UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

THE STATE OF CONNECTICUT,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

COMPLAINT AND JURY DEMAND

CV 08 955

WEINSTEIN, J.

MANN, M.J.

FILED
IN CLERK'S OFFICE
U.S. DISTRICT COURT E.D.N.Y.

★ MAR 06 2008 ★

BROOKLYN OFFICE

I. PARTIES 6
A. PLAINTIFF: THE STATE OF CONNECTICUT 6
B. DEFENDANT: ELI LILLY AND COMPANY, INC. 6
II. JURISDICTION 6
III. FACTUAL BACKGROUND 7
A. PAYMENT OF HEALTH CARE COSTS BY THE STATE OF CONNECTICUT AND CONSUMERS 7
1. Connecticut Non-Medicaid Health Care Programs 8
2. Connecticut's Medicaid Program 8
B. THE RISE AND EARLY PROMOTION OF ZYPREXA BY LILLY 10
1. Schizophrenia, Traditional Antipsychotics Drugs and Emergence of Atypical or Second Generation Antipsychotic Medications 10
2. FDA Approval Process for Olanzapine 13
3. Lilly's Promotional Campaign Strategy and the Formation of the Unlawful Marketing Enterprises 16
C. LILLY'S POST-APPROVAL OPERATIONS 30
1. Fraudulent and Unlawful Acts Regarding Safety and Efficacy 31
2. Fraudulent and Unlawful Acts Regarding Off-Label Promotions for Elderly Usage 35
3. Fraudulent and Unlawful Acts Regarding Off-Label Promotions for Pediatric Usage 36
D. DESPITE LILLY'S EFFORTS, THE TRUTH BEGINS TO EMERGE 37
1. The FDA Requires Additional Warnings Regarding Treatment-Emergent Diabetes and Hyperglycemia in Late 2003 37
2. The Diabetes Consensus Statement Focuses on Olanzapine's Risks in 2004 39
3. The New England Journal of Medicine Publishes the Results of the CATIE Trials in 2005 40
4. The FDA Requires Further Changes to the Zyprexa Label in 2007 42
E. SUMMARY OF LILLY'S ACTIVITIES 42
IV. FIRST CLAIM FOR RELIEF: USE OF DECEPTIVE TRADE PRACTICES IN VIOLATION OF THE CONNECTICUT UNFAIR TRADE PRACTICES ACT 46
V. SECOND CLAIM FOR RELIEF: WILLFUL USE OF DECEPTIVE TRADE PRACTICES IN VIOLATION OF THE CONNECTICUT UNFAIR TRADE PRACTICES ACT 48
VI. THIRD CLAIM FOR RELIEF: USE OF UNFAIR TRADE PRACTICES IN VIOLATION OF THE CONNECTICUT UNFAIR TRADE PRACTICES ACT 49
VII. FOURTH CLAIM FOR RELIEF: WILLFUL USE OF UNFAIR TRADE PRACTICES IN VIOLATION OF THE CONNECTICUT UNFAIR TRADE PRACTICES ACT 50
VIII. FIFTH CLAIM FOR RELIEF: SUBMISSION OF FALSE CLAIMS IN VIOLATION OF THE CONNECTICUT UNFAIR TRADE PRACTICES ACT 51
IX. SIXTH CLAIM FOR RELIEF: VIOLATION OF 18 U.S.C § 1962(C) 53
X. SEVENTH CLAIM FOR RELIEF: VIOLATION OF U.S.C. § 1962(D) BY CONSPIRING TO VIOLATE 18 U.S.C. § 1962(C) 58

XI. DEMAND FOR RELIEF 60
XII. DEMAND FOR JURY TRIAL 60

INTRODUCTION

1. The State of Connecticut ("Plaintiff" or "the State"), represented by Richard Blumenthal, Attorney General of the State of Connecticut, acting at the request of Jerry Farrell, Jr., Commissioner of Consumer Protection, brings this action pursuant to the Connecticut Unfair Trade Practices Act ("CUTPA"), Chapter 735a of the Connecticut General Statutes, and more particularly, Conn. Gen. Stat. §§42-110m and 42-110o, for the purpose of seeking appropriate relief for violations of Conn. Gen. Stat. §42-110b(a). The State seeks, pursuant to CUTPA, to obtain restitution, civil penalties under applicable laws, and injunctive and other equitable relief against Defendant Eli Lilly and Company, Inc. ("Defendant" or "Lilly") for payments made for prescriptions of Zyprexa and associated health care covered by the State of Connecticut's publicly funded health programs, as well as for consumers, who were injured as a result the deceptive marketing practices Lilly utilized, and continues to utilize, in the promotion of its brand name drug Zyprexa.

2. The State of Connecticut similarly brings this action pursuant to the federal Racketeering Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. §§1961 and 1962. Lilly associated itself with a discrete and identifiable number of medical marketing firms, physicians, public officials, and others in order to form RICO associations-in-fact and engage in a pattern of racketeering activity including multiple episodes of mail and wire fraud, all designed to fraudulently induce the writing of prescriptions and payments for Zyprexa. Lilly and its co-conspirators engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of the conspiracy to violate RICO. The State and consumers were injured in their property as a result of the deceptive practices undertaken by the RICO associations-in-fact and seek to obtain treble damages and other injunctive and equitable relief against Lilly for payments made for

prescriptions of Zyprexa and associated health care.

3. The State of Connecticut, through the Connecticut Department of Social Services ("DSS"), administers the Connecticut Medical Assistance Program ("CMAP"). The CMAP includes the Connecticut Medicaid program, as well as the Connecticut Pharmaceutical Assistance Contract to the Elderly and the Disabled ("ConnPACE"), State Administered General Assistance ("SAGA"), Connecticut AIDS Drug Assistance Program ("CADAP") and Healthcare for Uninsured Kids and Youth ("HUSKY"). The CMAP pays for medical benefits, including Zyprexa and other prescription drugs, for certain low income and disabled Connecticut residents and reimburses physicians, pharmacists, and other health care providers for certain drugs, diagnostic procedures and/or other health care services prescribed for, dispensed, and/or administered to CMAP recipients. Similarly, many Connecticut consumers pay all or part of their own medical expenses, including purchases of Zyprexa and associated health care.

4. Lilly's deceptive marketing practices involved promoting Zyprexa for non-medically approved uses, which caused the CMAP to expend millions of dollars in public health funds for the purchase of prescriptions that were ineligible for reimbursement, and further injured consumers. Lilly's practices similarly involved the deliberate concealment and affirmative misrepresentation of health risks associated with Zyprexa, and of the comparative efficacy of Zyprexa. These deceptions resulted in injuries faced by many of the CMAP recipients, as well as consumers. The CMAP was and will continue to be forced to bear millions of dollars of expenses in treating those injuries. Injured consumers were and will continue to be forced to bear the financial burden of treating those injuries.

5. Lilly markets and sells Zyprexa, or olanzapine, an antipsychotic drug approved by the FDA for the treatment of schizophrenia and bipolar mania. Zyprexa entered the U.S. market

in 1996 and no generic version of the drug has yet been made available.

6. Lilly knowingly misrepresented and otherwise deceptively concealed the risks associated with Zyprexa, including side effects such as diabetes, cardiovascular problems, and significant weight gain. Lilly also wrongfully marketed and promoted Zyprexa for off-label uses without proof of the drug's efficacy or safety in treating these unapproved indications.

7. Connecticut physicians have prescribed Zyprexa to many CMAP recipients and other Connecticut consumers based on Lilly's knowing misrepresentations about and concealment of the risks associated with Zyprexa. These prescriptions were paid for, or submitted for reimbursement by CMAP and/or consumers and include prescriptions for off-label uses of the drug.

8. As a result of using Zyprexa, CMAP recipients and Connecticut consumers have suffered serious health effects. The CMAP and Connecticut consumers have unjustly borne, and will continue to bear, financial responsibility for the costs of the extensive medical treatment and health-related care and services required by patients harmed by Zyprexa.

9. Because of Lilly's wrongful actions and representations, the CMAP has been forced to spend more than $190 million purchasing Zyprexa, as well as millions of additional dollars in state funds treating participants in CMAP for injuries related to their use of Zyprexa. Connecticut consumers have also continued to bear financial responsibility for these injuries.

10. Lilly knew that the CMAP and Connecticut consumers would be injured to the extent they were forced to provide, pay and/or reimburse for unnecessary prescription drug expenditures as well as the provision of health care products, services and facilities for those CMAP recipients and Connecticut consumers who were harmed by Zyprexa. The State seeks restitution to CMAP and to injured Connecticut consumers for the expenses incurred in

purchasing or reimbursing for prescriptions of Zyprexa as well as the expenses incurred in providing medical treatment necessitated by illnesses caused by Zyprexa.

I. PARTIES

A. Plaintiff: The State of Connecticut

11. The State of Connecticut brings this action in its sovereign capacity.

B. Defendant: Eli Lilly and Company, Inc.

12. Defendant Eli Lilly and Company, Inc. is an Indiana corporation with its principal place of business located at Lilly Corporate Center, Indianapolis, Indiana 46285. At all times relevant hereto, Eli Lilly was engaged in the business of licensing, manufacturing, distributing, marketing, advertising, and/or selling, either directly or indirectly, through third-parties of related entities, the pharmaceutical prescription drug Zyprexa.

13. Defendant Eli Lilly has, during all times relevant to this complaint, engaged in the trade or commerce of manufacturing, selling and/or distributing pharmaceutical products which are ultimately sold or distributed to providers in the State of Connecticut and/or prescribed, dispensed and/or administered to CMAP beneficiaries and other Connecticut consumers.

II. JURISDICTION

14. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331, because this action arises under the laws of the United States, and 18 U.S.C. §1964(c), because this action alleges violation of the Racketeer Influenced Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1962.

15. This Court has supplemental jurisdiction pursuant to 28 U.S.C. § 1367 over Plaintiff's state law claims.

16. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391 (b) and (c)

and 18 U.S. § 1965 because Defendant transacts business, is found, and/or has agents in this district. Lilly has conducted substantial business in this district. Further, this district is also the location of the Zyprexa Products Liability Multi-District Litigation. *See In re Zyprexa Products Liability Litigation*, MDL 1596 (E.D.N.Y. 2004).

III. FACTUAL BACKGROUND

A. Payment of Health Care Costs by the State of Connecticut and Consumers

17. Health care costs for Connecticut citizens are borne by a variety of parties and include consumers, private insurers, and the State of Connecticut. Many consumers in the State of Connecticut have paid all or part of the costs of their purchases of Zyprexa and associated health care since Zyprexa entered the market.

18. The State of Connecticut, through the Connecticut Department of Social Services ("DSS"), administers the Connecticut Medical Assistance Program ("CMAP"). The CMAP includes the Connecticut Medicaid program, as well as the Connecticut Pharmaceutical Assistance Contract to the Elderly and the Disabled ("ConnPACE"), State Administered General Assistance ("SAGA"), Connecticut AIDS Drug Assistance Program ("CADAP") and Healthcare for Uninsured Kids and Youth ("HUSKY").

19. Through these programs, the State pays all or part of enrollees' medical benefits, including prescription drugs, for families with children under the age of 21, pregnant women and newborns, adults without children, adults with disabilities, people age 65 and older, and people living in nursing homes. Much of the budget of the Connecticut Department of Social Services, which is comprised of federal, state, and local funds, is devoted to these health care programs. The CMAP reimburses physicians, pharmacists, and other health care providers for certain drugs (including Zyprexa) prescribed, dispensed, and/or administered to the program's participants.

1. Connecticut Non-Medicaid Health Care Programs

20. The Connecticut Pharmaceutical Assistance Contract to the Elderly and the Disabled ("ConnPACE") aids the elderly and disabled with prescription expenses.

21. The State Administered General Assistance program ("SAGA") provides financial and medical assistance to indigent Connecticut residents and families who do not qualify for Medicaid.

22. The Connecticut AIDS Drug Assistance Program ("CADAP") pays for select drugs that may prevent the further deterioration of the health of persons with HIV or AIDS.

23. The Healthcare for Uninsured Kids and Youth ("HUSKY") program provides prescription drug and other health care benefits to children and eligible caregivers in Connecticut. Benefits are offered on a sliding scale, depending upon family income. HUSKY currently covers more than 230,000 children and teens in Connecticut

24. The State of Connecticut provides prescription drug and/or health care benefits to certain of its residents through a variety of additional programs or departments, including the State's community health centers, public hospitals and Department of Corrections.

2. Connecticut's Medicaid Program

25. The Connecticut Medicaid program works to ensure low income families with dependent children and individuals that are blind, aged, or disabled have access to adequate health care. Connecticut Medicaid provides prescription drug and other health benefits to many thousands of individuals residing in the State.

26. While every state runs a unique Medicaid program with distinct rules and regulations, the federal statutory scheme imposes certain obligations upon each state and its programs. Under the Medicaid statutory scheme, states are entitled to federal financial participation to reimburse a portion of the amount the state pays pharmacies for covered

outpatient drugs. 42 U.S.C.A. § 1396r-8. Only drugs used for medically accepted indications – an FDA approved indication, or an indication supported by the American Hospital Formulary Service Drug Information, the United States Pharmacopeia Drug Information and the DRUGDEX Information System – fall within the definition of "covered outpatient drugs." *See* 42 U.S.C.A. § 1396r-8(k)(3), 42 U.S.C.A. § 1396r-8(k)(6); 42 U.S.C.A. § 1396r-8(g)(1)(B)(i).

27. Another condition of receiving federal financial participation requires states, including the State of Connecticut, to seek recovery of health care costs paid for by the state's Medicaid funds from other responsible or liable parties. Examples of such parties include:

- Drug manufacturers, for drug rebates mandated by the Omnibus Budget Reconciliation Act of 1990 ("OBRA 90"), as a condition of coverage of their prescription drug products;
- Liable third parties, under the third-party liability provisions of the statute and regulations (see 42 C.F.R. § 433.138 *et seq.* (2006) (stating, "The agency must take reasonable measures to determine the legal liability of the third parties who are liable to pay for services furnished under the plan")); and
- Health care providers, whether as a result of error, overpayment, fraud or abuse (see 42 C.F.R. § 433.300 et seq. (2002)).

28. Between 1996 and 2006, the State of Connecticut paid or reimbursed more than $190 million for Zyprexa, spending an average of about $240 per one month's supply of 10mg Zyprexa. It has spent countless additional funds on medical expenditures relating to injuries arising out of the use of Zyprexa.

29. The State of Connecticut has instituted a number of programs and policies designed to monitor and help control the costs of prescription drug reimbursement under its public health care programs.

30. The State has been unable to institute controls to influence or reduce the incidence of prescriptions of Zyprexa (or any other antipsychotic medication). The Centers for Medicare & Medicaid Services ("CMS"), the federal agency which administers the Medicare, Medicaid

and State Children's Health Insurance Program, mandates that all state Medicaid programs cover antipsychotic medications.

31. Similarly, the State has been unable to monitor or curtail off-label prescriptions of Zyprexa as physicians are not required to, and thus do not regularly use, diagnosis codes when prescribing Zyprexa to patients.

32. Lilly expected that and intended for its promotional efforts to cause claims for reimbursement for prescriptions of Zyprexa to be submitted to Connecticut under the State's Medicaid and public health care programs.

33. Lilly knew or should have known about the Medicaid regulations governing prescription drug reimbursement. It had, and still has, a duty to refrain from conduct which could cause submission of non-medically accepted and/or medically unnecessary prescriptions to Medicaid for reimbursement. Lilly breached this duty by knowingly causing prescriptions for non-medically accepted indications and/or medically unnecessary uses of Zyprexa to be submitted to Connecticut's Medicaid and other public health care programs for reimbursement.

34. As detailed below, Lilly exploited its position, superior knowledge of Zyprexa's characteristics and knowledge that payers such as the State of Connecticut rely on suppliers and sellers to comply with governing regulations when it engaged in deceptive marketing and promotional practices designed to foster prescriptions of Zyprexa paid for by public funds and resulting in injuries to beneficiaries of those funds.

B. The Rise and Early Promotion of Zyprexa by Lilly

1. Schizophrenia, Traditional Antipsychotics Drugs and Emergence of Atypical or Second Generation Antipsychotic Medications

35. Schizophrenia is one of the most complex and challenging psychiatric disorders. It represents a heterogeneous syndrome of disorganized and bizarre thoughts, delusions,

hallucinations, inappropriate affect and impaired psycho-social functioning. 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/or negative symptoms.[1]

36. 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 referred to as schizophrenia.

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

38. Over the years, treatment of schizophrenia has relied on antipsychotic drugs that target dopamine D2 receptors. The many antipsychotic drugs introduced during the following decades were increasingly potent, as medicinal chemists improved the drugs' affinity for the D2 receptor.

39. 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 1990s, the typical antipsychotics were the

---

[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 persons 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 medical disorder or substance use.

common drug therapy for schizophrenia.

40. Despite the existence of numerous traditional antipsychotics, because the drugs had similar mechanisms of action, they showed similar side effects, including extrapyramidal syndromes ("EPS")[2] such as parkinsonian effects and tardive dyskinesia ("TD"), a long-lasting movement disorder frequently arising with prolonged treatment. And as to efficacy, the early promise that these drugs might dramatically improve patients' long term psychosocial and cognitive disabilities was only partially fulfilled.

41. By the 1980s, manufacturers began turning to new chemicals and drugs in hopes of finding treatment options that reduced the incidence of movement disorders in patients taking antipsychotic medications. Drug manufacturers investigated clozapine for the treatment of schizophrenia on this theory. Researchers termed clozapine an atypical antipsychotic because it had an "atypical index" when measuring its effect on activity in different parts of the brain and hypothesized that the different effects of clozapine on the areas of the brain that control movement meant that the compound would cause less movement disorder. The hypothesis held true and clozapine was found to offer greater effectiveness and fewer movement side effects. However, the potential of clozapine to cause truly toxic side effects, including agranulocytosis, limited its prescription to about 10 percent of persons with schizophrenia.

42. During the 1990s, pharmaceutical companies, acting on the "atypical" hypothesis, introduced newer drugs attempting to capture the enhanced therapeutic effect of clozapine minus its toxicity and avoid the increased EPS caused by traditional antipsychotics. These atypical antipsychotics include clozapine (Clozaril), olanzapine (Zyprexa), quetiapine (Seroquel), risperidone (Risperdal), aripiprazole (Abilify), and ziprasidone (Geodon), and are considered the

---

[2] Extrapyramidal syndromes are caused by the blockage of dopaminergic neurotransmission in the basal ganglia.

second generation antipsychotics (SGA).

43. 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 approximately 90% of antipsychotic drugs prescribed for all psychiatric purposes, regardless of whether they were approved for those indications or not. In part, this lawsuit describes how Lilly achieved, through a series of unlawful acts and practices, the largest United States market share for atypical antipsychotics, both for FDA-approved purposes and for unapproved purposes.

2. FDA Approval Process for Olanzapine

44. In the early 1990s, Lilly developed and sought approval for its own atypical antipsychotic: olanzapine, the eventual trade name for which would be Zyprexa. Olanzapine is a selective monoaminergic antagonist with a high affinity binding to the subtypes of serotonin, dopamine and other receptors. Thus, as is the case with other antipsychotics, the proposed efficacy of olanzapine for schizophrenia is mediated through a combination of dopamine and serotonin type II (5HT2) antagonism.

45. In seeking approval of olanzapine for the treatment of psychotic disorders, Lilly submitted two controlled studies showing olanzapine to be superior to placebo in the treatment of psychosis in patients with schizophrenia during short term (six week long) studies. As such, the FDA approval of olanzapine for the treatment of psychotic disorders constituted the regulatory minima traditional for FDA approval – olanzapine had been proven as better than nothing (i.e., a placebo) in the short term. Approval did not support, and did not constitute, an endorsement by the FDA that olanzapine was better than or equal to any other antipsychotic, traditional or atypical, in terms of efficacy.

46. Moreover, the short-term controlled trials were limited to inpatients who met the

diagnosis criteria for schizophrenia included in the *Diagnostic & Statistical Manual of Mental Disorders, 3rd Edition, Revised* for schizophrenia. Thus, the FDA limited the original approved indication to adults with psychotic disorders.[3]

47. Because the mechanisms of actions for olanzapine were fundamentally the same as other SGAs, the FDA required (and Lilly was constrained to acquiesce) to warnings for Zyprexa that included neuroleptic malignant syndrome ("NMS") and TD.

48. Medical literature dating as far back as the 1950s, and Lilly'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 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 Lilly, i.e., effects on dopamine, serotonin, and histamine systems in the brain. Therefore Lilly should have been concerned about Zyprexa causing neurological problems, weight gain, diabetes, pancreatitis, hyperglycemia, cardiovascular complications, and metabolic syndrome. And yet neither Zyprexa's original label nor its subsequent label changes adequately warned of these adverse effects.

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

50. Despite knowing that Zyprexa increased the risks of weight gain, hyperglycemia, other adverse metabolic events, and certain cardiovascular issues, Lilly fought to keep fair and

---

[3] Although a single haloperidol arm was included as a comparative treatment in one of the two trials, this trial did not compare these two drugs over a full range of clinically relevant doses for both.

balanced disclosures regarding these risks from the Zyprexa label. During the FDA approval process, two important facts regarding the marketing of Zyprexa became apparent: 1) the need for restraint with respect to claims of efficacy, which according to the FDA had only been minimally demonstrated; and 2) Lilly's aversion to providing warnings about weight gain, much less the potential for diabetes.

51. In September of 1996, the FDA approved Zyprexa for use in the treatment of schizophrenia. Between October 1996 and early-September 2003, Lilly 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 until it was forced to do so by the FDA in mid-September of 2003.

52. Since Lilly introduced Zyprexa in 1996, it has been prescribed to more than twelve million people worldwide and became Lilly's top-selling drug, grossing an estimated $22 billion to date. Net worldwide sales of Zyprexa in 2006 alone topped $4.3 billion.

53. In the early 2000s, state Medicaid programs paid more than $1.5 billion each year for Zyprexa, spending over a half a billion dollars more on Zyprexa than any other single drug.[4] From launch through the present, spending in Connecticut under Medicaid for Zyprexa exceeded $190 million.

54. Crucial to this blockbuster success was Lilly and its co-conspirators' aggressive marketing of Zyprexa, which consisted chiefly of overstating the drug's uses, while understating (if not outright concealing) its life-threatening side effects.

---

[4] *See* CMS Medicaid Drug Utilization data, ranked by Drug, 2003-2006.

3. Lilly's Promotional Campaign Strategy and the Formation of the Unlawful Marketing Enterprises

55. Lilly's strategy to market Zyprexa began prior to the drug's approval in 1996. Lilly designed studies in order to deliver desired results, results that were supported by paid consultants and researchers who touted these studies as supporting the safety and efficacy of Zyprexa for a broad range of unapproved uses. Lilly's strategy included downplaying the potential side effects of Zyprexa while promoting their newest drug for a broad array of mood and thought disorder symptoms. The purpose of this pre-market planning was to maximize the number of prescriptions written and the price paid for Zyprexa out of the gate.

56. Beginning in 1996 and continuing to the present, Lilly implemented a marketing, advertising and promotion campaign by combining its own significant personnel and financial resources with medical marketing firms, peer physicians, public officials and purported charities. By creating this unlawful marketing campaign, Lilly was able to falsely and deceptively oversell the safety and efficacy of Zyprexa compared to other antipsychotics and unlawfully promoted Zyprexa for use in unapproved populations where the efficacy and potential side effects of Zyprexa had not been adequately established though clinical evidence.

57. Lilly established this campaign to accomplish several goals instrumental to a scheme to market Zyprexa (1) through fraudulent, or false and deceptive, claims of efficacy and safety, (2) for unlawful, off-label purposes and (3) without adequate warnings to (and indeed with affirmative misleading of) physicians, consumers, and public and private payors about the severe side effects of Zyprexa, including weight gain, hyperglycemia, diabetes and cardiovascular effects.

58. To be successful, Lilly had to create parallel marketing structures that appeared independent from Lilly's ordinary promotion forces – both to avoid federal regulations

concerning off-label promotion and to create the façade of independence behind the misleading messages of safety, efficacy and non-indicated usage it wished to promote. For example, Lilly funded and hosted scores of events where doctors trained and/or approved by the company falsely oversold the efficacy and safety of Zyprexa while providing favorable information on off-label use of the drug, generally in settings wherein physicians would be compensated for attending the presentation. Lilly helped select and control the content of the message and the presenters at such "educational" events. Among the information Lilly, the participating vendors and the participating physicians deliberately omitted from the events sponsored by the company was the following:

- the lack of clinical trial evidence to support Zyprexa's off-label uses;
- negative clinical trial results that demonstrated that Zyprexa was no more effective than other, less costly, medications;
- negative evidence that Zyprexa did not work for off-label conditions;
- information that virtually all publications and studies that allegedly supported Zyprexa's off-label use had been funded by Defendant;
- information that virtually all publications and studies that allegedly supported Zyprexa's off label use had been initiated by Defendant pursuant to a corporate marketing plan designed to increase off-label sales;
- information that the participating doctors who were conducting the peer selling had been paid substantial subsidies to use Zyprexa on their patients for off-label purposes;
- that the events the physicians were attending were neither fair nor balanced and were created to insure the physicians would not hear a fair and balanced examination of Zyprexa for off-label uses;
- information that the events were not funded, as advertised, by an "unrestricted" grant from the Defendant, but that the grants were conditioned upon the participating vendors and sponsoring institutions putting on presentations that painted the off-label use of Zyprexa in the most favorable light; and
- information with respect to dangerous side effects revealed through Lilly's internal research, adverse event reports, and independent research.

59. Second, to successfully execute its publication strategy, favorable articles had to be generated and published that appeared to emanate from independent physicians, and continuing legal education marketing schemes needed to flood the information market, all of which would give the appearance of independent peer-to-peer credibility. Lilly paid large sums of money, often in the form of research grants, to physicians in order to publish such articles. In some cases, the physician was not required to perform any research or even write the article. Marketing firms financed by Lilly ghostwrote articles under the physicians' names: physicians merely had to "lend" their names to the articles, in exchange for a payment. Even in cases where physician-authors drafted the articles themselves, they did so under Lilly's direction and control.

60. Publications distributed by Lilly as part of this strategy intentionally misrepresented the company's role in the creation and sponsorship of the publications. Physicians who reviewed these publications were led to believe that the publications were the independent, unbiased research of the authors of the articles. They were not made aware of the fact that Lilly had in fact solicited these articles or that they had paid significant sums of money in various forms to the physician authors to induce them to make favorable statements about Zyprexa.

61. Third, Lilly targeted pharmacies, particularly those that serviced long term care facilities, in its marketing of Zyprexa. Such facilities primarily treat the elderly and children with behavioral problems and symptoms. The sales division responsible for marketing to long term care facilities targeted both of these populations. Not surprisingly, the growth of sales in the long term sales division was heavily weighted to pediatric use, all of which was off label, and to off label uses in the elderly population.

62. Fourth, given the predominant usage of antipsychotics in the public sector (e.g.

Medicaid, which covers a significant population of the mentally ill), to be successful in its unlawful promotional efforts. Lilly corrupted thought leaders in state public agencies to use, and indeed have themselves promote, atypical antipsychotics, including Zyprexa. Lilly employed a strategy to capture Medicaid and Medicare markets that involved a focus on a relatively small group of customers – state officials who oversee treatment for many people with serious mental illness. These patients are found in state mental hospitals and state mental health clinics and are on Medicaid, and they are among the largest users of antipsychotic drugs. Lilly entered into agreements with state public officials in a number of states, paying them substantial sums of money and enlisting them in an ongoing course of conduct to spread falsehoods regarding the efficacy, safety, and side effects of Zyprexa and to promote its off-label use.

63. All of these goals were complimentary and mutually reinforcing. The production of favorable publications helped create a positive image for Zyprexa: peer-to-peer marketing and promotion allowed aggressive sales pitches to continue with the veneer of legitimacy, state public officials were co-opted to promote and over utilize atypical antipsychotics such as Zyprexa and all these effects would spill over to other state Medicaid agencies and to private payer networks.

64. To achieve all these goals, Lilly created a number of associations-in-fact, denominated herein as the Zyprexa Unlawful Marketing Enterprises. Three such associations-in-fact or sub-enterprises are laid out in greater detail below: the Peer-Selling Enterprise, the Publication-Enterprise, and the Public Payer-Enterprise.

a. Peer-Selling Enterprise

65. Lilly's peer-to-peer marketing scheme centered on hosting numerous events where doctors trained and/or approved by Lilly would falsely oversell the efficacy and safety of Zyprexa and would provide favorable information on the off-label use of Zyprexa, often under

conditions where physicians would be compensated for attending the presentation. Because Lilly was prohibited from directly producing such events, it created and controlled a Peer-Selling Enterprise composed of medical marketing firms (the "vendor participants") and several dozen physicians (the "physician participants") who routinely promoted Zyprexa to other physicians in venues all across the country. Lilly maintained sufficient control over the enterprise to select and approve the content of the programs and the physician participants that would deliver the off-label message. The physicians who attended these events were deceived into thinking that the events were educational in nature and independent of Lilly.

66. The Peer-Selling Enterprise employed improper and unlawful sales and marketing practices, including: (a) deliberately misrepresenting the safety and medical efficacy of Zyprexa for a variety of off-label uses; (b) knowingly misrepresenting the existence and findings of scientific data, studies, reports and clinical trials concerning the safety and medical efficacy of Zyprexa for both approved indications as well as a variety of off-label uses; (c) deliberately concealing negative findings or the absence of positive findings relating to Zyprexa's and/or its off-label uses; (d) wrongfully and illegally compensating physicians for causing the prescribing Zyprexa; (e) knowingly publishing articles, studies and reports misrepresenting the scientific credibility of data and touting the medical efficacy of Zyprexa for both on-label and off-label uses; (f) intentionally misrepresenting and concealing Defendant's role and participation in the creation and sponsorship of a variety of events, articles and publications used to sell Zyprexa to off-label markets; and (g) intentionally misrepresenting and concealing the financial ties between Defendant and other participants in the Enterprise.

67. Lilly's scheme reaped it significant financial gain. From 1995 to 2004, revenues from the sale of Zyprexa soared into the billions. Sales of the drug have grown at a significant

rate each year.

68. All of the participants in the Peer-Selling Enterprise associated with Lilly with the common purpose of aiding it in marketing Zyprexa for off-label uses and to achieve "market expansion" of these uses. Each of the participants received substantial revenue from the scheme to promote Zyprexa off-label. The more successful these marketing events were, the more events there would be in the future and the more fees each of the participants would receive for participating in the events. For these reasons, all of the participants knowingly and willingly agreed to assist Lilly in its off-label promotion of Zyprexa, notwithstanding the fact that such a promotional campaign required the systematic repetition of false and misleading statements to, and the commercial bribery (through kickbacks) of, a score or more physicians throughout the United States, and that the promotion of Zyprexa for off-label indications by Lilly was illegal.

69. Lilly controlled the Peer-Selling Enterprise. It compensated the other participants for their efforts, and controlled the money flow to the participating vendors and physicians. Lilly closely monitored all events to insure the expected representations related to off-label Zyprexa were made to physicians attending the events.

(1) Role of Medical Marketing Firms in Peer-Selling Enterprise

70. Third party medical marketing firms were critical to Lilly's scheme to promote Zyprexa off-label from the scheme's inception. Lilly's marketing plans called for off-label information concerning Zyprexa to be widely disclosed in continuing medical education programs, "consultants' meetings", and other programs where physicians could instruct other doctors how to use Zyprexa for unapproved indications. Bona fide continuing medical education programs and similar educational events were exempt from FDA rules prohibiting off-label promotion because the sponsoring organization—which was often a nonprofit, like a medical school, was independent and was supposed to control the programs' content. In practice,

however, these programs were produced with the assistance of third party medical marketing firms, and these firms supplied content and controlled the selection of presenting physicians.

71. Lilly's marketing strategies turned the proper practices for presenting continuing medical education programs on their head. Instead of accredited institutions planning independent programs and then approaching third party vendors and financial sponsors, Defendant intended to create turnkey medical programs, with financing already included, and then find "independent" institutions that would present the package in the format Lilly and its enterprise created.

72. Lilly and participating vendors and physicians deliberately omitted a variety of information from sponsored events, including, among other things, the lack of clinical trial evidence to support Zyprexa's off-label uses; negative evidence that Zyprexa did not work for off-label conditions; negative clinical trial results that demonstrated that Zyprexa was no more effective than other, less costly, medications; and dangerous side effects revealed through Lilly's internal research, adverse event reports, and independent research.

73. Each of the participating vendors was in regular communication with Lilly. In connection with major medical congresses or conventions of the specialists that were the target of the off-label promotion campaign, the participating vendors coordinated their events to ensure their off-label message reached the most physicians in the most effective manner. All of the participating vendors were also in regular communication with the participating physicians, and individual participating physicians would give the same presentation (or a substantially equivalent presentation) at different participating vendors' events.

74. The planning and coordination of all of these events by the third party medical marketing firms required extensive use of the wires and mails, including the mailing of

invitations to physicians, the mailing of proposals to the accrediting institutions, booking of hotels and airplane tickets, the arrangement of meals, the scheduling of teleconference calls, the development and modification of the tactical plans, and the coordination of the content of the presentations on Zyprexa to be presented at the event.

(2) Role of Physicians in the Peer-Selling Enterprise

75. One of Lilly's principal strategies for marketing Zyprexa was to target key physicians to serve as thought leaders. These doctors would promote Zyprexa to their peers through peer selling programs by (i) touting Zyprexa's supposed off-label uses; (ii) claiming that Zyprexa was being widely used by other physicians for off-label uses; (iii) suggesting mechanisms of action that could explain Zyprexa's efficacy, safety profile and use in off-label areas, even though the mechanism of action in any area was not, and still is not, understood; and (iv) claiming that they were privy to the latest clinical data that had not been released yet, but which would support off-label use.

76. To lure physicians to participate in the Peer-Selling Enterprise, Lilly personnel approached target doctors and informed them of the company's interest in funding research opportunities and clinical trials at their institutions. Doctors who were willing to speak favorably about Zyprexa could likely receive substantial funds in the form of research grants. Lilly instructed its sales departments to select doctors at the major teaching hospitals to become "Zyprexa experts" who would in turn deliver the Zyprexa message to other physicians to grow Zyprexa sales. This could be done formally to other physicians at marketing events or informally to colleagues within a hospital or medical practice.

77. Having recruited these physicians, the Peer-Selling Enterprise created an explosion in the off-label use of Zyprexa by artificially creating the perception that physicians were clinically using Zyprexa and investigating its efficacy in off-label uses on their own

initiative, and not as a result of the illegal marketing activities. Lilly developed a stable of physicians to create this perception and, principally through the vendor participants, paid these physicians to induce them to write journal articles and letters to the editor that favorably discussed the off-label use of Zyprexa. Lilly also paid these physicians (in addition to providing free travel to resorts, free lodging and free meals) to induce them to give talks at medical education seminars, advisory boards, consultants' meetings, speakers bureaus and similar events that favorably discussed the off-label uses of Zyprexa. The physicians who accepted these benefits and agreed to promote Zyprexa off-label to other doctors were physician participants in the Peer-Selling Enterprise. The individual physician participants received tens of thousands of dollars to promote Zyprexa's off-label uses.

78. Physician participants were absolutely critical to the success of the Peer-Selling Enterprise and all of the marketing plans drafted by Lilly and the vendor participants required their participation. The participation of physicians allowed Lilly and vendor participants to disguise promotional events as educational events or consultants' meetings. Moreover, as noted above, Lilly and vendor participants knew that peer-to-peer selling was far more persuasive than traditional detailing. By funneling the payments to the physician participants through the vendor participants, the Enterprise could hide the speakers' financial ties with Lilly, the Enterprise was able to mislead physician-listeners into believing that the speakers were not biased and that the events were not promotional. The large amounts of money the participating physicians received from Lilly, for speaking and other purposes, was hidden from the physicians who attended events at which the participating physicians spoke.

79. Physician participants worked with, and were retained by, multiple vendor participants. Frequently, Lilly personnel recommended specific individual participants for

events.

80. Some physicians participated in the Peer-Selling Enterprise by publishing favorable journal articles and letters to the editor about off-label use of Zyprexa. Lilly paid large sums of money, often in the form of research grants. to the physician participants in order to publish such articles. In some cases, the physician was not required to perform any research or even write the article. Marketing firms who were financed by Lilly ghostwrote articles under the physician participants' names. Physicians merely had to "lend" their names to the articles, in exchange for a payment.

81. Physicians who participated in the Peer-Selling Enterprise, either as speakers or as authors, entered into a mutually advantageous relationship with the Defendant. The more favorable a physician's statements were, the more he or she could expect to receive in the form of speaker fees and research grants. Physicians who refused to deliver the favorable off-label message that Lilly wanted were blackballed and would not receive additional payments.

82. The participating physicians knew that minimal scientific evidence supported the use of Zyprexa for the off-label uses and that the type of clinical evidence that existed was insufficient, under the usual standards in the medical profession, to represent that Zyprexa worked for the unapproved indications.

(3) Role of Pharmacies in the Peer-Selling Enterprise

83. Lilly also targeted pharmacies, particularly those that serviced long term care facilities, in its marketing of Zyprexa. Such facilities primarily treat the elderly and children with behavioral problems and symptoms. The sales division responsible for marketing to long term care facilities targeted both of these populations. Not surprisingly, the growth of sales in the long term sales division was heavily weighted to pediatric use, all of which was off label, and to off label uses in the elderly population.

84. Long term facilities are not serviced by traditional retail pharmacies. Instead they use "closed end" pharmacies that service only long term facilities. The long term care pharmacy market is dominated by a few companies, including Omnicare, Pharmerica, and Neighbor Care.

85. Lilly sales representatives, working very closely with long term care facility pharmacies, often used unrestricted educational grants to effectuate their off label scheme with the pharmacies. Typically, the interaction was as follows: a Lilly sales representative and a pharmacy would agree that the pharmacy would request funding from Lilly in order to present an educational program. For instance, the sales representative and the pharmacy might agree that the pharmacy would present an educational program for the treatment of dementia. Both the pharmacy and the Lilly sales representative would agree that the program would include a presentation for the off label use of Zyprexa to treat dementia and the Lilly sales representative would recommend a doctor it knew would make a presentation on the off label use of Zyprexa for dementia. The Lilly sales representative would then file a form with Lilly headquarters in Indianapolis requesting that a check be issued to the pharmacy for an educational grant. Lilly headquarters would issue the check in the name of the pharmacy. The pharmacy would then issue a check to the doctor making the presentation. Since the pharmacy theoretically "controlled" the presentation, Lilly believed that these events could contain off label information without running afoul of FDA regulations on off label marketing.

86. Each sales representative in the long term care sales division had a quarterly budget of approximately $10,000 to request unrestricted educational grants from Lilly headquarters. Lilly was able to use the unrestricted grants to funnel a constant flow of money to all parts of the country for purposes of off label marketing to the long term care market of elderly and children populations.

87. Lilly's off label pharmacy scheme may have not escaped detection of the federal government. Lilly recently announced that, in October of 2005, the United States Attorneys Office in the District of Massachusetts issued a subpoena to Lilly seeking documents relating to Lilly's business relationship with a long term care pharmacy and Zyprexa.

88. The long term care division was ultimately shut down by Lilly when it was merged with the hospital sales division in or about June of 2003. At approximately the same time, Lilly acknowledged the existence of ongoing federal investigations into the company's off label marketing activities.

b. Publication Enterprise

89. In order to execute its publication strategy, Lilly also needed to generate favorable articles about Zyprexa's off-label uses. However, Lilly's apparent control of this strategy had to be kept to an absolute minimum. Articles had to appear as if they emanated from independent physicians who were investigating Zyprexa independently. To perform these tasks Lilly established a sub-enterprise of the Zyprexa Unlawful Marketing Enterprises, which would create "independent" publications. Like the Peer-Selling Enterprise, the Publication Enterprise was an association in fact of medical marketing companies, participating physicians and Lilly, for the purpose of promoting off-label uses of Zyprexa. Alternatively, the Publication Enterprise can be viewed as an enterprise which was separate and distinct from the other Zyprexa Unlawful Marketing Enterprises.

90. Lilly's "publication strategy" required publications from independent physicians when in fact no such publications existed. Lilly created the Publication Enterprise to hire non-physician technical writers to create the necessary articles and then paid actual specialists to be the articles' author. This practice is referred to in the publishing world as ghostwriting.

91. In order to monitor the status of publications, and in order to coordinate and

execute the ghostwriting plan, marketing firms were necessary. The role played by the firms in assisting Lilly in creating publications was very similar to the role played by marketing firms in the coordination of peer-to-peer marketing events.

92. Publications that Lilly distributed as part of their "publication strategy," intentionally misrepresented Lilly's role in the creation and sponsorship of the publications. Physicians who reviewed these publications were led to believe that the publications were the independent, unbiased research of the authors of the articles. They were not made aware of the fact that Lilly had in fact solicited these articles or that they had paid significant sums of money in various forms to the physician authors to induce them to make favorable statements about Zyprexa.

93. Even in cases where physician-authors drafted the articles themselves, they did so under the same system of direction and control through which Lilly controlled speaker content. Physicians were promised grants and other gifts if they wrote favorable articles. If a physician attempted to write a negative article, Lilly would attempt to intervene and have a more favorable draft written. If this failed, Lilly would do their best efforts to suppress the article or restrict its dissemination.

94. The final method by which Lilly controlled the stream of published information was through its policy of publishing only favorable results of its own internal trials and suppressing results that were unfavorable. In the case of an early trial that failed to show Zyprexa's efficacy for migraine, the results were never published. In the case of a clinical trial that failed to show Zyprexa's efficacy for bipolar disorder, the publication of results was delayed until the patent life was set to expire, and even then, Lilly never forwarded a copy of the article to DRUGDEX.

95. Although Plaintiff is aware of the policy of suppressing unfavorable studies because of the express terms of the corporate decisions implementing the Publication Strategy, all information regarding negative studies funded by Lilly remains in the sole possession of Lilly and/or members of the Zyprexa Unlawful Marketing Enterprises. Without access to records of the studies that were funded and the results of those studies, Plaintiff cannot identify specific negative findings. Defendant has never produced the results of these studies to the public.

c. Public Payer Enterprise

96. Beginning in the 1990's and continuing to today, Lilly and other atypical antipsychotic drug manufacturers employed a strategy to capture Medicaid and Medicare markets that involved a focus on a relatively small group of customers – state officials who oversee treatment for many people with serious mental illness. These patients are found in state mental hospitals and state mental health clinics and are on Medicaid, and they are among the largest users of antipsychotic drugs.

97. Lilly entered into agreements with state public officials in, among others, Texas, Tennessee, Pennsylvania and Ohio, paying them substantial sums of money. Lilly directly and indirectly worked with and controlled certain state officials, enlisting them in an ongoing course of conduct to spread falsehoods regarding the efficacy, safety, and side effects of Zyprexa and to promote its off-label use.

98. In addition to influencing and corrupting state officials, Lilly influenced prescribing physicians to over-medicate senior citizens in nursing homes with antipsychotics. The use, as much as about 75% of the long-term care elderly residents in various demographic areas have received psychotropic medications. Lilly also influenced prescribing physicians to over-medicate adolescents in detention centers and other institutions.

C. Lilly's Post-Approval Operations

99. Following the September 30, 1996 approval of Zyprexa by the FDA for the treatment of schizophrenia and despite this limited approval market, in eight years, Zyprexa grew to become the third best-selling drug in the world. In its first full year of sales, Zyprexa's worldwide sales netted $500 million dollars in revenue. In 2004, worldwide Zyprexa sales exceeded $4.4 billion.

100. To achieve such massive sales for a drug intended to treat an admittedly small market, Lilly deliberately over-promoted Zyprexa to physicians and patients for symptoms and indications unrelated to schizophrenia (and, later, to bipolar mania).

101. The over-promotion of Zyprexa by Lilly was a deliberate and calculated campaign designed to increase sales of the drug without regard for the safety of patients. The campaign also sought to distinguish Zyprexa as expensive but well worth the extra cost given its efficacy – which Lilly claims keeps schizophrenia patients out of the hospital more often than their competitors' drugs.

102. The campaign was closely supervised. Every Lilly-sponsored research paper, clinical study, sales representative training session, physician education luncheon and press release was crafted to further the campaign. The control exercised by Lilly over its marketing campaign was most apparent when outside forces began to affect Zyprexa sales. As reports of diabetes and weight gain related to Zyprexa began to escalate, Lilly carefully responded with focused papers and articles, physician-targeted educational seminars, and letters, even when the "new" message contradicted earlier messages.

103. The Zyprexa Unlawful Marketing Enterprises routinely and knowingly provided false, inaccurate, misleading, distorted, unfair and unbalanced information about Zyprexa's use

for unapproved indications.

1. Fraudulent and Unlawful Acts Regarding Safety and Efficacy

104. When presenting off-label information about Zyprexa to physicians in response to unsolicited requests for information on unapproved uses, Lilly was required to provide fair and balanced information. Lilly was also required to provide fair and balanced information whenever it engaged in promotional activities: fair balance was not limited to written materials but was to be included all presentations. Lilly knew that by requiring fair and balanced information, federal law and industry standards compelled it to provide any negative information alongside positive information about its drug products.

105. Within the medical community, the terms "effective" and "efficacy" have specific and well understood meanings in the context of describing properties of approved prescription drugs. Because the FDA will only find a drug product to be effective if the proposed use is supported by well designed, placebo-controlled clinical trials that establish a causal relationship to a statistically significant degree, a statement that a drug is "effective," or "works," or "has been proven to . . . " is understood to mean that well controlled clinical studies support the use. To make such a statement without such clinical trial proof is misleading. Further, failure to inform physicians that no placebo-controlled clinical trials support a representation of drug efficacy is a violation of a pharmaceutical company's obligation to disclose.

106. Although Lilly has extensively promoted Zyprexa for off-label purposes, few placebo-controlled, clinical studies have been conducted on off-label uses of Zyprexa. Most of those that have been conducted produced negative or inconclusive results. Placebo-controlled clinical trials for Zyprexa's use for bipolar disorder, unipolar disorder, essential tremor, spasticity, controlled diabetic pain, and panic disorder have all failed to show that Zyprexa is

effective for those conditions.

107. Any presentation concerning Zyprexa's use for indications other than those approved by the FDA that purports to rely on clinical or published evidence must also describe those clinical studies that have found that Zyprexa is not effective for off-label uses. Where such information is not provided, any statements about Zyprexa's effectiveness for off-label use are false, misleading, distorted, inaccurate, unfair, imbalanced and omit material facts required to be disclosed.

108. Federal law, Connecticut state law, and industry standards also prohibited Defendant from misrepresenting scientific evidence that supported (or failed to support) claims that a drug was effective for a specific condition. Thus, anecdotal evidence of a drug's usefulness for a given condition could not be presented as the equivalent of the findings of a well-designed clinical trial. Lilly's failure to comply with these standards violated its legal duty to provide accurate and non-misleading information.

109. In order to gain additional sales and to compete with other antipsychotics such as Risperdal, Lilly undertook a scheme to market and promote Zyprexa for off-label purposes, including use in the treatment of children and adolescents, "soccer moms", and the elderly. Lilly also devised a campaign to market primary care physicians ("PCPs") that was used to educate them about the patients in their practices whose symptoms might suggest Zyprexa use, albeit off-label.

110. Lilly understood that off-label use of Zyprexa was the key to increased sales and employed the services of various third-party marketing firms in order to effectuate its scheme to market Zyprexa for such off-label purposes. These firms undertook the marketing of Zyprexa for off-label uses at Lilly's direction and control. The rise in the use of Zyprexa for off-label use

is a well documented phenomenon: Lilly's promotion of Zyprexa for off-label uses, with the assistance of intermediary marketing firms, accounts in large part for the meteoric rise in Zyprexa sales and in the income derived by Defendant for sales of Zyprexa.

111. Lilly not only promoted off-label use, it carefully tracked Zyprexa's progress in these markets. For each patient and physician population, a separate marketing campaign was developed in conjunction with various third-party marketing firms with accompanying promotional materials, educational seminars, training sessions, and timely Lilly-sponsored published research and opinion papers.

a. Fraudulent and Unlawful Acts Regarding the Suppression of the Risk of Weight Gain

112. Weight gain is an acknowledged side effect of both first and second generation antipsychotic medications. Nearly fifty years of research have linked antipsychotics to weight gain as a side effect. For example, chlorpromazine and similar conventional antipsychotics have been known to impair glucose metabolism, which can lead to weight gain, following its introduction in the 1940s. Nevertheless, Lilly went to great lengths to conceal this potentially sales-crushing side effect until, at last, confrontation of the weight gain issue became unavoidable.

113. Prior to the launch in 1996, Lilly knew or should have known that Zyprexa causes weight gain. Plaintiff has reason to believe that Lilly's own pre-market studies evidenced significant weight gain among participants.

b. Fraudulent and Unlawful Acts Regarding the Suppression of the Risk of Hyperglycemia and Diabetes

114. While Zyprexa sales continued to escalate exponentially each year, Lilly continued to hide the adverse effects its drug was having on the elderly, children, those diagnosed with schizophrenia and others.

115. Even before the case reports in the peer-reviewed medical literature became known to the general medical public, Lilly was aware of large numbers of diabetes-related adverse events associated with Zyprexa, as reflected in the adverse event reports ("AERs") on file in the FDA's Medwatch database. The numbers of AERs over the first four years of Zyprexa's market life – nearly 200 AERs in the first two years, 400 AERs after three years, and approximately 600 diabetes-related AERs in Zyprexa's fourth year of distribution – were reported to the FDA and known to Lilly.

116. These numbers are very conservative. It is well understood that for prescription drugs, adverse event reports represent only 1% to 10% of the total estimated population of all complications.[5] 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 most adverse events). As a result, the number of reported complications must be multiplied by a factor of between 10 and 100 in order to arrive at the true estimated number of complications. Recognizing that, the true number of diabetes-related adverse events from market introduction in 1996 to year end 2000 may fall anywhere between 6,000 and 60,000, a staggeringly high number considering the indications being treated and the availability of far safer alternatives.

117. As of September 1998, although approximately 150 diabetes-related AERs had been reported, the Zyprexa label made not a single reference to these significant adverse event reports. Indeed, no post-market adverse event references of any type appeared on the Zyprexa U.S. label until September 30, 1998.

118. Between September 30, 1998 and March 17, 2000, Lilly made three label changes

---

[5] See, e.g., *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.

but failed to add any references to diabetes-related adverse events, despite the fact that more than 400 such AERs had been reported by that time. Instead, the label reflected that the only adverse event was "priapism".

119. On April 12, 2000, Lilly finally included a reference to "diabetic coma" together with priapism as an adverse event that had been reported since Zyprexa's market introduction. Given the timing, however, this change did not make its way into the 2000 edition of the Physicians' Desk Reference ("PDR"), an oft-consulted compendium of drug information and labeling, but is instead first found in the 2001 PDR. Further, the reference to diabetic coma was again buried deep within the label, as inconspicuously as possible, and failed to reference the hundreds of other diabetes-related injuries of which Lilly was aware, namely, diabetic deaths, ketoacidosis not resulting in coma, diabetes, and hyperglycemia.

120. Lilly knew by 1996 that Zyprexa's link to diabetes was well established scientifically in the medical literature and in its own clinical trials and that the link warranted an adequate warning to the medical community. It failed to put forth such a warning. And after being confronted by an alarming number of post-marketing AERs, Lilly still did nothing to warn the medical community of the true dangers linked to Zyprexa. Lilly simply ignored the reports of adverse events concerning diabetes, elevated glucose levels, and hyperglycemia.

2. Fraudulent and Unlawful Acts Regarding Off-Label Promotions for Elderly Usage

121. From Zyprexa's launch, Lilly's marketing campaign included promotion of the drug for use in the elderly for both dementia symptoms and Alzheimer's disease.

122. Defendant's decision to target the State's elderly had two particularly salient results, both of which Lilly knew and could have expected. First, non-medically accepted and medically unnecessary claims for Zyprexa were submitted to the Connecticut Health Care

Programs for payment and/or reimbursement. Second, taking Zyprexa resulted in disastrous health consequences for geriatric patients.

123. In April 2005, the FDA determined that the treatment of behavioral disorders in elderly patients with dementia with atypical antipsychotic medications is associated with increased mortality. In a total of seventeen placebo controlled trials performed with Zyprexa, Abilify, Risperdal, or Seroquel in elderly demented patients with behavioral disorders, fifteen showed numerical increases in mortality in the drug-treated group compared to the placebo-treated patients. Although the atypical antipsychotics are FDA approved for the treatment of schizophrenia, none have been approved for the treatment of behavioral disorders in patients with dementia. As a result of the findings, the agency required the manufacturers, including Lilly, to include a black box warning in their labeling describing this risk and that these drugs were not approved for this indication.

3. Fraudulent and Unlawful Acts Regarding Off-Label Promotions for Pediatric Usage

124. Lilly's scheme to gain additional sales and to compete with other antipsychotics such as Risperdal included marketing and promoting Zyprexa for use in the treatment of children suffering from disorders such as depression, anxiety, Attention Deficit Disorder, Attention Deficit Hyperactivity Disorder, and sleep disorders and to generally promote Zyprexa's use in children as a mood stabilizer. Zyprexa is not now and never has been approved by the FDA for any use in children, not even for use in children with schizophrenia and bipolar disorder.

125. Unfortunately, use of Zyprexa and other atypical antipsychotics in children and adolescents has become commonplace. One investigative report concerning the use of antipsychotic medication in treatment centers for troubled children in Westchester, Rockland and Putnam counties in the State of New York, indicated that between 60% and 90% were on some

sort of psychotropic drugs. At the St. Agatha Home in Nanuet, New York it has been reported that about 85 of the 100 children are treated with psychotropic drugs. The home's psychiatrist conceded that pharmaceutical representatives visit him about three times a week. The reporter noted that, "A small purple clock with a white Zyprexa logo sat on his desk, a gift from a pharmaceutical representative." Similarly, in a November 1, 2005 story in *The Wall Street Journal*, Leila Abboud reported that "By some estimates, there are 1.4 million to 4.2 million children who meet the criteria for conduct disorders alone. Today, many of these kids are placed on powerful psychiatric medications such as Eli Lilly and Co.'s Zyprexa and Johnson and Johnson's Risperdal that aren't well studied in children."

126. Despite the lack of any clinical trials or FDA approval for the use of Zyprexa in children, Lilly specifically addressed the promotion of pediatricians and trained its sales force on how to persuade pediatricians to obtain and prescribe Zyprexa to their young patients.

127. Children and adolescents remain a powerful market for Lilly's Zyprexa. Pediatric sales of Zyprexa totaled approximately $500 million between 1999 and 2005.

128. Zyprexa has never been proven safe or effective for the off-label uses for which Lilly and the intermediary marketing firms promoted it. As a result children were and continue to be exposed to medication which, at best, is ineffective and, at worst, can and does cause life-threatening illnesses such as diabetes and diabetes-related complications. Despite these risks, Lilly continues to promote Zyprexa for the treatment of children participating in the Connecticut Health Care Programs.

D. Despite Lilly's Efforts, the Truth Begins to Emerge

1. The FDA Requires Additional Warnings Regarding Treatment-Emergent Diabetes and Hyperglycemia in Late 2003

129. On September 11, 2003, the FDA notified Lilly that based on "an extensive

review of data available for patients treated with atypical antipsychotics over a number of years", the agency had determined what Lilly had known for years: that "epidemiological studies suggest an increased risk of treatment-emergent hyperglycemia-related adverse events in patients treated with atypical antipsychotics."

130. The FDA required Lilly to place the following "WARNING" about hyperglycemia and diabetes mellitus on the Zyprexa label and package insert:

> Hyperglycemia and Diabetes Mellitus
>
> 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 complicatd 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 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.

131. Despite the FDA's mandate the Lilly immediately warn of the dangers described

above, the company waited until March 1, 2004 – nearly six months later – to send a "Dear Doctor" letter to physicians, advising of the new warnings.

2. The Diabetes Consensus Statement Focuses on Olanzapine's Risks in 2004

132. In February 2004, the American Diabetes Association, the American Psychiatric Association, the American Association of Clinical Endocrinologists, and the North American Association for the Study for Obesity issued a Consensus Development Statement regarding antipsychotic drugs, obesity and diabetes. Among other things, the Consensus Statement observed that there is considerable evidence that use of atypical antipsychotics can cause a rapid increase in body weight, and that olanzapine was one of the worst offenders. The Consensus Statement also observed that numerous case reports had documented the onset and exacerbation of diabetes, including the occurrence of hyperglycemic crises, following the initiation of therapy with many atypical antipsychotics, among them olanzapine. Furthermore, the Consensus Statement observed that clozapine and olanzapine caused the greatest weight gain and are associated with the greatest increases in total cholesterol, LDL cholesterol, and triglycerides and with decreased HDL cholesterol.

133. The Consensus Statement acknowledged that diabetes is a very serious disease that afflicts millions of Americans. Some of the more common complications of diabetes include heart disease, stroke, circulatory problems (which can lead to amputation of limbs), neuropathy, and retinopathy. Obviously, a drug such as Zyprexa that both causes the onset of diabetes and exacerbates its onset and the complications associated with it in those predisposed to the affliction poses a very serious public health risk – particularly when the medical community is not adequately warned of these side effects.

134. The Consensus Statement concluded:

- "[T]he data consistently show an increased risk for diabetes in patients treated

with clozapine or olanzapine..."

- "Patients treated with olanzapine and clozapine have higher fasting and post-prandial insulin levels than patients treated with FGAs, even after adjusting for body weight"

135. The Consensus Statement supported these claims:

- The Risk of Diabetes Affects Drug Choice: "[T]he risks of obesity, diabetes and dyslipidemia have considerable clinical implications in this patient population and should...influence drug choice."

- Monitoring is Necessary to Prevent Against Diabetes and Diabetes Related Injuries: "Given the serious health risks, patients taking SGAs should receive appropriate baseline screening and ongoing monitoring."

- Patients Must Be Informed: "Health professionals, patients, family members, and caregivers should be aware of the signs and symptoms of diabetes and, especially those associated with the acute decompensation of diabetes such as DKA [diabetic ketoacidosis]."

3. The New England Journal of Medicine Publishes the Results of the CATIE Trials in 2005

136. On September 22, 2005, the New England Journal of Medicine published the results of the Clinical Antipsychotic Trials of Intervention Effectiveness ("CATIE" or "CATIE study"). The CATIE study was initiated by the National Institute of Mental Health ("NIMH") to compare the relative effectiveness of atypical antipsychotic drugs with older, first generation agents and was conducted between January 2001 and December 2004 at scores of clinical sights across the United States.

137. The CATIE study grew out of a number of concerns surrounding the SGAs, the first of which involved questions of efficacy. Although clozapine was introduced after studies indicated that it was more effective than first generation drugs, the other atypical antipsychotic agents were approved and marketed based on studies showing only that they were more effective than placebo. The issue of whether they, like clozapine, were truly more effective than first generation antipsychotic drugs remained largely unanswered.

138. Other concerns focused on side effects and price of the drugs. Although the atypical antipsychotic drugs generally fulfilled their promise of causing less movement disorder, new problematic side effects – severe weight gain, often accompanied by type 2 diabetes mellitus and hypercholesterolemia – emerged. (Weight gain had occurred with the older drugs, although it was generally less substantial.) In addition, the cost of the newer medications, coupled with unknowns regarding safety and efficacy, caused payors to question their purported value.

139. NIMH, without any pharmaceutical company funding, undertook a multisite, double-blind comparison between perphenazine, an older drug, and a series of the newer drugs; clozapine was omitted because it had already been observed to have superior efficacy.

140. The CATIE study reaffirmed what Lilly had long known – that Zyprexa was associated with greater weight gain and increased measures of glucose and lipid metabolism than all of the other antipsychotics. Approximately two thirds of the Zyprexa patients discontinued use of the medication prior to the end of the eighteen month study period because of intolerable side effects. Regarding efficacy, the study's authors concluded that the SGAs – including Zyprexa – were no more effective than perphenazine, the first generation antipsychotic, in treating schizophrenia with regard to symptom relief and side effect burden. The study found that during the eighteen months of the trial, initial assignment to perphenazine was less costly but not less effective than assignment to each of four atypical antipsychotic drugs, including Zyprexa.[6]

---

[6] Two years earlier, in 2003, Robert Rosenheck, lead author of the cost-effectiveness portion of the CATIE results, published an article entitled "Effectiveness and Cost of Olanzapine and Haloperidol Treatment of Schizophrenia" in the Journal of the American Medical Association. The article, based on a study of 309 patients at seventeen VA hospitals, concluded the therapeutic benefits of Zyprexa were only marginally, if at all, better than those of haldol/benzotropine combination therapy in treating schizophrenia. The study also noted, however, that Zyprexa

4. The FDA Requires Further Changes to the Zyprexa Label in 2007

141. In March 2007, Lilly received a letter from the FDA raising questions about the information to be included on the label for Symbyax – a combination of Zyprexa and the antidepressant Prozac. In the letter, the FDA noted "We are concerned that the proposed labeling is deficient with regard to information about weight gain" as well as high levels of fat and sugar in the blood of patients on the drug and stated "We do not feel that current labeling for either Symbyax or Zyprexa provides sufficient information on these risks." The FDA delayed approval of Symbyax as it waited for additional information about the metabolic side effects.

142. On October 5, 2007, Lilly added new warnings to Zyprexa's label, acknowledging for the first time that the drug has a greater tendency to cause high blood sugar than other atypical antipsychotic medications, contradicting previous statements by the company that Zyprexa did not cause high blood sugar at a more frequent rate than other SGAs. The new label also warns that patients on Zyprexa may gain weight and may continue to do so for up to two years after beginning treatment, noting that one in six patients will gain more than thirty-three pounds after two years of Zyprexa use.

E. Summary of Lilly's Activities

143. Zyprexa and the other SGAs were developed with the intent that they would be as or more effective than first generation antipsychotics and result in fewer and less severe side effects.

144. Zyprexa, in all of its formulations, has only received FDA approval for the treatment of schizophrenia and bipolar mania. Despite this limited approved market, in just

---

patients incurred $3,000 to $9,000 higher treatment costs than the haldol/benzotropine patients. The higher costs were due to the greater cost of the drug – more than $8 per day for Zyprexa compared to approximately $0.10 per day for the combination therapy – and greater hospitalization due to weight gain and diabetes suffered by the Zyprexa patients.

seven years. Zyprexa became the third best selling drug in the world. Zyprexa's worldwide sales in 1997, its first full year on the market, accounted for approximately $500 million in revenue. In 2004, worldwide Zyprexa sales exceeded $4.4 billion.

145. Through the use of a massive sales force and other various marketing techniques, Lilly deliberately over-promoted Zyprexa to physicians and downplayed its risks, resulting in Zyprexa's meteoric rise.

146. Zyprexa is defective because it directly or indirectly causes new onset diabetes and diabetes-related injuries (i.e. hyperglycemia, hypoglycemia, ketoacidosis, and pancreatitis) and/or can exacerbate and aggravate a person's pre-existing diabetes or diabetes-related injuries.

147. Lilly failed to adequately warn about Zyprexa's known association with diabetes and diabetes-related injuries and of the need to provide baseline screening and monitoring to prevent against such complications from occurring. Lilly failed to adequately test Zyprexa despite knowing of a well-established effect for causing hypoglycemia and diabetes and failed to inform the medical community that Zyprexa was especially insidious with respect to these side effects.

148. Given the number of adverse events reported in the United States and elsewhere, the label change effected in September 2003/March 2004, though still inadequate to warn of the significant and potentially catastrophic risks, should have been made far earlier. Lilly had every legal responsibility to undertake this change: 21 CFR 201.57(e) requires that "[t]he labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with the drug; a causal relationship need not have been proved."

149. The appropriate warnings were not added to the label for purely financial reasons. Lilly did not want to hurt Zyprexa's souring sales. During the time that Lilly refused to change

its label warning about the risk of diabetes-related injuries and the need to monitor patients on Zyprexa. Lilly was able to reap billions of dollars in revenue each year.

150. Lilly has not adequately warned consumers in this country, including Plaintiff, about the risk of diabetes, hyperglycemia, diabetic ketoacidosis, or other serious injuries caused by Zyprexa.

151. Lilly misrepresented and failed to appropriately warn consumers, including Plaintiff and the medical and psychiatric communities, of the dangerous risk of developing diabetes, pancreatitis, hyperglycemia, diabetic ketoacidosis, and diabetic coma, as well as other severe and permanent health consequences caused by Zyprexa, and consequently placed its profits above the safety of its customers.

152. Lilly aggressively marketed and sold Zyprexa by misleading potential users about the product and by failing to adequately warn users of serious dangers which Lilly knew or should have known resulted from the use of Zyprexa. Lilly extensively and successfully marketed Zyprexa throughout the United States in order to induce widespread use. This marketing campaign resulted in numerous individuals taking Zyprexa and suffering serious injuries as a result, all at a time when other safer, efficacious drugs were available.

153. Had individuals known the risks and dangers associated with Zyprexa, and had Lilly disclosed such information, consumers would not have taken Zyprexa nor been subject to its catastrophic side effects and Plaintiff and the citizens of Connecticut would not have suffered the payment for the prescriptions or the payment of medical expenses related thereto.

154. On information and belief, as a result of the manufacturing, marketing, selling and distributing of Zyprexa, Lilly has reaped millions of dollars in profits at the expense of the health of individuals such as the citizens of Connecticut.

155. Plaintiff and the citizens of Connecticut were injured as a direct and proximate result of Lilly's scheme to market Zyprexa for off-label uses. As a result of Lilly's actions and those of the intermediary marketing firms, Plaintiff and citizens of Connecticut paid all or part of the cost of Zyprexa for off-label uses for which they would not have paid absent Lilly's illegal conduct.

156. Connecticut physicians have prescribed Zyprexa to many CMAP recipients and other Connecticut consumers. Many of these prescriptions were for unapproved indications or were medically unnecessary. Further, as a result of using Zyprexa, a significant number of CMAP recipients and Connecticut consumers have suffered serious health effects, which now require further and more extensive medical treatment and health-related care and services. The State has financial responsibiity for the provision of these services to CMAP recipients. As the financially responsible party, the State has thus suffered and will continue to suffer additional financial loss by virtue of the care provided to those Medicaid recipients who consumed prescriptions for Zyprexa which were ineffective, unsafe, and actively harmful. Further, many Connecticut consumers will bear personal financial responsibility for this harm.

157. Had Lilly adequately warned Connecticut physicians of the risks and serious side effects associated with Zyprexa, while steering clear of any promotion of the drug for indications for which it was not approved, physicians could have made informed decisions when prescribing medications to Connecticut patients. As a result, the State would not have incurred the level of expenditures necessary to treat the illnesses and injuries caused by Zyprexa that were sustained by CMAP beneficiaries, and Connecticut consumers would not have been harmed.

IV. FIRST CLAIM FOR RELIEF: USE OF DECEPTIVE TRADE PRACTICES IN VIOLATION OF THE CONNECTICUT UNFAIR TRADE PRACTICES ACT

158. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows.

159. Defendant's course of conduct, as alleged herein, has been undertaken in the conduct of trade or commerce, as defined in Conn. Gen. Stat. § 42-110a(4).

160. Defendant systematically and continually conducts business throughout the State of Connecticut in that it markets, advertises, and sells Zyprexa within Connecticut. The Connecticut statutes prohibiting consumer fraud and unfair and deceptive trade practices apply because Defendant's deceptive scheme was carried out in Connecticut and affected Plaintiff and the citizens of Connecticut who took Zyprexa.

161. Defendant violated the Connecticut Unfair Trade Practices Act as codified in Conn. Gen. Stat. §§ 42-110b(a), by engaging in deceptive trade practices, from and including 1996, through the marketing and advertising of Zyprexa. Particular violations include the following:

a. Defendant published advertisements and generated marketing materials that included deceptive and misleading statements about the safety and efficacy of Zyprexa (with the intent to sell greater quantities of Zyprexa) after learning of the risks associated with Zyprexa, in violation of the Connecticut Unfair Trade Practices Act, Conn. Gen. Stat. §§ 42-110b(a). Defendant further violated the Statute when it failed to comply with FDA requirements and failed to adequately warn consumers and the medical community of the safety risks associated with Zyprexa.

b. Defendant intentionally concealed and failed to disclose the risks associated with Zyprexa in violation of the Connecticut Unfair Trade Practices Act, Conn. Gen. Stat. §§ 42-110b(a). Defendant represented that Zyprexa was a safe and effective drug, and intended that patients and physicians rely on those representations when deciding if Defendant's product was optimal for meeting the patient's needs. Defendant misled the CMAP and its recipients, as well as Connecticut consumers, as to the benefits and dangers of Zyprexa. As a direct and proximate result of Defendant's wrongful conduct, Plaintiff has incurred substantial health care costs related to the use of Zyprexa that it would not have paid for but for Defendant's

unfair and deceptive conduct and Connecticut consumers have been similarly harmed.

c. Defendant knowingly misrepresented, either directly or indirectly, the true quality of Zyprexa, in violation of the Connecticut Unfair Trade Practices Act, Conn. Gen. Stat. §§ 42-110b(a).

d. Defendant's marketing campaigns represented Zyprexa as safe and effective, while Lilly knew or should have known of significant risks associated with the use of the drug. Defendant denied the public and medical community access to information about these risks in order to avoid corporate responsibility, in violation of the Connecticut Unfair Trade Practices Act, Conn. Gen. Stat. §§ 42-110b(a). Defendant concealed these risks for the purpose of higher profits and increased sales. The violations include the following:

    - Defendant has violated Conn. Gen. Stat. §§ 42-110b(a) by representing that Zyprexa has characteristics, uses, and benefits that it does not have.

    - Defendant has violated Conn. Gen. Stat. §§ 42-110b(a) by representing Zyprexa as safe and effective medication of a particular standard, quality, or grade when Defendant knew or should have known that these claims were false.

    - Defendant has violated Conn. Gen. Stat. §§ 42-110b(a) by advertising, marketing, and selling Zyprexa as safe and effective when Defendant knew or should have known that these claims were false.

    - Defendant has violated Conn. Gen. Stat. §§ 42-110b(a) by creating a likelihood of confusion about the efficacy and mechanical soundness of its medical device, comparing Zyprexa with other safer and more effective products.

e. Defendant failed to provide adequate warnings to physicians, the general public, or the State as the prescribers, users, and financially responsible party, respectively, of Zyprexa.

f. Defendant unlawfully advertised, marketed, and promoted use of Zyprexa in unapproved populations and for unapproved indications. Defendant utilized advertising, labeling, and sales representative contacts with Connecticut physicians to misrepresent material facts about Zyprexa's appropriateness as a treatment for non-medically accepted indications and non-medically necessary uses.

g. Defendant impliedly warranted to the State of Connecticut, its physicians, CMAP recipients and Connecticut consumers that Zyprexa was fit for the particular purposes for which it advertised, marketed, and promoted the drug, including off-label indications. As Zyprexa is not fit for off-label purposes, and is neither as

safe nor as effective as declared by Defendant. Defendant breached its implied warranties, in violation of Conn. Gen. Stat. §§ 42-110b(a).

162. As a direct result of Defendant's deceptive, unfair, unconscionable, and fraudulent conduct, the CMAP and Connecticut consumers have been injured by paying substantial sums for Zyprexa and other heath care costs related to the use of Zyprexa that it would not have paid for but for Defendant's unfair and deceptive conduct.

163. Defendant's misrepresentations, as alleged herein, have been and are material, false and likely to mislead and, therefore, constitute deceptive acts or practices in violation of Conn. Gen. Stat. §42-110b(a).

164. By doing the aforesaid acts or practices, the Defendants have engaged in unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b(a).

V. SECOND CLAIM FOR RELIEF: WILLFUL USE OF DECEPTIVE TRADE PRACTICES IN VIOLATION OF THE CONNECTICUT UNFAIR TRADE PRACTICES ACT

165. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows.

166. Defendant has used deceptive trade practices and violated Conn. Gen. Stat. §42-110b(a) willfully.

167. As a direct result of Defendant's willful deceptive, unfair, unconscionable, and fraudulent conduct, the CMAP and Connecticut consumers have been injured by paying substantial sums for Zyprexa and other heath care costs related to the use of Zyprexa that it would not have paid for but for Defendant's unfair and deceptive conduct.

168. Defendant's misrepresentations, as alleged herein, have been and are material, false and likely to mislead and, therefore, constitute deceptive acts or practices in violation of Conn. Gen. Stat. §42-110b(a).

169. By doing the aforesaid acts or practices, the Defendants have engaged in deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b(a).

170. Under the provisions of Conn. Gen. Stat. §42-110o(b), Defendant is liable for civil penalties of up to $5,000 for each willful violation of the statute.

171. These costs and penalties are in addition to and not a substitute for the claim for restitution and other equitable relief alleged in this complaint.

VI. THIRD CLAIM FOR RELIEF: USE OF UNFAIR TRADE PRACTICES IN VIOLATION OF THE CONNECTICUT UNFAIR TRADE PRACTICES ACT

172. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows.

173. Defendant's course of conduct was and is immoral, unethical, oppressive, unscrupulous, and caused and continues to cause substantial injury to Connecticut consumers and CMAP.

174. Defendant's course of wrongful conduct, as alleged herein, violates the public policy of the State of Connecticut, as pleaded above, in part as follows:

a. Defendant intentionally concealed and failed to disclose the risks associated with Zyprexa in violation of the public policy as embodied in 21 U.S.C. §§ 331 and 352, prohibiting the introduction of pharmaceuticals with false and/or misleading labeling into interstate commerce. Defendant represented that Zyprexa was a safe and effective drug, and intended that patients and physicians rely on those representations when deciding if Defendant's product was optimal for meeting the patient's needs. Defendant misled the CMAP and its recipients, as well as Connecticut consumers, as to the benefits and dangers of Zyprexa. As a direct and proximate result of Defendant's wrongful conduct, Plaintiff has incurred substantial health care costs related to the use of Zyprexa that it would not have paid for but for Defendant's unfair and deceptive conduct and Connecticut consumers have been similarly harmed.

b. Defendant unlawfully advertised, marketed, and promoted use of Zyprexa in unapproved populations and for unapproved indications in violation of the public policy as embodied in 21 U.S.C. §§ 331, 352 and 355, prohibiting the introduction of an unapproved new drug or a drug marketed for an unapproved use into interstate commerce. Defendant utilized advertising, labeling, and sales

representative contacts with Connecticut physicians to misrepresent material facts about Zyprexa's appropriateness as a treatment for non-medically accepted indications and non-medically necessary uses.

c. Defendant impliedly warranted to the State of Connecticut, its physicians, CMAP recipients and Connecticut consumers that Zyprexa was fit for the particular purposes for which it advertised, marketed, and promoted the drug, including off-label indications. As Zyprexa is not fit for off-label purposes, and is neither as safe nor as effective as declared by Defendant, Defendant breached its implied warranties, in violation of the public policy embodied in Conn. Gen. Stat. §§ 42a-2-314.

d. Defendant failed to provide adequate warnings to physicians, the general public, or the State as the prescribers, users, and financially responsible party, respectively, of Zyprexa in violation of the public policy as embodied in 21 U.S.C. §§ 331 and 352, prohibiting the introduction of pharmaceuticals with false and/or misleading labeling into interstate commerce.

e. Through its course of deceptive and unfair conduct, Defendant caused the writing of unnecessary prescriptions of Zyprexa and the payment of those unnecessary prescriptions by the State of Connecticut, in violation of the public policy embodied in 31 U.S.C. §§ 3729-3733 prohibiting the perpetration of fraud against the government.

175. As a direct result of Defendant's deceptive, unfair, unconscionable, and fraudulent conduct, the CMAP and Connecticut consumers have been injured by paying substantial sums for Zyprexa and other heath care costs related to the use of Zyprexa that it would not have paid for but for Defendant's unfair and deceptive conduct.

176. Defendant's misrepresentations, acts, and practices, as alleged herein, constitute unfair acts or practices in violation of Conn. Gen. Stat. §42-110b(a).

177. By doing the aforesaid acts or practices, the Defendants have engaged in unfair acts or practices in violation of Conn. Gen. Stat. § 42-110b(a).

VII. FOURTH CLAIM FOR RELIEF: WILLFUL USE OF UNFAIR TRADE PRACTICES IN VIOLATION OF THE CONNECTICUT UNFAIR TRADE PRACTICES ACT

178. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows.

179. Defendant has violated Conn. Gen. Stat. §42-110b(a) willfully.

180. Defendant's willful course of conduct was and is immoral, unethical, oppressive, unscrupulous, and caused and continues to cause substantial injury to Connecticut consumers and CMAP.

181. Defendant's course of wrongful conduct, as alleged herein, violates the public policy of the State of Connecticut.

182. As a direct result of Defendant's willful deceptive, unfair, unconscionable, and fraudulent conduct, the CMAP and Connecticut consumers have been injured by paying substantial sums for Zyprexa and other heath care costs related to the use of Zyprexa that it would not have paid for but for Defendant's unfair and deceptive conduct.

183. Defendant's misrepresentations, acts, and practices, as alleged herein, constitute unfair acts or practices in violation of Conn. Gen. Stat. §42-110b(a).

184. By doing the aforesaid acts or practices, the Defendants have engaged in unfair acts or practices in violation of Conn. Gen. Stat. § 42-110b(a).

185. Under the provisions of Conn. Gen. Stat. §42-110o(b), Defendant is liable for civil penalties of up to $5,000 for each willful violation of the statute.

186. These costs and penalties are in addition to and not a substitute for the claim for restitution and other equitable relief alleged in this complaint.

VIII. FIFTH CLAIM FOR RELIEF: SUBMISSION OF FALSE CLAIMS IN VIOLATION OF THE CONNECTICUT UNFAIR TRADE PRACTICES ACT

187. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows.

188. Defendant's course of conduct, as alleged herein, has been undertaken in the conduct of trade or commerce, as defined in Conn. Gen. Stat. § 42-110a(4).

189. Defendant systematically and continually conducts business throughout the State of Connecticut in that it markets, advertises, and sells Zyprexa within Connecticut. The Connecticut statutes prohibiting consumer fraud and unfair and deceptive trade practices apply because Defendant's deceptive scheme was carried out in Connecticut and affected Plaintiff and the citizens of Connecticut who took Zyprexa

190. Defendant violated the Connecticut Unfair Trade Practices Act as codified in Conn. Gen. Stat. §§ 42-110b(a), by engaging in deceptive trade practices through the marketing and advertising of Zyprexa. Particular violations include the following:

191. The funding and administration of Connecticut's Medicaid program is subject to a number of federal regulations and requirements.

192. In exchange for federal funding, Connecticut is obligated under the federal Medicaid statutes to provide coverage for approved prescription drugs of any manufacturer with which the Centers for Medicare & Medicaid Services maintains a rebate contract, including Lilly. *See* 42 C.F.R. § 1396r-8(d)(4) (2008) (stating "A State may establish a formulary if the formulary... includes the covered outpatient drugs of any manufacturer which has entered into and complies with an agreement under subsection (a) [requiring manufacturers to enter into rebate agreements with the Secretary of Health and Human Services on behalf of the States]").

193. In exchange for federal funding, Connecticut is obligated under the federal Medicaid statutes to seek recovery of Medicaid health care costs incurred by the State from responsible parties. *See* 42 C.F.R. § 433.138 *et seq.* (2006) (stating "The agency must take reasonable measures to determine the legal liability of the third parties who are liable to pay for services furnished under the plan").

194. Defendant has knowingly caused false claims for payment to be submitted to CMAP, including Medicaid, by intentionally promoting non-medically accepted indications and non-medically necessary uses of their respective drug to prescribing physicians for the purpose of receiving greater compensation than that to which they are largely 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 available for non-medically accepted indications or non-medically necessary uses.

195. As a proximate and legal result of Defendant's fraudulent misrepresentations, the State of Connecticut and Connecticut consumers have been harmed.

196. Defendant's misrepresentations, as alleged herein, have been and are material, false and likely to mislead and, therefore, constitute deceptive acts or practices in violation of Conn. Gen. Stat. §42-110b(a).

197. By doing the aforesaid acts or practices, Defendant has engaged in unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b(a).

198. Under the provisions of Conn. Gen. Stat. §42-110o(b), Defendant is liable for civil penalties of up to $5,000 for each willful violation of the statute.

199. These costs and penalties are in addition to and not a substitute for the claim for restitution and other equitable relief alleged in this complaint.

IX. SIXTH CLAIM FOR RELIEF: VIOLATION OF 18 U.S.C § 1962(C)

200. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows.

201. Defendant is a "person" within the meaning of 18 U.S.C. § 1961(3) who conducted the affairs of enterprises, the Zyprexa Unlawful Promotion Enterprises, through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

202. The Zyprexa Unlawful Marketing Enterprises are associations-in-fact within the meaning of 18 U.S.C. § 1961(4), consisting of Defendant, including its employees and agents, and the marketing firms employed by Defendant to promote Zyprexa for off-label uses. The Zyprexa Unlawful Marketing Enterprises are ongoing organizations that function as continuing units. The Enterprises were created and/or used as tools to effectuate a pattern of racketeering activity. The Defendant is a "person" distinct from the Zyprexa Unlawful Marketing Enterprises.

203. Defendant and the other members of the Zyprexa Unlawful Marketing Enterprises created and maintained systematic links for a common purpose-to aid in marketing Zyprexa for off label uses. Each of the participants in the Zyprexa Unlawful Marketing Enterprises received substantial revenue from the scheme to promote Zyprexa off-label. Such revenue was exponentially greater than it would have been if Zyprexa was marketed appropriately. All participants were aware of Defendant's control over the activities of the Zyprexa Unlawful Marketing Enterprises promoting Zyprexa off-label. Furthermore, each portion of the enterprise benefited from the existence of other parts.

204. The Zyprexa Unlawful Marketing Enterprises engaged in and affected interstate commerce, because, *inter alia*, it marketed, sold, purchased, or provided Zyprexa to thousands of individuals throughout the United States.

205. Defendant has exerted control over the Zyprexa Unlawful Marketing Enterprises and management of the affairs of the Zyprexa Unlawful Marketing Enterprises.

206. Defendant has conducted and participated in the affairs of the Zyprexa Unlawful Marketing Enterprises through a pattern of racketeering activity that includes acts indictable under 18 U.S.C. § 1341 (mail fraud), 1343 (wire fraud), 1952 (use of interstate facilities to

conduct unlawful activity).

207. Defendant used thousands of mail and interstate wire communications to create and manage its fraudulent scheme. Defendant's scheme involved national marketing and sales plans and programs, and encompassed physicians, medical marketing firms, and victims across the country.

208. Defendant's use of the mails and wires to perpetrate its fraud involved thousands of communications, including, but not limited to:

a. marketing and advertising materials about the off-label uses of Zyprexa for which the drug is not proven to be safe, medically efficacious, and useful, such materials being sent to doctors across the country;

b. communications, including financial payments, with the vendor and physician participants discussing and relating to the publication of articles misrepresenting off-label uses of Zyprexa;

c. communications with vendor and physician participants that fraudulently misrepresented that Zyprexa was scientifically prove to be safe, medically efficacious, and useful for off-label purposes;

d. communications with health insurers and patients, including Plaintiff, inducing payments for Zyprexa to be made based on misrepresentations concerning the safety, efficacy, and usefulness of Zyprexa; and

e. receiving the proceeds of Defendant's improper scheme.

209. In addition, Defendant's corporate headquarters have communicated by United States mail, telephone, and facsimile with various local district managers, medical liaisons, and pharmaceutical representatives in furtherance of Defendant's scheme.

210. Defendant's pattern of racketeering activity includes acts indictable as mail fraud under 18 U.S.C. § 1341 and wire fraud under U.S.C. § 1343. Defendant fraudulent scheme consisted of, *inter alia*: deliberately misrepresenting the uses for which Zyprexa was safe and effective so that Plaintiff and citizens of the State of Connecticut paid for this drug to treat

symptoms for which it was not scientifically proven to be safe and effective actively concealing and causing others to conceal, information about the true safety and efficacy of Zyprexa to treat conditions for which it had not been approved by the FDA.

211. In implementing its fraudulent scheme, Defendant was acutely aware that Plaintiff and citizens of the State of Connecticut depended on the honesty and integrity of Defendant in representing the medical efficacy of Zyprexa's uses. It is impractical and unduly expensive for States to perform their own clinical trials or assemble all known medical evidence relating to Zyprexa's uses. Plaintiff also relies on federal law obligating Defendant to provide fair and balanced information about their drug products and reasonably presume that when making such marking of Zyprexa was conducted, it complied with Defendant's obligations under federal law.

212. Defendant's scheme was calculated to ensure that Plaintiff would pay for Zyprexa to treat uses which Defendant knew were not necessarily treatable with Zyprexa.

213. The conduct of the Zyprexa Unlawful Marketing Enterprises described above constitutes "racketeering activity" within the meaning of 18 U.S.C. § 1961(1). Defendant decision for the Zyprexa Unlawful Marketing Enterprises to routinely conduct its transactions in such a manner constitutes a "pattern of racketeering activity" within the meaning of 18 U.S.C. § 1961(5).

214. Defendant's fraudulent marketing scheme depended upon its concealing its involvement in off-label promotion of Zyprexa. Indeed, the Unlawful Marketing Enterprises were created precisely to make it appear to the public that Defendant did not have a hand in any discussions or promotion of off-label use. Additionally, as described above, Defendant had the Unlawful Marketing Enterprises perform off-label promotion in the semblance of legitimate consultants' meetings, continuing education seminars, journal articles, and medical education

events. Also as described above. Defendant's involvement was hidden because Defendant hid its financial connections with the physician participants and used the vendor participants as payment intermediaries. These activities and others described above concealed Defendant's fraudulent promotional activities and Plaintiff could not have discovered the scheme alleged herein earlier in the exercise of reasonable diligence. Indeed. much of the scheme to this day remains concealed by Defendant.

215. The earliest Plaintiff could have reasonably become aware of the fraudulent marketing scheme was 2005.

216. Any applicable statutes of limitations have been tolled by Defendant's knowing and active concealment and denial of the facts alleged herein. Plaintiff has been kept in ignorance of vital information essential to the pursuit of these claims, without any fault or lack of diligence on their part. Plaintiff could not reasonably have discovered the fraudulent nature of Defendant's conduct. Accordingly, Defendant is estopped from relying on any statute of limitations to defeat any of Plaintiff's claims.

217. The above described racketeering activities amounted to a common course of conduct intended to deceive and harm Plaintiff and the citizens of Connecticut. Each such racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiff and the citizens of Connecticut. Defendant's racketeering activities are part of their ongoing business and constitute a continuing threat to the property of Plaintiff and the citizens of Connecticut.

218. Plaintiff and the citizens of Connecticut have been injured in their business and property by reason of these violations in that they have made millions of dollars in payment for

Zyprexa that they would not have made had Defendant not engaged in its pattern of racketeering activity. By reason of the unlawful acts engaged in by Defendant, Plaintiff and the citizens of Connecticut have suffered ascertainable loss and damages.

219. Plaintiff and the citizens of Connecticut have sustained injuries that were directly and proximately caused by Defendant's racketeering activity as described above.

220. By virtue of these violations of 18 U.S.C. § 1962(c), Defendant is liable to Plaintiff and the citizens of Connecticut for three times the damages they have sustained, plus the cost of this suit, including reasonable attorney's fees.

X. SEVENTH CLAIM FOR RELIEF: VIOLATION OF U.S.C. § 1962(D) BY CONSPIRING TO VIOLATE 18 U.S.C. § 1962(C)

221. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows.

222. Section 1962(d) of RICO provides that it "shall be unlawful for any person to conspire to violate any of the provision of subsection (a), (b), or (c) of this section."

223. Defendant has violated § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c). The object of this conspiracy has been and is to conduct or participate in, directly or indirectly, the conduct of the affairs of the Zyprexa Unlawful Marketing Enterprises described previously through a pattern of racketeering activity.

224. Defendant's co-conspirators have engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of the conspiracy, including material misrepresentations and omissions designed to defraud Plaintiff of money.

225. The nature of the above-described Defendant's co-conspirators' acts, material misrepresentations, and omissions in furtherance of the conspiracy gives rise to an inference that they not only agreed to the objective of an 18 U.S.C. § 1962(d) violation of RICO by conspiring

to violate 18 U.S.C. § 1962(c), but they were aware that their ongoing fraudulent and extortionate acts have been and are part of an overall patter of racketeering activity.

226. As a direct and proximate result of Defendant's overt acts and predicate acts in furtherance of violating 18 U.S.C. § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c), Plaintiff and the citizens of Connecticut have been and are continuing to be injured in their business or property as set forth more fully above. By reason of the unlawful acts engaged in by Defendant, Plaintiff and the citizens of Connecticut have suffered ascertainable loss and damages.

227. Defendant sought to and has engaged in the commission of and continues to commit overt acts, including the following unlawful racketeering predicate acts:

a. Multiple instances of mail and wire fraud violations of 18 U.S.C. §§ 1341 and 1342;

b. Multiple instances of mail fraud violation of 18 U.S.C. §§ 1341 and 1346;

c. Multiple instances of wire fraud violations of 18 U.S.C. §§ 1341 and 1346;

d. Multiple instances of unlawful activity in violation of 18 U.S.C. § 1952.

228. Defendant's violations of the above federal laws and the effects thereof detailed above are continuing and will continue. Plaintiff and the citizens of Connecticut have been injured in their property by reason of these violations in that Plaintiff and the citizens of Connecticut have made millions of dollars in payments for Zyprexa that they would not have made had Defendant not conspired to violate 18 U.S.C. § 1962(c).

229. Injuries suffered by Plaintiff and the citizens of Connecticut were directly and proximately caused by Defendant's racketeering activity as described above.

230. By virtue of these violations of 18 U.S.C. § 1962(d), Defendant is liable to Plaintiff and the citizens of Connecticut for three times the damages Plaintiff and the citizens of

Connecticut have sustained, plus the cost of this suit, including reasonable attorney's fees.

XI. DEMAND FOR RELIEF

231. WHEREFORE, Plaintiff demands judgment against Defendant in each claim for relief, jointly and severally, as follows:

a. On Plaintiff's Connecticut Unfair Trade Practices Act claims, as outlined in the First, Second, Third, Fourth, and Fifth Claims for Relief: restitution to the State of Connecticut and injured consumers, injunctive and equitable relief as appropriate, and civil penalties for each willful violation of the Act, plus Plaintiff's costs in this suit, including reasonable attorney's fees;

b. On Plaintiff's RICO claims, as outlined in the Sixth and Seventh Claims for Relief: three times the damages Plaintiff and the citizens of Connecticut have sustained as a result of Defendant's conduct, such amount to be determined at trial, plus Plaintiff's costs in this suit, including reasonable attorneys' fees;

c. Awarding Plaintiff other appropriate equitable relief;

d. Awarding Plaintiff costs and expenses in this litigation, including reasonable attorneys' fees and expert fees; and

e. Awarding Plaintiff such other and further relief as may be just and proper under the circumstances.

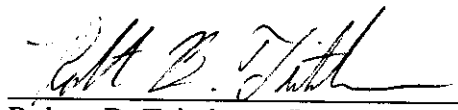
XII. DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff demands a trial by jury on all issues so triable.

Dated: 3/5/08

Respectfully submitted,
STATE OF CONNECTICUT

RICHARD BLUMENTHAL
ATTORNEY GENERAL



Robert B. Teitelman, RT-2222
Thomas J. Saadi
Assistant Attorneys General
55 Elm Street, P.O. Box 120
Hartford, Connecticut 06141-0120
Phone: (860) 808-5355
Fax: (860) 808-5391

Thomas M. Sobol
David S. Nalven, DN-2374
Lauren Guth Barnes
Hagens Berman Sobol Shapiro LLP
1 Main Street, 4th Floor
Cambridge, MA 02155
Phone: (617) 482-3700
Fax: (617) 482-3003