

JURISDICTION AND VENUE

1. Jurisdiction over the subject matter of this complaint is based upon Title 26, Chapter 20 of the Utah Health Code, which provides remedies to redress Defendant's actions under the Utah False Claims Act. The Attorney General files this action pursuant to Title 67, Chapter 5, Section 1(18) of the Utah Code.

2. Personal jurisdiction over Defendant is proper under the Utah Long Arm Statute as codified in §§ 78-27-22 and 78-27-24 of the Utah Code Annotated.

3. Venue is proper in the Third Judicial District and Salt Lake County pursuant to Utah Code Annotated § 78-13-7, in that many of the unlawful acts committed by Defendant were committed in Salt Lake County, including the making of false statements and misrepresentations of material fact to the State of Utah, its departments, agencies, instrumentalities, and contractors, and to the Utah Medicaid Program.

PARTIES

4. Plaintiff is the State of Utah.

5. Defendant Eli Lilly & Company is an Indiana corporation with its principal place of business in Indianapolis, Indiana. At all times relevant hereto, Eli Lilly & Company was engaged in the business of licensing, manufacturing, marketing, distributing, and/or selling, either directly or indirectly, through third parties or related entities, the prescription drug Zyprexa (hereinafter "Zyprexa" or "the product"). At all times relevant to this action, Eli Lilly did business within the State of Utah by marketing and selling Zyprexa within the State to the State, its agencies, and to the general public.

NATURE OF THE CASE

6. This is a civil action for damages and civil penalties pursuant to the Utah False Claims Act and other statutory and common law causes of action.

THE MEDICAID PROGRAM

7. The Utah Medicaid program provides medical assistance to low-income state residents. The primary purpose of the Medicaid program is to enable the State to furnish medical assistance on behalf of families with dependent children and of aged, blind or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services. Utah enjoys a broad measure of flexibility in tailoring the scope and coverage of its Medicaid plan. By state law, Utah is required to recover Medicaid funds which have been improperly provided to participants and suppliers.

8. Utah's Medicaid plan includes an optional prescription drug program. Pursuant to Utah Code Annotated 26-18-2.4(1)(a) this plan provides care, including prescription drugs, that must be based upon clinical and cost-related factors, including "medical necessity."

9. Under State administrative rule, drug prescriptions are only to be covered under Utah Medicaid when "medically efficacious." "Medically efficacious" means that a prescription has been determined effective, is widely utilized as a standard medical practice for specific conditions, and has been approved on the basis of "medical necessity." This requirement that a prescription be "medically efficacious" is included within the administrative rules governing the Medicaid plan.

ALLEGATIONS OF FACT

10. Prior to selling its product Zyprexa, Lilly knew there was a risk of Zyprexa patients developing severe and harmful health conditions including, but not limited to, hyperglycemia (dangerously high blood sugar levels), acute weight gain, exacerbation of diabetes mellitus (hereinafter "diabetes"), and pancreatitis. Furthermore, Lilly was aware of internal studies linking Zyprexa to these conditions, yet failed to warn the United States Food and Drug Administration (hereinafter "the FDA"), the State, physicians, and consumers. This failure to warn the FDA of these known risks is relevant to Plaintiff's complaint.

11. At all times relevant to this action, Lilly was responsible for, or involved in, the design, manufacture, marketing, advertising, distribution, and sale of Zyprexa.

12. In 1996, the FDA approved Zyprexa for use as a treatment of manifestations of schizophrenia in adults.

13. In 2000, the FDA approved Zyprexa for use as a short-term treatment of acute manic or mixed episodes associated with bipolar I disorder (also known as "manic depression") in adults.

14. In 2004, the FDA approved Zyprexa for maintenance treatment of bipolar I disorder in adults, and for acute agitation in adults with schizophrenia or bipolar I disorder.

15. Notwithstanding the limited uses approved by the FDA and a few uses supported by standard pharmaceutical compendia, Lilly advertised and sold Zyprexa for a number of non-approved or "off-label" uses. These unapproved uses include Alzheimer's disease, geriatric dementia, Tourette's syndrome, pervasive developmental delay, autism, anorexia nervosa, and

general depression. This was in spite of the fact that no FDA-approved testing had demonstrated the effectiveness of Zyprexa for such uses, and such uses were not supported by any standard compendium.

16. Lilly marketed Zyprexa as being medically superior to other antipsychotic medication, claiming that no blood tests or other monitoring was necessary with the drug. Further, it represented that Zyprexa patients could be given a therapeutic dose immediately, rather than starting with non-therapeutic doses to build up the patient's tolerance. Lilly knew these claims to be false because the increased risk of hyperglycemia, weight gain, diabetes and diabetic condition required medical monitoring and blood tests.

17. Shortly after the Defendant began selling Zyprexa, the FDA began to receive reports of Zyprexa patients developing hyperglycemia, acute weight gain, exacerbation of diabetes mellitus, pancreatitis, and other severe diseases and conditions.

18. Beginning in 1998, scientific journals began to publish studies that established an association between Zyprexa and the development or exacerbation of both diabetes and hyperglycemia. Subsequent studies have consistently found a relationship between Zyprexa and these dangerous conditions.

19. In April, 2002, the British Medicines Control Agency warned about the risk of diabetes for Zyprexa patients. The agency reported forty known incidents of diabetes, hyperglycemia, diabetic ketoacidosis (a severe exacerbation of diabetes), and diabetic coma among Zyprexa patients, as well as one death attributed to the drug. Subsequently, the British government required Lilly to warn consumers about the risk of diabetes and diabetic

ketoacidosis, and further required Lilly to instruct Zyprexa users to monitor their blood sugar levels.

20. In that same month, the Japanese Health and Welfare Ministry issued emergency safety information regarding the risk of diabetes, diabetic ketoacidosis, and diabetic coma for Zyprexa users. The Ministry also required physicians prescribing Zyprexa to monitor blood sugar levels.

21. Lilly has not warned consumers in this country, including the State, about the serious risks of diabetes, hyperglycemia, diabetic ketoacidosis, and other serious conditions associated with Zyprexa.

22. Lilly had actual knowledge, or acted either in deliberate ignorance or in reckless disregard of the truth or falsity of the risks involved in consuming Zyprexa. Furthermore, since 1998 Lilly had actual knowledge of studies and scholarly articles linking the use of Zyprexa with these and other severe diseases.

23. Lilly misrepresented this association and failed to appropriately warn consumers, including the State, its physicians, and Medicaid recipients, of the dangerous and permanent health consequences linked to the use of Zyprexa. Lilly thus placed profits above the safety of its customers.

24. Beginning in the 1990s, Lilly began to aggressively market and sell Zyprexa by willfully misleading potential users about the drug's serious risks. Lilly launched a marketing "blitz," extolling the virtues of Zyprexa – both real and fabricated – in order to induce widespread use. This marketing campaign consisted of print and media advertisements,

telephone conferences, live conferences, direct promotional literature to doctors and other healthcare providers, and other promotional materials provided directly to Zyprexa users. Lilly also marketed Zyprexa for off-label uses, including geriatric dementia, pediatric symptoms, and for general depression. This was in spite of the lack of FDA or compendia support for such uses.

25. The marketing program sought to create the impression and belief by consumers and physicians (particularly primary care physicians and "family doctors") that Zyprexa was safe for human use and had fewer side effects or adverse reactions than other antipsychotic medications. Lilly knew these representations to be false, or acted either in deliberate ignorance or in reckless disregard of the truth or falsity of this information.

26. The marketing program purposefully downplayed the risks associated with Zyprexa use, including serious illness and death. Lilly relayed only positive information and relied upon manipulated statistics to suggest widespread acceptability. At the same time, Lilly concealed adverse factual material concerning Zyprexa's serious health risks. In particular, the marketing materials produced by Lilly falsely represented the severity, frequency, and nature of adverse health effects caused by Zyprexa. Further, it falsely represented that adequate testing had been done on Zyprexa for off-label uses and to determine the drug's side effects.

27. As a result of Lilly's marketing campaign, Zyprexa has been the company's top-selling drug since 2001 – the same year Lilly's patent for Prozac expired. Zyprexa has since then accounted for almost one-third of Lilly's total sales. Zyprexa has been prescribed to nearly 20 million people worldwide. In 2003, approximately seven million prescriptions for Zyprexa were dispensed, making it the seventh largest-selling drug in the country. Zyprexa has generated over

\$4 billion in annual worldwide sales for each year since that time. Lilly is on pace to match those numbers again, having sold \$1.1 billion in the first quarter of 2007.

28. Shortly after Lilly began selling Zyprexa, it received reports of Zyprexa users developing severe and harmful health conditions including, but not limited to, hyperglycemia, acute weight gain, exacerbation of diabetes, and pancreatitis. This information was knowingly withheld or misrepresented to the FDA, the State, and the general public. This information was material and relevant to Plaintiff and its Medicaid program.

29. In making Zyprexa available to Medicaid patients and advocating its use, Lilly knowingly misrepresented to the State of Utah that Zyprexa was safe and effective. The State of Utah allowed the purchase of Zyprexa for Utah Medicaid recipients based upon such representations by Lilly. In fact, Zyprexa was no more effective for the treatment of schizophrenia and bipolar I disorder than older antipsychotic medications, which did not carry the risks of weight gain and diabetes.

30. Lilly also sought to increase the market for Zyprexa by manipulating Utah Medicaid procedures, including influence of the Drug Utilization Board (the body which regulates the utilization of certain medications within the Medicaid program). Lilly organized a Medicaid marketing plan which offered "assistance" to the State in monitoring and dispensing atypical antipsychotic medication under the guise that this would save the State money. In reality, the design and effect of this effort was to increase Zyprexa sales by (a) instilling a preference for Zyprexa over other atypical antipsychotics for FDA-approved uses, and (b) expanding the State Medicaid criteria for the use of and payment for Zyprexa for off-label uses.

31. Zyprexa has been prescribed by Utah physicians to many Medicaid recipients. As a result of ingesting Zyprexa, Utah Medicaid patients have suffered serious adverse health effects, which now require further and more extensive medical treatment and healthcare services. The State is the financially responsible party for these services. The State has thus suffered and will continue to suffer additional financial loss in the care of those Medicaid recipients who consumed prescriptions which were ineffective, unsafe, and actively harmful. In addition, the State has inappropriately paid for Zyprexa prescriptions for off-label uses which were not medically necessary.

32. The State, through its Attorney General, has the right to bring this suit pursuant to the Utah False Claims Act. The Act further provides that the State of Utah is entitled to recover the cost of its investigators, attorneys, and other state employees.

33. This Complaint is based solely upon the laws of the State of Utah, and contains causes of action found within those laws. To the extent that any claim contained herein raises a question of federal law or a federal cause of action, Plaintiff hereby disavows any such claim.

FIRST CLAIM FOR RELIEF
(Utah False Claims Act)

34. Plaintiff incorporates paragraphs 1 through 33 as if fully set forth herein, and further alleges as follows:

35. Pursuant to the Utah False Claims Act, it is illegal to make a claim for Medicaid payment of a service, procedure, or product that is not “medically necessary.” Similarly, causing such a claim to be made, or aiding and abetting such a claim, is also prohibited.

36. In representing Zyprexa to be safe and effective for off-label and unapproved uses, and representing that Zyprexa was safe without medical monitoring and blood tests, Lilly either caused claims to be made by physicians and patients, or aided and abetted such claims for a drug which was not "medically necessary."

37. "Medically necessary" reimbursements are limited to uses approved by the FDA or uses which were supported by the United States Pharmacopeia-Drug Information, the DRUGDEX Information System, or the American Hospital Formulary System Drug Information.

38. The FDA has approved Zyprexa only for adults who suffer from schizophrenia, mixed or manic episodes of bipolar I disorder, or for its intramuscular formulation only, agitation associated with schizophrenia or bipolar I disorder. As of March, 2007, of the three designated compendia, only the DRUGDEX Information System supports any additional uses, and only for adults. These uses include psychotic reaction to cannabis, psychotic disorder associated with Alzheimer's disease, anxiety associated with Alzheimer's-type dementia, delirium, depressive episodes of bipolar I disorder, and trichotillomania (hair-pulling).

39. Neither the Compendia cited above nor the FDA supports the use of Zyprexa by infants, children, or adolescents for any indication, or by adults with bipolar II disorder, dementia, depression, ADD, ADHD, sleep disorders, anger management, mood enhancement, mood stabilization, or any other use not listed in paragraph 38. Such uses are known as "off-label" uses and are not "medically accepted indications."

40. As a result of inappropriate marketing of Zyprexa for off-label uses, the State of Utah has paid millions of dollars for inappropriate and medically unnecessary doses of Zyprexa.

As a result, Lilly has been illegally enriched at the expense of the State. Further, the state has been required and will be required to pay the costs of treatment, including medical monitoring and blood tests, for state residents actively harmed by Lilly's actions.

41. In making representations that Zyprexa was appropriate for these "off-label" uses, Lilly acted with actual knowledge of the falsity of the representations or acted in either deliberate ignorance or reckless disregard of the truth or falsity of the information.

42. Accordingly, under the Utah False Claims Act the State is entitled to restitution for medically unnecessary prescriptions, for the resulting cost of care, and a civil penalty of three times the restitution and not less than \$5,000 or more than \$10,000 for each unnecessary prescription. In addition, the State seeks the costs of enforcement, including the cost of investigators, attorneys, and other state employees. These damages are in addition to, and not a substitute for, the damages alleged in paragraph 31.

SECOND CLAIM FOR RELIEF

(Liability of Commercial Product Sellers not Based on Product Defect at Time of Sale Restatement (Third) of Torts: Chapter 2, Section 9)

43. Plaintiff incorporates paragraphs 1 through 42 as if fully set forth herein, and further alleges as follows:

44. Eli Lilly & Company was engaged in the business of selling or otherwise distributing the pharmaceutical Zyprexa.

45. In connection with the sale of Zyprexa, Lilly made fraudulent, negligent or innocent misrepresentations concerning both the safety and the effectiveness of Zyprexa as alleged more particularly above.