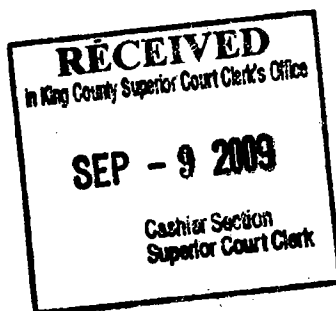




STATE OF WASHINGTON
KING COUNTY SUPERIOR COURT

STATE OF WASHINGTON,

Plaintiff,

v.

PFIZER INC.,

Defendant.

NO. 09-2-33085-9 SEA

CONSENT DECREE

(CLERK'S ACTION REQUIRED)

JUDGMENT SUMMARY

Judgment Creditor:	State of Washington
Judgment Debtors:	Pfizer Inc.
Principal Judgment Amount:	\$33 million to all 43 states nationally with \$807,977.00 allotted to Washington State to be used for cy pres and/or costs and fees as provided for in Section VII of this Consent Decree.
Total Judgment:	\$807,997.00
Post Judgment Interest Rate:	12% per annum
Attorney for Judgment Creditor:	Robert Lipson, Senior Counsel
Attorney for Judgment Debtors:	Russell Wuehler, DLA Piper LLP (US)

FINDINGS

A. This Court has jurisdiction over the subject matter of this lawsuit and over all Parties.

B. The terms of this Judgment shall be governed by the laws of the State of Washington.

C. Entry of this 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 Judgment.

E. Pfizer is willing to enter into this 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 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 Judgment.¹

1. Pfizer is entering into this 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 Judgment under those laws. No part of this Judgment, including its statements and commitments, shall constitute evidence of any liability, fault, or wrongdoing by Pfizer. This document and its

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

1 contents are not intended for use by any third party for any purpose, including submission to
2 any court for any purpose.
3

4 2. This Judgment shall not be construed or used as a waiver or limitation of
5 any defense otherwise available to Pfizer in any action, or of Pfizer's right to defend itself
6 from, or make any arguments in, any private individual, regulatory, governmental, or class
7 claims or suits relating to the subject matter or terms of this Judgment. This Judgment is made
8 without trial or adjudication of any issue of fact or law or finding of liability of any kind.
9 Notwithstanding the foregoing, a State may file an action to enforce the terms of this
10 Judgment.

11 3. It is the intent of the Parties that this Judgment not be admissible in other
12 cases or binding on Pfizer in any respect other than in connection with the enforcement of this
13 Judgment.
14

15 4. No part of this Judgment shall create a private cause of action or confer
16 any right to any third party for violation of any federal or state statute except that a State may
17 file an action to enforce the terms of this Judgment.

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

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

24 (a) take any action that is prohibited by the FDCA or any regulation
25 promulgated thereunder, or by FDA; or
26

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

8 DEFINITIONS

9
10 The following definitions shall be used in construing this Judgment:

11 1. "Author" shall mean an HCP or health care institution engaged to produce
12 articles or other publications relating to Geodon®.

13
14 2. "Clinically Relevant Information" shall mean information that reasonably
15 prudent clinicians would consider relevant when making prescribing decisions regarding
16 Geodon®.

17 3. "Consultant" shall mean an HCP engaged for services other than for speaker
18 programs (e.g., as a member of an advisory board or to attend consultant meetings) that relate
19 to Promotional and Product Related Functions.

20
21 4. "Covered Conduct" shall mean Pfizer's promotional and marketing practices,
22 sampling practices, dissemination of information and remuneration to HCPs regarding the
23 prescription drug Geodon® through the Effective Date of the Agreement.

1 5. “Effective Date” shall mean the date on which a copy of this Judgment, duly
2 executed by Pfizer and by the Signatory Attorney General, is approved by, and becomes a
3 Judgment of, the Court, whichever is later.
4

5 6. “Geodon®” shall mean all Pfizer Products that are FDA-approved drug
6 formulations containing ziprasidone or ziprasidone mesylate.
7

8 7. “Health Care Professional” or “HCP” shall mean any physician or other health
9 care practitioner who is licensed to provide health care services or to prescribe pharmaceutical
10 products.
11

12 8. “Labeling” shall mean all FDA-approved labels, which are a display of written,
13 printed, or graphic matter upon the immediate container of any article, and other written,
14 printed, or graphic matters (a) upon any article or any of its containers or wrappers, or (b)
15 accompanying such article.
16

17 9. “Medical Information Letter” shall mean a non-Promotional, scientific
18 communication to address Unsolicited Requests for medical information from HCPs.
19

20 10. “Medical Outcomes Specialists” shall mean Pfizer personnel who have
21 expertise working with managed care to determine suitable drugs on a formulary and are
22 assigned to the Medical Outcomes Specialists group of Pfizer.
23

24 11. “Medical Reference Publication” shall have the meaning ascribed to the term
25 “reference publication” found in 21 C.F.R. 99.3(i).
26

 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

1 Pfizer to provide scientific analysis and/or scientific information to HCPs and includes
2 Regional Medical Research Specialists.

3
4 13. "Multistate Executive Committee" shall mean the Attorneys General and their
5 staffs representing Arizona, Colorado, Delaware, District of Columbia, Florida, Kentucky,
6 Maryland, Massachusetts, North Carolina, Ohio and Pennsylvania.

7
8 14. "Multistate Working Group" shall mean the Attorneys General and their staff
9 representing Alabama, Arkansas, Arizona, California, Colorado, Connecticut, Delaware,
10 District of Columbia, Florida, Hawaii, Idaho, Illinois, Iowa, Kansas, Kentucky, Louisiana,
11 Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nebraska,
12 Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North
13 Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee,
14 Texas, Vermont, Washington, West Virginia, and Wisconsin.

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

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

19
20 17. "Payment" is defined to include all payments or transfers of value (whether in
21 cash or in kind) made to physicians including all payments (including, for example, honoraria
22 payments, other payments, and reimbursement for lodging, travel and other expenses) made in
23 connection with physicians serving as speakers, participating in speaker training, or serving as
24 Consultants or Authors; payments or compensation for services rendered; grants; fees;
25 payments relating to research; payments relating to education; and payment or reimbursement
26 for food, entertainment, gifts, trips or travel, product(s)/item(s) provided for less than fair

1 market value, or other economic benefit paid or transferred. The term also includes all
2 payments or transfers of value made to Related Entities on behalf of, at the request of, for the
3 benefit or use of, or under the name of a physician for whom Pfizer would otherwise report a
4 Payment if made directly to the physician. The term "Payments" includes any Payments made,
5 directly or indirectly, by Pfizer to a physician or Related Entity in connection with, or under
6 the auspices of, a co-promotion arrangement. The term "Payments" does not include: i)
7 samples of drug products that meet the definition set forth in 21 C.F.R. § 203.3(i), or ii)
8 discounts, rebates, or other pricing terms. Only for purposes of the reporting of Payments on
9 March 31, 2011, the term "Payments" does not include: i) individual Payments of less than \$25
10 per instance, or ii) aggregate Payments in a year to a physician or Related Entity of less than
11 \$500. Beginning with the March 31, 2012 report and all reports thereafter, individual Payments
12 under \$25 per instance and aggregate Payments of less than \$500 shall be included in the
13 Payment amounts listed in the applicable report.

14
15 18. "Pfizer Inc." or "Pfizer" shall mean Pfizer Inc., including all of its affiliates,
16 subsidiaries and divisions, predecessors, successors and assigns doing business in the United
17 States.

18
19 19. "Pfizer Medical Education Grants Office" shall mean the U.S.-based
20 organization within Pfizer responsible for oversight of the continuing medical education
21 (CME) grant process, including the acceptance, review, and approval of all non-clinical CME
22 grant requests.

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

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

3
4 22. "Pfizer Sales" shall mean the Pfizer sales force responsible for U.S. Geodon®
5 sales, including but not limited to Medical Outcomes Specialists.

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

9
10 24. "Promotional and Product Related Functions" includes: (a) the selling,
11 detailing, marketing, advertising, promoting, or branding of Geodon®; (b) the development,
12 preparation, or dissemination of materials or information about, or the provision of services
13 relating to, Geodon® including those functions relating to material review committees and
14 Pfizer's Medical Information Department; and (c) research, development, and publication
15 related-activities involving Geodon®, including postmarketing and other studies, and the
16 authorship, publication and disclosure of study results.

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

19
20 26. "Promotional Slide Kit" shall mean Promotional Materials regarding Geodon®
21 in the form of a slide kit for use in speaker programs.

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

24
25 28. "Related Entity" is any entity by or in which any physician receiving Payments
26 is employed, has tenure, or has an ownership interest.

1 29. “Reprints Containing Off-Label Information” shall mean articles or reprints
2 from a peer reviewed journal or reference publication describing an Off-Label use of
3 Geodon®.
4

5 30. “Signatory Attorney General” shall mean the Attorney General of Washington,
6 or his/her authorized designee, who has agreed to this Judgment.
7

8 31. “State Consumer Protection Laws” shall mean the consumer protection laws
9 under which the Attorneys General have conducted the investigation.²
10

11 ² ALABAMA – Alabama Deceptive Trade Practices Act, Ala. Code § 8-19-1 et seq.; ARIZONA – *Arizona Consumer Fraud Act*, A.R.S. § 44-
12 1521 et seq.; ARKANSAS – Arkansas Deceptive Trade Practices Act, Ark. Code Ann. § 4-88-101, et seq.; CALIFORNIA – Bus. & Prof Code
13 §§ 17200 et seq. and 17500 et seq.; COLORADO – *Colorado Consumer Protection Act*, Colo. Rev. Stat. § 6-1-101 et seq.; CONNECTICUT –
14 *Connecticut Unfair Trade Practices Act*, Conn. Gen. Stat §§ 42-110a et seq.; DELAWARE – *Delaware Consumer Fraud Act*, Del. CODE
15 ANN. tit. 6, §§ 2511 to 2527; DISTRICT OF COLUMBIA, *District of Columbia Consumer Protection Procedures Act*, D.C. Code §§ 28-3901
16 et seq.; FLORIDA – *Florida Deceptive and Unfair Trade Practices Act, Part II*, Chapter 501, Florida Statutes, 501.201 et seq.; HAWAII –
17 *Uniform Deceptive Trade Practice Act*, Haw. Rev. Stat. Chpt. 481A and Haw. 501.201 et seq.; IDAHO – *Consumer Protection Act*, Idaho
18 Code Section 48-601 et seq.; ILLINOIS – *Consumer Fraud and Deceptive Business Practices Act*, 815 ILCS 505/2 et seq.; IOWA – *Iowa*
19 *Consumer Fraud Act*, Iowa Code Section 714.16; KANSAS – *Kansas Consumer Protection Act*, K.S.A. 50-623 et seq. KENTUCKY –
20 *Kentucky Consumer Protection Act*, KRS Ch. 367.110, et seq.; LOUISIANA – *Unfair Trade-Practices and Consumer Protection Law*, LSA-
21 R.S. 51:1401, et seq.; MAINE – *Unfair Trade Practices Act*, 5 M.R.S.A. § 207 et seq.; MARYLAND – *Maryland Consumer Protection Act*,
22 Md. Code Ann., Com. Law §§ 13-101 et seq.; MASSACHUSETTS – Mass. Gen. Laws c. 93A, §§ 2 and 4; MICHIGAN – *Michigan*
23 *Consumer Protection Act*, MCL § 445.901 et seq.; MINNESOTA – *Minnesota Deceptive Trade Practices Act*, Minn. Stat. §§ 325D.43-48;
24 *Minnesota False Advertising Act*, Minn. Stat. § 325F.67; *Minnesota Consumer Fraud Act*, Minn. Stat. §§ 325F.68-70; *Minnesota Deceptive*
25 *Trade Practices Against Senior Citizens or Disabled Persons Act*, Minn. Stat. § 325F.71.; MISSOURI – *Missouri Merchandising Practices*
26 *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
HAMPSHIRE – *New Hampshire Consumer Protection Act*, RSA 358-A; NEW JERSEY – *New Jersey Consumer Fraud Act*, NJSA 56:8-1 et
seq.; NEW MEXICO – NMSA 1978, § 57-12-1 et seq.; NEW YORK – General Business Law Art. 22-A, §§ 349-50, and Executive Law §
63(12); NORTH CAROLINA – *North Carolina Unfair and Deceptive Trade Practices Act*, N.C.G.S. 75-1.1, et seq.; NORTH DAKOTA –
Unlawful Sales or Advertising Practices, N.D. Cent. Code § 51-15-02 et seq.; OHIO – *Ohio Consumer Sales Practices Act*, R.C. 1345.01, et
seq.; OKLAHOMA – *Oklahoma Consumer Protection Act* 15 O.S. §§ 751 et seq.; OREGON – *Oregon Unlawful Trade Practices Act*, ORS
646.605 et seq.; PENNSYLVANIA – *Pennsylvania Unfair Trade Practices and Consumer Protection Law*, 73 P.S. 201-1 et seq.; RHODE
ISLAND – *Rhode Island Deceptive Trade Practices Act*, Rhode Island General Laws § 6-13-1-1, et seq.; SOUTH 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).

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®.

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:

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

4 ii. Pfizer shall include a short-hand reference to the
5 statement described in Section I.D.1.a.(i) on the same
6 slide as each subsequent reference to selected symptoms
7 (e.g., "See complete list of FDA-approved indications at
8 p. X"); and
9

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

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

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

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

21 II. Dissemination and Exchange of Medical Information

22 A. The content of Pfizer's communications concerning Off-Label uses of
23 Geodon® shall not be false, misleading or deceptive.
24
25
26

1 B. Medical Information Letters

2
3 1. The following subsections shall be effective for nine years from the
4 Effective Date of this Judgment.

5 2. Pfizer Medical shall have ultimate responsibility for developing and
6 approving the medical content for all Medical Information Letters regarding Geodon®,
7 including any that may describe Off-Label information. Additional approvals may be provided
8 by Pfizer's legal department. Pfizer shall not distribute any such materials unless:

9 a. Clinically Relevant Information is included in these materials to
10 provide scientific balance;

11 b. Data in these materials are presented in an unbiased, non-
12 Promotional manner; and

13 c. These materials are clearly distinguishable from sales aids and
14 other Promotional Materials.
15

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

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

22 5. Pfizer shall not knowingly disseminate any Medical Information Letter
23 describing any Off-Label use of Geodon® that makes any false, misleading or deceptive
24 representation regarding Geodon® or any false, misleading or deceptive statement concerning
25 a competing product.
26

1 C. Responses to Unsolicited Requests for Off-Label Information

2
3 1. The following subsections shall be effective for nine years from the
4 Effective Date of this Judgment.

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

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

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

- 16 a. an existing Medical Information Letter prepared in accordance
17 with Section II.B;
- 18 b. a Medical Information Letter or other document prepared in
19 response to the request in accordance with Section II.B; or
- 20 c. a report containing the results of a reasonable literature search
21 using terms from the request.
22

23 5. Pfizer Sales and Pfizer Marketing personnel may respond in writing to
24 an Unsolicited Request for Off-Label information regarding Geodon® from an HCP only by
25 informing the HCP of the presence or absence of published studies concerning the Off-Label
26

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

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

22 D. Reprints

23
24 1. Pfizer shall not disseminate any information describing any Off-Label
25 use of Geodon® if such use has been submitted to the FDA for approval and the FDA has
26 either advised Pfizer that it refuses to approve such application or that FDA-identified

1 deficiencies must be resolved before approval can be granted unless Pfizer has first clearly and
2 conspicuously disclosed to the recipient of the information that the FDA had issued such
3 advice regarding such Off-Label use. Pfizer may disclose to any recipient of such information
4 whether the information was presented to the FDA prior to the FDA's issuance of such advice
5 regarding the Off-Label use.

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

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

17 b. the information is accompanied by a comprehensive
18 bibliography of publications discussing adequate and well-
19 controlled clinical studies published in a medical journal or
20 medical or scientific text that have been previously published
21 about the use of Geodon® covered by the information (unless the
22 information is a peer reviewed journal or Reference Publication
23 which already includes such a bibliography); and
24
25
26

- 1 c. in cases in which experts qualified by scientific training or
2 experience to evaluate the safety or effectiveness of Geodon®
3 would consider the conclusion of the information to have been
4 specifically called into question by another article(s) or text(s)
5 that experts qualified by scientific training or experience to
6 evaluate the safety or effectiveness of Geodon® would consider
7 to be scientifically sound, the information must be disseminated
8 with a representative publication that reaches contrary or
9 different conclusions regarding the Off-Label use.
10

11 3. Reprints Containing Off-Label Information

- 12 a. Pfizer Medical shall be responsible for the identification,
13 selection, approval and dissemination of Reprints Containing
14 Off-Label Information regarding Geodon®.
15 b. Reprints Containing Off-Label Information regarding Geodon®:
16 (i) shall be accompanied by the full prescribing information
17 for the product and contain a disclosure in a prominent
18 location, which would include the first page or as a cover
19 page where practicable, indicating that the article may
20 discuss Off-Label information; and
21 (ii) shall not be referred to or used in a Promotional manner.
22 c. Reprints Containing Off-Label Information regarding Geodon®
23 may only be disseminated by Pfizer Medical personnel to HCPs.
24 Pfizer Sales or Pfizer Marketing personnel shall not disseminate
25 these materials to HCPs, absent the exception described below in
26 (i); provided, however, that Medical Outcomes Specialists may

1 disseminate reprints relating to pharmacoeconomics or health
2 outcomes to third party payors, including but not limited to
3 managed care organizations and employers responsible for the
4 administration of health benefits, but not prescribers unless
5 employed or engaged by payors in a non-prescribing role.

6 (i) In the event of an extraordinary circumstance in which
7 there is a clinical necessity to have Pfizer Sales or Pfizer
8 Marketing personnel disseminate a Reprint Containing
9 Off-Label information directly to HCPs, the President of
10 Pfizer Worldwide Pharmaceutical Operations may
11 approve a Clinical Necessity Exception to the prohibition
12 described in Section II.D.3.c above for that Reprint
13 Containing Off-Label information.

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

20 (a) If a Signatory Attorney General believes the Reprint
21 Containing Off-Label information to be disseminated
22 does not meet the Clinical Necessity Exception, then
23 the State will provide Pfizer with written notice
24 within 30 business days and provide Pfizer an
25 opportunity to discuss its desired use of the Reprint
26

1 Containing Off-Label information pursuant to the
2 limited exception.

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

8 (c) If the State initiates legal action to prevent the
9 dissemination of the Reprint Containing Off-Label
10 information by Pfizer Sales or Pfizer Marketing
11 personnel, Pfizer shall not use Pfizer Sales or Pfizer
12 Marketing personnel to disseminate such Reprint
13 Containing Off-Label information in that State until
14 the issue has been resolved.

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

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

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

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

10
11 III. Continuing Medical Education (CME) and Grants

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

14 B. Pfizer shall disclose information about grants, including CME grants, regarding
15 Geodon® consistent with the current disclosures of the Pfizer Medical Education Grants Office
16 at: http://www.pfizer.com/responsibility/grants_payments/medical_education_grants.jsp
17 hereinafter, "Pfizer Medical Education Grants Office website") or as required by applicable
18 law.

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

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

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

- 5 1. Pfizer Sales and Pfizer Marketing personnel shall not initiate, coordinate
6 or implement grant applications on behalf of any customer or HCP;
- 7 2. Pfizer Sales and Pfizer Marketing personnel shall not be involved in
8 selecting grantees or CME-funded speakers; and
- 9 3. Pfizer Sales and Pfizer Marketing personnel shall not measure or attempt
10 to track in any way the impact of grants or speaking fees on the
11 participating HCPs' subsequent prescribing habits, practices or patterns.

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

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

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

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

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

3 IV. Payments to Speakers and HCPs

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

8 B. After the initial posting, Pfizer shall post annual listings on March 31, 2012 and
9 March 31 of each of the three successive years. The annual listing on March 31, 2012 and
10 thereafter shall include cumulative information about Payments made by Pfizer during each of
11 the respective prior calendar years.

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

18 D. Each listing made pursuant to this section shall include a complete list of all
19 individual physicians, and/or Related Entities to whom or to which Pfizer directly or indirectly
20 made Payments in the preceding calendar year for 2011 and after June 1, 2012 for the
21 preceding quarter or year (as applicable). Each listing shall be arranged alphabetically
22 according to the physicians' last name or the name of the Related Entity. The Payment
23 amounts in the lists shall be reported in \$10,000 increments (e.g., \$0 - \$10,000; \$10,001-
24 \$20,000; etc.) or in the actual amount paid, provided, however, that the Payment amounts shall
25 be listed in the same way (incrementally or in actual amounts) for all physicians and/or Related
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1 Entities on the listing. For each physician, the applicable listing shall include the following
2 information: i) physician's full name; ii) name of any Related Entities (if applicable); iii) city
3 and state that the physician or Related Entity has provided to Pfizer for contact purposes; and
4 (iv) the aggregate value of the Payment(s) in the preceding quarter(s) or year (as applicable).
5 If Payments for multiple physicians have been made to one Related Entity, the aggregate value
6 of all Payments to the Related Entity will be the reported amount.

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

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

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

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

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

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

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

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

15 VI. Clinical Research

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

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

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

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

6 2. use the concept of statistical significance to support a claim that has not
7 been demonstrated to have clinical significance or validity, or fails to reveal the range of
8 variations around the quoted average results;

9 3. use statistical analyses and techniques on a retrospective basis to
10 discover and cite findings not soundly supported by the study, or to suggest scientific validity
11 and rigor for data from studies the design or protocol of which are not amenable to formal
12 statistical evaluations;

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

15 5. use statistics on numbers of patients, or counts of favorable results or
16 side effects, derived from pooling data from various insignificant or dissimilar studies in a way
17 that suggests either that such statistics are valid if they are not or that they are derived from
18 large or significant studies supporting favorable conclusions when such is not the case.

19 VII. Terms Relating to Payment

20 A. No later than 30 days after the Effective Date of this Judgment, Pfizer shall pay
21 a total amount of \$33 million to be divided and paid by Pfizer directly to each Signatory
22 Attorney General of the Multistate Working Group in an amount to be designated by and in the
23 sole discretion of the Multistate Executive Committee. Said payment shall be used by the
24 States as and for attorneys' fees and other costs of investigation and litigation, or to be placed
25 in, or applied to, the consumer protection enforcement fund, including future consumer
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1 protection enforcement, consumer education, litigation or local consumer aid fund or revolving
2 fund, used to defray the costs of the inquiry leading hereto, and may be used to fund or assist in
3 funding programs directed at mental illness treatment, including but not limited to education
4 and outreach or for other uses permitted by state law, at the sole discretion of each Signatory
5 Attorney General. The Parties acknowledge that the payment described herein is not a fine
6 penalty, or payment in lieu thereof.

7 VIII. Release

8 A. By its execution of this Judgment, the State of Washington releases Pfizer and
9 all of its past and present subsidiaries, affiliates, predecessors and successors (collectively, the
10 "Released Parties") from the following: all civil claims, causes of action, damages, restitution,
11 fines, costs, and penalties that the Washington Attorney General could have asserted against
12 the Released Parties under the above-cited consumer protection statutes resulting from the
13 Covered Conduct up to and including the Effective Date that is the subject of this Judgment.

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

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

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

- 23 a) State or federal antitrust violations;
24 b) Reporting practices, including "best price", "average wholesale
25 price" or "wholesale acquisition cost;"
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- 1 c) Medicaid violations, including federal Medicaid drug rebate
2 statute violations, Medicaid fraud or abuse, and/or kickback
3 violations related to any State's Medicaid program; and,
4 d) State false claims violations.

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

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

10 X. Dispute Resolution

11 A. For the purposes of resolving disputes with respect to compliance with this
12 Judgment, should any of the Signatory Attorneys General have a reasonable basis to believe
13 that Pfizer has engaged in a practice that violates a provision of this Judgment subsequent to
14 the Effective Date of this Judgment, then such Attorney General shall notify Pfizer in writing
15 of the specific objection, identify with particularity the provisions of this Judgment that the
16 practice appears to violate, and give Pfizer thirty (30) days to respond to the notification;
17 provided, however, that a Signatory Attorney General may take any action if the Signatory
18 Attorney General concludes that, because of the specific practice, a threat to the health or
19 safety of the public requires immediate action. Upon receipt of written notice, Pfizer shall
20 provide a good-faith written response to the Attorney General notification, containing either a
21 statement explaining why Pfizer believes it is in compliance with the Judgment, or a detailed
22 explanation of how the alleged violation occurred and a statement explaining how Pfizer
23 intends to remedy the alleged breach. Nothing in this paragraph shall be interpreted to limit
24 the state's Civil Investigative Demand ("CID") or investigative subpoena authority, to the
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1 extent such authority exists under applicable state law, and Pfizer reserves all of its rights with
2 respect to a CID or investigative subpoena issued pursuant to such authority.

3 B. Upon giving Pfizer thirty (30) days to respond to the notification described
4 above, the Signatory Attorney General shall also be permitted reasonable access to inspect
5 and copy relevant, non-privileged, non-work product records and documents in the
6 possession, custody or control of Pfizer that relate to Pfizer's compliance with each provision
7 of this Judgment as to which cause that is legally sufficient in the State has been shown. If the
8 Signatory Attorney General makes or requests copies of any documents during the course of
9 that inspection, the Signatory Attorney General will provide a list of those documents to
10 Pfizer.

11 C. The State may assert any claim that Pfizer has violated this Judgment in a
12 separate civil action to enforce compliance with this Judgment, or may seek any other relief
13 afforded by law, but only after providing Pfizer an opportunity to respond to the notification
14 described in Paragraph X.A. above; provided, however, that a Signatory Attorney General
15 may take any action if the Signatory Attorney General concludes that, because of the specific
16 practice, a threat to the health or safety of the public requires immediate action.

17
18 XI. General Provisions

19 A. This Judgment represents the full and complete terms of the settlement entered
20 into by the Parties hereto. In any action undertaken by the Parties, no prior versions of this
21 Judgment and no prior versions of any of its terms that were not entered by the Court in this
22 Judgment, may be introduced for any purpose whatsoever.

23 B. This Court retains jurisdiction of this Judgment and the Parties hereto for the
24 purpose of enforcing and modifying this Judgment and for the purpose of granting such
25 additional relief as may be necessary and appropriate.
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1 C. This Judgment may be executed in counterparts, and a facsimile or PDF
2 signature shall be deemed to be, and shall have the same force and effect as, an original
3 signature.

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

6
7 Douglas M. Lankler
8 Senior Vice President
9 And Chief Compliance Officer
Pfizer Inc.
10 150 East 42nd Street
New York, New York 10017

11 Robert Lipson
12 Senior Counsel
13 State of Washington
Office of Attorney General
14 800 5th Avenue, Suite 2000
Seattle, WA 98104

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1 E. To the extent that any provision of this Judgment obligates Pfizer to change any
2 policy(ies) or procedure(s) and to the extent not already accomplished, Pfizer shall implement
3 the policy(ies) or procedure(s) as soon as reasonably practicable, but no later than 120 days
4 after the Effective Date of this Judgment.

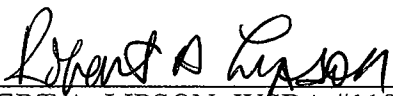
5 DONE IN OPEN COURT this SEP - 9 2009 day of September, 2009.

6 **DONALD HALEY**

7 **JUDGE/COURT COMMISSIONER**

8 Approved for Entry and Presented By:

9 ROBERT M. MCKENNA
10 ATTORNEY GENERAL

11 By: 
12 ROBERT A. LIPSON, WSBA #11889
13 Senior Counsel
State of Washington

Date: 9/4/09

14 Approved For Entry, Notice of Presentation Waived:

15 DLA PIPER LLP (US)

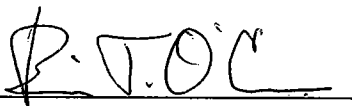
16 By: 
17 RUSSELL WUEHLER, WSBA # 37941
18 Counsel to Pfizer Inc.

Date: 9/4/09

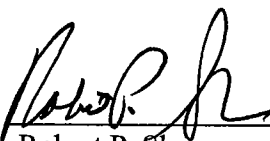
For Pfizer Inc.:

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

Date: 9/8/09

By: 
Brien 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