STATE OF MAINE
KENNEBEC, SS.

SUPERIOR COURT
CIVIL ACTION
DOCKET NO.

STATE OF MAINE	)	
	)	
	)	
	)	
Plaintiff,	)	
	)	**COMPLAINT FOR INJUNCTIVE**
v.	)	**AND OTHER RELIEF**
	)	
ELI LILLY AND COMPANY,	)	
	)	
Defendant.	)	

1. Plaintiff, State of Maine, by and through its Attorney General G. Steven Rowe, brings this action complaining of Defendant ELI LILLY AND COMPANY, an Indiana corporation, for violating the Maine Unfair Trade Practices Act as follows:

PARTIES

2. Plaintiff, State of Maine, is represented by the Attorney General who brings this action in the public interest pursuant to 5 M.R.S.A. § 209.

3. Defendant ELI LILLY AND COMPANY ("Lilly" or "Defendant") is an Indiana corporation that conducts business nationwide, including in the State of Maine; its principal place of business is Lilly Corporate Center, Indianapolis, Indiana 46285. Eli Lilly, at all times relevant hereto, engaged and trade and commerce within the meaning of the Maine Unfair Trade Practices Act, 5 M.R.S.A. § 205-A *et seq.*, in the State of Maine.

JURISDICTION AND VENUE

4. This court has jurisdiction over the subject matter and defendants of this action pursuant to 5 M.R.S.A. § 209.

5. In accordance with 5 M.R.S.A. § 209, venue is proper in this court.

6. The Maine Unfair Trade Practices Act, 5 M.R.S.A. § 205-A *et seq.*, makes unlawful unfair or deceptive acts or practices in the conduct of any trade or commerce, and authorizes the Attorney General to bring enforcement actions to obtain permanent injunctive relief and recover restitution and civil penalties up to $10,000 for each intentional violation. 5 M.R.S.A. § 207, 209.

BACKGROUND

7. 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, it was hypothesized that they might be used as long-term treatment for schizophrenia without posing the same risks as first-generation antipsychotics. More specifically, experts thought that atypical antipsychotics would be less likely to produce extrapyramidal symptoms ("EPS") and tardive dyskinesia ("TD").

8. While these drugs may reduce the risk of EPS and TD associated with first-generation antipsychotics, they also produce dangerous side effects, including weight gain, hyperglycemia, diabetes, cardiovascular complications, and other severe conditions. Zyprexa has been shown to pose a high risk of weight gain, hyperglycemia, and diabetes.

DEFENDANT'S COURSE OF CONDUCT

9. Lilly began marketing Zyprexa to health care professionals for the treatment of schizophrenia in 1996. Since then, the Food and Drug Administration ("FDA") has approved

Zyprexa for, *inter alia,* the treatment of acute mixed or manic episodes of bipolar I disorder and for maintenance treatment in bipolar disorder.

10. In 2001, Lilly engaged in an aggressive marketing campaign called "Viva Zyprexa!" As part of that campaign, the company marketed Zyprexa for a number of uses for which it was not approved by the FDA. For example, Lilly marketed Zyprexa for pediatric use, for use at high dosage levels, for the treatment of symptoms rather than diagnosed conditions, and for the treatment and/or chemical restraint of patients suffering from dementia.

11. Through this Viva Zyprexa! campaign, and all of the company's efforts to promote Zyprexa for uses for which it was not approved by the FDA, Lilly misrepresented the drug's approved uses, its safety, and its effectiveness.

VIOLATIONS OF LAW

12. The allegations contained in paragraphs 1-11 are incorporated herein by reference.

13. The Defendant, in the course of advertising, soliciting, selling, promoting and distributing the prescription drug Zyprexa, has engaged in a course of trade or commerce which constitutes unfair or deceptive acts or practices, and is therefore unlawful under the Maine Unfair Trade Practices Act by misrepresenting that Zyprexa had characteristics, uses, benefits, and qualities that it does not have.

PRAYER FOR RELIEF

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

A. Issuing a permanent injunction prohibiting Defendant, its agents, employees,

and all other persons and entities, corporate or otherwise, in active concert or participation with any of them, from engaging in unfair or deceptive conduct;

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

C. Ordering Defendant to pay civil penalties for each and every violation of the Maine Unfair Trade Practices Act; and

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

Respectfully submitted,

PLAINTIFF STATE OF MAINE

G. STEVEN ROWE
ATTORNEY GENERAL

Dated: October 7, 2008

BY: Christina M. Moylan

Christina M. Moylan
Assistant Attorney General
Department of Attorney General
6 State House Station
Augusta, Maine 04333-0006
Maine Bar No. 7095

Tine

STATE OF MAINE | **SUPERIOR COURT**

KENNEBEC, SS. | **CIVIL ACTION**

Docket No. ~~CV-08-327~~ BCD-WB-CV-08-38

STATE OF MAINE,	:	
	:	
Plaintiff	:	
v.	:	
	:	**CONSENT JUDGMENT**
ELI LILLY AND COMPANY,	:	
	:	
Defendant	:	

PREAMBLE

A. The Attorneys General of the States of Alabama, Arizona, California, Delaware, District of Columbia, Florida, Hawaii, Illinois, Indiana, Iowa, Kansas, Maine, Maryland, Massachusetts, Michigan, Missouri, Nebraska, Nevada, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, 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

B. The Plaintiff, State of Maine, acting through Attorney General G. Steven Rowe, has brought this action pursuant to the Maine Unfair Trade Practices Act, 5 M.R.S.A. § 205-A *et seq.*, having filed a complaint against Eli Lilly; and

C. Eli Lilly is willing to enter into a Consent Judgment (the "Judgment") regarding its promotional practices, sampling practices, dissemination of information, and remuneration to Health Care Professionals regarding Zyprexa® ("Covered Conduct") in order to resolve the 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. Eli Lilly denies the allegations of the Complaint and denies having violated the Unfair Trade Practices Act; and

D. The Parties have agreed to resolve the issues raised by the Covered Conduct by 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

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

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

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

IT IS HEREBY ORDERED that:

DEFINITIONS

The following definitions shall be used in construing this Judgment:

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

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

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

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

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

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

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

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

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

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

11. "Lilly Marketing" shall mean Lilly personnel assigned to the Lilly U.S. 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.

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

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

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

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

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

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

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

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

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

25. "Promotional Speaker" shall mean a non-Lilly HCP speaker used to 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 Maine, 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 seq.; DELAWARE - Consumer Fraud Act, 6 Del.C. Section 2511, et seq.; DISTRICT OF COLUMBIA - Consumer Protection Procedures Act, D.C. Code § 28-3901, et seq.; FLORIDA - Deceptive and Unfair Trade Practices Act, Fla. Stat. Ch. 501.201 et seq.; HAWAII - Uniform Deceptive Trade Practice Act, Haw. Rev. Stat. Ch. 481A and Haw. Rev. Stat. § 480-2.;

ILLINOIS - Consumer Fraud and Deceptive Business Practices Act, 815 ILCS § 505/1 et seq.; INDIANA - Deceptive Consumer Sales Act, Ind. Code § 24-5-0.5-1 et seq.; IOWA - Iowa Consumer Fraud Act, Iowa Code Section 714.16; KANSAS - Consumer Protection Act, K.S.A. 50-623 et seq.; MAINE - Unfair Trade Practices Act, 5 M.R.S.A. § 207 et seq.; MARYLAND - Consumer Protection Act, Md. Code Ann., Com. Law § 13-101 et seq.; MASSACHUSETTS - Consumer Protection Act, M.G.L. c. 93A et seq.; MICHIGAN - Michigan Consumer Protection Act, MCL 445.901 et seq.; MISSOURI - Missouri Merchandising Practices Act, Mo. Rev. Stat. § 407.010 et seq.; NEBRASKA - Uniform Deceptive Trade Practices Act, NRS §§ 87-301 et seq.; NEVADA - Deceptive Trade Practices Act, Nevada Revised Statutes 598.0903 et seq.; NEW JERSEY - New Jersey Consumer Fraud Act, 56:8-1 et seq.; NEW YORK - General Business Law Article 22-A Sections 349, 350 and Executive Law 63 (12); NORTH CAROLINA - Unfair and Deceptive Trade Practices Act, N.C. Gen. Stat. § 75-1.1 et seq.; NORTH DAKOTA -Unlawful Sales or Advertising Practices, N.D. Cent. Code. § 51-15-02 et seq.; OHIO- Consumer Sales Practices Act, R.C. 1345.01, et seq.; OKLAHOMA - Oklahoma Consumer Protection Act 15 O.S. §§ 751 et seq.; OREGON - Unlawful Trade Practices Act, ORS 646.605 to 646.656; PENNSYLVANIA - Unfair Trade Practices and Consumer Protection Law, 73 P.S. § 201-1 et seq.; RHODE ISLAND - R.I. Gen. L. § 6-13.1-1 et seq.; SOUTH DAKOTA - Deceptive Trade Practices Act, S.D. Codified Laws § 37-24, et seq.; TENNESSEE - Tennessee Consumer Protection Act, Tenn. Code Ann. §§ 47-18-101 et seq.; 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, R.C.W. 19.86 et seq.; WISCONSIN - Wis. Stat. § 100.18 (Fraudulent Representations).

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

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

COMPLIANCE PROVISIONS

I. Promotional Activities

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

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

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

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

a. With respect to Promotional Slide Kits:

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

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

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

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

II. Dissemination of Medical Information

A. General Terms

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

B. Medical Letters and Medical References

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

2. Lilly Medical shall have ultimate responsibility for developing and 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 provided by Lilly Regulatory and Lilly Legal. Lilly shall not distribute any such materials unless:

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

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

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

3. Lilly Sales and Lilly Marketing personnel shall not develop the medical content of Medical References or Medical Letters regarding Zyprexa. This provision does not

prohibit Lilly Sales or Lilly Marketing personnel from suggesting topics for Medical Letters or Medical References.

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

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

C. Responses to Unsolicited Requests for Off-Label information

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

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

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

4. Any written response to an Unsolicited Request for Off-Label information 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.

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

D. Reprints

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

2. Reprints Containing Off-Label Information

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

b. Reprints Containing Off-Label Information regarding Zyprexa:

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

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

(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 Lilly with written notice within 30 business days and provide Lilly an opportunity to discuss its desired use of the

Reprint Containing Off-Label Information pursuant to the limited exception.

(b) If the State and Lilly 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 Lilly Non-Medical personnel.

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

3. Nothing in this Judgment shall preclude Lilly from disseminating reprints 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.2.b(i) in a prominent location, as defined above.

E. Health Care Economic Information

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

III. Continuing Medical Education (CME) and Grants

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

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

C. The Lilly Grant Office shall manage all requests for funding related to CME 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.

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

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

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

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

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

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

G. Lilly Sales and Lilly Marketing personnel shall not approve grant requests 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.

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

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

IV. Payments to Consultants and Speakers

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

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

C. Lilly shall provide to each Signatory Attorney General, in an electronic spreadsheet format, a list of HCP Promotional Speakers and Consultants who were paid by Lilly 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 additional information with respect to each individual Promotional Speaker and/or Consultant:

1. total compensation from Lilly for any Consulting or Promotional speaking fees;

2. total number of Promotional speaking events paid for by Lilly;

3. the state the Promotional Speaker/Consultant has provided to Lilly for contact purposes;

4. the state(s) in which the Promotional Speaker gave the Promotional presentations; and

5. any other compensation from Lilly as set forth in IRS Form 1099.

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

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

V. Product Samples

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

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

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 practitioner can speak directly with a Lilly representative who will provide answers to their questions about Zyprexa and may provide them with samples if appropriate (i.e., if the physician requests the sample for an on-label use).

VI. Clinical Research

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

1. To the extent permitted by the National Library of Medicine and as required by the FDA Amendments Act (Public Law No. 110-85), Lilly shall register clinical trials and submit results to the registry and results data bank regarding Zyprexa as required by the FDA Amendments Act and any accompanying regulations that may be promulgated pursuant

to that Act. With respect to Zyprexa, Lilly will register on a publicly accessible website the initiation of all Lilly-sponsored Phase II, III, and IV clinical trials beginning after July 1, 2005 and will post results on a publicly accessible website of all Lilly-sponsored Phase II, III and IV clinical trials that were completed after July 1, 2004. Nothing in this paragraph shall be construed to exempt Lilly from full compliance with Maine's Prescription Drug Clinical Trial Reporting Rule: DHHS Rule 10-144 ch. 275 AG Rule 26-0259 Ch. 111.

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

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

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

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

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

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

VII. Terms Relating to Payment

A. No later than 30 days after the Effective Date of this Judgment, Lilly shall pay $62 million to be divided and paid by Lilly directly to each Signatory Attorney General of the Multistate Working Group in an amount to be designated by and in the sole discretion of the Multistate Executive Committee. Said payment shall be used by the States as and for attorneys' fees and other costs of investigation and litigation, or to be placed in, or applied to, the consumer protection enforcement fund, including future consumer protection enforcement, consumer education, litigation or local consumer aid fund or revolving fund, used to defray the costs of the inquiry leading hereto, and may be used to fund or assist in funding programs directed at mental illness treatment, including but not limited to education and outreach or for other uses permitted by state law, at the sole discretion of each Signatory Attorney General. The Parties acknowledge that the payment described herein is not a fine or penalty, or payment in lieu thereof.

VIII. Conflicts

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

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

IX. Release

A. By its execution of this Judgment, State of Maine releases and forever discharges, to the fullest extent permitted by law, Eli Lilly and all of its past and present subsidiaries, divisions, affiliates, co-promoters, controlled joint ventures, predecessors, successors, and assigns and each and all of their current and former officers, directors, shareholders, employees, agents, contractors, and attorneys (collectively, the "Released Parties") of and from the following: all civil claims, causes of action, damages, restitution, fines, costs, attorneys fees, and penalties that the Maine Attorney General could have asserted against the Released Parties under the Maine Unfair Trade Practices Act, successor statutes, or common law claims concerning unfair, deceptive or fraudulent trade practices impacting consumers related to any conduct that has occurred at any time up to and including the Effective Date of this Judgment arising from the Covered Conduct that is the subject of this Judgment (collectively, the "Released Claims").

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

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

2. Any civil or administrative liability that any person or entity, including Released Parties, has or may have to the State of Maine that is not expressly covered by the release in Section IX.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, Medicaid-related common law claims; and/or kickback violations related to any State's Medicaid program;

d. State false claims violations;

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

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

X. Cure Provision

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

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

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

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

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

XI. General Provisions

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

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

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

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

Nina Gussack
Pepper Hamilton
3000 Two Logan Square
Eighteenth and Arch Streets
Philadelphia, PA 19103-2799

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

XII. SIGNATURES

FOR ELI LILLY:

By: _____

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

Date: 10/1/08

Approved as to form:

By: _____

Nicholas Gess, Bar No. 002504
Bingham McCutchen LLP
2020 K Street NW
Washington, DC 20006
202-373-6218
202-373-6491-Fax
Nicholas.gess@bingham.com

Attorney for Eli Lilly and Company

Date: October 2, 2008

FOR THE STATE:

ATTORNEY GENERAL G. STEVEN ROWE

By: Christina M. Moylan

Christina M. Moylan, Assistant Attorney General
Office of the Maine Attorney General
111 Sewall Street
6 State House Station
Augusta, Maine 04333-0006

Date: 10-7-08

APPROVED:

Judge/Justice

11/3/08

Date