Exhibit A
State Court Pleadings

STATE OF SOUTH CAROLINA	)	
	)	**IN THE COURT OF COMMON PLEAS**
COUNTY OF SPARTANBURG	)	
	)	
STATE OF SOUTH CAROLINA ex rel Henry McMaster, in his capacity as Attorney General of the State of South Carolina	)	**CIVIL ACTION COVERSHEET**
Plaintiff(s)	)	
	)	**07 - CP - 42 - 1855**
vs.	)	
	)	
Eli Lilly & Company, Inc.	)	
Defendant(s)	)	

(Please Print)		**SC Bar #:**	5996
Submitted By: John B. White, Jr.		**Telephone #:**	864-585-5100
Address: 178 W. Main St./Spartanburg, SC 29306		**Fax #:**	864-542-2993
PO Box 3547/Spartanburg, SC 29304		**Other:**	
		E-mail:	JWhite@spartanlaw.com

NOTE: The cover sheet and information contained herein neither replaces nor supplements the filing and service of pleadings or other papers as required by law. This form is required for the use of the Clerk of Court for the purpose of docketing. It must be filled out completely, signed, and dated. A copy of this cover sheet must be served on the defendant(s) along with the Summons and Complaint.

DOCKETING INFORMATION *(Check all that apply)*

If Action is Judgment/Settlement do not complete

☒ **JURY TRIAL** demanded in complaint. ☐ **NON-JURY TRIAL** demanded in complaint.

☐ This case is subject to **ARBITRATION** pursuant to the Circuit Court Alternative Dispute Resolution Rules.

☐ This case is subject to **MEDIATION** pursuant to the Circuit Court Alternative Dispute Resolution Rules.

☐ This case is exempt from ADR (certificate attached).

NATURE OF ACTION *(Check One Box Below)*

Contracts
- ☐ Constructions (100)
- ☐ Debt Collection (110)
- ☐ Employment (120)
- ☐ General (130)
- ☐ Breach of Contract (140)
- ☐ Other (199)

Torts - Professional Malpractice
- ☐ Dental Malpractice (200)
- ☐ Legal Malpractice (210)
- ☐ Medical Malpractice (220)
- ☐ Other (299)

Torts – Personal Injury
- ☐ Assault/Slander/Libel (300)
- ☐ Conversion (310)
- ☐ Motor Vehicle Accident (320)
- ☐ Premises Liability (330)
- ☐ Products Liability (340)
- ☐ Personal Injury (350)
- ☐ Other (399)

Real Property
- ☐ Claim & Delivery (400)
- ☐ Condemnation (410)
- ☐ Foreclosure (420)
- ☐ Mechanic's Lien (430)
- ☐ Partition (440)
- ☐ Possession (450)
- ☐ Building Code Violation (460)
- ☐ Other (499)

Inmate Petitions
- ☐ PCR (500)
- ☐ Sexual Predator (510)
- ☐ Mandamus (520)
- ☐ Habeas Corpus (530)
- ☐ Other (599)

Judgments/Settlements
- ☐ Death Settlement (700)
- ☐ Foreign Judgment (710)
- ☐ Magistrate's Judgment (720)
- ☐ Minor Settlement (730)
- ☐ Transcript Judgment (740)
- ☐ Lis Pendens (750)
- ☐ Other (799)

Administrative Law/Relief
- ☐ Reinstate Driver's License (800)
- ☐ Judicial Review (810)
- ☐ Relief (820)
- ☐ Permanent Injunction (830)
- ☐ Forfeiture (840)
- ☐ Other (899)

Appeals
- ☐ Arbitration (900)
- ☐ Magistrate-Civil (910)
- ☐ Magistrate-Criminal (920)
- ☐ Municipal (930)
- ☐ Probate Court (940)
- ☐ SCDOT (950)
- ☐ Worker's Comp (960)
- ☐ Zoning Board (970)
- ☐ Administrative Law Judge (980)
- ☐ Public Service Commission (990)
- ☐ Employment Security Comm (991)
- ☐ Other (999)

Special/Complex /Other
- ☐ Environmental (600)
- ☐ Automobile Arb. (610)
- ☐ Medical (620)
- ☒ Pharmaceuticals (630)
- ☐ Unfair Trade Practices (640)
- ☐ Other (699)

Submitting Party Signature: _____ **Date:** 7/25/07

Note: Frivolous civil proceedings may be subject to sanctions pursuant to SCRCP, Rule 11, and the South Carolina Frivolous Civil Proceedings Sanctions Act, S.C. Code Ann. §15-36-10 et. seq.

COMPUTER CB

****FOR MANDATED ADR COUNTIES ONLY**

SUPREME COURT RULES REQUIRE THE SUBMISSION OF ALL CIVIL CASES TO AN ALTERNATIVE DISPUTE RESOLUTION PROCESS, UNLESS OTHERWISE EXEMPT.

You are required to take the following action(s):

1. The parties shall select a neutral within 210 days of filing of this action, and the Plaintiff shall file a "Stipulation of Neutral Selection" on or before the 224th day after the filing of the action. If the parties cannot agree upon the selection of the neutral within 210 days, the Plaintiff shall notify the Court by filing a written "Request for the Appointment of a Neutral" on or before the 224th day after the filing of this action. The Court shall then appoint a neutral from the Court-approved mediator/arbitrator list.

2. The initial ADR conference must be held within 300 days after the filing of the action.

3. Case are exempt from ADR only upon the following grounds:

    a. Special proceeding, or actions seeking extraordinary relief such as mandamus, habeas corpus, or prohibition;

    b. Cases which are appellate in nature such as appeals or writs of certiorari;

    c. Post Conviction relief matters;

    d. Contempt of Court proceedings;

    e. Forfeiture proceedings brought by the State;

    f. Cases involving mortgage foreclosures; and

    g. Cases that have been submitted to mediation with a certified mediator prior to the filing of this action.

4. Motion of a party to be exempt from payment of neutral fees due to indigency should be filed with the Court within ten (10) days after the ADR conference had been concluded.

Please Note: **You must comply with the Supreme Court Rules regarding ADR. Failure to do so may affect your case or may result in sanctions.**

** Florence, Horry, Lexington, Richland, Greenville, and Anderson

STATE OF SOUTH CAROLINA) IN THE COURT OF COMMON PLEAS

COUNTY OF SPARTANBURG) FOR THE SEVENTH JUDICIAL CIRCUIT

STATE OF SOUTH CAROLINA ex rel **Henry McMaster**, in his capacity as Attorney General of the State of South Carolina, **PLAINTIFF,** v. **ELI LILLY & COMPANY, INC.** **DEFENDANT.**	SUMMONS Case No.: 07-CP-42-1855

TO THE ABOVE NAMED DEFENDANT:

You are hereby summoned and required to answer the Complaint in this action, a copy of which is attached hereto and herewith served upon you, and to serve a copy of your answer to same upon the subscribed at 178 West Main Street, Post Office Box 3547, Spartanburg, South Carolina 29304, within thirty (30) days after the service of same, exclusive of the day of such service. If you fail to answer same within thirty (30) day period, the Plaintiff will apply to the Court for the relief demanded therein and judgment will be taken against you be default.

HARRISON, WHITE, SMITH & COGGINS

BY: _____

John B. White, Jr., Esq.
Federal Bar # 4619
SC Bar #: 5996
PO Box 3547
Spartanburg, South Carolina 29304
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May 25, 2007

STATE OF SOUTH CAROLINA	)	IN THE COURT OF COMMON PLEAS
COUNTY OF SPARTANBURG	)	FOR THE SEVENTH JUDICIAL CIRCUIT

STATE OF SOUTH CAROLINA ex rel **Henry McMaster**, in his capacity as Attorney General of the State of South Carolina,

PLAINTIFF,

v.

ELI LILLY & COMPANY, INC.

DEFENDANT.

Case No.: 2007-CP-42-1855

FILED
CLERK OF COURT
SPARTANBURG COUNTY
2007 MAY 25 AM 8:36
MARC KITCHENS

CIVIL ACTION COMPLAINT

The State of South Carolina, Plaintiff herein, by and through its Attorney General ("the State"), according to law and equity, and as *parens patriae*, brings this action on behalf of the State Medicaid program, the South Carolina Department of Mental Health ("SCDMH") and the South Carolina State Employees Health Plan ("SHP") as injured purchasers and/or reimbursers of prescription drugs. Under the South Carolina Constitution and other positive law of the State, including South Carolina's common law and including, among other laws, S.C. CODE ANN. §§43-7-20, *et seq.*, 39-5-10, *et seq.*, and 1-7-10, *et seq.*, the State is responsible for, and has a duty to protect, the health, safety and welfare of its citizens. The State is further entitled to bring these actions pursuant to 42 U.S.C. §1396, *et seq.*, also known as the Social Security Act, Chapter 7, subchapter XIX, entitled Grants to States for Medical Assistance Programs. The State seeks to obtain compensatory, punitive and other damages, restitution, civil penalties, injunctive and other equitable relief against Defendant Eli Lilly & Company, Inc. ("Defendant"), as more fully set forth below and, in support thereof, would show as follows:

FILING FEE PAID
CLERK OF COURT

PARTIES

1. The plaintiff is the State of South Carolina, with this suit being brought by its Attorney General, Henry McMaster, in the State's capacity as sovereign, in its proprietary capacity, and in a *parens patriae* capacity on behalf of the Department of Health & Human Services, SCDMH and the SHP.

2. The Attorney General is statutorily authorized to initiate and maintain this action, and does so, pursuant to S.C. CODE ANN. §1-7-40, the South Carolina Unfair Trade Practices Act, S.C. CODE ANN. §39-5-50 and S.C. CODE ANN. §43-7-60(E), 90. This action is also maintained pursuant to the Attorney General's common law *parens patriae* powers.

3. Defendant is a corporation organized and existing under the laws of the state of Indiana with its principal place of business located at Lilly Corporate Center Indianapolis, Indiana 46285. Lilly is authorized to conduct business in South Carolina, and its registered agent for service of process is National Registered Agents, Inc., 2 Office Park Ct., Columbia, South Carolina 29223.

4. The acts alleged to have been done by Defendant herein were authorized, ordered done and/or ratified by Defendant's officers, directors, agents, employees or representatives while engaged in the management, direction, control or transaction of Defendant's business affairs.

JURISDICTION & VENUE

5. The jurisdiction of this Court is founded upon S.C. CONST. ANN. ART. V. §11 which gives the Circuit Court general jurisdiction over civil actions.

6. This Court has personal jurisdiction over Defendant because Defendant does business in South Carolina and/or has the requisite minimum contacts with South Carolina

necessary to constitutionally permit the Court to exercise jurisdiction with such jurisdiction also being within the contemplation of the South Carolina "long arm" statute (S.C. CODE ANN. §36-2-803).

7. Defendant did, individually or in conjunction with others, research, develop manufacture, create, design, test, label, sterilize, package, distribute, supply, market, sell, promote, advertise, warn and otherwise distribute Olanzapine ("Zyprexa") in South Carolina and specifically in Spartanburg County.

8. Venue in this Court is proper pursuant to the Rules of the South Carolina Supreme Court and the South Carolina Code.

INTRODUCTION

9. This is an action to recover funds expended by the State in providing medical treatment to Medicaid, SCDMH and SHP participants suffering from Zyprexa-related illnesses and to recover funds expended in purchasing Zyprexa for uses not covered by the State's Medicaid, SCDMH and SHP programs. Many of the details and critical facts related to Defendant's scheme are exclusively known by Defendant.

10. The State seeks reimbursement of funds expended by South Carolina pursuant to the Medicaid program, the SCDMH and its State Employees Health Plan ("SHP"). The State is required by 42 U.S.C. §1396a(a)(25)(A),(B) to take all reasonable measures to ascertain the legal liability of third parties to pay for care and services available under the Medicaid Act, and to seek reimbursement to the public fund to the extent of such legal liability.

11. The State seeks to recover damages to its SHP. The SHP is a State-sponsored program that administers prescription drug benefits for the State's SHP participants. The South Carolina Budget and Control Board oversees the SHP, which currently covers approximately

350,000 individuals. The SHP reimburses pharmacies, doctors and hospitals for prescriptions written for and dispensed to SHP participants.

12. The State seeks to recover damages to the SCDMH. The SCDMH is a State-sponsored program that purchases Zyprexa for the State's mental hospitals, clinics and centers, joint State and community sponsored mental health clinics and centers and facilities for the treatment and care of alcohol and drug addicts. The SCDMH is a direct purchaser of Zyprexa for patients under its care.

13. The State has discovered that Defendant has engaged in a protracted and willful course of corporate misconduct and misrepresentation in violating numerous State laws, and in actionable breach of the duties owed to the State and its citizens. Defendant has concealed its wrongdoing from the State.

14. The State brings this action exclusively under the common law and statutes of the State of South Carolina. No federal claims are being asserted and to the extent that any claim or factual assertion set forth herein may be construed to have stated any claim under federal law, such claim is expressly and undeniably disavowed and disclaimed by the State.

15. The claims asserted herein are brought solely by the State, and result from the damages incurred by the State itself and are wholly independent of any claims that individual users of Zyprexa may have against Defendant.

16. Defendant manufactures Zyprexa and promotes the drug to physicians in South Carolina. For years, the State has incurred significant expenses associated with the provision of necessary health care and other assistance necessary under its Medicaid, SCDMH and SHP programs to citizens who suffer, or who have suffered, from Zyprexa-related injuries, diseases or sickness.

APPLICABLE STATUTORY FRAMEWORK

17. The State participates in the Medicaid program to promote the general welfare of its citizens and meet the specific objective that adequate and high quality health care is available to those South Carolina citizens who cannot afford it.

18. Under the Medicaid system, whether the use of a drug is medically necessary is material to the State's decision to reimburse for the prescription. The State does not intend to reimburse providers for drugs whose uses are medically unnecessary or are likely to result in adverse medical outcomes.

19. Defendant is deemed to be on notice of Medicaid regulations regarding the scope of prescription drug reimbursement. Defendant has a duty to prevent non-medically necessary prescriptions for Zyprexa from being submitted to Medicaid for reimbursement. Upon information and belief, Defendant breached this duty by knowingly causing prescriptions for non-medically necessary uses of Zyprexa to be submitted to Medicaid for reimbursement.

20. S.C. CODE ANN. §43-7-60 provides as follows:

> (B) It is unlawful for a provider of medical assistance, goods, or services to knowingly and willfully make or cause to be made a false claim, statement, or representation of a material fact: (1) in an application or request, including an electronic or computer generated claim, for a benefit, payment, or reimbursement from a state...agency which administers or assists in the administration of the state's medical assistance or Medicaid program; or (2) on a report, certificate, or similar document, including an electronic or computer generated claim, submitted to a state...agency which administers or assists in the administration of the state's Medicaid program in order for a provider or facility to qualify or remain qualified under the state's Medicaid program to provide assistance, goods, or services, or receive reimbursement, payment, or benefit for this assistance, goods or services.
>
> (C) It is unlawful for a provider of medical assistance, goods, or services knowingly and willfully to conceal or fail to disclose any material fact, event, or transaction which affects the:

a. Provider's initial or continued entitlement to payment, reimbursement, or benefits under the state's Medicaid plan; or

b. Amount of payment, reimbursement, or benefit to which the provider may be entitled for services, goods, or assistance rendered.

For purposes of this subsection, each fact, event, or transaction concealed or not disclosed constitutes a separate offense.

(E) In addition to all other remedies provided by law, the Attorney General may bring an action to recover damages equal to three times the amount of an overstatement or overpayment and the court may impose a civil penalty of two thousand dollars for each false claim, representation, or overstatement made to a state...agency which administers funds under the state's Medicaid program.

21. As persons receiving payment, reimbursement and/or benefit for services, goods or assistance rendered under the State's public assistance program, Defendant is a provider within the meaning of S.C. CODE ANN. §43-7-60(A)(1). According to the South Carolina legislature, the purpose of Medicaid Fraud Act is to preserve the integrity of the Medicaid Program by providing a statutory deterrent to any person or entity causing the submission of inappropriate claims to the Program.

22. The State of South Carolina, as is true of many states, lacks a practical means of ensuring that each prescription for every drug constitutes a medically necessary use of that drug. The State thus relies on persons or entities receiving payment and benefits to turn square corners in their dealings with the Medicaid, SCDMH and SHP Programs. Nevertheless, this lack of practical ability represents a loophole in the scheme of the Medicaid, SCDMH and SHP Programs.

23. Defendant has recognized and aggressively exploited this loophole in two ways. First Defendant has engaged in a direct, illegal, nationwide program of promotion of the use of Zyprexa for non-medically necessary uses. Defendant has conducted this program of promotion knowing that prescriptions for Zyprexa are generally reimbursed by the State Medicaid, SCDMH

and SHP programs even though prescriptions for non-medically necessary uses of Zyprexa fall outside the coverage of state programs.

24. Second, since the inception of their promotion of Zyprexa, Defendant has falsely represented to the State, and to the public in general, that Zyprexa is safer and more effective than less expensive, first generation antipsychotics.

25. Finally, Defendant's failure to provide an adequate warning of the risks of using Zyprexa has compromised the general health and welfare of South Carolina citizens. The State, in its common law duty to act as *parens patriae*, thus has standing to recover its necessary costs of treatment of South Carolina citizens resulting from Zyprexa-related injuries for which Defendant is liable.

<u>ZYPREXA'S CLINICAL PROFILE</u>

26. In September of 1996, the FDA approved Zyprexa oral tablets for use in the treatment of adults with schizophrenia at a target dose of 10 mg/d. In 2001, Zyprexa tablets were approved for treatment of adults suffering from acute manic episodes associated with bipolar I disorder in doses up to 20mg/day. In July of 2003, Zyprexa tablets were approved for the short-term treatment of adults suffering from acute manic episodes associated with Bipolar I Disorder, in combination with lithium or valproate, with recommended doses of 10-20 mg/d. In January of 2004, Zyprexa tablets were approved for long-term treatment of adults with bipolar I disorder in doses up to 20 mg/day.

27. There is no legitimate scientific support for any use of Zyprexa by children or for treatment of adults with depression, anxiety, ADD, ADHD, sleep disorders, anger management, mood enhancement or mood stabilization.

28. Schizophrenia is one of the most complex and challenging of psychiatric disorders. It represents a heterogeneous syndrome of disorganized and bizarre thoughts, delusions, hallucinations, inappropriate affect and impaired psycho-social functioning. Fortunately, schizophrenia is somewhat rare, occurring in only about 1% of the population.

29. There are many clinical presentations of schizophrenia. Despite common misconceptions of schizophrenia as a "split-personality," in fact schizophrenia is a chronic disorder of thought and affect. The Diagnostic and Statistical Manual of Mental Disorders, 4th edition, (DSM-IV) assigns a diagnosis of schizophrenia when a patient suffers two or more of the following characteristic symptoms: delusions, hallucinations, disorganized speech, grossly disorganized or catatonic behavior and negative symptoms.[1]

30. Although the etiology of schizophrenia is unknown, research has demonstrated various abnormalities in schizophrenic brain structure and function. The cause of schizophrenia is likely multi-factorial, that is, multiple pathophysiologic abnormalities may play a role in producing the similar but varying clinical phenotypes we refer to as schizophrenia.

31. Since the discovery of the effects of antipsychotics, such as chlorpromazine in the 1950s, and the observation that traditional anti-psychotic drugs are post-synaptic dopamine-receptor antagonists, the hypothesis has emerged that dopamine hyperactivity underscores the neurochemical basis for the primary symptoms of schizophrenia.

32. Over the years, treatment of schizophrenia has relied on antipsychotic drugs that target dopamine D2 receptors. The many antipsychotic drugs introduced during the following

[1] Only one of these criteria are required if delusions are bizarre or if hallucinations consist of a voice keeping a running commentary on the person's behavior or two or more voices conversing with each other. To achieve a diagnosis of schizophrenia, schizo-affective or mood disorder must be excluded, and the disorder must not be due to a medical disorder or substance use

decades were increasingly potent, as medicinal chemists improved the drugs' affinity for the D2 receptor.

33. The traditional or "typical" antipsychotics include chlorpromazine (Thorazine), fluphenzine (Proxilin), haloperidol (Haldol), loxapine (Loxitane), molindone (Moban), mesoridazine (Serentil), perphenazine (Trilafon), thioridazine (Mellaril), thiothixene (Navane), and trifluoperazine (Stelazine). Until the early 1990's, the typical antipsychotics were the common drug therapy for schizophrenia.

34. Although there were many traditional antipsychotics, the efficacy of these drugs was similar because they all had similar mechanisms of action. A troubling side effect of typical antipsychotics was that the blockage of dopaminergic neurotransmission in the basal ganglia caused extrapyramidal syndromes (EPS) such as parkinsonian effects. A long-lasting movement disorder, tardive dyskinesia, also occurred with prolonged treatment.

35. By the 1980s, clozapine was being investigated for the treatment of schizophrenia on the theory that it might be more effective and cause less movement disorder than other antipsychotics. However, the potential of clozapine to cause toxic side effects, including agranulocytosis, limited its prescription to about 10 percent of persons with schizophrenia.

ZYPREXA'S SAFETY PROFILE

36. During the 1990's pharmaceutical companies, acting on the "atypical" hypothesis, introduced newer drugs attempting to capture the enhanced therapeutic effect of clozapine without its toxicity and without the increased EPS caused by traditional antipsychotics. Before 1993, the only atypical antipsychotic in the United States market was clozapine, and due to its toxicity it had very little market share. Ten years later, atypical antipsychotics such as Zyprexa

would account for about 90% of all antipsychotic drugs prescribed for all psychiatric purposes, regardless of whether they were approved for those indications.

37. The atypical antipsychotics include clozapine (Clozaril), Zyprexa, quetiapine (Seroquel), Risperidone (Risperdal), aripiprazole (Abilify), and ziprasidone (Geodon), and are considered the second-generation antipsychotics (SGA).

38. In part, this lawsuit describes how Defendant achieved, through a series of unlawful acts and practices, the largest United States market share for atypical antipsychotics.

39. Medical literature dating as far back as the 1950s, and Defendant's own pre-clinical studies of Zyprexa, demonstrated that Zyprexa, like older antipsychotic medications, had the potential to cause diabetes, diabetes-related injuries (e.g. weight gain and hyperglycemia), cardiovascular and cerebrovascular complications, and other severe adverse effects. By the time Zyprexa was first marketed, the neurochemical bases for the efficacy and side-effects were generally known to Defendant, i.e., effects on dopamine, serotonin, and histamine systems in the brain. Therefore, prior to marketing Zyprexa, Defendant should have been concerned about Zyprexa causing neurological problems, weight gain, diabetes, pancreatitis, hyperglycemia, cardiovascular complications, and metabolic syndrome. And yet Zyprexa's original label, and all label changes until 2004, did not adequately warn of these adverse effects.

40. Zyprexa's pre-marketing clinical trials did not support an assertion that it was less likely to cause extra pyramidal symptoms ("EPS") than traditional antipsychotics. Upon information and belief, Defendant's trials were designed to produce similar rates of EPS in patients sorted into placebo groups and those taking Zyprexa. In order to produce their desired result, Defendant selected patients for the placebo groups that were already in the course of treatment with high doses of typical antipsychotics.

41. The manifestation of EPS in a patient taking antipsychotic drugs is largely dose-dependent. In other words, the larger the dose, the more likely EPS become. Further, patients that develop EPS generally continue to experience EPS for months, even after discontinuing antipsychotic drug treatment. Because of this, patients in Defendant's placebo groups continued to experience EPS at the rate at which they had experienced EPS while on antipsychotic drug treatment before participating in the trials. Meanwhile, patients in the Zyprexa group predictably developed EPS at the rate to be expected in a population taking antipsychotic medication, a rate which essentially matched the placebo group.

42. Based on the similar levels of EPS in the placebo and Zyprexa group, Defendant claimed, in their marketing, that patients taking Zyprexa were as likely to develop EPS as patients taking nothing and thus less likely to develop EPS than patients taking traditional antipsychotics.

43. Despite having been on notice, for years, of the potential for deadly diabetes-related side effects, Defendant opted for the bare minima of clinical trials, of limited duration, such that no side effects were likely to be revealed.

44. Defendant had actual knowledge that Zyprexa causes weight gain, which significantly increases a patient's risk of contracting diabetes. Despite such knowledge, Defendant failed to include a Warning of the potential for weight gain and the possible development of diabetes as a result of the use of Zyprexa in its U.S. labeling for years. In fact, Defendant concealed the true safety profile of Zyprexa from patients from 1997 until 2004. Even then, Defendant did not warn citizens of the State of the risk of diabetes associated with Zyprexa.

45. Upon information and belief, long before case reports in peer-reviewed medical literature became known to the general medical public, Defendant was aware of large numbers of diabetes-related adverse events associated with Zyprexa.

46. For example, an analysis of the number of Adverse Event Reports ("AERs") over the first four years of Zyprexa's market life shows nearly 200 AERs after 2 years, 400 AERs after 3 years, and nearly 600 diabetes-related AERs in Zyprexa's fourth year of distribution. These AERs were reported to the FDA and known to Defendant.

47. The number of reports of AERs is a very conservative representation of the actual number of AERs actually occurring. It is well understood that adverse drug event reports represent between 1% and 10% of the total estimated population of all complications. (*See* Physician Knowledge, Attitude and Behavior Related to Reporting, Archives of Internal Medicine, 1988: 148; 1589-1592; Underreporting of Hemorrhagic Stroke Associated with Phenylpropanolamine, 286 (24) JAMA (2001); Rhode Island Physician's Recognition and Reporting of Adverse Drug Reactions, RI Medical Journal 1987: 70:311-316.).

48. The reality of under-reporting is due mainly to the fact that the adverse event reporting system in the U.S. is a voluntary system (*i.e.* doctors are under no obligation to report an adverse event). As a result, the number of reported adverse events must be multiplied by a factor of between 10 and 100 in order to arrive at an accurate estimate.

49. After adding the unreported adverse events for Zyprexa to the above figures, the true number of diabetes-related adverse events from market introduction in 1996 to year end 2000, is estimated to be as low as 6,000 and as high as 60,000, a staggeringly high number considering the indications being treated and the availability of far safer alternatives.

50. Defendant did not entirely ignore the reports of adverse events concerning diabetes and elevated glucose levels. Rather, it implemented marketing strategies that blamed diabetes and hyperglycemia on the schizophrenic population at large, rather than on Zyprexa. Thus, upon information and belief, despite the fact that Defendant's own internal studies and adverse event data revealed that Zyprexa increased the risk of diabetes, even among schizophrenics, Defendant refused to adequately warn patients of this known risk. At the same time, Defendant affirmatively misrepresented that the incidence of diabetes associated with Zyprexa was due only to background incidence inherent in the schizophrenic population.

51. Less than seven weeks after Zyprexa's approval, Defendant faced charges that it was suppressing side effects. The FDA sent a letter to Defendant on November 14, 1996 outlining labeling pieces and promotional activities considered to be "false or misleading, and in violation of the Federal Food, Drug, and Cosmetic Act" by the Division of Drug Marketing, Advertising, and Communications ("DDMAC").

52. According to the agency, the promotional campaign lacked "appropriate balance, thereby creating a misleading message about Zyprexa" in that the pieces "emphasize efficacy but do not provide sufficient balance relating to adverse events and cautionary information." In addition, the materials did not "adequately or prominently discuss several important adverse events specifically selected for emphasis in the approved labeling", including weight gain. In conclusion, the letter stated that the labeling pieces "present a misleading impression of Zyprexa as a superior, highly effective, virtually free of side effects, easy to use product. This impression is contrary to the approved labeling."

53. The FDA's letter specifically referenced an interactive teleconference conducted by Dr. Gary Tollefson, Vice President of Lilly Research Laboratories, on October 2, 1996 – two days after FDA approval. The letter states:

> When asked a question about weight gain, Dr. Tollefson's response misleadingly turned an adverse event into a therapeutic benefit. He states, "So we went back and analyzed our data and saw that the vast majority of weight gain reported initially as an adverse event, in fact, was weight gain occurring in patients who had baseline before starting treatment, had been below their ideal body weight. So we really look at this in the majority of patients as being part of a therapeutic recovery rather than an adverse event. That data I think was fairly compelling because it was included in our labeling.

54. The information on weight gain was indeed included in the approved labeling, but as an adverse event, not a therapeutic benefit. Since the product was approved at the time of this teleconference, Dr. Tollefson knew or should have known what information the approved labeling contained and in what section it appeared. His statements were therefore false and misleading. Further, Dr. Tollefson's misrepresentations about weight gain on the phone conference were belied by Defendant's own study's conclusion. Tollefson claimed that the weight gain was mostly observed in patients whose weights were abnormally low before taking Zyprexa, hence the alleged therapeutic effect. However, upon information and belief, Defendant's own study in 1993 concluded that "weight gain was evident and uniform in all subjects, with an average weight gain of nearly 9 pounds over the study duration. Dr. Tollefson's interactive telephone conference is an eerie and early illustration of the lies, misrepresentations and data manipulations concerning the risks and benefits of Zyprexa that Defendant has continued to report for more than a decade.

55. Moreover, the FDA complained that the October 1, 1996 teleconference had "presented a misleading impression of Zyprexa as a superior, highly effective, virtually free of

side effects, easy to use product." Dr. Tollefson had said that olanzapine had no Parkinson's-like side effects: "We're very pleased that the labeling in the U.S. will show by objective rating scales that both Parkinsons like side effects and restlessness or Acathisia, the incidence across all doses of Zyprexa was comparable to placebo. That is essentially this drug did not induce persistent Parkinsonian problems." And: "[W]e've been able to show that there is a statistically and significantly lower incidence of this neurological [Tardive Dyskinesia] side effect with Zyprexa than with conventional drugs." Not only was this a clearly deceptive analysis of the clinical trial results, years later Lilly admitted on its "Patient Information Sheet Revised 04/2005" for Zyprexa that it could "cause serious problems such as . . .A movement problem called tardive dyskinesia (TD)."

56. In the October 1, 1996 conference call, Dr. Tollefson announced that prolactin would not be a problem: "In our labeling it will be clear that Zyprexa is not associated with these persistent, high long term elevations of prolactin . . ." As a major selling point, Dr. Tollefson pointed out that olanzapine was distinct from its competitors because it required no blood monitoring "[W]ith some of the other agents, such as Clozapine or clozaril that you may be familiar with, of course there are prerequisites for blood monitoring on a weekly basis because of some of the safety concerns with those drugs. Of course this is very troublesome to patients and very costly. We're very pleased that we have no requirements for any type of blood monitoring with Zyprexa."

57. Upon information and belief, Defendant believed, as early as 1996, that blood glucose monitoring should be recommended for patients on Zyprexa. Nevertheless, it allowed its spokesman, Dr. Tollefson, to distinguish Zyprexa from its competitors as a treatment option that

did not require monitoring, leaving the impression that Zyprexa was less expensive to prescribe than other antipsychotics because it did not require blood monitoring.

58. Dr. Tollefson continued: "Lastly I think particularly important to the prescriber and patient, unlike make [sic] of the anti-psychotics currently in the marketplace that require the prescriber to start with very low doses that are subtherapeutic because of safety concerns then gradually work the patient into a therapeutic range where they can begin to get benefit, Zyprexa will have a starting does [sic] on day one of ten milligrams, which is also an effective therapeutic dose. So the bottom line is, there is no need for this historic, mandatory titration of drug. We can start with the therapeutically effective does [sic] on day one." By contrast, however, Lilly's official label says that patients should commence with 2.5 to 5 mg on day one.

59. From the inception of Zyprexa's marketing, and with full knowledge of Defendant's highest executives, scientists and medical officers, Lilly engaged in systematic overpromotion of Zyprexa, by exaggerating benefits, especially in non-medically necessary uses, and understating risks.

60. Defendant endorsed, adopted, and repeated Dr. Tollefson's misleading statements to physicians about Zyprexa. In an October 1, 1996 press release titled "Lilly's Zyprexa (olanzapine) Cleared for Marketing for Treatment of Psychotic Disorders" issued by Lilly press spokesperson, Lori Roberts, Defendant said that Zyprexa had "no requirement for blood monitoring and a therapeutic starting dose without a requirement for titration for most patients," quoting Dr. Gary Tollefson, VP of Lilly's Research Laboratories and "head of the olanzapine heavyweight team." Further, the press release promised that "Zyprexa patients will not have to submit to weekly blood monitoring tests."

61. Defendant never provided a prominent warning about the increased risk of diabetes and hyperglycemia and of the need to provide baseline diabetes screening and glucose monitoring. A warning did not appear until it was forced by the FDA in mid-September of 2003.

62. On September 11, 2003, the FDA informed all manufacturers of atypical antipsychotic drugs, including Defendant, that due to an increasing prevalence of diabetes-related illnesses associated with this class of drugs, that all labeling must bear the following language in the Warnings section:

> Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given these confounders, the relationship between atypical antipsychotic use and hyperglycemia-related adverse events is not completely understood. However, epidemiologic studies suggest an increased risk of treatment emergent hyperglycemia-related adverse events in patients treated with atypical antipsychotics. Precise risk estimates for hyperglycemia-related adverse events in patients treated with atypical antipsychotics are not available.
>
> Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e.g., obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation of anti-diabetic treatment despite discontinuation of the suspect drug.

63. Despite the FDA's mandate that Defendant immediately warn of the dangers described above, Defendant waited five more months, until March of 2004, to send prescribing physicians a "Dear Doctor Letter" advising of the new warnings.

64. Prior to Zyprexa's FDA approval, Defendant had a well-developed strategy to expand the use of Zyprexa beyond patients with schizophrenia. Upon information and belief, Defendant sought ghost written research and paid "thought leaders" to support Defendant's marketing aims. These "thought leaders" were nothing more than third-party consultants and researchers who were put on Defendant's payroll to support and lend credibility to Defendant's scientific and marketing goals.

65. Among these goals were plans to create a series of studies designed to illustrate Zyprexa's superior profile to both (a) placebo and (b) a representative conventional antipsychotic while providing funding to engage key opinion leaders in publication worthy trials.

66. Since Defendant introduced Zyprexa in 1996, it has been prescribed to more than twelve million people worldwide and become Defendant's top-selling drug. In 2003, approximately seven million prescriptions for Zyprexa were dispensed, resulting in more than $2 billion in sales. Zyprexa was the seventh largest selling drug in the United States by retail sales in 2003. In 2004, Zyprexa sales exceeded $4.4 billion. Crucial to this blockbuster success was Defendant's aggressive marketing of Zyprexa, which consisted chiefly of overstating the drug's uses, while concealing its life-threatening side effects.

67. From launch to the present, Defendant's marketing campaigns included promotion for use in the elderly for both dementia symptoms and Alzheimer's disease.

68. Defendant's decision to target the State's elderly had two results: Medically unnecessary claims for Zyprexa were submitted to Medicaid, SHP and SCDMH for reimbursement, and the drugs caused disastrous health consequences for geriatric patients.

69. In April of 2005, the FDA determined that the treatment of behavioral disorders in elderly patients with dementia through atypical antipsychotic drugs is associated with increased

mortality. In a total of seventeen placebo controlled trials performed with Zyprexa in elderly demented patients with behavioral disorders, fifteen trials revealed increases in mortality in the drug-treated group compared to the placebo-treated patients. Examination of specific causes of death revealed that most were due to either heart related events such as heart failure and sudden death or infections, such as pneumonia.

70. Although Zyprexa FDA-approved for the treatment of schizophrenia, it is not approved for the treatment of behavioral disorders in patients with dementia. As a result of the findings, the FDA required Defendant to include a Boxed Warning or "black box warning" in Zyprexa's labeling describing this risk and emphasizing that it is not approved for this indication.

71. Further, in October of 2005, the article *Dementia Drugs Can Increase Death Risks* concluded that,

> ...drugs often used to treat elderly patients with dementia-related aggression and delusions can raise their risk of death, according to a study that reinforces new warning labels required on medications. The researchers pooled results of 15 previous studies on drugs known as atypical anti-psychotics and sold under the brand names Zyprexa, Risperdal, Seroquel and Abilify. Among more than 5,000 elderly dementia patients, those taking any of the drugs faced a 54 percent increased risk of dying within 12 weeks of starting the medication, compared with patients taking dummy pills. There were 118 deaths among the 3,353 drug users versus 40 in the 1,757-patient placebo group, or 3.5 percent compared with 2.3 percent. The risks were similar for each of the drugs...The study appears in Wednesday's Journal of the American Medical Association.

72. Upon information and belief, despite the foregoing, Defendant continues to promote Zyprexa as safe and effective treatment for dementia in elderly patients.

73. Such promotion is particularly sinister given the results of a study Defendant performed in 1995, before Zyprexa was initially approved by the FDA. Upon information and belief, Defendant learned that olanzapine, the active ingredient in Zyprexa, was ineffective in

treating such conditions as dementia and Alzheimer's. Nevertheless, from the inception of marketing, Lilly promoted Zyprexa for symptoms of dementia and Alzheimer's in the elderly.

74. There is no valid scientific evidence to support Defendant's contention that Zyprexa is safe and effective for treatment of any off label indication, including any use in children. There is no valid scientific evidence concerning the therapeutic equivalence of Zyprexa for any off label indication, including any use in children.

75. Further, even in cases where treatment with an antipsychotic was appropriate, Zyprexa prescriptions should not have been submitted to the State, as Zyprexa is no safer or more effective than less expensive first generation antipsychotics.

ALLEGATIONS

76. Defendant did business in the State of South Carolina; made contracts to be performed in whole or in part in South Carolina and/or manufactured, tested, sold, offered for sale, supplied or placed in the stream of commerce, or in the course of business materially participated with others in so doing, Zyprexa, which Defendant knew to be defective, unreasonably dangerous and hazardous, and which Defendant knew would be substantially certain to cause injury to the State and to persons within the State thereby negligently and intentionally causing injury to persons within South Carolina and to the State, and as described herein, committed and continues to commit tortious and other unlawful acts in the State of South Carolina.

77. From the 1997 product launch of Zyprexa to the present, Defendant engaged in widespread fraudulent statements and conduct, and pervasive false and misleading marketing, advertising and promotion of Zyprexa. Defendant deceived physicians, consumers, the State, and others regarding the comparative efficacy of Zyprexa to other traditional and atypical

antipsychotics. Defendant failed to warn – and affirmatively misled – physicians, consumers, the State, and others in the medical community regarding Zyprexa's association with diabetes, diabetes-related conditions and other adverse effects. Defendant actively marketed and promoted Zyprexa in several populations where the efficacy and safety of the drug had yet to be established – marketing Zyprexa for the treatment of various conditions or symptoms in children, marketing Zyprexa for treatment in the elderly for dementia, and marketing Zyprexa for treatment of patients who experience depressive or other physiological conditions.

78. From the outset of marketing, Defendant plotted and schemed to increase the sales of Zyprexa. The scheme consisted of elaborate and clandestine promotion of non-medically necessary uses of Zyprexa.

79. Upon information and belief, this scheme was carried out by: employing the illegal direct solicitation of physicians to prescribe Zyprexa for non-medically necessary uses; the making of false statements to physicians and pharmacists concerning the efficacy and safety of Zyprexa for non-medically necessary uses; the use of active concealment to avoid the utilization policies of Medicaid, SCDMH and SHP, which are intended to refuse payment for uses of drugs which are medically unnecessary; and the active training of Defendant's employees in methods of avoiding detection of their activities.

80. The State spends millions of dollars each year to provide or pay for health care and other necessary facilities and services on behalf of indigents and other eligible citizens whose said health care costs are directly caused by Zyprexa-induced diabetes, stroke, pancreatitis, seizures and other diseases.

81. Defendant sold or aided and abetted in the sale of Zyprexa which was and is defective and unreasonably dangerous.

82. Upon information and belief, at all pertinent times, Defendant knew, or should have known, that Zyprexa was and is unreasonably hazardous to human health.

83. Defendant, through its funding and control of certain studies concerning the affects of Zyprexa on human health, its control over trade publications, promoting, marketing, and/or through other agreements, understandings and joint undertakings and enterprises, conspired with, cooperated with and/or assisted in the wrongful suppression, active concealment and/or misrepresentation of the true relationship between Zyprexa and various diseases, all to the detriment of the public health, safety and welfare and thereby causing harm to the State.

84. Zyprexa is inherently, abnormally, and unreasonably dangerous. The health risks and costs of Zyprexa to the citizens of the State and to the State greatly outweigh any claimed utility of Zyprexa. Defendant knew or should have known of the dangers inherent in the use of Zyprexa, and that the public and the State would be harmed by the intended and foreseeable use of Zyprexa.

85. As a direct and proximate result of the defective marketing practices of Defendant, Zyprexa was and is defective and unreasonably dangerous.

86. Zyprexa reached the users and consumers thereof in substantially the same condition which it was in when originally manufactured, distributed and sold by Defendant. At the time Zyprexa was sold or placed on the market, it was in a defective condition and unreasonably dangerous to users and consumers.

87. The defective condition of Zyprexa directly and proximately caused South Carolina residents to suffer various Zyprexa-induced diseases, injuries and sicknesses, and directly and proximately caused the State to expend millions of dollars in order to provide

necessary health care to these citizens through its Medicaid, SCDMH and SHP programs, thereby directly damaging the State.

88. At all pertinent times, it was foreseeable by Defendant that certain of the South Carolina Medicaid, SCDMH and SHP participants who used Zyprexa would become ill and suffer injury, disease and sickness as a result of using Zyprexa as Defendant intended, and it was further foreseeable by Defendant that the State would be required to expend millions of dollars each year in order to provide necessary medical treatment and facilities to those citizens.

89. Defendant individually, and through their representatives, fraudulently mislead the public, physicians treating Medicaid, SCDMH and SHP participants and the State, with regard to the health risks of Zyprexa, all for the purpose of increasing Defendant's profits from the sale of Zyprexa.

90. Specifically, and in addition to the allegations above, Defendant knew of the hazards associated with Zyprexa. Defendant nevertheless affirmatively and actively concealed information which clearly demonstrated the dangers of Zyprexa and affirmatively misled the public and physicians treating Medicaid, SCDMH and SHP participants with regard to the material and clear risks of Zyprexa. Defendant did so with the intent that physicians treating Medicaid, SCDMH and SHP participants would continue to prescribe Zyprexa. However, Defendant knew that prescribing physicians would not be in a position to discover the true risks of Zyprexa and would rely upon the misleading information that Defendant promulgated. Defendant further knew that physicians treating Medicaid, SCDMH and SHP participants would write Zyprexa prescriptions that would be paid for by the State's Medicaid, SCDMH and SHP program.

91. At all pertinent times, Defendant purposefully and intentionally engaged in these activities, and continues to do so, knowing that when the State's Medicaid, SCDMH and SHP participants use Zyprexa as it was and is intended to be used, that the State's Medicaid, SCDMH and SHP participants would be substantially certain to suffer disease, injury and sickness, including diabetes, stroke, pancreatitis, seizures and other illnesses, and that the State would be directly injured thereby, all as described above.

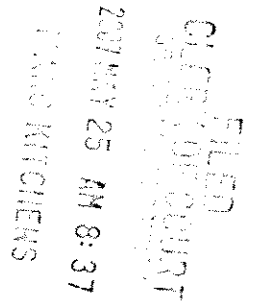
92. Also at all pertinent times, Defendant purposefully and intentionally engaged in these activities, and continues to do so, knowing that the State, in the absence of any such efforts by Defendant, would be obligated to, and would, provide health care and other necessary facilities and services for certain of the State's Medicaid, SCDMH and SHP participants harmed by the intended use of Zyprexa, and that the State itself would thereby be directly harmed.

93. Upon information and belief, the statements, representations and promotional schemes publicized by Defendant were deceptive, false, incomplete, misleading and untrue. Defendant knew, or should have known, that their statements, representations and advertisements were deceptive, false, incomplete, misleading and untrue at the time of making such statements. Defendant had an economic interest in making such statements. Neither the State nor the physicians in South Carolina who prescribed Zyprexa had knowledge of the falsity or untruth of Defendant's statements, representations and advertisements when Medicaid, SCDMH and SHP claims for Zyprexa were submitted; moreover, the State had a right to rely on Defendant to act honestly when dealing with the State. Each of the Defendant's statements, representations and advertisements were material to the State's purchase of Zyprexa in that the State would not have reimbursed for or purchased Zyprexa if it had known that Defendant's statements

representations and advertisements related to Zyprexa were deceptive, false, incomplete, misleading and untrue.

94. The State has a right to rely upon the representations of Defendant and was directly and proximately injured by such reliance, all as described above.

95. A significant percentage of South Carolina Medicaid, SCDMH and SHP participants, believed to number in the hundreds, if not thousands, suffered serious diseases and/or potentially life-threatening medical conditions after taking Zyprexa and such risks of use were known, or should have been known, to Defendant who failed to warn South Carolina physicians treating Medicaid, SCDMH and SHP participants of those risks.



COUNT I

SUBMISSION OF FALSE & FRAUDULENT CLAIMS UNDER MEDICAID PROGRAM

96. The State incorporates by reference the foregoing allegations as if set forth at length herein.

97. A significant percentage of patients who use or have used Zyprexa are persons whose prescriptions are paid for in whole or in part by Medicaid.

98. Defendant's aggressive, illegal scheme of off-label promotion has induced a dispensation of State Medicaid funds through a pattern of fraudulent conduct by causing the State to pay out sums for prescriptions that were medically unnecessary. Defendant's conduct constitutes Medicaid fraud within the meaning of S.C. CODE ANN. §43-7-60.

99. Defendant has, as alleged, actively concealed its promotion of Zyprexa for non-medically necessary uses from the State. Said active concealment is motivated by the desire to, and has had the effect of, preserving the flow of State funds to reimburse Zyprexa prescriptions for non-medically necessary uses. Said active concealment constitutes a pattern of fraudulent conduct through which State payments are derived, and constitutes Medicaid fraud within the meaning of S.C. CODE ANN. §43-7-60.

100. Defendant has knowingly caused false claims for payment to the State's Medicaid program by intentionally promoting non-medically necessary uses of Zyprexa to prescribing physicians for the purpose of receiving greater compensation than that to which they are legally entitled, with the costs ultimately being borne, in whole or in part, by the State through its Medicaid reimbursement to pharmacies. These prescriptions constitute false claims because Medicaid reimbursement is not intended for non-medically necessary uses of Zyprexa.

101. Violation of the Medicaid statute entitles the State to reimbursement of all funds for which payment was fraudulently induced, including but not limited to, all funds paid by the State for reimbursement of non-medically necessary uses of Zyprexa.

102. Further, Defendant caused the foregoing false claims to be submitted with knowledge that they were not medically necessary. Such conduct entitles the State to recover an amount equal to three times the amount wrongfully reimbursed and two thousand dollars per false claim.

WHEREFORE, the State respectfully requests that this Honorable Court enter judgment in its favor and against Defendant and that the State be awarded reimbursement for all expenditures made for non-medically necessary prescriptions of Zyprexa, three times the amount Defendant knowingly caused to be submitted for wrongful reimbursement of Zyprexa, two thousand dollars per false claim and such other relief as justice and equity may require.

COUNT II

SUBMISSION OF FALSE & FRAUDULENT CLAIMS UNDER MEDICAID PROGRAM

103. The State incorporates by reference the foregoing allegations as if set forth at length herein.

104. A significant percentage of patients who use or have used Zyprexa are persons whose prescriptions are paid for in whole or in part by Medicaid.

105. Defendant has fraudulently represented that Zyprexa is safer and more effective than less expensive, generic forms of first generation antipsychotics. Defendant's conduct constitutes Medicaid fraud within the meaning of S.C. CODE ANN. §43-7-60.

106. Since the inception of its marketing of Zyprexa, Defendant knowingly misrepresented that Zyprexa is more effective in the treatment of the negative symptoms of

schizophrenia and less likely to produce certain adverse events involving involuntary movement disorders, which are commonly associated with first generation antipsychotics. Defendant knew these representations were false at the time they were made and that Zyprexa is no more effective than appropriate doses of first generic antipsychotic drugs and no less likely to produce these adverse events. Defendant touted Zyprexa's added efficacy dimension and the reduction of these adverse events as justification for its higher cost. As a result of these representations, and in an effort to spare their patients from experiencing these adverse effects, certain South Carolina doctors treating Medicaid participants opted for Zyprexa instead of less expensive, generic forms of first generation antipsychotics.

107. Defendant has knowingly caused false claims to be submitted to the Medicaid Program by fraudulently representing that Zyprexa is safer and more effective than less expensive, generic forms of first generation antipsychotics. The increased incremental cost of Zyprexa, relative to available generic form of first generation antipsychotics, was borne by the State and resulted in excessive payment to Defendant. All prescriptions for Zyprexa submitted to the State's Medicaid Program constitute false claims under the Medicaid Fraud Act.

108. Violation of the Medicaid statute entitles the State to reimbursement of all funds for which payment was fraudulently induced, including but not limited to the incremental cost of purchasing Zyprexa instead of less expensive, generic forms of first generation antipsychotics.

109. Further, Defendant caused the foregoing false claims to be submitted with knowledge that they were medically unnecessary. Such conduct entitles the State to recover an amount equal to three times the amount wrongfully reimbursed and two thousand dollars per false claim.

WHEREFORE, the State respectfully requests that this Honorable Court enter judgment in its favor and against Defendant and that the State be awarded reimbursement for the amount of the incremental cost of reimbursement for Zyprexa instead of available, generic forms of first generation antipsychotics, three times the amount Defendant knowingly caused to be submitted for wrongful reimbursement of Zyprexa, two thousand dollars per false claim and such other relief as justice and equity may require.

COUNT III

RECOVERY OF THE COST OF TREATMENT FOR INJURIES CAUSED BY ZYPREXA

110. The State incorporates by reference the foregoing allegations as if set forth at length herein.

111. The method by which Zyprexa was marketed in South Carolina rendered it defective and unreasonably dangerous.

112. The design and/or manufacture of Zyprexa rendered it a dangerously defective drug in that its use causes dangerous, and potentially life-threatening, medical conditions when taken as recommended by Defendant and such risks were not generally known by South Carolina physicians, the State and/or South Carolina Medicaid, SCDMH and SHP participants.

113. Zyprexa was a dangerously defective drug in that Defendant failed to conduct adequate pre-marketing testing, notwithstanding the known side effects associated with Zyprexa, atypicals as a class and anti-psychotic medications generally.

114. Zyprexa was dangerously defective because it lacked a sufficient warning of the risks associated with its use and also because:

(a) the lack of an adequate warning caused South Carolina physicians treating Medicaid, SCDMH and SHP participants to prescribe Zyprexa in inappropriate circumstances and on inappropriate classes of patients;

(b) Defendant had a duty to warn South Carolina physicians treating Medicaid, SCDMH and SHP participants of the risks and potentially life-threatening side effects associated with Zyprexa use and failed to do so; and

(c) the warning and/or labeling provided by Defendant for Zyprexa failed to include the risks and or potentially life-threatening side effects associated with Zyprexa use that were known to, or readily ascertainable by, Defendant and such risks were concealed from South Carolina physicians treating Medicaid, SCDMH and SHP participants.

115. Zyprexa is abnormally and unreasonably dangerous as marketed in that the health risks and costs associated with Zyprexa greatly outweigh any claimed utility of Zyprexa to the State and its Medicaid, SCDMH and SHP participants.

116. Zyprexa reached the users and consumers thereof in substantially the same condition as when originally manufactured, distributed and sold by Defendant. At the time Zyprexa was sold or placed on the market, it was in a defective condition and unreasonably dangerous to South Carolina Medicaid, SCDMH and SHP participants.

117. South Carolina Medicaid, SCDMH and SHP participants, and their physicians, used Zyprexa in the manner in which it was intended to be used, without any substantive alteration or change in the product.

118. As a result of Zyprexa's defective nature, certain South Carolinians whose care is provided by Medicaid, SCDMH and SHP were injured.

119. The State was forced to expend significant sums of money, through its Medicaid, SCDMH and SHP programs, to treat Medicaid, SCDMH and SHP participants who sustained Zyprexa-related injuries.

120. The State is entitled to recover the costs of such treatment as *parens patriae*.

WHEREFORE, the State respectfully requests that this Honorable Court enter judgment in its favor and against Defendant and award the State compensatory damages and any other relief as justice may require.

COUNT IV

VIOLATION OF THE SOUTH CAROLINA UNFAIR TRADE PRACTICES ACT

121. The State incorporates by reference the foregoing allegations as if set forth at length herein.

122. By labeling, distributing, marketing, promoting and selling Zyprexa through South Carolina physicians and pharmacies to the State, and South Carolina consumers, Defendant is engaging in trade or commerce directly, or indirectly, affecting the people of the State.

123. Defendant has repeatedly and willfully engaged in the following conduct which constitutes a deceptive trade practice and a violation of the SCUTPA:

(a) Misrepresenting that Zyprexa is safe and effective for indications for which safety and efficacy had not been demonstrated which caused South Carolina physicians treating Medicaid, SCDMH and SHP participants to prescribe Zyprexa in inappropriate, non-medically necessary circumstances;

(b) Making false and misleading misrepresentations of fact regarding Zyprexa's risk profile, including but not limited to misrepresenting the likelihood and severity of the side effects associated with Zyprexa, including diabetes, stroke, high blood pressure, weight gain and other serious and potentially life-threatening conditions;

(c) Misrepresenting and concealing material facts and/or failing to inform and educate South Carolina physicians as to the risks and dangers associated with Zyprexa use when such facts were well known to, or readily ascertainable by, Defendant;

(d) Misrepresenting and concealing material facts which were known to Defendant, and unknown to South Carolina physicians, when Defendant knew that South Carolina physicians rely on such facts when deciding whether to prescribe Zyprexa to their patients;

(e) Misrepresenting that Zyprexa is safer and more effective than less expensive, generic forms of first generation antipsychotics;

(f) Misrepresenting that Zyprexa is of a particular standard, quality or grade when it is not; and

(g) Intentionally creating a likelihood of confusion or misunderstanding in the minds of South Carolina physicians as to whether Zyprexa was safe, effective or medically necessary for Medicaid, SCDMH and SHP participants.

124. Defendant made, and continues to make, orally and in writing, false, misleading or deceptive representations in advertisements, promotions and statements, and otherwise disseminated, and continues to disseminate, false, misleading or deceptive information to the public, including South Carolina citizens, physicians and the State regarding non-medically necessary uses of Zyprexa and the health risks and benefits associated with using Zyprexa.

125. Defendant acted knowingly and willfully in committing the violations of the SCUTPA described herein.

126. Each Zyprexa prescription written without an adequate warning, for a non-medically necessary use or where a generic form of a first generation antipsychotic was available, constitutes a separate and distinct violation of the SCUTPA.

127. As a consequence of Defendant's illegal and deceptive sales and marketing practices, the State made monetary expenditures on behalf of South Carolina Medicaid, SCDMH and SHP participants who were prescribed Zyprexa for conditions which were not medically necessary, and/or where a first generation antipsychotic was as safe and effective and less expensive.

128. As a further consequence of Defendant's illegal and deceptive sales and marketing practices, many South Carolina Medicaid, SCDMH and SHP participants, including

children, were prescribed Zyprexa by their physicians and sustained serious and potentially life-threatening side effects.

129. The State was forced to expend significant sums of money for the treatment of those South Carolina Medicaid, SCDMH and SHP participants who sustained serious and potentially life-threatening injuries as a result of using Zyprexa.

130. The Attorney General has determined that the imposition of an injunction against Defendant prohibiting the conduct set forth herein is in the public interest.

131. The State seeks the entry of a permanent injunction prohibiting Defendant's unlawful and deceptive conduct and the imposition of all appropriate remedies available under the SCUTPA.

132. The State seeks restitution for all expenditures resulting from non-medically necessary uses of Zyprexa caused by Defendant's unlawful and deceptive sales and marketing practices and the difference in cost between the State's expenses for Zyprexa and what the State would have spent on first generation antipsychotics, absent Defendant's violations of the SCUTPA.

133. The State seeks compensatory damages for all State expenditures resulting from the treatment of those South Carolina Medicaid, SCDMH and SHP participants who sustained injuries, side effects and/or adverse medical events after using Zyprexa.

WHEREFORE, the State respectfully requests that this Honorable Court enter judgment in its favor and against Defendant and also seeks;

(a) a permanent injunction preventing Defendant from deceptively marketing and/or promoting Zyprexa as appropriate for non-medically necessary uses;

(b) restitution of all State expenditures for prescriptions caused by Defendant's deceptive marketing and/or promotion of Zyprexa;

(c) compensatory damages for all expenditures made by the State on behalf of South Carolina Medicaid, SCDMH and SHP participants who sustained injuries associated with Zyprexa use;

(d) imposition of $5,000 SCUTPA civil penalty for each method, act or practice deemed to violate this Act;

(e) three times the actual damages sustained by the State; and

(f) such further relief as justice and equity may require.

COUNT V

NEGLIGENCE

134. The State incorporates by reference the foregoing allegations as if set forth at length herein.

135. Defendant owed the State a duty to use reasonable care in the design, manufacture and marketing of its product, Zyprexa.

136. Defendant negligently, carelessly, recklessly, willfully and/or intentionally engaged in the following conduct:

(a) Marketing and/or promoting Zyprexa for non-medically necessary uses;

(b) Failing to adhere to all applicable laws and regulations pertaining to the marketing, promotion and/or labeling of pharmaceutical products, such as Zyprexa;

(c) Marketing and/or promoting Zyprexa as appropriate for children;

(d) Failing to adequately train its sales force so that when South Carolina physicians treating Medicaid, SCDMH and SHP participants raised safety concerns regarding Zyprexa important safety information was withheld;

(e) Supplying a product that it knew, or should have known, contained inadequate warnings of side effects and risks that were known to, or based on facts available to Defendant;

(f) Supplying a product lacking sufficient warnings and/or instructions when it knew, or should have known, the side effects associated with Zyprexa were not generally known by South Carolina physicians treating Medicaid, SCDMH and SHP participants;

(g) Representing that Zyprexa was safer than less expensive, first generation antipsychotics;

(h) Continuing to promote, market and/or sell Zyprexa after it knew, or should have known, of the serious side effects and risks associated with Zyprexa use;

(i) Allowing Zyprexa to be used indiscriminately for uses far beyond its indications, which are limited to schizophrenia and, recently, mania associated with bipolar disorder; and

(j) Not disclosing data pertaining to such use.

137. Defendant's negligent, careless, reckless, willful and/or intentional conduct was the proximate cause of injuries and damages sustained by the State.

138. At all relevant times, Defendant knew, or should have known, that Zyprexa was, and is, hazardous to human health.

139. Zyprexa is abnormally and unreasonably dangerous as marketed in that the health risks and costs associated with Zyprexa greatly outweigh any claimed utility of Zyprexa to Medicaid, SCDMH and SHP participants.

140. As a direct result of the unreasonable marketing practices of Defendant, Zyprexa was, and is, defective and unreasonably dangerous.

141. Zyprexa reached the users and consumers thereof in substantially the same condition as when originally manufactured, distributed and sold by Defendant. At the time Zyprexa was sold or placed on the market, it was in a defective condition and unreasonably dangerous to Medicaid, SCDMH and SHP participants.

142. South Carolina Medicaid, SCDMH and SHP participants used Zyprexa in the manner in which it was intended to be used, without any substantive alteration or change in the product.

143. Due to the negligent, careless, reckless, willful and/or intentional conduct of Defendant, as set forth above, the State dispensed millions of dollars of Medicaid, SCDMH and SHP funds in purchasing Zyprexa prescriptions and was also forced to expend significant sums of money for the care and treatment of South Carolina Medicaid, SCDMH and SHP participants injured by Zyprexa, all of which was foreseeable to Defendant.

144. The reprehensible nature of Defendant's conduct entitles the State to an award of punitive damages.

WHEREFORE, the State respectfully requests that this Honorable Court enter judgment in its favor and against Defendant and award the State compensatory and punitive damages and any other relief as justice may require.

COUNT VI

BREACH OF WARRANTY

145. The State incorporates by reference the foregoing allegations as if set forth at length herein.

146. Through its sales and marketing practices to South Carolina physicians treating Medicaid, SCDMH and SHP participants, Defendant warranted that Zyprexa was fit and appropriate for patients suffering from conditions less serious than schizophrenia and bipolar disorder, the only conditions for which Zyprexa was arguably proven safe and effective.

147. Through its sales and marketing practices to South Carolina physicians treating Medicaid, SCDMH and SHP participants, Defendant warranted that Zyprexa was fit and appropriate for pediatric use.

148. Through its sales and marketing practices to South Carolina physicians treating Medicaid, SCDMH and SHP participants, Defendant warranted that Zyprexa had no significant

risks or side effects that were not identified on its labeling. Defendant further warranted that Zyprexa was safer than less expensive, generic forms of first generation antipsychotics.

149. South Carolina physicians treating Medicaid, SCDMH and SHP participants relied on the warranties made by Defendant regarding the appropriate uses and safety profile for Zyprexa.

150. Defendant breached the express and implied warranties they made to the State, through South Carolina physicians treating Medicaid, SCDMH and SHP participants, since the product was not appropriate for use in children, or for adults with conditions less serious than schizophrenia and bipolar disorder. Also, Zyprexa was far less safe than warranted by Defendant.

151. The State dispensed millions of dollars in Medicaid, SCDMH and SHP expenditures for non-medically necessary uses of Zyprexa and in purchasing Zyprexa when a less expensive, generic form of a first generation antipsychotic was available. The State also spent significant sums of money, through its Medicaid, SCDMH and SHP programs, for medical treatment for those South Carolina citizens who developed serious side effects and/or adverse reactions after using Zyprexa. The State's expenses were caused by Defendant's express and implied warranties.

WHEREFORE, the State respectfully requests that this Honorable Court enter judgment in its favor and against Defendant and award the State compensatory damages and any other relief as justice may require.

COUNT VII

FRAUD & MISREPRESENTATION

152. The State incorporates by reference the foregoing allegations as if set forth at length herein.

153. As part of its promotion of Zyprexa, Defendant, through its sales representatives and other advertising and promotion, willfully, knowingly and deceptively communicated to South Carolina physicians treating Medicaid, SCDMH and SHP participants that Zyprexa was safe and effective for South Carolina children and elderly, that it was safe and effective for South Carolina Medicaid, SCDMH and SHP participants suffering from conditions less serious than schizophrenia and bipolar disorder and that it was safer and more effective than less expensive first generation antipsychotics, all of which were knowingly false.

154. Defendant had a duty to disclose the conditions for which Zyprexa was proven safe and effective, and not to go beyond those indications in its sales and marketing to South Carolina physicians, the intermediaries between Defendant and the State.

155. Defendant intended to induce South Carolina physicians treating Medicaid, SCDMH and SHP participants to prescribe Zyprexa for South Carolina Medicaid, SCDMH and SHP participants for whom Zyprexa was not appropriate or medically necessary.

156. South Carolina physicians treating Medicaid, SCDMH and SHP participants as well as the State, were justified in relying on Defendant to educate physicians as to the appropriate uses, indications and risks of Zyprexa.

157. The State, through its Medicaid, SCDMH and SHP programs, was forced to expend significant amounts of money for non-medically necessary Zyprexa prescriptions which were directly caused by the fraudulent and misleading statements of Defendant.

158. Defendant willfully, knowingly and deceptively withheld material facts regarding the risks and side effects associated with Zyprexa use from South Carolina physicians treating Medicaid, SCDMH and SHP participants.

159. Defendant had a duty to disclose known risks and side effects associated with Zyprexa use, particularly, but not solely, when specifically asked about those risks by South Carolina physicians.

160. Defendant intentionally withheld information regarding the safety risks and side effects associated with Zyprexa use with the intention of inducing South Carolina physicians to prescribe Zyprexa for South Carolina Medicaid, SCDMH and SHP participants in greater quantities than they otherwise would have, or was otherwise appropriate.

161. South Carolina physicians treating Medicaid, SCDMH and SHP participants, as well as the State, were justified in their reliance on Defendant to educate them as to the risks and dangerous and potentially life-threatening side effects associated with Zyprexa use.

162. Defendant knew that the State and South Carolina Medicaid, SCDMH and SHP participants, particularly children, would not be in a position to discover and understand the true risks of using Zyprexa, and the public relied upon the misleading information that Defendant promulgated to South Carolina physicians to the detriment of the State.

163. Defendant knew that the representations that were relied on by South Carolina physicians treating Medicaid, SCDMH and SHP participants were false or were made recklessly without any knowledge of the truth.

164. Each of Defendant's misleading and deceptive statements, representations and advertisements related to non-medically necessary uses of Zyprexa were material to the State's

purchase of Zyprexa in that the State would not have been required to reimburse pharmacies for non-medically necessary uses of Zyprexa if Defendant had marketed Zyprexa legally.

165. The State, through its Medicaid, SCDMH and SHP programs, was forced to expend significant amounts of money to treat South Carolina citizens who contracted serious and potentially life-threatening medical conditions resulting from Defendant's deceptively withholding adequate safety information regarding Zyprexa use and/or misrepresenting Zyprexa's safety profile.

WHEREFORE, the State respectfully requests that this Honorable Court enter judgment in its favor and against Defendant and award the State compensatory and punitive damages and any other relief as justice may require.

COUNT VIII

UNJUST ENRICHMENT

166. The State incorporates by reference the foregoing allegations as if set forth at length herein.

167. Defendant knowingly, willfully and intentionally marketed and promoted Zyprexa for conditions and illnesses for which it was not medically necessary.

168. Defendant knowingly, willfully and intentionally withheld information from South Carolina physicians treating Medicaid, SCDMH and SHP participants regarding the risks associated with Zyprexa use.

169. As a result of the deceptive marketing practices of Defendant, South Carolina physicians treating Medicaid, SCDMH and SHP participants prescribed Zyprexa in far greater numbers than would have been generated absent Defendant's deceptive and illegal conduct. The

inflated levels of Zyprexa reimbursement for Medicaid, SCDMH and SHP participants resulted in a financial windfall for Defendant.

170. The State paid, reimbursed and/or otherwise conferred a benefit upon Defendant to the extent of the inflated numbers of Zyprexa prescriptions that directly resulted from Defendant's fraudulent marketing practices relative to South Carolina Medicaid, SCDMH and SHP participants who were not suffering from illnesses for which Zyprexa is a medically necessary treatment.

171. Further, Defendant has been unjustly enriched as a result of its false representations that Zyprexa is safer and more effective than less expensive, generic forms of first generation antipsychotics. The State would not have purchased Zyprexa instead of first generation antipsychotics in the absence of Defendant's fraudulent representations.

172. Defendant has been unjustly enriched to the extent of the increased revenue received by Defendant from Zyprexa prescriptions that were ultimately reimbursed by the State and resulted from Defendant's deceptive and illegal marketing program.

WHEREFORE, the State respectfully requests that this Honorable Court enter judgment in its favor and against Defendant and that Defendant be required to make restitution to the State for all expenditures made for non-medically necessary prescriptions of Zyprexa as well as the incremental cost of reimbursing for Zyprexa instead of less expensive, generic forms of first generation antipsychotics and such other relief as justice and equity may require.

REQUEST FOR JURY TRIAL

The State respectfully requests that all issues presented by its above Complaint be tried before a jury, with the exception of those issues that, by law, must be tried before the court.

Respectfully submitted,

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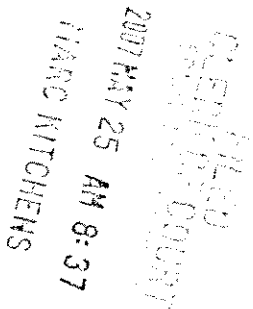

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