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12 ARIZONA SUPERIOR COURT

13 COUNTY OF PIMA

14 State of Arizona, ex rel. Terry Goddard,
15 Attorney General,

16 Plaintiff

17 vs.

18 Pfizer Inc.,

19 Defendant.
20

No. _____

**JOINT MOTION TO ENTER CONSENT
JUDGMENT**

21 The parties, by and through undersigned counsel, respectfully move this Court
22 to enter an Order to Consent Judgment, a copy of which is filed contemporaneously
23 herewith.

24 1. The State of Arizona filed a Complaint alleging violations of A.R.S. § 44-
25 1521 *et seq.*, the Consumer Fraud Act, against defendant PFIZER INC.

26 2. The State of Arizona, by its counsel, and Pfizer, by its counsel, have
27 agreed to the entry of this Order by the Court without trial or adjudication of any issue
28

1 of fact or law, and without admission of any wrongdoing or admission of any of the
2 violations of the Act as alleged in the Complaint.

3 3. This Court has jurisdiction over the subject matter of this Consent
4 Judgment and over all parties.

5 4. The terms of the Consent Judgment ("Judgment") shall be governed by
6 the laws of the State of Arizona.

7 **FINDINGS**

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

10 B. The terms of this Judgment/Order shall be governed by the laws of the
11 State of Arizona.

12 C. Entry of this Judgment/Order is in the public interest and reflects a
13 negotiated agreement among the Parties.

14 D. The Parties have agreed to resolve the issues related to the Covered
15 Conduct involving the prescription drug Geodon® by entering into this
16 Judgment/Order.

17 E. Pfizer is willing to enter into this Judgment/Order regarding the Covered
18 Conduct in order to resolve the Attorneys General's concerns under the State
19 Consumer Protection Laws as to the matters addressed in this Judgment/Order and
20 thereby avoid unnecessary expense, inconvenience, and uncertainty.

21 F. The Parties have agreed to resolve the issues raised by the Covered
22 Conduct by entering into this Judgment/Order.¹

23 1. Pfizer is entering into this Judgment/Order solely for the purpose
24 of settlement, and nothing contained herein may be taken as or construed to be an
25 admission or concession of any violation of law, rule, or regulation, or of any other
26 matter of fact or law, or of any liability or wrongdoing, all of which Pfizer expressly
27

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

1 denies. Pfizer does not admit any violation of the State Consumer Protection Laws set
2 forth in footnote 1, and does not admit any wrongdoing that was or could have been
3 alleged by any Attorney General before the date of the Judgment/Order under those
4 laws. No part of this Judgment/Order, including its statements and commitments, shall
5 constitute evidence of any liability, fault, or wrongdoing by Pfizer. This document and
6 its contents are not intended for use by any third party for any purpose, including
7 submission to any court for any purpose.

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

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

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

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

26 H. Nothing in this Judgment/Order shall require Pfizer to:

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

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
3 this Judgment/Order which is the same, or materially the same, as the language
4 required or agreed to by the Director of Division of Drug Marketing, Advertising and
5 Communication or the Director of the Center for Drug Evaluation and Research or their
6 authorized designees in writing shall not constitute a violation of this Judgment/Order,
7 unless facts are or become known to Pfizer that cause the claim to be false,
8 misleading or deceptive.

9 DEFINITIONS

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

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

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

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

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

23 5. "Effective Date" shall mean the date on which a copy of this
24 Judgment/Order, duly executed by Pfizer and by the Signatory Attorney General, is
25 approved by, and becomes a Judgment/Order of, the Court, whichever is later.

26 6. "Geodon®" shall mean all Pfizer Products that are FDA-approved drug
27 formulations containing ziprasidone or ziprasidone mesylate.

1 7. “Health Care Professional” or “HCP” shall mean any physician or other
2 health care practitioner who is licensed to provide health care services or to prescribe
3 pharmaceutical products.

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

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

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

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

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

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

22 14. “Multistate Working Group” shall mean the Attorneys General and their
23 staff representing Alabama, Arkansas, Arizona, California, Colorado, Connecticut,
24 Delaware, District of Columbia, Florida, Hawaii, Idaho, Illinois, Iowa, Kansas,
25 Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota,
26 Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico,
27 New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania,
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1 Rhode Island, South Dakota, Tennessee, Texas, Vermont, Washington, West Virginia,
2 and Wisconsin.

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

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

7 17. "Payment" is defined to include all payments or transfers of value
8 (whether in cash or in kind) made to physicians including all payments (including, for
9 example, honoraria payments, other payments, and reimbursement for lodging, travel
10 and other expenses) made in connection with physicians serving as speakers,
11 participating in speaker training, or serving as Consultants or Authors; payments or
12 compensation for services rendered; grants; fees; payments relating to research;
13 payments relating to education; and payment or reimbursement for food,
14 entertainment, gifts, trips or travel, product(s)/item(s) provided for less than fair market
15 value, or other economic benefit paid or transferred. The term also includes all
16 payments or transfers of value made to Related Entities on behalf of, at the request of,
17 for the benefit or use of, or under the name of a physician for whom Pfizer would
18 otherwise report a Payment if made directly to the physician. The term "Payments"
19 includes any Payments made, directly or indirectly, by Pfizer to a physician or Related
20 Entity in connection with, or under the auspices of, a co-promotion arrangement. The
21 term "Payments" does not include: i) samples of drug products that meet the definition
22 set forth in 21 C.F.R. § 203.3(i), or ii) discounts, rebates, or other pricing terms. Only
23 for purposes of the reporting of Payments on March 31, 2011, the term "Payments"
24 does not include: i) individual Payments of less than \$25 per instance, or ii) aggregate
25 Payments in a year to a physician or Related Entity of less than \$500. Beginning with
26 the March 31, 2012 report and all reports thereafter, individual Payments under \$25
27 per instance and aggregate Payments of less than \$500 shall be included in the
28 Payment amounts listed in the applicable report.

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

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

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

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

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

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

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

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

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

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

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

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

8 30. "Signatory Attorney General" shall mean the Attorney General of
9 Arizona, or his/her authorized designee, who has agreed to this Judgment/Order.

10 31. "State Consumer Protection Laws" shall mean the consumer protection
11 laws under which the Attorneys General have conducted the investigation.²

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

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16 ² ALABAMA – *Alabama Deceptive Trade Practices Act*, Ala. Code § 8-19-1 et seq.; ARIZONA – *Arizona Consumer Fraud Act*,
17 A.R.S. § 44-1521 et seq.; ARKANSAS – *Arkansas Deceptive Trade Practices Act*, Ark. Code Ann. § 4-88-101, et seq.;
18 CALIFORNIA – *Bus. & Prof Code §§ 17200 et seq. and 17500 et seq.*; COLORADO – *Colorado Consumer Protection Act*, Colo.
19 Rev. Stat. § 6-1-101 et seq.; CONNECTICUT - *Connecticut Unfair Trade Practices Act*, Conn. Gen. Stat. §§ 42-110a et seq.;
20 DELAWARE – *Delaware Consumer Fraud Act*, Del. CODE ANN. tit. 6, §§ 2511 to 2527; DISTRICT OF COLUMBIA, *District of*
21 *Columbia Consumer Protection Procedures Act*, D.C. Code §§ 28-3901 et seq.; FLORIDA – *Florida Deceptive and Unfair Trade*
22 *Practices Act, Part II*, Chapter 501, Florida Statutes, 501.201 et seq.; HAWAII – *Uniform Deceptive Trade Practice Act*, Haw. Rev.
23 Stat. Chpt. 481A and Haw. 501.201 et seq.; IDAHO – *Consumer Protection Act*, Idaho Code Section 48-601 et seq.; ILLINOIS –
24 *Consumer Fraud and Deceptive Business Practices Act*, 815 ILCS 505/2 et seq.; IOWA – *Iowa Consumer Fraud Act*, Iowa Code
25 Section 714.16; KANSAS - *Kansas Consumer Protection Act*, K.S.A. 50-623 et seq. KENTUCKY – *Kentucky Consumer Protection*
26 *Act*, KRS Ch. 367.110, et seq.; LOUISIANA – *Unfair Trade-Practices and Consumer Protection Law*, LSA-R.S. 51:1401, et seq.;
27 MAINE – *Unfair Trade Practices Act*, 5 M.R.S.A. § 207 et seq.; MARYLAND - *Maryland Consumer Protection Act*, Md. Code Ann.,
28 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 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*, Or. Rev. Stat. § 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)*.

1 **COMPLIANCE PROVISIONS**

2 **I. Promotional Activities**

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

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

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

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

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

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

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

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

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

27 2. Promotional Materials have a reference indicating that the full
28 constellation of symptoms and the relevant diagnostic criteria are available in the

1 Diagnostic and Statistical Manual of Mental Disorders (DSM-IV or current version),
2 where applicable.

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

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

7 **II. Dissemination and Exchange of Medical Information**

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

10 B. Medical Information Letters

11 1. The following subsections shall be effective for nine years from
12 the Effective Date of this Judgment/Order.

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

18 a. Clinically Relevant Information is included in these materials to
19 provide scientific balance;

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

22 c. These materials are clearly distinguishable from sales aids and
23 other Promotional Materials.

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

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

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

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

8 1. The following subsections shall be effective for nine years from
9 the Effective Date of this Judgment/Order.

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

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

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

21 a. an existing Medical Information Letter prepared in
22 accordance with Section II.B;

23 b. a Medical Information Letter or other document
24 prepared in response to the request in accordance with Section II.B; or

25 c. a report containing the results of a reasonable
26 literature search using terms from the request.

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

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

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

25 D. Reprints

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

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

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

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

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

22 c. in cases in which experts qualified by scientific training or
23 experience to evaluate the safety or effectiveness of Geodon® would consider the
24 conclusion of the information to have been specifically called into question by another
25 article(s) or text(s) that experts qualified by scientific training or experience to evaluate
26 the safety or effectiveness of Geodon® would consider to be scientifically sound, the
27 information must be disseminated with a representative publication that reaches
28 contrary or different conclusions regarding the Off-Label use.

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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.

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(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 Judgment/Order 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

1 these materials combined with detailing, advertising, sampling, or other Promotional
2 activities Promote Off-Label use of Geodon®.

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

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

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

14 A. The following subsections shall be effective for six years from the
15 Effective Date of this Judgment/Order.

16 B. Pfizer shall disclose information about grants, including CME grants,
17 regarding Geodon® consistent with the current disclosures of the Pfizer Medical
18 Education Grants Office at:

19 http://www.pfizer.com/responsibility/grants_payments/medical_education_grants.jsp

20 (hereinafter, "Pfizer Medical Education Grants Office website") or as required by
21 applicable law.

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

26 C. The Pfizer Medical Education Grants Office shall manage all requests for
27 funding related to CME relating to Geodon®. Approval decisions shall be made by the
28

1 Pfizer Medical Education Grants Office and Pfizer Medical, and shall be kept separate
2 from the Pfizer Sales and Pfizer Marketing organizations.

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

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

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

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

12 E. Pfizer shall not condition funding of a CME program grant request
13 relating to 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
15 specific topic, title, content, speakers or audience for CMEs relating to Geodon®,
16 consistent with ACCME guidelines.

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

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

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

1 **IV. Payments to Speakers and HCPs**

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

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

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

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

1 physician or Related Entity has provided to Pfizer for contact purposes; and (iv) the
2 aggregate value of the Payment(s) in the preceding quarter(s) or year (as applicable).
3 If Payments for multiple physicians have been made to one Related Entity, the
4 aggregate value of all Payments to the Related Entity will be the reported amount.

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

13 F. If the proposed Physician Payments Sunshine Act of 2009 or similar
14 legislation is enacted, the State shall determine whether the purposes of this section
15 are reasonably satisfied by Pfizer's compliance with such legislation. In such case,
16 and in its sole discretion, the State may agree to modify or terminate provisions of this
17 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
22 with a U.S.-based physician prior to July 1, 2009. Pfizer agrees that it shall not include
23 any such confidentiality provisions in any new or renewed clinical research
24 agreements entered after the Effective Date of this Judgment/Order that require any
25 Payment to a U.S.-based physician.

26 **V. Product Samples**

27 A. The following subsections shall be effective for nine years from the
28 Effective Date of this Judgment/Order.

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

4 C. If a HCP whose clinical practice is inconsistent with the product's
5 Labeling requests samples, Pfizer personnel shall refer the practitioner to 1-800-438-
6 1985 where the practitioner can speak directly with a Pfizer representative who will
7 provide answers to the HCP's questions about Geodon® and may provide them with
8 samples only if appropriate (*i.e.*, if the physician requests the sample for an on-label
9 use).

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

12 VI. Clinical Research

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

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

25 B. When presenting information about a clinical study regarding Geodon®
26 in any Promotional Materials, Pfizer shall not do any of the following:
27
28

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

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

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

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

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

18 **VII. Terms Relating to Payment**

19 A. No later than 30 days after the Effective Date of this Order, Pfizer shall
20 pay a total amount of \$33 million to be divided and paid by Pfizer directly to each
21 Signatory Attorney General of the Multistate Working Group in an amount to be
22 designated by and in the sole discretion of the Multistate Executive Committee. The
23 Arizona Attorney General shall deposit the full amount of its payment into the
24 Consumer Revolving Fund to be used in the sole discretion of the Arizona Attorney
25 General for consumer fraud education and investigative and enforcement operations
26 of the consumer protection division pursuant to A.R.S. § 44-1531.01 costs and
27 attorneys' fees pursuant to A.R.S. §§ 44-1534. The Parties acknowledge that the
28 payment described herein is not a fine, penalty, or payment in lieu thereof.

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VIII. Release

A. By its execution of this Judgment/Order, the State of Arizona 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 Arizona 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 Judgment/Order.

B. Notwithstanding any term of this Judgment/Order, 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 Arizona.

2. Any civil or administrative liability that any person and/or entity, including Released Parties, has or may have to the State of Arizona 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 Arizona'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.

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

4 X. Dispute Resolution

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

23 B. Upon giving Pfizer thirty (30) days to respond to the notification
24 described above, the Signatory Attorney General shall also be permitted reasonable
25 access to inspect and copy relevant, non-privileged, non-work product records and
26 documents in the possession, custody or control of Pfizer that relate to Pfizer's
27 compliance with each provision of this Judgment/Order as to which cause that is
28 legally sufficient in the State has been shown. If the Signatory Attorney General

1 makes or requests copies of any documents during the course of that inspection, the
2 Signatory Attorney General will provide a list of those documents to Pfizer.

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

10 **XI. General Provisions**

11 A. This Judgment/Order represents the full and complete terms of the
12 settlement entered into by the Parties hereto. In any action undertaken by the Parties,
13 no prior versions of this Judgment/Order and no prior versions of any of its terms that
14 were not entered by the Court in this Judgment/Order, may be introduced for any
15 purpose whatsoever.

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

19 C. This Judgment/Order may be executed in counterparts, and a facsimile
20 or PDF signature shall be deemed to be, and shall have the same force and effect as,
21 an original signature.

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

24 Douglas M. Lankler
25 Senior Vice President
26 And Chief Compliance Officer
27 Pfizer Inc.
28 150 East 42nd Street
New York, New York 10017

and

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Noreen R. Matts
Unit Chief Counsel
Taren M. Ellis
Assistant Attorney General
400 W. Congress, S-Bldg., Suite 315
Tucson, Arizona 85701

E. To the extent that any provision of this Judgment/Order 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 Judgment/Order.

TERRY GODDARD
ARIZONA ATTORNEY GENERAL

By: Noreen R. Matts
Noreen R. Matts, Unit Chief Counsel
Consumer Protection and Advocacy Section

Date: 9/2/09

BY: Taren M. Ellis
Taren M. Ellis
Assistant Attorney General
Consumer Protection and Advocacy Section

Date: 9/2/09

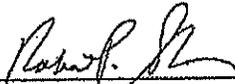
For Pfizer Inc.:

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

1 Approved as to form:

2

3 By: Cynthia A Ricketts/ICLF

4 Cynthia A. Ricketts

5 DLA Piper LLP (US)

6 2525 East Camelback Road, Suite 1000

7 Phoenix, Arizona 85016-4245

8 T: (480) 606-5112

9 F: (480) 606-5512

10 M: (602-920-7071

11 Cindy.Ricketts@dlapiper.com

12

13 Date: 9/2/09

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