

OFFICE COPY
ATTORNEY GENERAL

F I L E D
Clerk of the Superior Court

OCT 08 2008

By: R. SMITH, Deputy

SUPERIOR COURT OF THE STATE OF CALIFORNIA
FOR THE COUNTY OF SAN DIEGO

THE PEOPLE OF THE STATE OF CALIFORNIA

Plaintiff,

v.

ELI LILLY and COMPANY

Defendant.

FINAL JUDGMENT

Case No. **37-2008-00093311-CU-PT-CTL**

Plaintiff the People of the State of California, ("Plaintiff" or the "People"), having filed its complaint and appearing through its attorney, Edmund G. Brown Jr., Attorney General, by Albert Norman Shelden, Special Assistant Attorney General and Judith Fiorentini, Deputy Attorney General, and Eli Lilly and Company ("Eli Lilly" or "Defendant") by its attorneys Pepper Hamilton by James N. Godes having stipulated as follows:

That this Final Judgment (hereafter "Judgment") may be signed by any judge of the San Diego Superior Court; and,

That Plaintiff has filed its Complaint in this matter pursuant to California Business and Professions Code sections 17200 and 17500 *et seq.*; and, Eli Lilly denies the allegations of the Complaint and denies any alleged violations; and,

That this Judgment is made without trial or adjudication of any issue of fact or law or finding of wrongdoing or liability of any kind, and that Eli Lilly does not admit any violation of law or any wrongdoing and that no part of this Judgment, including its statements and commitments, shall constitute evidence of any liability, fault or wrongdoing by Eli Lilly; and,

1 The Court having considered the pleadings and the Stipulation for Entry of Final Judgment
2 executed by the Plaintiff and Eli Lilly and filed herewith, and good cause appearing,

3 IT IS HEREBY ORDERED, ADJUDGED AND DECREED as follows:

4 **PARTIES and JURISDICTION**

5 I. The People of the State of California is the Plaintiff in this case and Eli Lilly and
6 Company, is the Defendant in this case.

7 II. The Court has jurisdiction over the subject matter of this action, jurisdiction over the
8 parties to this action, and venue is proper in this Court.

9 **DEFINITIONS**

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

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

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

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

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

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

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

27 G. "Health Care Professional" or "HCP" shall mean any physician or other health
28 care practitioner who is licensed to provide health care services or to prescribe

1 pharmaceutical products.

2 H. "Labeling" shall mean all FDA-approved labels, which are a display of written,
3 printed, or graphic matter upon the immediate container of any article, and other written,
4 printed, or graphic matters (1) upon any article or any of its containers or wrappers, or (2)
5 accompanying such article.

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

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

11 K. "Lilly Marketing" shall mean Lilly personnel assigned to the Lilly U.S. Zyprexa
12 marketing team.

13 L. "Lilly Medical" shall mean Lilly personnel assigned to the Lilly U.S. medical
14 organization.

15 M. "Lilly Non-Medical" shall mean Lilly personnel other than Lilly personnel
16 assigned to the U.S. Zyprexa medical organization.

17 N. "Lilly Regulatory" shall mean Lilly personnel or their designee responsible for
18 Lilly's adherence with FDA regulations.

19 O. "Lilly Sales" shall mean the Lilly sales force responsible for U.S. Zyprexa sales.

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

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

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

27

28 S. "Multistate Working Group" shall mean the Attorneys General and their staff

1 representing Alabama, Arizona, California, Delaware, District of Columbia, Florida,
2 Hawaii, Illinois, Indiana, Iowa, Kansas, Maine, Maryland, Massachusetts, Michigan,
3 Missouri, Nebraska, Nevada, New Jersey, New York, North Carolina, North Dakota, Ohio,
4 Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Texas,
5 Vermont, Washington, and Wisconsin.

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

9 U. "Parties" shall mean Lilly and the Signatory Attorney General.

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

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

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

17 Y. "Promotional Speaker" shall mean a non-Lilly HCP speaker used to Promote
18 Zyprexa.

19 Z. "Reprints Containing Off-Label Information" shall mean articles or reprints from
20 a peer reviewed journal or reference publication describing an Off-Label use of Zyprexa.

21 AA. "Signatory Attorney General" shall mean the Attorney General of California, or
22 his authorized designee, who has agreed to this Judgment.

23 BB. "State Consumer Protection Laws" shall mean the consumer protection laws
24 under which the Attorney General has conducted the investigation, ALABAMA- Deceptive
25 Trade Practices Act, Ala. Code §§ 8-19-1 et seq.; ARIZONA - Consumer Fraud Act, A.R.S.
26 § 44-1521, et seq.; CALIFORNIA - Bus. & Prof. Code, §§ 17200 et seq., and 17500 et seq.;
27 DELAWARE-Consumer Fraud Act, 6 Del.C. Section 2511, et seq.; DISTRICT OF
28 COLUMBIA - Consumer Protection Procedures Act, D.C. Code § 28-3901, et seq.;

1 FLORIDA - Deceptive and Unfair Trade Practices Act, Fla. Stat. Ch. 501.201 et seq.;

2 HAWAII- Uniform Deceptive Trade Practice Act, Haw. Rev. Stat. Ch. 481A and Haw. Rev.

3 Stat. § 480-2.; ILLINOIS - Consumer Fraud and Deceptive Business Practices Act, 815

4 ILCS § 505/1 et seq.; INDIANA - Deceptive Consumer Sales Act, Ind. Code §§ 24-5-0.5-1

5 et seq; IOWA - Iowa Consumer Fraud Act, Iowa Code Section 714.16; KANSAS -

6 Consumer Protection Act, K.S.A. 50-623 et seq.; MAINE - Unfair Trade Practices Act, 5

7 M.R.S.A. § 207 et seq.; MARYLAND - Consumer Protection Act, Md. Code Ann., Com.

8 Law § 13-101 et seq.; MASSACHUSETTS - Consumer Protection Act, M.G.L. c. 93A et

9 seq.; MICHIGAN - Michigan Consumer Protection Act, MCL 445.901 et seq.; MISSOURI

10 - Missouri Merchandising Practices Act, Mo. Rev. Stat. § 407.010 et seq.; NEBRASKA -

11 Uniform Deceptive Trade Practices Act, NRS §§ 87-301 et seq.; NEVADA - Deceptive

12 Trade Practices Act, Nevada Revised Statutes 598.0903 et seq.; NEW JERSEY - New

13 Jersey Consumer Fraud Act, 56:8-1 et seq.; NEW YORK - General Business Law Article

14 22-A Sections 349, 350 and Executive Law 63 (12); NORTH CAROLINA - Unfair and

15 Deceptive Trade Practices Act, N.C. Gen. Stat. § 75-1.1 et seq.; NORTH DAKOTA

16 -Unlawful Sales or Advertising Practices, N.D. Cent. Code. § 51-15-02 et seq.; OHIO-

17 Consumer Sales Practices Act, R.C. 1345.01, et seq.; OKLAHOMA - Oklahoma Consumer

18 Protection Act 15 O.S. §§ 751 et seq.; OREGON - Unlawful Trade Practices Act, ORS

19 646.605 to 646.656; PENNSYLVANIA - Unfair Trade Practices and Consumer Protection

20 Law, 73 P.S. § 201-1 et seq.; RHODE ISLAND - R.I. Gen. L. § 6-13.1-1 et seq.; SOUTH

21 DAKOTA - Deceptive Trade Practices Act, S.D. Codified Laws § 37-24, et seq.;

22 TENNESSEE-Tennessee - Consumer Protection Act, Tenn. Code Ann. §§ 47-18-101 et

23 seq.; TEXAS - Deceptive Trade Practices - Consumer Protection Act, Tex. Bus. and Com.

24 Code § 17.47, et seq.; VERMONT - Consumer Fraud Act, 9 V.S.A. § 2451 et seq.;

25 WASHINGTON - Unfair Business Practices/Consumer Protection Act, R.C.W. 19.86 et

26 seq.; WISCONSIN - Wis. Stat. § 100.18 (Fraudulent Representations).

27 CC. "Unsolicited Request" shall mean a request for information regarding Zyprexa

28 from a HCP communicated to an agent of Lilly that has not been prompted.

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

3 **COMPLIANCE PROVISIONS**

4 IV. Promotional Activities

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

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

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

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

15 a. With respect to Promotional Slide Kits:

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

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

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

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

1 applicable.

2 V. Dissemination of Medical Information

3 A. General Terms

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

6 B. Medical Letters and Medical References

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

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

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

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

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

20 3. Lilly Sales and Lilly Marketing personnel shall not develop the medical
21 content of Medical References or Medical Letters regarding Zyprexa. This provision
22 does not prohibit Lilly Sales or Lilly Marketing personnel from suggesting topics for
23 Medical Letters or Medical References.

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

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

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

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

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

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

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

- 15 a. an existing Medical Letter prepared in accordance with Section V.B;
- 16 b. a Medical Letter or other document such as slides prepared in response
17 to the request in accordance with Section V.B; or
- 18 c. a report containing the results of a reasonable literature search using
19 terms from the request.

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

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

1 information.

2 D. Reprints

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

5 2. Reprints Containing Off-Label Information

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

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

10 (i) shall be accompanied by the full prescribing information for the
11 product and contain a disclosure in a prominent location, which would
12 include the first page or as a cover page where practicable, indicating that
13 the article may discuss Off-Label information; and

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

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

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

25 (ii) If the Clinical Necessity Exception is invoked, Lilly will notify
26 each Signatory Attorney General of its intent to invoke the Clinical
27 Necessity Exception at least 30 business days prior to disseminating through
28 Lilly Sales representatives of any Reprint Containing Off-Label Information

1 on Zyprexa.

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

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

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

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

21 E. Health Care Economic Information

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

28 VI. Continuing Medical Education (CME) and Grants

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

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

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

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

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

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

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

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

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

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

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

1 H. Lilly shall contractually require the CME provider to disclose to CME program
2 attendees Lilly's financial support of the CME program and any financial relationship with
3 faculty and speakers at such CME. As part of the disclosure of a financial relationship with
4 faculty and speakers, Lilly shall contractually require the CME program to identify the URL
5 of a Lilly website, and reference that website as the source for further information
6 concerning grant funding regarding Zyprexa and certain speakers or Consultants as
7 referenced below.

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

11 VII. Payments to Consultants and Speakers

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

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

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

- 22 1. total compensation from Lilly for any Consulting or Promotional speaking
23 fees;
- 24 2. total number of Promotional speaking events paid for by Lilly;
- 25 3. the state the Promotional Speaker/Consultant has provided to Lilly for
26 contact purposes;
- 27 4. the state(s) in which the Promotional Speaker gave the Promotional
28 presentations; and

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

2 On or before July 1, 2009, Lilly shall provide the data requested in Nos. 1-4 for the period
3 January 1, 2009-March 31, 2009. On or before October 1, 2009, Lilly shall provide the data
4 requested in Nos. 1-4 for the period April 1, 2009-June 30, 2009. On or before January 1, 2010,
5 Lilly shall provide the data requested in Nos. 1-4 for the period July 1, 2009-September 30,
6 2009. On or before April 1, 2010 and on or before April 1 of each subsequent year, Lilly shall
7 provide the data requested in Nos. 1-5 for the full preceding calendar year.

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

10 VIII. Product Samples

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

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

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

22 IX. Clinical Research

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

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

1 promulgated pursuant to that Act. With respect to Zyprexa, Lilly will register on a
2 publicly accessible website the initiation of all Lilly-sponsored Phase II, III, and IV
3 clinical trials beginning after July 1, 2005 and will post results on a publicly accessible
4 website of all Lilly-sponsored Phase II, III and IV clinical trials that were completed
5 after July 1, 2004.

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

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

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

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

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

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

26 X. Terms Relating to Payment

27 No later than 30 days after the Effective Date of this Judgment, Lilly shall pay
28 \$62 million to be divided and paid by Lilly directly to each Signatory Attorney General of

1 the Multistate Working Group in an amount to be designated by and in the sole discretion of
2 the Multistate Executive Committee. Said payment shall be used by the States as and for
3 attorneys' fees and other costs of investigation and litigation, or to be placed in, or applied
4 to, the consumer protection enforcement fund, including future consumer protection
5 enforcement, consumer education, litigation or local consumer aid fund or revolving fund,
6 used to defray the costs of the inquiry leading hereto, and may be used to fund or assist in
7 funding programs directed at mental illness treatment, including but not limited to
8 education and outreach or for other uses permitted by state law, at the sole discretion of
9 each Signatory Attorney General. Plaintiff may, if it so chooses, forward the sum, or any
10 portion thereof, that it receives to a third party organization, entity, or person of its
11 choosing, which shall act as the administrator in distributing such funds for the purposes set
12 forth in this paragraph.

13 XI. Conflicts

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

28 B. If, subsequent to the Effective Date of this Judgment, the laws or regulations of

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

6 XII. Release

7 A. By its execution of this Judgment, State of California releases and forever
8 discharges, to the fullest extent permitted by law, Eli Lilly and all of its past and present
9 subsidiaries, divisions, affiliates, co-promoters, controlled joint ventures, predecessors,
10 successors, and assigns and each and all of their current and former officers, directors,
11 shareholders, employees, agents, contractors, and attorneys (collectively, the "Released
12 Parties") of and from the following: all civil claims, causes of action, damages, restitution,
13 fines, costs, attorneys fees, and penalties that the California Attorney General could have
14 asserted against the Released Parties under California Business and Professions Code
15 sections 17200 and 17500, successor statutes, or common law claims concerning unfair,
16 deceptive or fraudulent trade practices impacting consumers related to any conduct that has
17 occurred at any time up to and including the Effective Date of this Judgment arising from
18 the Covered Conduct that is the subject of this Judgment (collectively, the "Released
19 Claims").

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

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

25 2. Any civil or administrative liability that any person or entity, including
26 Released Parties, has or may have to the State of California that is not expressly
27 covered by the release in Section XII.A. above, including but not limited to any and all
28 of the following claims:

- 1 a. State or federal antitrust violations;
- 2 b. Reporting practices, including "best price," "average wholesale price,"
- 3 or "wholesale acquisition cost;"
- 4 c. Medicaid violations, including federal Medicaid drug rebate statute
- 5 violations, Medicaid fraud or abuse, Medicaid-related common law claims; and/or
- 6 kickback violations related to any State's Medicaid program;
- 7 d. State false claims violations;
- 8 e. actions of state program payors arising from the purchase of Zyprexa,
- 9 except for the release of civil penalties under the state consumer protection laws;
- 10 and
- 11 f. Any liability under the State of California's above-cited Consumer
- 12 Protection Law which the Released Parties have or may have to individual
- 13 consumers.

14 XIII. Cure Provision

15 A. The Parties agree that a State will provide Lilly with written notice if it believes

16 that Lilly is in violation of any of its obligations under the Judgment ("Notice"). Lilly shall

17 have 30 business days after the date of receipt of the Notice to demonstrate to the State's

18 satisfaction that:

- 19 1. Lilly is in compliance with the obligations of the Judgment cited by that
- 20 State as being violated;
- 21 2. the violation has been cured, including, but not limited to, by remedial
- 22 actions having been taken against an employee for actions inconsistent with this
- 23 Judgment; or
- 24 3. the alleged violation cannot be cured within the 30 business day period, but
- 25 that: (a) Lilly has begun to take action to cure the violation; (b) Lilly is pursuing such
- 26 action with due diligence; and (c) Lilly has provided a reasonable timetable for curing
- 27 the violation.

28 B. Except as set forth in Section XIII.D. below, the State may not take any action

1 during the 30 business day cure period. Nothing shall prevent the State from agreeing in
2 writing to provide Eli Lilly with additional time beyond the 30 business days to respond to
3 the notice.

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

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

8 XIV. General Provisions

9 A. Except in an action brought by the Attorney General to enforce this Judgment,
10 this Judgment shall not be construed or used as a waiver or limitation of any defense
11 otherwise available to Eli Lilly, including, but not limited to the defense of federal
12 preemption, in other matters, or of Eli Lilly's right to defend itself from, or make any
13 arguments in, any other matter, including, but not limited to, any investigation or litigation
14 relating to the existence, subject matter or terms of this Judgment.

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

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

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

28 Nina Gussack
Pepper Hamilton

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

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

E. The Clerk is ordered to enter this Judgment forthwith.

Dated: October 8, 2008

KEVIN A. ENRIGHT

JUDGE OF THE SUPERIOR COURT