

STATE OF OREGON
MARION COUNTY COURTS
OCT - 6 2008
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4 IN THE CIRCUIT COURT OF THE STATE OF OREGON
5 FOR THE COUNTY OF MARION

6 STATE OF OREGON ex rel HARDY
7 MYERS, Attorney General for the State of
8 Oregon,

9 Plaintiff,

10 v.

11 ELI LILLY COMPANY,

12 Defendant.

Case No. 08C22942

STIPULATED GENERAL JUDGMENT

13 The parties voluntarily enter in this Stipulated General Judgment on the terms and
14 conditions set forth below:

15 **PREAMBLE**

16 A The Attorneys General of the States of Alabama, Arizona, California, Delaware,
17 District of Columbia, Florida, Hawaii, Illinois, Indiana, Iowa, Kansas, Maine, Maryland,
18 Massachusetts, Michigan, Missouri, Nebraska, Nevada, New Jersey, New York, North Carolina,
19 North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee,
20 Texas, Vermont, Washington, and Wisconsin. (collectively, the "Attorneys General," and the
"AGs"), conducted an investigation under the State Consumer Protection Laws regarding certain
Eli Lilly and Company ("Eli Lilly" or "Lilly") practices concerning Zyprexa®; and

21 B. Eli Lilly is willing to enter into a Consent Judgment (the "Judgment") regarding
22 its promotional practices, sampling practices, dissemination of information, and remuneration to
23 Health Care Professionals regarding Zyprexa® ("Covered Conduct") in order to resolve the
24 AGs' investigation under the State Consumer Protection Laws and arrive at a complete and total
settlement and resolution of any disagreement as to the matters addressed in this Judgment and
thereby avoid unnecessary expense, inconvenience, and uncertainty; and

25 C. The Parties have agreed to resolve the issues raised by the Covered Conduct by
26 entering into this Judgment. Eli Lilly 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 or regulation, or of any other matter of fact or law, or of any

1 liability or wrongdoing, all of which Eli Lilly expressly denies. Lilly does not admit any
2 violation of the State Consumer Protection Laws, and does not admit any wrongdoing that was or
3 could have been alleged by any Attorney General before the date of the Judgment under those
4 laws. No part of this Judgment, including its statements and commitments, shall constitute
5 evidence of any liability, fault, or wrongdoing by Eli Lilly. Except in an action brought by an
6 Attorney General to enforce this Judgment, this Judgment shall not be construed or used as a
7 waiver or limitation of any defense otherwise available to Eli Lilly, including, but not limited to
8 the defense of federal preemption, in other matters, or of Eli Lilly's right to defend itself from, or
9 make any arguments in, any other matter, including, but not limited to, any investigation or
10 litigation relating to the existence, subject matter or terms of this Judgment. This Judgment is
11 made without trial or adjudication of any issue of fact or law or finding of wrongdoing or
12 liability of any kind. It is the intent of the Parties that this Judgment shall not be admissible in
13 any other matter, including, but not limited to, any investigation or litigation, or bind Eli Lilly in
14 any respect other than in connection with the enforcement of this Judgment. No part of this
15 Judgment shall create a private cause of action or confer any right to any third party for violation
16 of any federal or state statute except that a State may file an action to enforce the terms of this
17 Judgment. All obligations undertaken by Eli Lilly in this Judgment shall apply prospectively;
18 and nothing contained herein prevents or prohibits the use of this Judgment for purposes of
19 enforcement by the AGs; and

20 D. The AGs have reviewed the terms of the Judgment and find that such terms serve
21 the public interest; and

22 E. This Judgment (or any portion thereof) shall in no way be construed to prohibit
23 Eli Lilly from making representations with respect to Zyprexa that are permitted under Federal
24 law or in Labeling for the drug under the most current draft or final standard promulgated by the
25 FDA or the most current draft or final FDA Guidances for Industry, or permitted or required
26 under any Investigational New Drug Application, New Drug Application, Supplemental New
27 Drug Application, or Abbreviated New Drug Application approved by FDA, so long as the
28 representation, taken in its entirety, is not false, misleading or deceptive; and

29 IT IS HEREBY ORDERED that:

30 DEFINITIONS

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

32 1. "Clinically Relevant Information" shall mean information that reasonably
33 prudent clinicians would consider relevant when making prescribing decisions regarding
34 Zyprexa.

35 2. "Consultant" or "Consulting" shall mean a non-Lilly Health Care
36 Professional engaged to advise regarding marketing or promotion of Zyprexa.

1 3. “Effective Date” shall mean the date on which a copy of this Judgment,
2 duly executed by Lilly and by the Signatory Attorney General, is approved by, and becomes a
3 Judgment of, the Court or on November 1st, 2008, whichever is later.

4 4. “Eli Lilly and Company” shall mean Eli Lilly and Company, including all
5 of its affiliates, subsidiaries and divisions, predecessors, successors and assigns doing business in
6 the United States.

7 5. “FDA Guidances for Industry” shall mean draft or final documents
8 published by the United States Department of Health and Human Services, Food and Drug
9 Administration (“FDA”) that represent the FDA’s thinking on a topic.

10 6. “Health Care Economic Information” shall mean data and other
11 information relating to the inputs and outcomes of health care therapies and services, including,
12 but not limited to, the price, cost-effectiveness, and quality of life implications of Zyprexa.

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

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

20 9. “Lilly Grant Office” shall mean the U.S.-based organization within Eli
21 Lilly responsible for oversight of the grant process, including the acceptance, review, and
22 payment of all non-clinical grant requests.

23 10. “Lilly Legal” shall mean personnel of the Lilly Law Division or its
24 designee providing legal advice to Lilly.

25 11. “Lilly Marketing” shall mean Lilly personnel assigned to the Lilly U.S.
26 Zyprexa marketing team.

 12. “Lilly Medical” shall mean Lilly personnel assigned to the Lilly U.S.
 medical organization

 13. “Lilly Non-Medical” shall mean Lilly personnel other than Lilly personnel
 assigned to the U.S. Zyprexa medical organization.

 14. “Lilly Regulatory” shall mean Lilly personnel or their designee
 responsible for Lilly’s adherence with FDA regulations.

 15. “Lilly Sales” shall mean the Lilly sales force responsible for U.S. Zyprexa
 sales.

1 16. “Medical Letter” shall mean a non-promotional, scientific communication
2 to address Unsolicited Requests for medical information from HCPs.

3 17. “Medical Reference” shall mean a non-promotional reference
4 communication that is used for responding to or answering a HCP’s Unsolicited Request for
5 medical information.

6 18. “Multistate Executive Committee” shall mean the Attorneys General and
7 their staffs representing Arizona, California, Florida, Illinois, Ohio, Oregon, Texas and Vermont.

8 19. “Multistate Working Group” shall mean the Attorneys General and their
9 staff representing Alabama, Arizona, California, Delaware, District of Columbia, Florida,
10 Hawaii, Illinois, Indiana, Iowa, Kansas, Maine, Maryland, Massachusetts, Michigan, Missouri,
11 Nebraska, Nevada, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma,
12 Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Texas, Vermont, Washington,
13 and Wisconsin.

14 20. “Off-Label” shall mean a use not consistent with the indications section of
15 the Zyprexa Labeling approved by the FDA at the time information regarding such use was
16 communicated.

17 21. “Parties” shall mean Lilly and the Signatory Attorney General.

18 22. “Promotional,” “Promoting” or “Promote” shall mean claims to HCPs
19 about Zyprexa intended to increase sales or attempt to influence prescribing practices of the
20 HCPs.

21 23. “Promotional Materials” shall mean any item with the product name, logo,
22 or message used to Promote Zyprexa.

23 24. “Promotional Slide Kit” shall mean Promotional Materials regarding
24 Zyprexa in the form of a slide kit for use in speaker programs.

25 25. “Promotional Speaker” shall mean a non-Lilly HCP speaker used to
26 Promote Zyprexa.

 26 “Reprints Containing Off-Label Information” shall mean articles or
reprints from a peer reviewed journal or reference publication describing an Off-Label use of
Zyprexa.

 27. “Signatory Attorney General” shall mean the Attorney General of
Oregon, or his authorized designee, who has agreed to this Judgment.

 28. “State Consumer Protection Laws” shall mean the consumer protection
laws under which the Attorneys General have conducted the investigation, ALABAMA -
Deceptive Trade Practices Act, Ala Code § 8-19-1 et seq ; ARIZONA - Consumer Fraud Act,
A.R.S. § 44-1521, et seq ; CALIFORNIA - Bus. & Prof. Code, §§ 17200 et seq., and 17500 et

1 seq.; DELAWARE-Consumer Fraud Act, 6 Del.C. Section 2511, et seq.; DISTRICT OF
2 COLUMBIA - Consumer Protection Procedures Act, D.C. Code § 28-3901, et seq.; FLORIDA -
3 Deceptive and Unfair Trade Practices Act, Fla. Stat. Ch. 501.201 et seq.; HAWAII- Uniform
4 Deceptive Trade Practice Act, Haw. Rev. Stat. Ch. 481A and Haw. Rev. Stat. § 480-2.;
5 ILLINOIS - Consumer Fraud and Deceptive Business Practices Act, 815 ILCS § 505/1 et seq.;
6 INDIANA - Deceptive Consumer Sales Act, Ind. Code § 24-5-0.5-1 et seq.; IOWA - Iowa
7 Consumer Fraud Act, Iowa Code Section 714.16; KANSAS - Consumer Protection Act, K.S.A.
8 50-623 et seq.; MAINE - Unfair Trade Practices Act, 5 M.R.S.A. § 207 et seq.; MARYLAND -
9 Consumer Protection Act, Md. Code Ann., Com. Law § 13-101 et seq.; MASSACHUSETTS -
10 Consumer Protection Act, M.G.L. c. 93A et seq.; MICHIGAN - Michigan Consumer Protection
11 Act, MCL 445.901 et seq.; MISSOURI - Missouri Merchandising Practices Act, Mo. Rev. Stat.
12 § 407.010 et seq.; NEBRASKA - Uniform Deceptive Trade Practices Act, NRS §§ 87-301 et
13 seq.; NEVADA - Deceptive Trade Practices Act, Nevada Revised Statutes 598.0903 et seq.;
14 NEW JERSEY - New Jersey Consumer Fraud Act, 56:8-1 et seq.; NEW YORK - General
15 Business Law Article 22-A Sections 349, 350 and Executive Law 63 (12); NORTH
16 CAROLINA - Unfair and Deceptive Trade Practices Act, N.C. Gen. Stat. § 75-1.1 et seq.;

17 29. "Unsolicited Request" shall mean a request for information regarding
18 Zyprexa from a HCP communicated to an agent of Lilly that has not been prompted.

19 30. "Zyprexa®" shall mean all FDA approved drug formulations containing
20 olanzapine as its sole active ingredient and Promoted by Lilly.

21 COMPLIANCE PROVISIONS

22 I. Promotional Activities

23 A. Lilly shall not make any written or oral claim that is false, misleading or
24 deceptive regarding Zyprexa.

25 B. For six years from the Effective Date of this Judgment, Lilly shall not Promote
26 Zyprexa for Off-Label uses.

1 C. For six years from the Effective Date of this Judgment, Lilly shall not present
2 patient profiles/types based on selected symptoms of the FDA-approved indication(s) when
promoting Zyprexa, unless:

3 1. The drug's specific FDA-approved indication(s) being Promoted is/are
4 stated clearly and conspicuously in the same spread (i.e., on the same page or on a facing page)
in Promotional Materials as references to selected symptoms.

5 a. With respect to Promotional Slide Kits:

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

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

11 (iii) Lilly shall require any presenter of Lilly's Promotional
12 Slide Kits to present the statement required in Section
I.C.1.a.(i), as part of the mandatory slides.

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

16 II. Dissemination of Medical Information

17 A. General Terms

18 1. The content of Lilly's communications concerning Off-Label uses of
19 Zyprexa shall not be false, misleading or deceptive.

20 B. Medical Letters and Medical References

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

22 2. Lilly Medical shall have ultimate responsibility for developing and
23 approving the medical content for all Medical Letters and Medical References regarding
Zyprexa, including any that may describe Off-Label information. Additional approvals may be
24 provided by Lilly Regulatory and Lilly Legal. Lilly shall not distribute any such materials
25 unless:

26 a. Clinically Relevant Information is included in these materials to
provide scientific balance.

1 b. Data in these materials are presented in an unbiased, non-
2 Promotional manner.

3 c. These materials are distinguishable from sales aids and other
4 Promotional Materials.

5 3. Lilly Sales and Lilly Marketing personnel shall not develop the medical
6 content of Medical References or Medical Letters regarding Zyprexa. This provision does not
7 prohibit Lilly Sales or Lilly Marketing personnel from suggesting topics for Medical Letters or
8 Medical References.

9 4. Lilly Sales representatives shall not distribute Medical References or
10 Medical Letters regarding Zyprexa.

11 5. Lilly shall not knowingly disseminate any Medical Letter describing any
12 Off-Label use of Zyprexa that makes any false or misleading representation regarding Zyprexa
13 or any false or misleading statement concerning a competing product.

14 C. Responses to Unsolicited Requests for Off-Label information

15 1. The following subsections shall be effective for six years from the
16 Effective Date of this Judgment.

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

21 3. If Lilly elects to respond to an Unsolicited Request for Off-Label
22 information from a HCP regarding Zyprexa, Lilly Medical personnel shall provide specific,
23 accurate, objective, and scientifically balanced responses. Any such response shall not Promote
24 Zyprexa for an Off-Label use.

25 4. Any written response to an Unsolicited Request for Off-Label information
26 regarding Zyprexa shall include:

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

b. a Medical Letter or other document such as slides prepared in
 response to the request in accordance with Section II.B; or

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

5. Lilly Non-Medical personnel may not respond in writing to an Unsolicited
Request for Off-Label information regarding Zyprexa.

1 6. Lilly Non-Medical personnel may respond orally to an Unsolicited
2 Request for Off-Label information regarding Zyprexa from a HCP only by informing the HCP of
3 the presence or absence of published studies concerning the Off-Label topic or acknowledge
4 whether the topic is an area of research, and by offering to request on behalf of the HCP that a
5 Medical Letter or other information set forth above in II.C.4 be sent to the HCP in follow up.
6 Lilly Non-Medical personnel shall not characterize, describe, identify, name, or offer any
7 opinions about or summarize any such Off-Label information.

8 D. Reprints

9 1. The following subsections shall be effective for six years from the
10 Effective Date of this Judgment.

11 2. Reprints Containing Off-Label Information

12 a. Lilly Medical shall be responsible for the identification, selection,
13 approval and dissemination of Reprints Containing Off-Label
14 Information regarding Zyprexa

15 b. Reprints Containing Off-Label Information regarding Zyprexa:

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 Zyprexa may
23 only be disseminated by Lilly Medical personnel to HCPs. Lilly
24 Non-Medical personnel shall not disseminate these materials to
25 HCPs, absent the exception described below in (i).

26 (i) In the event of an extraordinary circumstance in which there
is a clinical necessity to have Lilly Non-Medical personnel
disseminate a Reprint Containing Off-Label Information
directly to HCPs, the President of LillyUSA may approve a
Clinical Necessity Exception to the prohibition described in
Section II D.2.c. above for that Reprint Containing Off-
Label Information.

 (ii) If the Clinical Necessity Exception is invoked, Lilly will
notify each Signatory Attorney General of its intent to
invoke the Clinical Necessity Exception at least 30 business
days prior to disseminating through Lilly Sales

1 representatives of any Reprint Containing Off-Label
2 Information on Zyprexa.

3 (a) If a Signatory Attorney General believes the Reprint
4 Containing Off-Label Information to be
5 disseminated does not meet the Clinical Necessity
6 Exception, then the State will provide Lilly with
7 written notice within 30 business days and provide
8 Lilly an opportunity to discuss its desired use of the
9 Reprint Containing Off-Label Information pursuant
10 to the limited exception.

11 (b) If the State and Lilly do not come to a resolution,
12 then the State may initiate legal action to prevent
13 the dissemination of the Reprint Containing Off-
14 Label Information by Lilly Non-Medical personnel.

15 (c) If the State initiates legal action to prevent the
16 dissemination of the Reprint Containing Off-Label
17 Information by Lilly Non-Medical personnel, Lilly
18 shall not use Lilly Non-Medical personnel to
19 disseminate such Reprint Containing Off-Label
20 Information in that State until the issue has been
21 resolved.

22 3. Nothing in this Judgment shall preclude Lilly from disseminating reprints
23 which have an incidental reference to Off-Label information. If reprints have an incidental
24 reference to Off-Label information, such reprints shall contain the disclosure required by Section
25 II.D 2 b(i) in a prominent location, as defined above.

26 E. Health Care Economic Information

27 1. Nothing in this Judgment shall preclude Eli Lilly from providing Health
28 Care Economic Information to a formulary committee or other similar entity or its members in
29 the course of the committee or entity carrying out its responsibilities for the selection of drugs for
30 managed care or other similar organization pursuant to the standards of FDAMA Section 114 if
31 the information directly relates to an approved indication for Zyprexa and if it is based on
32 competent and reliable scientific evidence.

33 III. Continuing Medical Education (CME) and Grants

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

36 B. Lilly shall disclose information about grants, including CME grants, regarding
Zyprexa consistent with the current disclosures of the Lilly Grant Office Registry at
www.lillygrantoffice.com (hereinafter, "LGO website") or as required by applicable law.

1 1. Lilly shall maintain this information on the LGO website once posted for
2 at least two years and shall maintain the information in a readily accessible format for review by
the States upon written request for a period of five years.

3 C. The Lilly Grant Office shall manage all requests for funding related to CME
4 regarding Zyprexa. Approval decisions shall be made by the Lilly Grant Office alone, and shall
be kept separate from the Lilly Sales and Lilly Marketing organizations.

5 D. Lilly shall not use grants to Promote Zyprexa. This provision includes, but is not
6 limited to, the following prohibitions:

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

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

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

12 E. Lilly shall not condition funding of a CME program grant request regarding
13 Zyprexa upon the requestor's selection or rejection of particular speakers.

14 F. Lilly shall not suggest, control, or attempt to influence selection of the specific
15 topic, title, content, speakers or audience for CMEs regarding Zyprexa, consistent with ACCME
guidelines.

16 G. Lilly Sales and Lilly Marketing personnel shall not approve grant requests
17 regarding Zyprexa, nor attempt to influence the Lilly Grant Office to reward any customers or
HCPs with grants for their prescribing habits, practices or patterns

18 H. Lilly shall contractually require the CME provider to disclose to CME program
19 attendees Lilly's financial support of the CME program and any financial relationship with
20 faculty and speakers at such CME. As part of the disclosure of a financial relationship with
21 faculty and speakers, Lilly shall contractually require the CME program to identify the URL of a
Lilly website, and reference that website as the source for further information concerning grant
funding regarding Zyprexa.

22 I. After the initial delivery of a CME program, Lilly shall not fund the same
23 program, nor shall it provide additional funding for re-distribution of the same program, if it
24 knows that the program's speakers are Promoting Zyprexa for Off-Label uses.

25 IV. Payments to Consultants and Speakers

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

1 B. This Section shall apply to U.S. based Consultants and Promotional Speakers to
the Lilly Marketing organization.

2 C. Lilly shall provide to each Signatory Attorney General, in an electronic
3 spreadsheet format, a list of HCP Promotional Speakers and Consultants who were paid by Lilly
4 any taxable income in excess of \$100 for Promotional speaking and/or Consulting performed for
Lilly in the U.S., a list of all titles of Promotional presentations made, and the following
5 additional information with respect to each individual Promotional Speaker and/or Consultant:

- 6 1. total compensation from Lilly for any Consulting or Promotional speaking
fees;
- 7 2. total number of Promotional speaking events paid for by Lilly;
- 8 3. the state the Promotional Speaker/Consultant has provided to Lilly for
9 contact purposes;
- 10 4. the state(s) in which the Promotional Speaker gave the Promotional
11 presentations; and
- 12 5. any other compensation from Lilly as set forth in IRS Form 1099.

13 On or before July 1, 2009, Lilly shall provide the data requested in Nos. 1-4 for the period
January 1, 2009-March 31, 2009. On or before October 1, 2009, Lilly shall provide the data
14 requested in Nos. 1-4 for the period April 1, 2009-June 30, 2009. On or before January 1, 2010,
Lilly shall provide the data requested in Nos. 1-4 for the period July 1, 2009-September 30,
15 2009. On or before April 1, 2010 and on or before April 1 of each subsequent year, Lilly shall
16 provide the data requested in Nos. 1-5 for the full preceding calendar year.

17 D. Lilly shall disclose to the Promotional Speaker or Consultant that the information
in Section IV.C. above may be disclosed.

18 V. Product Samples

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

21 B. Lilly Sales representatives may only sample Zyprexa to a HCP whose clinical
22 practice is consistent with the product's current Labeling. Currently, Lilly samples Zyprexa to
the following practices: emergency medicine, family practice, general practice, internal
23 medicine, and psychiatry.

24 C. If a HCP whose clinical practice is inconsistent with the product's Labeling
requests samples, Lilly personnel shall refer the practitioner to 1-800-LillyRx where the
25 practitioner can speak directly with a Lilly representative who will provide answers to their
26 questions about Zyprexa and may provide them with samples if appropriate (i.e., if the physician
requests the sample for an on-label use).

1 VI. Clinical Research

2 A. Lilly shall report research regarding Zyprexa in an accurate, objective and
3 balanced manner as follows or as required by applicable law:

4 1. To the extent permitted by the National Library of Medicine and as
5 required by the FDA Amendments Act (Public Law No. 110-85), Lilly shall register clinical
6 trials and submit results to the registry and results data bank regarding Zyprexa as required by
7 the FDA Amendments Act and any accompanying regulations that may be promulgated pursuant
8 to that Act. With respect to Zyprexa, Lilly will register on a publicly accessible website the
9 initiation of all Lilly-sponsored Phase II, III, and IV clinical trials beginning after July 1, 2005
10 and will post results on a publicly accessible website of all Lilly-sponsored Phase II, III and IV
11 clinical trials that were completed after July 1, 2004.

12 B. When presenting information about a clinical study regarding Zyprexa in all
13 Promotional Materials, Lilly shall not do any of the following in a manner that causes the
14 Promotional Materials to be false or misleading:

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

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

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

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

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

31 VII. Terms Relating to Payment

32 A. No later than 30 days after the Effective Date of this Judgment, Lilly shall pay
33 \$62 million to be divided and paid by Lilly directly to each Signatory Attorney General of the
34 Multistate Working Group in an amount to be designated by and in the sole discretion of the
35 Multistate Executive Committee. Said payment shall be used by the States as and for attorneys'
36 fees and other costs of investigation and litigation, or to be placed in, or applied to, the consumer
protection enforcement fund, including future consumer protection enforcement, consumer

1 education, litigation or local consumer aid fund or revolving fund, used to defray the costs of the
2 inquiry leading hereto, and may be used to fund or assist in funding programs directed at mental
3 illness treatment, including but not limited to education and outreach or for other uses permitted
4 by state law, at the sole discretion of each Signatory Attorney General.¹ The Parties
5 acknowledge that the payment described herein is not a fine or penalty, or payment in lieu
6 thereof.

7 VIII. Conflicts

8 A. If subsequent to the Effective Date of this Judgment, the federal government or
9 any state, or any federal or state agency, enacts or promulgates legislation or regulations with
10 respect to matters governed by this Judgment that creates a conflict with any provision of the
11 Judgment and Eli Lilly intends to comply with the newly enacted legislation or regulation, Eli
12 Lilly shall notify the Attorneys General (or the Attorney General of the affected state) of the
13 same. If the Attorney General agrees, he/she shall consent to a modification of such provision of
14 the Judgment to the extent necessary to eliminate such conflict. If the Attorney General disagrees
15 and the Parties are not able to resolve the disagreement, Eli Lilly shall seek a modification from
16 an appropriate court of any provision of this Judgment that presents a conflict with any such
17 federal or state law or regulation. Changes in federal or state laws or regulations with respect to
18 the matters governed by this Judgment, shall not be deemed to create a conflict with a provision
19 of this Judgment unless Eli Lilly cannot reasonably comply with both such law or regulation and
20 the applicable provision of this Judgment.

21 B. If, subsequent to the Effective Date of this Judgment, the laws or regulations of
22 the United States, or the draft or final FDA Guidances for Industry, are changed so as to
23 expressly authorize conduct that is expressly prohibited by this Judgment, then such conduct
24 shall not constitute a violation of this Judgment. Provided however, if Lilly intends to engage in
25 the expressly authorized conduct, Lilly shall notify the Attorneys General (or the Attorney
26 General of the affected state) within 30 business days prior to any change

IX. Release

27 A. By its execution of this Judgment, State of Oregon releases and forever
28 discharges, to the fullest extent permitted by law, Eli Lilly and all of its past and present
29 subsidiaries, divisions, affiliates, co-promoters, controlled joint ventures, predecessors,
30 successors, and assigns and each and all of their current and former officers, directors,
31 shareholders, employees, agents, contractors, and attorneys (collectively, the "Released Parties")
32 of and from the following: all civil claims, causes of action, damages, restitution, fines, costs,
33 attorneys fees, and penalties that the Oregon Attorney General could have asserted against the
34 Released Parties under the Oregon's Unlawful Trade Practices Act (ORS 646.605 *et seq*),
35 successor statutes, or common law claims concerning unfair, deceptive or fraudulent trade
36 practices impacting consumers related to any conduct that has occurred at any time up to and

¹ With respect to the State of Oregon said funds shall be deposited into the Consumer Protection & Education
Revolving Account established pursuant to ORS 180 095

1 including the Effective Date of this Judgment arising from the Covered Conduct that is the
2 subject of this Judgment (collectively, the “Released Claims”).

3 B. Notwithstanding any term of this Judgment, specifically reserved and excluded
4 from the Released Claims as to any entity or person, including Released Parties, are any and all
5 of the following:

6 1. Any criminal liability that any person or entity, including Released Parties,
7 has or may have to the State of Oregon;

8 2. Any civil or administrative liability that any person or entity, including
9 Released Parties, has or may have to the State of Oregon that is not expressly covered by the
10 release in Section IX.A. above, including but not limited to any and all of the following claims:

11 a. State or federal antitrust violations;

12 b. Reporting practices, including “best price,” “average wholesale
13 price,” or “wholesale acquisition cost;”

14 c. Medicaid violations, including federal Medicaid drug rebate statute
15 violations, Medicaid fraud or abuse, Medicaid-related common law
16 claims; and/or kickback violations related to any State’s Medicaid
17 program;

18 d. State false claims violations;

19 e. actions of state program payors arising from the purchase of
20 Zyprexa, except for the release of civil penalties under the state
21 consumer protection laws; and

22 f. Any liability under the State of Oregon’s above-cited Consumer
23 Protection Law which the Released Parties have or may have to
24 individual consumers.

25 X. Cure Provision

26 A. The Parties agree that a State will provide Lilly with written notice if it believes
that Lilly is in violation of any of its obligations under the Judgment (“Notice”). Lilly shall have
30 business days after the date of receipt of the Notice to demonstrate to the State’s satisfaction
that:

1. Lilly is in compliance with the obligations of the Judgment cited by that
State as being violated;

2. the violation has been cured, including, but not limited to, by remedial
actions having been taken against an employee for actions inconsistent with this Judgment; or

1 3. the alleged violation cannot be cured within the 30 business day period,
2 but that: (a) Lilly has begun to take action to cure the violation; (b) Lilly is pursuing such action
3 with due diligence; and (c) Lilly has provided a reasonable timetable for curing the violation.

4 B. Except as set forth in Section X.D. below, the State may not take any action
5 during the 30 business day cure period. Nothing shall prevent the State from agreeing in writing
6 to provide Eli Lilly with additional time beyond the 30 business days to respond to the notice.

7 C. The State may not take any action during which a modification request is pending
8 before a court pursuant to Section VIII.A, except as provided for in Section D below.

9 D. Nothing prohibits the States from taking actions necessary to protect public health
10 and safety as provided by applicable law.

11 XI General Provisions

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

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

19 C. All Notices under this Judgment shall be provided to Nina Gussack, Paul Kalb,
20 and the General Counsel of Eli Lilly and Company by Overnight Mail at:

21 Nina Gussack
22 Pepper Hamilton
23 3000 Two Logan Square
24 Eighteenth and Arch Streets
25 Philadelphia, PA 19103-2799

26 Paul E. Kalb
Sidley Austin LLP
1501 K Street, NW
Washington, DC 20005

General Counsel
Eli Lilly and Company
Lilly Corporate Center
Indianapolis, IN 46285

ACCEPTANCE OF LILLY

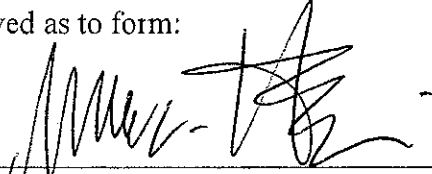
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By: _____ Date: 10/1/08

Michael J. Harrington
Deputy General Counsel
Lilly Corporate Center
Indianapolis, IN 46285

1 Approved as to form:

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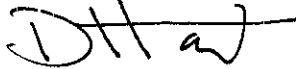
Date: October 1, 2008

Bruce Hamlin # 79254
Lane Powell PC
601 SW Second Avenue
Suite 2100
Portland, OR 97204
503-778-2158
503-753-6151-Cell
Hamlinb@LanePowell.com

1 ACCEPTANCE OF DOJ

2
3 Accepted this 6th day of October, 2008.

4
5 HARDY MYERS
Attorney General

6 

7 _____
David Hart #00275
Senior Assistant Attorney General
8 1162 Court Street, N.E.
9 Salem, OR 97301-4096
10 Phone: (503) 934-4400
11 Fax: (503) 378-5017
12 Email: david.hart@state.or.us

1 This STIPULATED GENERAL JUDGMENT is hereby accepted for entry of
2 JUDGMENT for all purposes as set forth herein

3 **IT IS SO ADJUDGED AND ORDERED:**

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5 DATED this 7 day of Oct, 2008

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CIRCUIT COURT JUDGE for Marion County