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December 18, 2008

The Honorable Timothy S. Bee  
President of the Senate  
1700 West Washington Street  
Phoenix, AZ 85007

The Honorable James P. Weiers  
Speaker of the House  
1700 West Washington Street  
Phoenix, AZ 85007

The Honorable Robert L. Burns  
Chairman, Joint Legislative Budget Committee  
1700 West Washington Street  
Phoenix, AZ 85007

Re: State v. Eli Lilly and Company

Dear Gentlemen:

Arizona recently joined with 32 other state Attorneys General to settle a multi-state action against Eli Lilly and Company ("Lilly") based on its allegedly unlawful promotion of the antipsychotic drug Zyprexa®.

The settlement, in the form of a Consent Judgment, resolves the States' one and one half year investigation of Lilly's promotional practices. (A copy of the signed Judgment is attached). Zyprexa® is the brand name for the prescription drug olanzapine. The drug was first marketed for use in adults with schizophrenia in 1996. Since then, the Food and Drug Administration ("FDA") has approved Zyprexa® for the treatment of certain types of bipolar disorder.

Zyprexa® belongs to a class of drugs traditionally used to treat schizophrenia and commonly referred to as "atypical antipsychotics." When these drugs were first introduced to the market in the 1990s, experts thought atypical antipsychotics would be less likely to produce side effects seen in the first generation of antipsychotics, such as motion disorders like tardive dyskinesia, and therefore could be used in the long-term treatment of

schizophrenia. While atypical antipsychotics may reduce some risks, according to the settlement documents they also produced dangerous side effects, including weight gain, hyperglycemia, diabetes, cardiovascular complications, and an increased risk of mortality in elderly patients with dementia. Zyprexa® has allegedly been associated with a high risk of weight gain, hyperglycemia, and diabetes.

As alleged in the Complaint, Eli Lilly began an aggressive marketing campaign called "Viva Zyprexa!" in late 2000. As part of that campaign, the company marketed Zyprexa® for a number of uses that were not approved by the FDA ("off-label" uses). For example, Lilly marketed Zyprexa® for pediatric use, for use at high dosage levels, for the treatment of symptoms rather than diagnosed conditions, and in the elderly for the treatment and/or chemical restraint of patients suffering from dementia. While a physician is allowed to prescribe drugs for off-label uses, the law prohibits pharmaceutical manufacturers from marketing their products for off-label uses. The FDA has never approved Zyprexa® for use in children, for use to treat symptoms rather than diagnosed conditions, or for the treatment of dementia in the elderly.

The Consent Judgment contains a number of restrictions to ensure that Lilly does not promote Zyprexa® for off-label uses and that it markets Zyprexa® in compliance with law. Among other things, under the Judgment Eli Lilly shall:

- Not make any false, misleading or deceptive claims regarding Zyprexa®;
- Not promote Zyprexa® using selected symptoms of the FDA-approved diagnoses unless certain disclosures are made regarding the approved diagnoses;
- Require its medical staff, rather than its marketing staff, to have ultimate responsibility for developing and approving the medical content for all medical letters and medical references regarding Zyprexa®, including those that may describe off-label information. This information shall not be distributed unless certain criteria are met;
- Provide specific, accurate, objective and scientifically balanced responses to unsolicited requests for off-label information from a health care provider regarding Zyprexa®;
- Not use grants to promote Zyprexa®, or condition CME funding on Eli Lilly's approval of speakers or program content;
- Contractually require continuing medical education providers to disclose Eli Lilly's financial support of their programs and any financial relationship with faculty and speakers; and
- Register clinical trials and submit results as required by federal law; register Zyprexa® Eli-Lilly sponsored Phase II, III and IV clinical trials beginning after July 1, 2005;

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and post on a publicly accessible website all Eli-Lilly sponsored Phase II, III and IV clinical trials completed after July 1, 2004.

In addition, the Consent Judgment requires Lilly to pay a total of \$62 million to the participating states. Arizona's share of the settlement is \$2,205,705. This recovery is to be deposited in the Consumer Fraud Revolving Fund, pursuant to the terms of the Judgment as well as A.R.S. § 44-1531.01(B). These monies are used pursuant to statute for investigating violations of the Consumer Fraud Act and enforcing its provisions, as well as for consumer education. A.R.S. § 44-1531.01(C).

Our notification to you of this settlement is made without prejudice to this office's long-standing position that it is not under any legal obligation to provide notices of settlements to the Joint Legislative Budget Committee. We are providing this notification to you as a courtesy so that you will be aware of this important settlement.

Thank you for your consideration of this matter. If you have any questions, please feel free to contact me at [dena.epstein@azag.gov](mailto:dena.epstein@azag.gov) or (602) 542-7717.

Sincerely,



Dena Rosen Epstein  
Acting Section Chief Counsel  
Consumer Protection and Advocacy Section

DRE/sp  
Enclosure

cc: The Honorable Russell K. Pearce  
The Honorable Marsha J. Arzberger  
The Honorable Phillip M. Lopes  
Mr. Richard S. Stavneak  
Ms. Leah B. Ruggieri  
Ms. Leezie Kim  
Ms. Sheryl A. Rabin  
Mr. David Gass  
Mr. John T. Stevens, Jr.

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MICHAEL K. JEANES, Clerk  
By C. D. Miller  
Deputy

8 **IN THE SUPERIOR COURT OF THE STATE OF ARIZONA**

9 **IN AND FOR THE COUNTY OF MARICOPA**

10 STATE OF ARIZONA, *ex rel.* TERRY  
GODDARD, Attorney General,

11 Plaintiff,

12 vs.

13 ELI LILLY AND COMPANY, an Indiana  
14 corporation,

15 Defendant.

Case No.: CV2008-024260

**CONSENT JUDGMENT**

(Assigned to the Honorable Jeanne Garcia)

16 The State of Arizona, having filed a Complaint alleging violations of the Arizona  
17 Consumer Fraud Act, A.R.S. § 44-1521, *et seq.*; Defendant Eli Lilly and Company, having been  
18 served with a copy of the Complaint; having been fully advised of the right to a trial in this  
19 matter and, after receiving advice of counsel, having waived the same; admits only that this  
20 Court has jurisdiction over the subject matter and the parties for purposes of entry of this  
21 Consent Judgment and acknowledges that this Court retains jurisdiction for the purpose of  
22 enforcing this Consent Judgment. Eli Lilly and Company denies the allegations of the  
23 Complaint and denies having violated the Consumer Fraud Act. Further, it acknowledges that  
24 the terms of this Consent Judgment shall be governed by the laws of the State of Arizona.

25 **PREAMBLE**

26 A. The Attorneys General of the States of Alabama, Arizona, California, Delaware,

1 District of Columbia, Florida, Hawaii, Illinois, Indiana, Iowa, Kansas, Maine, Maryland,  
2 Massachusetts, Michigan, Missouri, Nebraska, Nevada, New Jersey, New York, North Carolina,  
3 North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee,  
4 Texas, Vermont, Washington, and Wisconsin. (collectively, the "Attorneys General," and the  
5 "AGs"), conducted an investigation under the State Consumer Protection Laws regarding certain  
6 Eli Lilly and Company ("Eli Lilly" or "Lilly") practices concerning Zyprexa®; and

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

13 C. The Parties have agreed to resolve the issues raised by the Covered Conduct by  
14 entering into this Judgment. Eli Lilly is entering into this Judgment solely for the purpose of  
15 settlement and nothing contained herein may be taken as or construed to be an admission or  
16 concession of any violation of law or regulation, or of any other matter of fact or law, or of any  
17 liability or wrongdoing, all of which Eli Lilly expressly denies. Lilly does not admit any  
18 violation of the State Consumer Protection Laws, and does not admit any wrongdoing that was  
19 or could have been alleged by any Attorney General before the date of the Judgment under those  
20 laws. No part of this Judgment, including its statements and commitments, shall constitute  
21 evidence of any liability, fault, or wrongdoing by Eli Lilly. Except in an action brought by an  
22 Attorney General to enforce this Judgment, this Judgment shall not be construed or used as a  
23 waiver or limitation of any defense otherwise available to Eli Lilly, including, but not limited to  
24 the defense of federal preemption, in other matters, or of Eli Lilly's right to defend itself from,  
25 or make any arguments in, any other matter, including, but not limited to, any investigation or  
26 litigation relating to the existence, subject matter or terms of this Judgment. This Judgment is

1 made without trial or adjudication of any issue of fact or law or finding of wrongdoing or  
2 liability of any kind. It is the intent of the Parties that this Judgment shall not be admissible in  
3 any other matter, including, but not limited to, any investigation or litigation, or bind Eli Lilly in  
4 any respect other than in connection with the enforcement of this Judgment. No part of this  
5 Judgment shall create a private cause of action or confer any right to any third party for violation  
6 of any federal or state statute except that a State may file an action to enforce the terms of this  
7 Judgment. All obligations undertaken by Eli Lilly in this Judgment shall apply prospectively;  
8 and nothing contained herein prevents or prohibits the use of this Judgment for purposes of  
9 enforcement by the AGs; and

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

12 E. This Judgment (or any portion thereof) shall in no way be construed to prohibit Eli  
13 Lilly from making representations with respect to Zyprexa® that are permitted under Federal  
14 law or in Labeling for the drug under the most current draft or final standard promulgated by the  
15 FDA or the most current draft or final FDA Guidances for Industry, or permitted or required  
16 under any Investigational New Drug Application, New Drug Application, Supplemental New  
17 Drug Application, or Abbreviated New Drug Application approved by FDA, so long as the  
18 representation, taken in its entirety, is not false, misleading or deceptive.

#### 19 DEFINITIONS

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

21 1. "Clinically Relevant Information" shall mean information that reasonably prudent  
22 clinicians would consider relevant when making prescribing decisions regarding Zyprexa®.

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

25 3. "Effective Date" shall mean the date on which a copy of this Judgment, duly  
26 executed by Lilly and by the Signatory Attorney General, is approved by, and becomes a

1 Judgment of, the Court or on November 1st, 2008, whichever is later.

2 4. "Eli Lilly and Company" shall mean Eli Lilly and Company, including all of its  
3 affiliates, subsidiaries and divisions, predecessors, successors and assigns doing business in the  
4 United States.

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

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

11 7. "Health Care Professional" or "HCP" shall mean any physician or other health  
12 care practitioner who is licensed to provide health care services or to prescribe pharmaceutical  
13 products.

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

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

21 10. "Lilly Legal" shall mean personnel of the Lilly Law Division or its designee  
22 providing legal advice to Lilly.

23 11. "Lilly Marketing" shall mean Lilly personnel assigned to the Lilly U.S. Zyprexa®  
24 marketing team.

25 12. "Lilly Medical" shall mean Lilly personnel assigned to the Lilly U.S. medical  
26 organization.

1           13. "Lilly Non-Medical" shall mean Lilly personnel other than Lilly personnel  
2 assigned to the U.S. Zyprexa® medical organization.

3           14. "Lilly Regulatory" shall mean Lilly personnel or their designee responsible for  
4 Lilly's adherence with FDA regulations.

5           15. "Lilly Sales" shall mean the Lilly sales force responsible for U.S. Zyprexa® sales.

6           16. "Medical Letter" shall mean a non-promotional, scientific communication to  
7 address Unsolicited Requests for medical information from HCPs.

8           17. "Medical Reference" shall mean a non-promotional reference communication that  
9 is used for responding to or answering a HCP's Unsolicited Request for medical information.

10          18. "Multistate Executive Committee" shall mean the Attorneys General and their  
11 staffs representing Arizona, California, Florida, Illinois, Ohio, Oregon, Texas and Vermont.

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

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

21          21. "Parties" shall mean Lilly and the Signatory Attorney General.

22          22. "Promotional," "Promoting" or "Promote" shall mean claims to HCPs about  
23 Zyprexa® intended to increase sales or attempt to influence prescribing practices of the HCPs.

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

26          24. "Promotional Slide Kit" shall mean Promotional Materials regarding Zyprexa® in

1 the form of a slide kit for use in speaker programs.

2 25. "Promotional Speaker" shall mean a non-Lilly HCP speaker used to Promote  
3 Zyprexa®.

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

6 27. "Signatory Attorney General" shall mean the Attorney General of Arizona, or his  
7 authorized designee, who has agreed to this Judgment.

8 28. "State Consumer Protection Laws" shall mean the consumer protection laws under  
9 which the Attorneys General have conducted the investigation, ALABAMA – Deceptive Trade  
10 Practices Act, Ala. Code § 8-19-1 *et seq.*; ARIZONA – Consumer Fraud Act, A.R.S. § 44-1521,  
11 *et seq.*; CALIFORNIA – Bus. & Prof. Code, §§ 17200 *et seq.*, and 17500 *et seq.*; DELAWARE-  
12 Consumer Fraud Act, 6 Del.C. Section 2511, *et seq.*; DISTRICT OF COLUMBIA – Consumer  
13 Protection Procedures Act, D.C. Code § 28-3901, *et seq.*; FLORIDA – Deceptive and Unfair  
14 Trade Practices Act, Fla. Stat. Ch. 501.201 *et seq.*; HAWAII - Uniform Deceptive Trade  
15 Practice Act, Haw. Rev. Stat. Ch. 481A and Haw. Rev. Stat. § 480-2.; ILLINOIS – Consumer  
16 Fraud and Deceptive Business Practices Act, 815 ILCS § 505/1 *et seq.*; INDIANA – Deceptive  
17 Consumer Sales Act, Ind. Code § 24-5-0.5-1 *et seq.*; IOWA – Iowa Consumer Fraud Act, Iowa  
18 Code Section 714.16; KANSAS – Consumer Protection Act, K.S.A. 50-623 *et seq.*; MAINE –  
19 Unfair Trade Practices Act, 5 M.R.S.A. § 207 *et seq.*; MARYLAND – Consumer Protection  
20 Act, Md. Code Ann., Com. Law § 13-101 *et seq.*; MASSACHUSETTS – Consumer Protection  
21 Act, M.G.L. c. 93A *et seq.*; MICHIGAN – Michigan Consumer Protection Act, MCL 445.901 *et*  
22 *seq.*; MISSOURI – Missouri Merchandising Practices Act, Mo. Rev. Stat. § 407.010 *et seq.*;  
23 NEBRASKA – Uniform Deceptive Trade Practices Act, NRS §§ 87-301 *et seq.*; NEVADA –  
24 Deceptive Trade Practices Act, Nevada Revised Statutes 598.0903 *et seq.*; NEW JERSEY –  
25 New Jersey Consumer Fraud Act, 56:8-1 *et seq.*; NEW YORK – General Business Law Article  
26 22-A Sections 349, 350 and Executive Law 63 (12); NORTH CAROLINA – Unfair and

1 Deceptive Trade Practices Act, N.C. Gen. Stat. § 75-1.1 *et seq.*; NORTH DAKOTA -Unlawful  
2 Sales or Advertising Practices, N.D. Cent. Code. § 51-15-02 *et seq.*; OHIO- Consumer Sales  
3 Practices Act, R.C. 1345.01, *et seq.*; OKLAHOMA – Oklahoma Consumer Protection Act 15  
4 O.S. §§ 751 *et seq.*; OREGON – Unlawful Trade Practices Act, ORS 646.605 to 646.656;  
5 PENNSYLVANIA – Unfair Trade Practices and Consumer Protection Law, 73 P.S. § 201-1 *et*  
6 *seq.*; RHODE ISLAND – R.I. Gen. L. § 6-13.1-1 *et seq.*; SOUTH DAKOTA – Deceptive Trade  
7 Practices Act, S.D. Codified Laws § 37-24, *et seq.*; TENNESSEE – Tennessee Consumer  
8 Protection Act, Tenn. Code Ann. §§ 47-18-101 *et seq.*; TEXAS – Deceptive Trade Practices –  
9 Consumer Protection Act, Tex. Bus. and Com. Code § 17.47, *et seq.*; VERMONT – Consumer  
10 Fraud Act, 9 V.S.A. § 2451 *et seq.*; WASHINGTON – Unfair Business Practices/Consumer  
11 Protection Act, R.C.W. 19.86 *et seq.*; WISCONSIN – Wis. Stat. § 100.18 (Fraudulent  
12 Representations).

13 29. “Unsolicited Request” shall mean a request for information regarding Zyprexa®  
14 from a HCP communicated to an agent of Lilly that has not been prompted.

15 30. “Zyprexa®” shall mean all FDA approved drug formulations containing  
16 olanzapine as its sole active ingredient and Promoted by Lilly.

### 17 COMPLIANCE PROVISIONS

#### 18 I. Promotional Activities

19 A. Lilly shall not make any written or oral claim that is false, misleading or deceptive  
20 regarding Zyprexa®.

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

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

26 1. The drug’s specific FDA-approved indication(s) being Promoted is/are stated

1 clearly and conspicuously in the same spread (*i.e.*, on the same page or on a facing page) in  
2 Promotional Materials as references to selected symptoms.

3 a. With respect to Promotional Slide Kits:

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

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

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

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

## 17 II. Dissemination of Medical Information

### 18 A. General Terms

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

### 21 B. Medical Letters and Medical References

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

24 2. Lilly Medical shall have ultimate responsibility for developing and approving the  
25 medical content for all Medical Letters and Medical References regarding Zyprexa®, including  
26 any that may describe Off-Label information. Additional approvals may be provided by Lilly

1 Regulatory and Lilly Legal. Lilly shall not distribute any such materials unless:

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

4 b. Data in these materials are presented in an unbiased, non-Promotional  
5 manner.

6 c. These materials are distinguishable from sales aids and other Promotional  
7 Materials.

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

12 4. Lilly Sales representatives shall not distribute Medical References or Medical  
13 Letters regarding Zyprexa®.

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

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

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

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

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

1 Off-Label use.

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

- 4 a. an existing Medical Letter prepared in accordance with Section II.B;
- 5 b. a Medical Letter or other document such as slides prepared in response to  
6 the request in accordance with Section II.B; or
- 7 c. a report containing the results of a reasonable literature search using terms  
8 from the request.

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

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

18 D. Reprints

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

21 2. Reprints Containing Off-Label Information

22 a. Lilly Medical shall be responsible for the identification, selection, approval  
23 and dissemination of Reprints Containing Off-Label Information regarding  
24 Zyprexa®.

25 b. Reprints Containing Off-Label Information regarding Zyprexa®:

26 (i) shall be accompanied by the full prescribing information for the

1 product and contain a disclosure in a prominent location, which would  
2 include the first page or as a cover page where practicable, indicating that  
3 the article may discuss Off-Label information; and

4 (ii) shall not be referred to or used in a Promotional manner.

5 c. Reprints Containing Off-Label Information regarding Zyprexa® may only  
6 be disseminated by Lilly Medical personnel to HCPs. Lilly Non-Medical  
7 personnel shall not disseminate these materials to HCPs, absent the exception  
8 described below in (i).

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

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

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

26 (b) If the State and Lilly do not come to a resolution, then the

1 State may initiate legal action to prevent the dissemination of the  
2 Reprint Containing Off-Label Information by Lilly Non-Medical  
3 personnel.

4 (c) If the State initiates legal action to prevent the dissemination  
5 of the Reprint Containing Off-Label Information by Lilly Non-  
6 Medical personnel, Lilly shall not use Lilly Non-Medical personnel  
7 to disseminate such Reprint Containing Off-Label Information in  
8 that State until the issue has been resolved.

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

13 E. Health Care Economic Information

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

20 III. Continuing Medical Education (CME) and Grants

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

23 B. Lilly shall disclose information about grants, including CME grants, regarding  
24 Zyprexa® consistent with the current disclosures of the Lilly Grant Office Registry at  
25 [www.lillygrantoffice.com](http://www.lillygrantoffice.com) (hereinafter, "LGO website") or as required by applicable law.

26 1. Lilly shall maintain this information on the LGO website once posted for at least

1 two years and shall maintain the information in a readily accessible format for review by the  
2 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  
5 shall be kept separate from the Lilly Sales and Lilly Marketing organizations.

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

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

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

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

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

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

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

23 H. Lilly shall contractually require the CME provider to disclose to CME program  
24 attendees Lilly's financial support of the CME program and any financial relationship with  
25 faculty and speakers at such CME. As part of the disclosure of a financial relationship with  
26 faculty and speakers, Lilly shall contractually require the CME program to identify the URL of a

1 Lilly website, and reference that website as the source for further information concerning grant  
2 funding regarding Zyprexa®.

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

6 **IV. Payments to Consultants and Speakers**

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

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

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

- 16 1. total compensation from Lilly for any Consulting or Promotional speaking fees;
- 17 2. total number of Promotional speaking events paid for by Lilly;
- 18 3. the state the Promotional Speaker/Consultant has provided to Lilly for contact  
19 purposes;
- 20 4. the state(s) in which the Promotional Speaker gave the Promotional presentations;
- 21 and
- 22 5. any other compensation from Lilly as set forth in IRS Form 1099.

23 On or before July 1, 2009, Lilly shall provide the data requested in Nos. 1-4 for the  
24 period January 1, 2009-March 31, 2009. On or before October 1, 2009, Lilly shall provide the  
25 data requested in Nos. 1-4 for the period April 1, 2009-June 30, 2009. On or before January 1,  
26 2010, Lilly shall provide the data requested in Nos. 1-4 for the period July 1, 2009 -

1 September 30, 2009. On or before April 1, 2010 and on or before April 1 of each subsequent  
2 year, Lilly shall provide the data requested in Nos. 1-5 for the full preceding calendar year.

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

5 **V. Product Samples**

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

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

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

17 **VI. Clinical Research**

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

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

1 trials that were completed after July 1, 2004.

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

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

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

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

13 4. present the information in a way that implies that the study represents larger or  
14 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 side effects,  
16 derived from pooling data from various insignificant or dissimilar studies in a way that suggests  
17 either that such statistics are valid if they are not or that they are derived from large or  
18 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, Lilly shall pay \$62  
21 million to be divided and paid by Lilly directly to each Signatory Attorney General of the  
22 Multistate Working Group in an amount to be designated by and in the sole discretion of the  
23 Multistate Executive Committee. Said payment shall be used by the States as and for attorneys'  
24 fees and other costs of investigation and litigation, or to be placed in, or applied to, the consumer  
25 protection enforcement fund, including future consumer protection enforcement, consumer  
26 education, litigation or local consumer aid fund or revolving fund, used to defray the costs of the

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

5 **VIII. Conflicts**

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

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

25 **IX. Release**

26 A. By its execution of this Judgment, State of Arizona releases and forever

1 discharges, to the fullest extent permitted by law, Eli Lilly and all of its past and present  
2 subsidiaries, divisions, affiliates, co-promoters, controlled joint ventures, predecessors,  
3 successors, and assigns and each and all of their current and former officers, directors,  
4 shareholders, employees, agents, contractors, and attorneys (collectively, the "Released Parties")  
5 of and from the following: all civil claims, causes of action, damages, restitution, fines, costs,  
6 attorneys fees, and penalties that the Arizona Attorney General could have asserted against the  
7 Released Parties under the Arizona Consumer Fraud Act, A.R.S. § 44-1521, *et seq.*, successor  
8 statutes, or common law claims concerning unfair, deceptive or fraudulent trade practices  
9 impacting consumers related to any conduct that has occurred at any time up to and including  
10 the Effective Date of this Judgment arising from the Covered Conduct that is the subject of this  
11 Judgment (collectively, the "Released Claims").

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

15 1. Any criminal liability that any person or entity, including Released Parties, has or  
16 may have to the State of Arizona;

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

20 a. State or federal antitrust violations;

21 b. Reporting practices, including "best price," "average wholesale price," or  
22 "wholesale acquisition cost;"

23 c. Medicaid violations, including federal Medicaid drug rebate statute  
24 violations, Medicaid fraud or abuse, Medicaid-related common law claims; and/or  
25 kickback violations related to any State's Medicaid program;

26 d. State false claims violations;

1 e. actions of state program payors arising from the purchase of Zyprexa®,  
2 except for the release of civil penalties under the state consumer protection laws;  
3 and

4 f. Any liability under the State of Arizona's above-cited Consumer Protection  
5 Law which the Released Parties have or may have to individual consumers.

6 **X. Cure Provision**

7 A. The Parties agree that a State will provide Lilly with written notice if it believes  
8 that Lilly is in violation of any of its obligations under the Judgment ("Notice"). Lilly shall have  
9 30 business days after the date of receipt of the Notice to demonstrate to the State's satisfaction  
10 that:

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

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

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

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

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

23 D. Nothing prohibits a State from taking actions necessary to protect public health  
24 and safety as provided by applicable law.

25 **XI. General Provisions**

26 A. All Notices under this Judgment shall be provided to Nina Gussack, Paul Kalb,

1 and the General Counsel of Eli Lilly and Company by Overnight Mail at:

2 Nina Gussack  
3 Pepper Hamilton  
4 3000 Two Logan Square  
5 Eighteenth and Arch Streets  
6 Philadelphia, PA 19103-2799

7 Paul E. Kalb  
8 Sidley Austin LLP  
9 1501 K Street, NW  
10 Washington, DC 20005

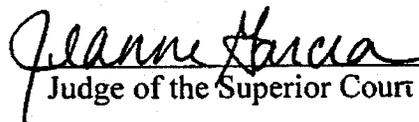
11 General Counsel  
12 Eli Lilly and Company  
13 Lilly Corporate Center  
14 Indianapolis, IN 46285

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

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

22 D. This Judgment may be executed in counterparts, and a facsimile or .pdf signature  
23 shall be deemed to be, and shall have the same force and effect as, an original signature.

24 DATED this 20 day of October, 2008.

25   
26 Judge of the Superior Court

TUC-CLU-2008-0015 / 295126

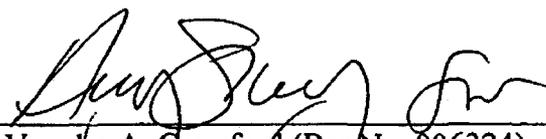
Hon. Jeanne Garcia



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FOR ELI LILLY:

Approved as to form:

By: 

Date: October 2, 2008

Vaughn A. Crawford (Bar No. 006324)  
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Counsel for Eli Lilly and Company

1 FOR THE STATE:

2

TERRY GODDARD

3

Attorney General

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By: *Dena Rosen Epstein*

Date: *October 7, 2008*

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Dena Rosen Epstein, Unit Chief Counsel

Noreen R. Matts, Unit Chief Counsel

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