

STATE OF MAINE  
KENNEBEC, SS

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2009 SEP -2 P 2: 12

MICHELE LUMBERT  
CLERK OF COURTS

SUPERIOR COURT  
CIVIL ACTION  
DOCKET NO. CV-09-237

STATE OF MAINE,

Plaintiff,

v.

PFIZER INC.,

Defendant

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CONSENT JUDGMENT

Plaintiff, the State of Maine, and Defendant, Pfizer Inc., voluntarily enter into this  
Consent Judgment on the terms and conditions set forth below.

FINDINGS

- A. This Court has jurisdiction over the subject matter of this lawsuit and over all Parties.
- B. The terms of this Consent Judgment shall be governed by the laws of the State of Maine.
- C. Entry of this Consent Judgment is in the public interest and reflects a negotiated agreement among the Parties.
- D. The Parties have agreed to resolve the issues related to the Covered Conduct involving the prescription drug Geodon® by entering into this Consent Judgment.
- E. Pfizer is willing to enter into this 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 Consent Judgment and thereby avoid unnecessary expense, inconvenience, and uncertainty.

F. The Parties have agreed to resolve the issues raised by the Covered Conduct by entering into this Consent Judgment.<sup>1</sup>

1. Pfizer is entering into this 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 violation of the State Consumer Protection Laws set forth in footnote 1, and does not admit any wrongdoing that was or could have been alleged by any Attorney General before the date of the Consent Judgment under those laws. No part of this 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.

2. This 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 Consent Judgment. This 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 Consent Judgment.

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<sup>1</sup> This agreement is entered into pursuant to and subject to the State Consumer Protection laws cited in footnote 2.

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

4. No part of this 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 Consent Judgment.

G. This Consent Judgment (or any portion thereof) shall in no way be construed to prohibit Pfizer from making representations with respect to Geodon® that are required under Federal law or required under any Investigational New Drug Application, New Drug Application, Supplemental New Drug Application, or Abbreviated New Drug Application approved by the FDA.

H. Nothing in this Consent Judgment shall require Pfizer to:

(a) take any action that is prohibited by the FDCA or any regulation promulgated thereunder, or by 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 promotional claim subject to this Consent Judgment which is the same, or materially the same, as the language required or agreed to by the Director of Division of Drug Marketing, Advertising and Communication or the Director of the Center for Drug Evaluation and Research or their authorized designees in writing shall not constitute a violation of this Consent Judgment, unless facts are or become known to Pfizer that cause the claim to be false, misleading or deceptive.

## DEFINITIONS

The following definitions shall be used in construing this Consent Judgment:

1. "Author" shall mean an HCP or health care institution engaged to produce articles or other publications relating to Geodon®.
2. "Clinically Relevant Information" shall mean information that reasonably prudent clinicians would consider relevant when making prescribing decisions regarding Geodon®.
3. "Consultant" shall mean an HCP engaged for services other than for speaker programs (e.g., as a member of an advisory board or to attend consultant meetings) that relate to Promotional and Product Related Functions.
4. "Covered Conduct" shall mean Pfizer's promotional and marketing practices, sampling practices, dissemination of information and remuneration to HCPs regarding the prescription drug Geodon® through the Effective Date of the Agreement.
5. "Effective Date" shall mean the date on which a copy of this Consent Judgment, duly executed by Pfizer and by the Signatory Attorney General, is approved by, and becomes a Consent Judgment of, the Court, whichever is later.
6. "Geodon®" shall mean all Pfizer Products that are FDA-approved drug formulations containing ziprasidone or ziprasidone mesylate.
7. "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.

8. "Labeling" shall mean all FDA-approved labels, which are a display of written, printed, or graphic matter upon the immediate container of any article, and other written, printed, or graphic matters (a) upon any article or any of its containers or wrappers, or (b) accompanying such article.

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

10. "Medical Outcomes Specialists" shall mean Pfizer personnel who have expertise working with managed care to determine suitable drugs on a formulary and are assigned to the Medical Outcomes Specialist group of Pfizer.

11. "Medical Reference Publication" shall have the meaning ascribed to the term "reference publication" found in 21 C.F.R. 99.3(i).

12. "Medical Science Liaison" shall mean a person, usually with an advanced scientific degree (e.g., a MD, PhD, or PharmD), assigned, employed, hired or retained by Pfizer to provide scientific analysis and/or scientific information to HCPs and includes Regional Medical Research Specialists.

13. "Multistate Executive Committee" shall mean the Attorneys General and their staffs representing Arizona, Colorado, Delaware, District of Columbia, Florida, Kentucky, Maryland, Massachusetts, North Carolina, Ohio and Pennsylvania.

14. "Multistate Working Group" shall mean the Attorneys General and their staff representing Alabama, Arkansas, Arizona, California, Colorado, Connecticut, Delaware, District

of Columbia, Florida, Hawaii, Idaho, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Texas, Vermont, Washington, West Virginia, and Wisconsin.

15. "Off-Label" shall mean a use not consistent with the indications section of the Geodon® Labeling approved by the FDA at the time information regarding such use was communicated.

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

17. "Payment" is defined to include all payments or transfers of value (whether in cash or in kind) made to physicians including all payments (including, for example, honoraria payments, other payments, and reimbursement for lodging, travel and other expenses) made in connection with physicians serving as speakers, participating in speaker training, or serving as Consultants or Authors; payments or compensation for services rendered; grants; fees; payments relating to research; payments relating to education; and payment or reimbursement for food, entertainment, gifts, trips or travel, product(s)/item(s) provided for less than fair market value, or other economic benefit paid or transferred. The term also includes all payments or transfers of value made to Related Entities on behalf of, at the request of, for the benefit or use of, or under the name of a physician for whom Pfizer would otherwise report a Payment if made directly to the physician. The term "Payments" includes any Payments made, directly or indirectly, by Pfizer to a physician or Related Entity in connection with, or under the auspices of, a co-promotion arrangement. The term "Payments" does not include: i) samples of drug products that

meet the definition set forth in 21 C.F.R. § 203.3(i), or ii) discounts, rebates, or other pricing terms. Only for purposes of the reporting of Payments on March 31, 2011, the term "Payments" does not include: i) individual Payments of less than \$25 per instance, or ii) aggregate Payments in a year to a physician or Related Entity of less than \$500. Beginning with the March 31, 2012 report and all reports thereafter, individual Payments under \$25 per instance and aggregate Payments of less than \$500 shall be included in the Payment amounts listed in the applicable report.

18. "Pfizer Inc." or "Pfizer" shall mean Pfizer Inc., including all of its affiliates, subsidiaries and divisions, predecessors, successors and assigns doing business in the United States.

19. "Pfizer Medical Education Grants Office" shall mean the U.S.-based organization within Pfizer responsible for oversight of the continuing medical education (CME) grant process, including the acceptance, review, and approval of all non-clinical CME grant requests.

20. "Pfizer Marketing" shall mean Pfizer personnel assigned to the Pfizer U.S. Geodon® marketing team(s).

21. "Pfizer Medical" shall mean Pfizer personnel assigned to the Pfizer medical organization.

22. "Pfizer Sales" shall mean the Pfizer sales force responsible for U.S. Geodon® sales, including but not limited to Medical Outcomes Specialists.

23. "Promotional," "Promoting" or "Promote" shall mean claims about Geodon® intended to increase sales or attempt to influence prescribing practices of HCPs, including direct-to-consumer as applicable.

24. "Promotional and Product Related Functions" includes: (a) the selling, detailing, marketing, advertising, promoting, or branding of Geodon®; (b) the development, preparation, or dissemination of materials or information about, or the provision of services relating to, Geodon® including those functions relating to material review committees and Pfizer's Medical Information Department; and (c) research, development, and publication related-activities involving Geodon®, including postmarketing and other studies, and the authorship, publication and disclosure of study results.

25. "Promotional Materials" shall mean any item with the product name, logo, or message used to Promote Geodon®.

26. "Promotional Slide Kit" shall mean Promotional Materials regarding Geodon® in the form of a slide kit for use in speaker programs.

27. "Promotional Speaker" shall mean a non-Pfizer employee HCP speaker used to Promote Geodon®.

28. "Related Entity" is any entity by or in which any physician receiving Payments is employed, has tenure, or has an ownership interest.

29. "Reprints Containing Off-Label Information" shall mean articles or reprints from a peer reviewed journal or reference publication describing an Off-Label use of Geodon®.



30. "Signatory Attorney General" shall mean the Attorney General of Maine, or her authorized designee, who has agreed to this Consent Judgment.

31. "State Consumer Protection Laws" shall mean the consumer protection laws under which the Attorneys General have conducted the investigation.<sup>2</sup>

32. "Unsolicited Request" shall mean a request for information regarding Geodon® from a non-Pfizer HCP communicated to an agent of Pfizer that has not been prompted.

### COMPLIANCE PROVISIONS

#### I. Promotional Activities

A. Pfizer shall not make any written or oral claim that is false, misleading or deceptive regarding Geodon®.

<sup>2</sup> ALABAMA – Alabama Deceptive Trade Practices Act, Ala. Code § 8-19-1 et seq.; ARIZONA – Arizona Consumer Fraud Act, A.R.S. § 44-1521 et seq.; ARKANSAS – Arkansas Deceptive Trade Practices Act, Ark. Code Ann. § 4-38-101, et seq.; CALIFORNIA – Bus. & Prof Code §§ 17200 et seq. and 17500 et seq.; COLORADO – Colorado Consumer Protection Act, Colo. Rev. Stat. § 6-1-101 et seq.; DELAWARE – Delaware Consumer Fraud Act, Del. CODE ANN. tit. 6, §§ 2511 to 2527; DISTRICT OF COLUMBIA, District of Columbia Consumer Protection Procedures Act, D.C. Code §§ 28-3901 et seq.; FLORIDA – Florida Deceptive and Unfair Trade Practices Act, Part II, Chapter 501, Florida Statutes, 501.201 et seq.; HAWAII – Uniform Deceptive Trade Practices Act, Haw. Rev. Stat. Chpt. 481A and Haw. 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.; IOWA – Iowa Consumer Fraud Act, Iowa Code Section 714.16; KANSAS – Kansas Consumer Protection Act, K.S.A. 50-623 et seq.; KENTUCKY – Kentucky Consumer Protection Act, KRS Ch. 367.110, et seq.; LOUISIANA – Unfair Trade-Practices and Consumer Protection Law, LSA-R.S. 51:1401, et seq.; MAINE – Unfair Trade Practices Act, 5 M.R.S.A. § 207 et seq.; MARYLAND – Maryland Consumer Protection Act, Md. Code Ann., Com. Law §§ 13-101 et seq.; MASSACHUSETTS – Mass. Gen. Laws c. 93A, §§ 2 and 4; MICHIGAN – Michigan Consumer Protection Act, MCL § 445.901 et seq.; MINNESOTA – Minnesota Deceptive Trade Practices Act, Minn. Stat. §§ 325D.43-48; Minnesota False Advertising Act, Minn. Stat. § 325F.67; Minnesota Consumer Fraud Act, Minn. Stat. §§ 325F.68-70; Minnesota Deceptive Trade Practices Against Senior Citizens or Disabled Persons Act, Minn. Stat. § 325F.71; MISSOURI – Missouri Merchandising Practices Act, Mo. Rev. Stat. §§ 407 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, N.J.S.A. 56:8-1 et seq.; NEW MEXICO – NMSA 1978, § 57-12-1 et seq.; NEW YORK – General Business Law Art. 22-A, §§ 349-50, and Executive Law § 63(12); NORTH CAROLINA – North Carolina Unfair and Deceptive Trade Practices Act, N.C.G.S. 75-1.1, et seq.; NORTH DAKOTA – Unlawful Sales or Advertising Practices, N.D. Cent. Code § 51-15-02 et seq.; OHIO – Ohio Consumer Sales Practices Act, R.C. 1345.01, et seq.; OREGON – Oregon Unlawful Trade Practices Act, Or. Rev. Stat. § 646.605 et seq.; PENNSYLVANIA – Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 P.S. 201-1 et seq.; SOUTH 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 17.47, et seq.; VERMONT – Consumer Fraud Act, 9 V.S.A. §§ 2451 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).

B. In Promotional Materials for Geodon®, Pfizer shall clearly and conspicuously disclose the most serious risks associated with the product as set forth in the product's labeling, including information in any black box warning and shall present information about effectiveness and information about risk in a balanced manner.

C. Pfizer shall not Promote Geodon® for Off-Label uses.

D. Pfizer shall not present patient profiles/types based on selected symptoms of the FDA-approved indication(s) when Promoting Geodon®, unless:

1. Geodon®'s specific FDA-approved indication(s) being Promoted is/are stated clearly and conspicuously on the same page or on a facing page in any physical Promotional Materials that reference the selected symptoms;

a. With respect to Promotional Slide Kits or computer tablet based Promotional Materials:

(i) Pfizer shall state clearly and conspicuously the FDA-approved indication(s) on the same slide in which selected symptoms are first presented;

(ii) Pfizer shall include a short-hand reference to the statement described in Section I.D.1.a.(i) on the same slide as each subsequent reference to selected symptoms (e.g., "See complete list of FDA-approved indications at p. X"); and

b. With respect to Promotional Slide Kits, Pfizer shall require any presenter of Pfizer's Promotional Slide Kits to present the statements required in Section I.D.1.a.(i), as part of the mandatory slides.

2. Promotional Materials have a reference indicating that the full constellation of symptoms and the relevant diagnostic criteria are available in the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV or current version), where applicable.

E. Pfizer shall ensure that all Promotional Speakers' Promotional Materials for Geodon® comply with Pfizer's obligations in the above Sections I.A. - D.

F. Pfizer shall not award prizes or other incentives to its sales force as rewards for the Off-Label sales or use of Geodon®.

## II. Dissemination and Exchange of Medical Information

A. The content of Pfizer's communications concerning Off-Label uses of Geodon® shall not be false, misleading or deceptive.

### B. Medical Information Letters

1. The following subsections shall be effective for nine years from the Effective Date of this Consent Judgment.

2. Pfizer Medical shall have ultimate responsibility for developing and approving the medical content for all Medical Information Letters regarding Geodon®, including

any that may describe Off-Label information. 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.

3. Pfizer Sales and Pfizer Marketing personnel shall not develop the medical content of Medical Information Letters regarding Geodon®. This provision does not prohibit Pfizer Sales or Pfizer Marketing personnel from suggesting topics for Medical Information Letters.

4. Pfizer Sales and Pfizer Marketing personnel shall not distribute Medical Reference Publications or Medical Information Letters regarding Geodon®.

5. Pfizer shall not knowingly disseminate any Medical Information Letter describing any Off-Label use of Geodon® that makes any false, misleading or deceptive representation regarding Geodon® or any false, misleading or deceptive statement concerning a competing product.

C. Responses to Unsolicited Requests for Off-Label Information

1. The following subsections shall be effective for nine years from the Effective Date of this Consent Judgment.

2. In responding to an Unsolicited Request for Off-Label information regarding Geodon®, including any request for a specific article related to Off-Label uses, Pfizer shall advise the requestor that the request concerns an Off-Label use and inform the requestor of the drug's FDA-approved indication(s) and/or dosage and other relevant Labeling information.

3. If Pfizer elects to respond to an Unsolicited Request for Off-Label information from a HCP regarding Geodon®, Pfizer Medical personnel shall provide specific, accurate, objective, and scientifically balanced responses. Any such response shall not Promote Geodon® for any Off-Label use(s).

4. Any written response to an Unsolicited Request for Off-Label information regarding Geodon® shall include:

- a. an existing Medical Information Letter prepared in accordance with Section II.B;
- b. a Medical Information Letter or other document prepared in response to the request in accordance with Section II.B; or
- c. a report containing the results of a reasonable literature search using terms from the request.

5. Pfizer Sales and Pfizer Marketing personnel may respond in writing to an Unsolicited Request for Off-Label information regarding Geodon® from an HCP only by

informing the HCP of the presence or absence of published studies concerning the Off-Label topic or by acknowledging whether the topic is an area of research, and by offering to request on behalf of the HCP that a Medical Information Letter or other information be sent to the HCP in follow up, provided it complies with sub-Section II.C.4 set forth above. Pfizer Sales and Pfizer Marketing personnel shall not characterize, describe, identify, name, or offer any opinions about or summarize any such Off-Label information. Notwithstanding the foregoing, Medical Outcomes Specialists may discuss in writing issues relating to pharmacoeconomics or health outcomes with third party payors, including but not limited to managed care organizations and employers responsible for the administration of health benefits, but not prescribers unless employed or engaged by payors in a non-prescribing role.

6. Pfizer Sales and Pfizer Marketing personnel may respond orally to an Unsolicited Request for Off-Label information regarding Geodon® from an HCP only by informing the HCP of the presence or absence of published studies concerning the Off-Label topic or by acknowledging whether the topic is an area of research, and by offering to request on behalf of the HCP that a Medical Information Letter or other information be sent to the HCP in follow up, provided it complies with sub-Section II.C.4 set forth above. Pfizer Sales and Pfizer Marketing personnel shall not characterize, describe, identify, name, or offer any opinions about or summarize any such Off-Label information. Notwithstanding the foregoing, Medical Outcomes Specialists may discuss orally issues relating to pharmacoeconomics or health outcomes with third party payors, including but not limited to managed care organizations and employers responsible for the administration of health benefits, but not prescribers unless employed or engaged by payors in a non-prescribing role.

**D. Reprints**

1. Pfizer shall not disseminate any information describing any Off-Label use of Geodon® 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 had issued such advice regarding such Off-Label use. 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.

2. Pfizer shall not disseminate a Medical Information Letter, an unabridged reprint or copy of an article from a peer reviewed journal or a Reference Publication, or written information through a Regional Medical Research Specialist ("RMRS") describing any Off-Label use of Geodon® in response to an Unsolicited Request unless:

- a. the information is about a clinical investigation with respect to Geodon® and experts qualified by scientific training or experience to evaluate the safety or effectiveness of Geodon® would consider the subject of the clinical investigation to be scientifically sound or the information is an unabridged reprint or copy of an article from a peer reviewed journal or a Reference Publication;

- b. the information is accompanied by a comprehensive bibliography of publications discussing adequate and well-controlled clinical studies published in a medical journal or medical or scientific text that have been previously published about the use of Geodon® covered by the information (unless the information is a peer reviewed journal or Reference Publication which already includes such a bibliography); and
- c. in cases in which experts qualified by scientific training or experience to evaluate the safety or effectiveness of Geodon® would consider the conclusion of the information to have been specifically called into question by another article(s) or text(s) that experts qualified by scientific training or experience to evaluate the safety or effectiveness of Geodon® would consider to be scientifically sound, the information must be disseminated with a representative publication that reaches contrary or different conclusions regarding the Off-Label use.

**3. 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 Geodon®.
- b. Reprints Containing Off-Label Information regarding Geodon®:



(i) shall be accompanied by the full prescribing information 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 Geodon® may only be disseminated by Pfizer Medical personnel to HCPs. Pfizer Sales or Pfizer Marketing personnel shall not disseminate these materials to HCPs, absent the exception described below in (i); provided, however, that Medical Outcomes Specialists may disseminate reprints relating to pharmacoeconomics or health outcomes to third party payors, including but not limited to managed care organizations and employers responsible for the administration of health benefits, but not prescribers unless employed or engaged by payors in a non-prescribing role.

(i) In the event of an extraordinary circumstance in which there is a clinical necessity to have Pfizer Sales or Pfizer Marketing personnel disseminate a Reprint Containing Off-Label information directly to HCPs, the President of Pfizer Worldwide Pharmaceutical Operations may approve a Clinical Necessity Exception to the prohibition described in

Section II.D.3.c above for that Reprint Containing Off-Label information.

(ii) If the Clinical Necessity Exception is invoked, Pfizer will notify each Signatory Attorney General of its intent to invoke the Clinical Necessity Exception at least 30 business days prior to disseminating through Pfizer sales representatives any Reprint Containing Off-Label information on Geodon®.

(a) If a Signatory Attorney General believes the Reprint Containing Off-Label information to be disseminated does not meet the Clinical Necessity Exception, then the State will provide Pfizer with written notice within 30 business days and provide Pfizer an opportunity to discuss its desired use of the Reprint Containing Off-Label information pursuant to the limited exception.

(b) If the State and Pfizer do not come to a resolution, then the State may initiate legal action to prevent the dissemination of the Reprint Containing Off-Label information by Pfizer Sales or Pfizer Marketing personnel.

(c) If the State initiates legal action to prevent the dissemination of the Reprint Containing Off-Label information by Pfizer Sales or Pfizer Marketing

personnel, Pfizer shall not use Pfizer Sales or Pfizer Marketing personnel to disseminate such Reprint Containing Off-Label information in that State until the issue has been resolved.

4. Nothing in this Consent Judgment shall preclude Pfizer from disseminating Reprints Containing Off-Label information which have an incidental reference to Off-Label information. If reprints have an incidental reference to Off-Label information, such reprints shall contain the disclosure required by Section II.D.3.b(i) in a prominent location, as defined above.

5. Pfizer shall not disseminate any reprint or copy of an article from a peer reviewed journal or a Medical Reference Publication describing any Off-Label use of Geodon® to physician specialties that do not customarily prescribe Geodon® if these materials combined with detailing, advertising, sampling, or other Promotional activities Promote Off-Label use of Geodon®.

6. In disseminating information about Off-label usage, Pfizer shall either follow the substantive procedures in Section IV of the January, 2009, FDA guidance entitled Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices or use an alternative approach provided such approach satisfies the requirements of the applicable statutes and regulations.

E. Pfizer shall develop, implement and maintain policies and procedures to ensure that Medical Science Liaisons do not promote Off-label uses of Geodon® and to ensure that they do not engage in the improper marketing of Geodon®.

**III. Continuing Medical Education (CME) and Grants**

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

B. Pfizer shall disclose information about grants, including CME grants, regarding Geodon® consistent with the current disclosures of the Pfizer Medical Education Grants Office registry at [http://www.pfizer.com/responsibility/grants\\_payments/medical\\_education\\_grants.jsp](http://www.pfizer.com/responsibility/grants_payments/medical_education_grants.jsp) (hereinafter, "Pfizer Medical Education Grants Office website") or as required by applicable law.

1. Once posted, Pfizer shall maintain this information on the Pfizer Medical Education Grants Office website for at least two years and shall maintain the information in a readily accessible format for review by the States upon written request for a period of five years.

C. The Pfizer Medical Education Grants Office shall manage all requests for funding related to CME relating to Geodon®. Approval decisions shall be made by the Pfizer Medical Education Grants Office and Pfizer Medical, and shall be kept separate from the Pfizer Sales and Pfizer Marketing organizations.

D. Pfizer shall not use grants to Promote Geodon®. This provision includes, but is not limited to, the following prohibitions:

1. Pfizer Sales and Pfizer Marketing personnel shall not initiate, coordinate or implement grant applications on behalf of any customer or HCP;

2. Pfizer Sales and Pfizer Marketing personnel shall not be involved in selecting grantees or CME-funded speakers; and

3. Pfizer Sales and Pfizer Marketing personnel shall not measure or attempt to track in any way the impact of grants or speaking fees on the participating HCPs' subsequent prescribing habits, practices or patterns.

E. Pfizer shall not condition funding of a CME program grant request relating to Geodon® upon the requestor's selection or rejection of particular speakers.

F. Pfizer shall not suggest, control, or attempt to influence selection of the specific topic, title, content, speakers or audience for CMEs relating to Geodon®, consistent with ACCME guidelines.

G. Pfizer Sales and Pfizer Marketing personnel shall not approve grant requests regarding Geodon®, nor attempt to influence the Pfizer Medical Education Grants Office to reward any customers or HCPs with grants for their prescribing habits, practices or patterns.

H. Pfizer shall contractually require the CME provider to disclose to CME program attendees Pfizer's financial support of the CME program and any financial relationship with faculty and speakers at such CME.

I. After the initial delivery of a CME program, Pfizer shall not fund the same program, nor shall it provide additional funding for re-distribution of the same program, if Pfizer Medical Education Grants Office or Pfizer Medical knows that the program's speakers are Promoting Geodon® for Off-Label uses, unless it takes specific action that ensures that such Promotion does not occur.

#### IV. Payments to Speakers and HCPs

A. On or before March 31, 2011, Pfizer shall post in a prominent position on its website an easily accessible and readily searchable listing of all U.S.-based physicians, and Related Entities who or which received Payments directly or indirectly from Pfizer between July 1, 2010 and December 31, 2010 and the aggregate value of such Payments.

B. After the initial posting, Pfizer shall post annual listings on March 31, 2012 and March 31 of each of the three successive years. The annual listing on March 31, 2012 and

thereafter shall include cumulative information about Payments made by Pfizer during each of the respective prior calendar years.

C. In addition, beginning on June 1, 2012, Pfizer shall include on its website a listing of all U.S. based physicians and Related Entities who or which received Payments from Pfizer during the first calendar quarter of 2012. Thereafter, 60 days after the end of each subsequent calendar quarter, Pfizer shall also post on its website a listing of updated information about all Payments provided during the preceding quarter(s) in each calendar year. The quarterly and annual reports shall be easily accessible and readily searchable.

D. Each listing made pursuant to this section shall include a complete list of all individual physicians, and/or Related Entities to whom or to which Pfizer directly or indirectly made Payments in the preceding calendar year for 2011 and after June 1, 2012 for the preceding quarter or year (as applicable). Each listing shall be arranged alphabetically according to the physicians' last name or the name of the Related Entity. The Payment amounts in the lists shall be reported in \$10,000 increments (e.g., \$0 - \$10,000; \$10,001- \$20,000; etc.) or in the actual amount paid, provided, however, that the Payment amounts shall be listed in the same way (incrementally or in actual amounts) for all physicians and/or Related Entities on the listing. For each physician, the applicable listing shall include the following information: i) physician's full name; ii) name of any Related Entities (if applicable); iii) city and state that the physician or Related Entity has provided to Pfizer for contact purposes; and (iv) the aggregate value of the Payment(s) in the preceding quarter(s) or year (as applicable). If Payments for multiple physicians have been made to one Related Entity, the aggregate value of all Payments to the Related Entity will be the reported amount.

E. Pfizer shall continue to make each annual listing and the most recent quarterly listing of Payments available on its website at least through March 31, 2014. Pfizer shall retain and make available to the State, upon request, all work papers, supporting documentation, correspondence, and records related to all applicable Payments and to the annual and quarterly listings of Payments. Nothing in this section affects the responsibility of Pfizer to comply with (or liability for noncompliance with) all applicable Federal health care program requirements and state laws as they relate to all applicable Payments made to physicians or Related Entities.

F. If the proposed Physician Payments Sunshine Act of 2009 or similar legislation is enacted, the State shall determine whether the purposes of this section are reasonably satisfied by Pfizer's compliance with such legislation. In such case, and in its sole discretion, the State may agree to modify or terminate provisions of this section as appropriate.

G. The term "physician" as used in this section does not include bona-fide employees of Pfizer or its subsidiaries.

H. Pfizer's posting of Payment information shall be subject to any applicable confidentiality provisions contained in clinical research agreements that were entered with a U.S.-based physician prior to July 1, 2009. Pfizer agrees that it shall not include any such confidentiality provisions in any new or renewed clinical research agreements entered after the Effective Date of this Consent Judgment that require any Payment to a U.S.-based physician.

V. Product Samples

A. The following subsections shall be effective for nine years from the Effective Date of this Consent Judgment.

B. Pfizer shall only provide samples of Geodon® to those HCPs who have specialties that customarily treat patients who have diseases for which treatment with Geodon® would be consistent with Geodon®'s Labeling.

C. If a HCP whose clinical practice is inconsistent with the product's Labeling requests samples, Pfizer personnel shall refer the practitioner to 1-800-438-1985 where the practitioner can speak directly with a Pfizer representative who will provide answers to the HCP's questions about Geodon® and may provide them with samples only if appropriate (*i.e.*, if the physician requests the sample for an on-label use).

D. Pfizer shall not disseminate samples of Geodon® with the intent of increasing Off-Label prescribing of Geodon®.

#### VI. Clinical Research

A. Pfizer shall report research regarding Geodon® in an accurate, objective and balanced manner as follows and as required by applicable law:

1. To the extent permitted by the National Library of Medicine and as required by the FDA Amendments Act (Public Law No. 110-85), Pfizer shall register clinical trials and submit results to the registry and results data bank regarding Geodon® as required by the FDA Amendments Act and any accompanying regulations that may be promulgated pursuant to that Act. With respect to Geodon®, Pfizer shall register on a publicly accessible website all Pfizer-sponsored Phase II, III and IV clinical trials, to the extent available, that were ongoing or initiated after July 1, 2005 and will post results on a publicly accessible website of all Pfizer-sponsored Phase II, III and IV clinical trials, to the extent available, that were completed after October 2002.



B. When presenting information about a clinical study regarding Geodon® in any Promotional Materials, Pfizer shall not do any of the following:

1. present favorable information or conclusions from a study that is inadequate in design, scope, or conduct to furnish significant support for such information or conclusions;

2. 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 quoted average results;

3. 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 studies the design or protocol of which are not amenable to formal statistical evaluations;

4. present the information in a way that implies that the study represents larger or more general experience with the drug than it actually does; or

5. use statistics on numbers of patients, or counts of favorable 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.

VII. Terms Relating to Payment

A. No later than 30 days after the Effective Date of this Order, Pfizer shall pay a total amount of \$33 million 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

and for 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, and may be used to fund or assist in funding programs directed at mental illness treatment, including but not limited to education and outreach or for other uses permitted by state law, at the sole discretion of each Signatory Attorney General. The Parties acknowledge that the payment described herein is not a fine penalty, or payment in lieu thereof.

#### VIII. Release

A. By its execution of this Consent Judgment, the State of Maine releases Pfizer and all of its past and present subsidiaries, affiliates, predecessors and successors (collectively, the "Released Parties") from the following: all civil claims, causes of action, damages, restitution, fines, costs, and penalties that the Maine Attorney General 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 that is the subject of this Consent Judgment.

B. Notwithstanding any term of this Consent Judgment, specifically reserved and excluded from the Release in Paragraph VIII.A. as to any entity or person, including Released Parties, are any and all of the following:

1. Any criminal liability that any person and/or entity, including Released Parties, has or may have to the State of Maine.

2. Any civil or administrative liability that any person and/or entity, including Released Parties, has or may have to the State of Maine not expressly covered by the release in Paragraph (A) above, including but not limited to any and all of the following claims:

- a) State or federal antitrust violations;
- b) Reporting practices, including “best price”, “average wholesale price” or “wholesale acquisition cost;”
- c) Medicaid violations, including federal Medicaid drug rebate statute violations, Medicaid fraud or abuse, and/or kickback violations related to any State’s Medicaid program; and,
- d) State false claims violations.

3. Any liability under the State of Maine’s above-cited consumer protection laws which any person and/or entity, including Released Parties, has or may have to individual consumers or State program payors of said State.

4. Any liability for failure to comply with Maine’s Prescription Drug Clinical Trial Reporting Rule: DHS Rule 10-144 Ch. 275, AG Rule 26-0259 Ch. 11 with respect to any drug other than Geodon.

IX Nothing contained in this Judgment Order shall relieve or release Pfizer of the obligations it maintains under any other Consent Judgment or agreement relating to any Pfizer product.

X. Dispute Resolution

A. For the purposes of resolving disputes with respect to compliance with this 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 Consent Judgment subsequent to the Effective Date of this Judgment, then such Attorney General shall notify Pfizer in writing of the specific objection, identify with particularity the provisions of this 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 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 paragraph shall be interpreted to limit the state's Civil Investigative Demand ("CID") or investigative subpoena authority, to the extent such authority exists under applicable state law, and Pfizer reserves all of its rights with respect to a CID or investigative subpoena issued pursuant to such authority.

B. 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 Consent Judgment as to which cause that is legally sufficient in the State 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 Pfizer.

C. The State may assert any claim that Pfizer has violated this Consent Judgment in a separate civil action to enforce compliance with this 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 X.A. 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.

#### XI. General Provisions

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

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

C. This 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.

D. All Notices under this Order shall be provided to the following via Overnight Mail:


|                         |                                                                                                                                |
|-------------------------|--------------------------------------------------------------------------------------------------------------------------------|
| For the State of Maine: | Chief, Consumer Protection Division<br>Office of the Maine Attorney General<br>6 State House Station<br>Augusta, ME 04333-0006 |
|-------------------------|--------------------------------------------------------------------------------------------------------------------------------|

|                  |                                                                                                                                                            |
|------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|
| For Pfizer Inc.: | Douglas M. Lankler<br>Senior Vice President<br>And Chief Compliance Officer<br>Pfizer Inc.<br>150 East 42 <sup>nd</sup> Street<br>New York, New York 10017 |
|------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|

E. To the extent that any provision of this 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 Consent Judgment.

IT IS HEREBY ORDERED, ADJUDGED AND DECREED.

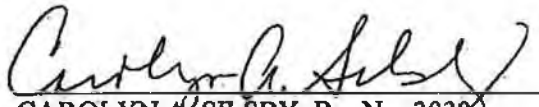
Dated: 9/10/09

  
\_\_\_\_\_  
JUSTICE  
Maine Superior Court

For Plaintiff:

JANET T. MILLS  
ATTORNEY GENERAL

Dated: September 2, 2009

  
\_\_\_\_\_  
CAROLYN A. SILSBY, Bar No. 3030  
ASSISTANT ATTORNEY GENERAL  
Office of the Maine Attorney General  
6 State House Station  
Augusta, ME 04333-0006  
(207)626-8829  
Carolyn.silsby@maine.gov

ATTORNEYS FOR THE STATE OF MAINE

For Defendant:

Dated: September 2 , 2009

A handwritten signature in black ink, appearing to read "Russell B. Pierce, Jr.", is written over a horizontal line. The signature is somewhat stylized and includes a large flourish on the right side.

RUSSELL B. PIERCE, JR., Bar No. 7322  
Norman, Hanson & DeTroy, LLC  
415 Congress Street  
P.O. Box 4600  
Portland, ME 04112-4600  
(207) 774 7000

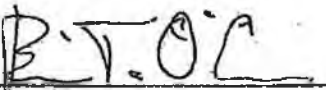
ATTORNEY FOR PFIZER INC.

**For Pfizer Inc.:**

By: 

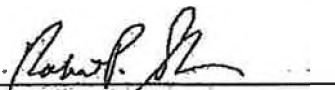
Douglas M. Lankler  
Senior Vice President  
And Chief Compliance Officer  
Pfizer Inc.

Date: 9/1/09

By: 

Brian T. O'Connor  
Ropes & Gray  
One International Place  
Boston, MA 02110

Date: 9/1/09

By: 

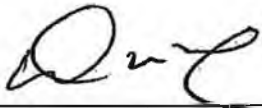
Robert P. Sherman  
DLA Piper LLP (US)  
33 Arch Street, 26th Floor  
Boston, MA 02110

Date: 9/1/09

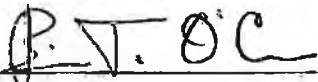
See  
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signatures  
filed on 9/10/09.



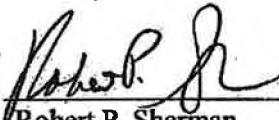
**For Pfizer Inc.:**

By:   
Douglas M. Lankler  
Senior Vice President  
And Chief Compliance Officer  
Pfizer Inc.

Date: \_\_\_\_\_

By:   
Brian T. O'Connor  
Ropes & Gray LLP  
One International Place  
Boston, MA 02110

Date: 9/8/09

By:   
Robert P. Sherman  
DLA Piper LLP (US)  
33 Arch Street, 26th Floor  
Boston, MA 02110

Date: 9/8/09



## JURISDICTION AND VENUE

4. This Court has jurisdiction over the subject matter of this action pursuant to 5 M.R.S.A. § 209 and 4 M.R.S.A. § 105. Venue is proper in this Court pursuant to 5 M.R.S.A. § 209.

## BACKGROUND

5. Geodon belongs to a class of drugs traditionally used to treat schizophrenia and commonly referred to as “atypical antipsychotics.” When these drugs were first introduced to the market in the 1990s, it was hypothesized that they might be used as long-term treatment for schizophrenia without posing the same risks as first-generation antipsychotics.

6. While these drugs may reduce some risks associated with first-generation antipsychotics, they also produce dangerous side effects, including weight gain, hyperglycemia, diabetes, cardiovascular complications, and other severe conditions.

7. Geodon was first approved by the Food and Drug Administration (“FDA”) for the treatment of schizophrenia in February, 2001. Since then, the FDA has approved various formulations of Geodon for the treatment of acute agitation in schizophrenic patients requiring rapid treatment, the treatment of acute manic or mixed episodes in Bipolar I Disorder, and/or the treatment of both schizophrenia and bipolar disorder.

## DEFENDANT’S COURSE OF CONDUCT

8. Pfizer not only began to market Geodon to health care professionals for the treatment of schizophrenia in 2001, it also marketed Geodon for a number of uses for which it was not approved by the FDA. For example, Pfizer illegally promoted Geodon for a variety of off-label purposes including, but not limited to, for use in pediatric patients and for use in higher than FDA-approved dosages.

9. Through all of the company's efforts to promote Geodon for uses that were not approved by the FDA, Pfizer misrepresented the drug's safety and effectiveness.

VIOLATIONS OF LAW

10. The allegations contained in paragraphs 1-9 are incorporated herein by reference.

11. The Defendant, in the course of advertising, soliciting, selling, promoting and distributing the prescription drug Geodon, has engaged in a course of trade or commerce which constitutes unfair or deceptive acts or practices, and which are therefore unlawful under § 207 of the UTPA by misrepresenting Geodon's safety and efficacy.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiff prays that this honorable Court enter an Order:

A. Issuing a permanent injunction prohibiting Defendant, its agents, employees, and all other persons and entities, corporate or otherwise, in active concert or participation with any of them, from engaging in unfair or deceptive conduct in violation of 5 M.R.S.A.

§ 207;

B. Ordering Defendant to pay all costs for the prosecution and investigation of this action, as provided by 5 M.R.S.A. § 209 and 14 M.R.S.A. § 1522(1)(A);

C. Ordering Defendant to pay civil penalties of \$10,000 for each and every intentional violation of 5 M.R.S.A. § 207; and

D. Granting such other and further relief as the Court deems equitable and proper.

Dated: September 2, 2009

Respectfully submitted,

JANET T. MILLS  
ATTORNEY GENERAL



---

CAROLYN A. SILSBY, Bar No. 3030  
ASSISTANT ATTORNEY GENERAL  
Office of the Maine Attorney General  
6 State House Station  
Augusta, ME 04333-0003  
(207) 626-8829  
[Carolyn.silsby@maine.gov](mailto:Carolyn.silsby@maine.gov)  
ATTORNEYS FOR THE STATE OF MAINE

STATE OF MAINE  
KENNEBEC, SS

SUPERIOR COURT  
CIVIL ACTION  
DOCKET NO. ~~CV-09-237~~

BCD - CV - 09 - 50

STATE OF MAINE,

Plaintiff

v.

PFIZER INC.,

Defendant.

**ORDER ON ASSENTED-TO MOTION  
TO AMEND CONSENT JUDGMENT**

Upo:  
matter, with

Accor  
be modified ar

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gment of September 9, 2009 in this  
ED.

aph 17 of the Consent Judgment shall


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payments relating to research; payments relating to education; and payment  
or reimbursement for food, entertainment, gifts, trips or travel, product(s)/item(s)  
provided for less than fair market value, or other economic benefit paid or transferred.  
The term also includes all payments or transfers of value made to Related Entities on  
behalf of, at the request of, for the benefit or use of, or under the name of a physician for  
whom Pfizer would otherwise report a Payment if made directly to the physician. The  
term “Payments” includes any Payments made, directly or indirectly, by Pfizer to a  
physician or Related Entity in connection with, or under the auspices of, a co-promotion  
arrangement. The term “Payments” does not include: i) samples of drug products that  
meet the definition set forth in 21 C.F.R. § 203.3(i), or ii) discounts, rebates, or other  
pricing terms. Only for purposes of the reporting of Payments on March 31, 2011, the  
term “Payments” does not include: i) individual Payments of less than \$25 per instance,  
or ii) aggregate Payments in a year to a physician or Related Entity of less than \$500.  
Beginning with the March 31, 2012 report and all reports thereafter, individual Payments  
of less than \$10 per instance to any individual physician or Related Entity may be

excluded from the Payment amounts listed in the applicable report, unless the sum of Payments to that individual physician or Related Entity in a calendar year exceeds \$100.

All other terms and conditions set forth in the Consent Judgment remain unchanged.

The Clerk is specifically directed pursuant to Rule 79(a) of the Maine Rules of Civil Procedure to enter this Order on the Civil Docket by notation incorporating it by reference.

Dated: 1/24/12

  
\_\_\_\_\_  
Justice, Superior Court