administered by the Special Committee. The Special Committee may retain an expert or experts from the Evaluation Subaccount to conduct evaluations of the National Advertising Program and the Prescriber and Consumer Education Program.

**IX. DISBURSEMENT OF PAYMENTS:  
PAYMENT TO THE STATES**

33. Within thirty (30) days of the Effective Date of this Assurance, Warner-Lambert shall pay ten million U.S. dollars (\$10,000,000.00), to be divided and paid by Warner-Lambert directly to each Signatory Attorney General in an amount to be designated by and in the sole discretion of the MSWG, as part of the consideration for the termination of their respective investigations under the State Consumer Protection Laws regarding the Subject Matter of this Assurance. Said payment shall be used by the States as and for attorneys' fees and other costs of investigation and litigation, or to be placed in, or applied to, the consumer protection enforcement fund, consumer education, litigation or local consumer aid fund or revolving fund, used to defray the costs of the inquiry leading hereto, or for other uses permitted by state law, at the sole discretion of each Signatory Attorney General.<sup>4</sup>

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<sup>4</sup> For ALASKA, said payment shall be used at the discretion of the Attorney General for consumer protection and antitrust investigation, enforcement, and education. In ARKANSAS, the money shall be placed in the Arkansas Attorney General's Consumer Education and Enforcement Fund and held in trust for purposes directly related to Arkansas consumer protection efforts. For COLORADO, such funds, along with interest thereon, shall be held in trust by the Attorney General and shall be used first for reimbursement of the Attorney General's actual costs and attorney fees and second, for consumer education and for consumer and/or antitrust enforcement efforts. DELAWARE'S payment will go to the Consumer Protection Fund. With respect to the State of GEORGIA, said payment shall be used for the reimbursement of costs, including monitoring of compliance, and any remainder, at the end of thirty-six (36) months, shall be delivered to the Georgia Consumer Preventative Education Plan pursuant to O.G.C.A. §10-1-381. In MASSACHUSETTS, the money shall be deposited into the Local Consumer Aid Fund pursuant to M.G.L. c. 12, section 11G. In OREGON, the money shall be deposited to the Consumer Protection and Education Revolving Account established pursuant to ORS 180.095. In PENNSYLVANIA, funds distributed to the Pennsylvania Office of Attorney General may be used for costs of investigation, attorney fees and for future consumer protection and public protection purposes. In WEST VIRGINIA, the money shall be placed in trust and used at the discretion of the Attorney General solely for consumer protection purposes, including but not limited to, restitution, consumer education, credit or bankruptcy counseling and education, conflict resolution programs, and costs associated with implementing restitution programs.

## **X. GENERAL PROVISIONS**

34. This Assurance shall be governed by the laws of the above named states.

35. This Assurance 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 Assurance.

36. Nothing in this Assurance constitutes any agreement by the Parties concerning the characterization of the amounts paid pursuant to this Assurance for purposes of the Internal Revenue Code or any state tax laws.

37. This Assurance does not constitute an approval by the Signatory Attorneys General of any of Warner-Lambert's business practices, including its promotional or marketing practices, and Warner-Lambert shall make no representation or claim to the contrary.

38. This Assurance sets forth the entire agreement between the Parties hereto and supersedes all prior agreements or understandings, whether written or oral, between the Parties and/or their respective counsel with respect to the subject matter hereof. This Assurance may be amended by written agreement between the Parties, subject to any further requirements under an individual Signatory Attorney General's state law.

39. This Assurance may be executed in counterparts, each of which shall be deemed an original, but all of which shall together be one and the same Assurance. This Assurance shall become effective on the Effective Date, which shall be the date on which Warner-Lambert receives a copy of this Assurance, duly executed by Warner-Lambert and by each of the Signatory Attorneys General.<sup>5</sup>

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<sup>5</sup> Warner-Lambert LLC agrees that the Attorney General of Minnesota may file this Assurance and any supporting documents pursuant to Minn. Stat. sec. 8.31 without counsel for Warner-Lambert LLC present.

## **XI. REPRESENTATIONS AND WARRANTIES**

40. Warner-Lambert warrants and represents that it and its predecessors, successors and assigns manufactured, sold, distributed and promoted the Product. Warner-Lambert further acknowledges that it is a proper party to this Assurance. Warner-Lambert further warrants and represents that the individual signing this Assurance on behalf of Warner-Lambert is doing so in his or her official capacity and is fully authorized by Warner-Lambert to enter into this Assurance and to legally bind Warner-Lambert to all of the terms and conditions of the Assurance.

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

42. Each of the Signatory Attorneys General warrants and represents that he or she is signing this Assurance in his or her official capacity, and that he or she is fully authorized by his or her state to enter into this Assurance, including but not limited to the authority to grant the release contained in Paragraphs 44 – 46 of this Assurance, and to legally bind his or her state to all of the terms and conditions of this Assurance.

43. Warner-Lambert acknowledges and agrees that the Signatory Attorneys General have relied on all of the representations and warranties set forth in this Assurance and that, if any representation is proved false, unfair, deceptive, misleading, or inaccurate in any material respect, the Signatory Attorney General has the right to seek any relief or remedy afforded by law or equity in the respective state.

## **XII. RELEASE**

44. Based on their inquiry into Neurontin promotional practices, the Signatory Attorneys General have concluded that this Assurance is the appropriate resolution of any alleged violations of the State Consumer Protection Laws. The Signatory Attorneys General acknowledge by their execution hereof that this Assurance terminates their inquiry under the State Consumer Protection

Laws into Warner-Lambert's promotional practices regarding Neurontin prior to the Effective Date of this Assurance.

45. In consideration of the Compliance Provisions, payments, undertakings, and acknowledgments provided for in this Assurance, and conditioned on Warner-Lambert's making full payment of the amounts specified in Paragraph 20 and 33, and subject to the limitations and exceptions set forth in Paragraph 46, each State releases and forever discharges, to the fullest extent permitted by law, Warner-Lambert and its past and present officers, directors, shareholders, employees, 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 Signatory Attorneys General could have asserted against the Releasees under the State Consumer Protection Law by reason of any conduct that has occurred at any time up to and including the Effective Date of this Assurance relating to or based upon the Subject Matter of this Assurance ("Released Claims").

46. The Released Claims set forth in Paragraph 45 specifically do not include the following claims:

(a) private rights of action by consumers, provided, however, that this Assurance 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; and

(e) claims to enforce the terms and conditions of this Assurance.



### **XIII. NO ADMISSION OF LIABILITY**

47. This Assurance does not constitute an admission by Warner-Lambert for any purpose, of any fact or of a violation of any state law, rule, or regulation, nor does this Assurance constitute evidence of any liability, fault, or wrongdoing. Warner-Lambert enters into this Assurance for the purpose of resolving the concerns of the Signatory Attorneys General regarding Warner-Lambert's promotional and marketing practices for Off-Label Uses of Neurontin. Warner-Lambert does not admit any violation of the State Consumer Protection Laws, and does not admit any wrongdoing that could have been alleged by the Signatory Attorneys General.

48. This Assurance shall not be construed or used as a waiver or any limitation of any defense otherwise available to Warner-Lambert. This Assurance is made without trial or adjudication of any issue of fact or law or finding of liability of any kind. Nothing in this Assurance, including this paragraph, shall be construed to limit or to restrict Warner-Lambert's right to use this Assurance 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.

### **XIV. DISPUTES REGARDING COMPLIANCE**

49. For the purposes of resolving disputes with respect to compliance with this Assurance, should any of the Signatory Attorneys General have legally sufficient cause (which shall include, at a minimum, a reasonable basis to believe that Warner-Lambert has violated a provision of this Assurance) to object to any promotional or marketing practices relating to Neurontin subsequent to the Effective Date of this Assurance, then such Attorney General shall notify Warner-Lambert in writing of the specific objection, identify with particularity the provisions of this Assurance and/or the State Consumer Protection Law that the practice appears to violate, and give Warner-Lambert thirty (30) business days to respond to the notification; provided, however, that a Signatory Attorney General may

take any action upon notice to Warner-Lambert where the Signatory Attorney General concludes that, because of the specific practice, a threat to the health or safety of the public requires immediate action.

50. Upon giving Warner-Lambert thirty (30) business days to respond to the notification described in Paragraph 49 above, the Signatory Attorney General shall be permitted reasonable access to inspect and copy relevant, non-privileged, non-work-product records and documents in the possession, custody or control of Warner-Lambert that relate to Warner-Lambert's compliance with each provision of this Assurance as to which legally sufficient cause has been shown. 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 Warner-Lambert.

#### **XV. PENALTIES FOR FAILURE TO COMPLY**

51. The State may assert any claim that Warner-Lambert has violated this Assurance in a separate civil action to enforce this Assurance, 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, contempt or breach, to the extent permitted by law. By this Paragraph 51, Warner-Lambert does not waive any evidentiary objection or any other objection it may have as permitted by law to the admissibility of any such evidence.

#### **XVI. COMPLIANCE WITH ALL LAWS**

52. Except as expressly provided in this Assurance, nothing in this Assurance shall be construed as

(a) relieving Warner-Lambert 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 Warner-Lambert pursuant to any state law, regulation or rule, or any right Warner-Lambert 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.

**XVII. NOTICES UNDER THIS ASSURANCE**

53. Any notices required to be sent to the State or to Warner-Lambert by this Assurance shall be sent by overnight United States mail. The documents shall be sent to the following addresses:

For the individual States:

to the addresses listed in Section XVIII.

For the MSWG and MSEC:

Julie Brill  
Assistant Attorney General  
Office of the Vermont Attorney General  
109 State Street  
Montpelier, VT 05609-1001

And

David Hart  
Assistant Attorney General  
Financial Fraud Section, Civil Enforcement  
Oregon Department of Justice  
1162 Court Street, NE  
Justice Building  
Salem, OR 97310

For Warner-Lambert:

James Murray, Esq.  
Davis Polk & Wardwell  
450 Lexington Avenue  
New York, NY 10017