FEBRUARY 2007

002836

Court of Common Pleas of Philadelphia County
Trial Division

Civil Cover Sheet

For Prothonotary Use Only (Docket Number)

PLAINTIFF'S NAME	DEFENDANT'S NAME
COMMONWEALTH OF PENNSYLVANIA C/O Office of General Counsel	ELI LILLY & COMPANY
PLAINTIFF'S ADDRESS 333 Market Street, 17th Floor Harrisburg, PA 17101	DEFENDANT'S ADDRESS Lilly Corporate Center Indianapolis, IN 46285
PLAINTIFF'S NAME	DEFENDANT'S NAME ASTRAZENECA PHARMACEUTICALS, L.P. C/O CT CORPORATION SYSTEMS
PLAINTIFF'S ADDRESS	DEFENDANT'S ADDRESS 1515 Market Street, Suite 1210 Philadelphia, PA 19102
PLAINTIFF'S NAME	DEFENDANT'S NAME JANSSEN PHARMACEUTICA, INC., trading as "JANSSEN, LP"
PLAINTIFF'S ADDRESS	DEFENDANT'S ADDRESS C/O CT Corporation Systems 1515 Market Street, Suite 1210 Philadelphia, PA 19102

Total No. of Plaintiffs	Total No. of Defendants	Commencement of Action
1	3	☒ Complaint ☐ Petition Action ☐ Notice of Appeal ☐ Writ of Summons ☐ Transfer From Other Jurisdictions

AMOUNT IN CONTROVERSY	COURT PROGRAMS
☐ $50,000.00 or less ☒ More than $50,000.00	☐ Arbitration ☐ Mass Tort ☐ Commerce ☐ Settlement ☒ Jury ☐ Savings Action ☐ Minor Court Appeal ☐ Minors ☐ Non-Jury ☐ Petition ☐ Statutory Action ☐ W/D/Survival ☐ Other:

CASE TYPE AND COSE (SEE INSTRUCTIONS)

2P – Product Liability

STATUTORY BASIS FOR CAUSE OF ACTION (SEE INSTRUCTIONS)

62 P.S. § 1407, 72 P.S. § 3761-521(a)

RELATED PENDING CASES (LIST BY CASE CAPTION AND DOCKET NUMBER	IS CASE SUBJECT TO COORDINATION ORDER? Yes ☐ No ☐

NAME OF PLAINTIFF'S/PETITIONER'S/APPEALLANT'S ATTORNEY	ADDRESS (SEE INSTRUCTIONS)
STEWART L. COHEN, ESQ./WILLIAM D. MARVIN, ESQ. PHONE NUMBER: 215-567-3500 FAX NUMBER: 215-567-6019	COHEN, PLACITELLA & ROTH, P.C. Two Commerce Square, Suite 2900 2001 Market Street Philadelphia, PA 19103
SUPREME COURT IDENTIFICATION NO. 25448/34265	E-MAIL ADDRESS scohen@cprlaw.com/wmarvin@cprlaw.com
SIGNATURE	DATE 2/26/2007

COHEN, PLACITELLA & ROTH
A Professional Corporation
By: STEWART L. COHEN
WILLIAM D. MARVIN
Attorney ID Nos. 25448/34265
scohen@cprlaw.com / wmarvin@cprlaw.com
Two Commerce Square, Suite 2900
2001 Market St.
Philadelphia, PA 19103
(215) 567-3500
(additional counsel listed below)

JURY TRIAL DEMANDED
THIS IS NOT AN ARBITRATION CASE
ASSESSMENT OF DAMAGES HEARING IS NOT REQUIRED

ATTORNEYS FOR PLAINTIFFS

(full caption on next page)
COMMONWEALTH OF PENNSYLVANIA

v.

ELI LILLY & COMPANY, INC.
ASTRAZENECA PHARMACEUTICALS, L.P.
and
JANSSEN PHARMACEUTICA, INC., trading as "JANSSEN, LP"

COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY

FEBRUARY TERM, 2007

No. 002836

CIVIL ACTION COMPLAINT
Jury Trial Demanded
2P Product Liability

NOTICE

You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this complaint and notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so the case may proceed without you and a judgment may be entered against you by the court without further notice for any money claimed in the complaint or for any other claim or relief requested by the plaintiff. You may lose money or property or other rights important to you.

YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER OR CANNOT AFFORD ONE, GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW TO FIND OUT WHERE YOU CAN GET LEGAL HELP.

Philadelphia Bar Association
Lawyer Referral & Information Service
One Reading Center
Philadelphia, Pennsylvania 19107
Telephone: (215) 238-6333

AVISO

La han demandado a usted en la corte. Si usted quiere defensersa de estas demandes expuentas en la paginas siguientes, usted tiene veinte (20) dias de plazo al partir de la focha de la demanda y la notificación. Hace falta asentar una comparencia escrita o en persona o con un abodago y entregar a la corte en forma escrita sus defensas or sus objeciones a las demandas en contra de su persona. Sea avisado que si usted no se defienda, la corte tomara medidas y puede continuar la domanda en contra suya sin previo aviso o notificación. Ademas, la corte puede docidir a favor del demandante y requiere que usted compla con todas las provisiones de esta demanda. Usted puede poder dinero o sus propiedades u otros derechos importantes para usted.

LLEVE ESTA DEMANDA A UN ABODAGO INMEDIATAMENTE. SI NO TIENE ABODAGO O SINO TIENE EL DINERO SUFICIENTE DE PAGAR TAL SERVICO, VAYA EN PERSONA O LLAME POR TELEFONO A LA OFICINA CUYA DIRECCION SE ENCUENTRA ESCRITA ABAJO PARA AVERIGUAR DONDE SE PUEDE CONSEGUIR ASISTENCIA LEGAL.

Associacion DeLicenciados De Filadelfia
Servicio DeReferencia E Información Legal
One Reading Center
Filadelfia, Pennsylvania 19107
Telefono: (215) 238-1701

COMMONWEALTH OF PENNSYLVANIA
c/o Office of General Counsel
333 Market St., 17th Floor
Harrisburg, PA 17101

v.

ELI LILLY & COMPANY, INC.
Lilly Corporate Center
Indianapolis, IN 46285

ASTRAZENECA PHARMACEUTICALS, L.P.
c/o CT Corporation Systems
1515 Market Street, Suite 1210
Philadelphia, PA 19102

and

JANSSEN PHARMACEUTICA, INC., trading as "JANSSEN, LP"
c/o CT Corporation Systems
1515 Market Street, Suite 1210
Philadelphia, PA 19102

COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY

JANUARY TERM, 2007

No.

CIVIL ACTION COMPLAINT
Jury Trial Demanded

The Commonwealth of Pennsylvania, on behalf of the Department of Public Welfare and the Department of Aging ("the Commonwealth"), brings this action as an injured purchaser and/or reimburser of prescription drugs. The Commonwealth seeks to obtain compensatory, punitive and other damages, restitution, civil penalties under applicable laws, injunctive and other equitable relief against Defendants Eli Lilly & Company, Inc. ("Lilly"), AstraZeneca Pharmaceuticals, LP ("AZ"), and Janssen Pharmaceutica, Inc., trading as "Janssen, LP" ("Janssen") and, in support thereof, avers as follows:

NATURE OF THE PROCEEDING

1. This case arises, in part, from Defendants' deceptive marketing practice of promoting their respective antipsychotic drugs for non-medically accepted uses (defined herein), which has caused the Commonwealth to expend millions of dollars in Medicaid and Pharmaceutical Assistance Contract for the Elderly[1] ("PACE") funds, for the purchase of prescribed antipsychotic drugs that were ineligible for reimbursement. In addition to defrauding the Plaintiff's Medicaid and PACE programs, Defendants deliberately concealed and affirmatively misrepresented the risks associated with their respective antipsychotic drugs. As a result of Defendants' omissions and misrepresentations of the risks of their antipsychotic drugs, certain participants in Plaintiff's Medicaid and PACE programs have been injured. The Plaintiff has expended millions of dollars treating Medicaid and PACE participants for injuries caused by Defendants' respective omissions of, and deliberate misrepresentations related to, critical information regarding the serious health risks of Zyprexa, Risperdal and Seroquel.

2. Lilly researched, developed, manufactured, created, designed, tested, labeled, sterilized, packaged, supplied, marketed, sold, promoted, advertised, warned and otherwise distributed the brand name drug Zyprexa in the Commonwealth of Pennsylvania.

3. AZ researched, developed, manufactured, created, designed, tested, labeled, sterilized, packaged, supplied, marketed, sold, promoted, advertised, warned and otherwise distributed the brand name drug Seroquel in the Commonwealth of Pennsylvania.

4. Janssen researched, developed, manufactured, created, designed, tested, labeled, sterilized, packaged, supplied, marketed, sold, promoted, advertised, warned and otherwise

[1] References to PACE herein also include the PACENET program, a component of PACE that serves higher income PACE participants.

distributed the brand name drug Risperdal in the Commonwealth of Pennsylvania. Upon information and belief, all acts attributed to Janssen herein were done by Janssen Pharmaceutica, Inc., as general partner, acting jointly with and through Janssen, LP.

5. A significant number of Pennsylvania Medicaid and PACE participants, believed to be in the hundreds, if not thousands, suffered serious diseases and/or potentially life threatening medical conditions after taking Defendants' antipsychotic drugs and such risks of use were known, or should have been known, to Defendants who failed to warn Pennsylvania physicians, particularly primary care physicians, of those risks.

6. Many Pennsylvanians injured by Defendants' antipsychotic drugs are participants in the Plaintiff's Medicaid and PACE programs. As such, their treatment costs, caused by Defendants, have been unjustly borne by the Commonwealth.

7. At all relevant times, Defendants purposefully and intentionally engaged in the activities described herein, and continue to do so, knowing that the use of their antipsychotic drugs by Pennsylvania Medicaid and PACE participants would result in a significant percentage of users contracting serious diseases and/or potentially life threatening medical conditions including but not limited to diabetes, pancreatitis, stroke, seizures, serious weight gain, neuraleptic malignant syndrome, tardive dyskinesia and heart failure. Defendants further knew that the Commonwealth itself would be injured to the extent it must provide, pay for and/or reimburse for the provision of health care products, services and facilities for those Pennsylvania Medicaid and PACE participants injured by Defendants' antipsychotic drugs.

8. The Commonwealth seeks to recover the expenses incurred in reimbursing pharmacies for the purchase of Defendants' antipsychotic drugs for non-medically accepted indications and non-medically necessary uses, as well as the expenses incurred in providing

medical treatment to Pennsylvanians suffering from illnesses caused by Defendants' antipsychotic drugs.

9. Further, Defendants' aggressive and illegal schemes to promote non-medically accepted indications and non-medically necessary uses for their antipsychotic drugs, done with the knowledge that prescriptions for such uses are not medically accepted indications and are not medically necessary, constitutes Medicaid and PACE fraud in that it has caused the Commonwealth to purchase vast quantities of non-medically accepted and non-medically necessary prescriptions and resulted in the unwarranted expenditure of millions of dollars in Medicaid and PACE funds.

PARTIES

COMMONWEALTH OF PENNSYLVANIA

10. The plaintiff Commonwealth of Pennsylvania brings this action in the its capacity as sovereign, in its proprietary capacity on behalf of the Pennsylvania Department of Public Welfare and the Pennsylvania Department of Aging and as representative of, and as *parens patriae* on behalf of, Pennsylvania Medicaid and PACE participants.

11. As more fully set forth below, the Commonwealth administers and finances programs to supply and/or pay for prescription medications, namely, the Medicaid program through its Department of Public Welfare, and the PACE program through its Department of Aging. These programs provide essential medical care for millions of Pennsylvania who might otherwise have no available coverage or resources to obtain such treatment and medicines.

12. The Office of Governor's General Counsel is statutorily authorized to initiate and maintain this action and does so, pursuant to the Commonwealth Attorneys Act, 71 P.S. §732-301. This action is also maintained pursuant to the Commonwealth's common law *parens patriae* powers.

DEFENDANTS

13. Defendant Lilly is a corporation organized and existing under the laws of the state of Indiana with its principal place of business located at Lilly Corporate Center Indianapolis, Indiana 46285. Lilly is authorized to conduct business in Pennsylvania, and its registered agent for service of process is National Registered Agents, Inc., 600 N. 2nd St., Suite 500, Harrisburg, PA 17101.

14. Defendant Janssen Pharmaceutica, Inc., is a Pennsylvania corporation and a citizen of Pennsylvania. The registered agent for Janssen Pharmaceutica, Inc. is CT Corporation Systems, 1515 Market Street, Suite 1210, Philadelphia, PA 19102. Janssen Pharmaceutica, Inc. is the general partner of Janssen, LP, which is a New Jersey limited partnership that is authorized to do business in Pennsylvania.

15. AstraZeneca Pharmaceuticals, L.P., ("AZ") is the U.S. subsidiary of a Swedish entity, AstraZeneca PLC, which has its principal place of business at S-151 85 Sodertalje, Sweden. AZ is a Delaware limited partnership with its principle place of business in Wilmington, Delaware. AstraZeneca is duly authorized to conduct business in the Commonwealth of Pennsylvania. Its registered agent for service of process is CT Corporation Systems, 1515 Market Street, Suite 1210, Philadelphia, PA 19102.

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

JURISDICTION AND VENUE

17. The jurisdiction of this Court over the Commonwealth's claims is founded upon 42 P.S. §761(b) and § 931(b), which give the Courts of Common Pleas concurrent jurisdiction over actions brought by the Commonwealth government.

18. Each of the Defendants regularly does business within the Commonwealth of Pennsylvania and the City and County of Philadelphia.

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

APPLICABLE MEDICAID & PACE REGULATIONS

20. The Commonwealth, through its Department of Public Welfare, participates in the Medicaid program to promote the general welfare of its citizens and meet the specific objective that adequate and high quality health care is available to those Pennsylvania citizens who cannot afford it.

21. The Medicaid program includes individualized provisions, by statute and regulation, concerning reimbursement for prescription drugs, drug utilization review, eligibility of various drugs for federal financial participation ("FFP"), price controls on prescription drugs, and drug manufacturer rebate agreements. Medicaid is also a direct payer of medically necessary inpatient and outpatient treatment for some of its participants.

22. According to the Social Security Act, States are entitled to FFP for reimbursement of pharmacies for covered outpatient drugs. 42 U.S.C.A. §1396r-8. The definition of covered outpatient drug is limited to drugs used for medically accepted indications. 42 U.S.C.A. §1396r-

8(k)(3). A medically accepted indication is any use approved by the Food & Drug Administration ("FDA") or supported by any of three specific compendia. *Id.* at (k)(6). The compendia are the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information and the DRUGDEX Information System. *Id.* at (g)(1)(B)(i). Whether a prescription is submitted for a medically accepted indication or medically necessary use is material to the Pennsylvania Department of Public Welfare's decision to reimburse.

23. In response to what the Pennsylvania Governor's Assembly characterized as a "major crisis" in Medicaid funding resulting from the ever-escalating costs of medical services, the Commonwealth has instituted various programs and policies to monitor and help control the cost of prescription drug reimbursement under its Medicaid program.

24. Among these programs and policies, the Commonwealth has adopted a Preferred Drug Listing and required prior approval for certain medications which are identified as "non-preferred" drugs on the Preferred Drug List.

25. Defendants expected and intended that their promotional efforts will cause claims for reimbursement to be submitted to Medicaid, and further that those promotional efforts would influence the selection and guidelines for the Preferred Drug List, as well as the prior authorization procedure, so that Pennsylvania's Medicaid program would pay those claims.

26. Until recently, the Department of Public Welfare was unaware of the manner in which Lilly, AZ and Janssen promote Zyprexa, Seroquel and Risperdal in the Commonwealth, respectively.

27. Defendants know or should know the Medicaid regulations governing prescription drug reimbursement. Defendants have a duty to refrain from conduct which could cause submission of non-medically accepted and medically unnecessary prescriptions to

Medicaid for reimbursement. Upon information and belief, Defendants breached this duty by knowingly causing prescriptions for non-medically accepted indications and non-medically unnecessary uses of their antipsychotic drugs to be submitted to Medicaid for reimbursement.

28. 62 P.S. § 1407 provides as follows:

(a) It shall be unlawful for any person to:

> (1) Knowingly or intentionally present for allowance or payment any false or fraudulent claim or cost report for furnishing services or merchandise under medal assistance, or to knowingly present for allowance or payment any claim or cost report for medically unnecessary services or merchandise under medical assistance, or to knowingly submit false information, for the purpose of obtaining greater compensation than that to which he is legally entitled for furnishing services or merchandise under medical assistance, or to knowingly submit false information for the purpose of obtaining authorization for furnishing services or merchandise under medical assistance.
>
> (2) Solicit or receive or offer or pay any remuneration, including any kickback, bribe or rebate, directly or indirectly, in cash or in kind from or to any person in connection with the furnishing of services or merchandise for which payment may be in whole or in part under the medical assistance program or in connection with referring an individual to a person for the furnish or arranging for the furnishing of any services or merchandise for which payment may be made in whole or in part under the medical assistance program.

29. Under 62 P.S. §1407(c)(1), the Commonwealth is authorized to initiate legal proceedings against any person that violates subsection (a) in the Court of Common Pleas for twice the amount of excess benefits or payments plus legal interest from the date of the violations. Further, the Commonwealth has the authority to use statistical sampling methods to determine the appropriate amount of restitution due. 62 P.S. § 1407(c)(1).

30. The Commonwealth created the PACE program to offer prescription drug coverage to low-income, elderly Pennsylvanians. The PACE program began on July 1, 1984 and is funded entirely by the Commonwealth. The stated purpose of PACE is to offer limited pharmaceutical assistance for qualified Pennsylvania residents consisting of "life-sustaining

prescription drugs." The program specifically excludes coverage for "experimental drugs." 72 P.S. §§ 3761-501, 502; PACE Pharmacy Benefit Manual, §IV.8. Further, the program covers drugs used in a manner consistent with the "medical needs" of the participant and does not reimburse for uses that are not "therapeutically appropriate." Manual, IV.9, V.1.

31. Whether the use of a drug is medically necessary is material to PACE's decision to reimburse for a prescription. In other words, PACE would refuse reimbursement for prescriptions it knew to be medically unnecessary.

32. Defendants cause claims to be submitted to PACE for reimbursement through their promotion efforts. Until recently, the Department of Aging was unaware of the manner in which Lilly, AZ and Janssen promote Zyprexa, Seroquel and Risperdal in the Commonwealth, respectively.

33. Defendants know or should know the PACE regulations governing prescription drug reimbursement. Defendants have a duty to refrain from conduct which could cause submission of medically unnecessary prescriptions to PACE for reimbursement. Upon information and belief, Defendants breached this duty by knowingly causing prescriptions for medically unnecessary uses of their antipsychotic drugs to be submitted to PACE for reimbursement.

34. Under Pennsylvania law, it is "unlawful for any person to submit a false or fraudulent claim" to PACE. 72 P.S. §3761-521(a). The act of submitting a false claim includes causing another to submit a false claim as well as "soliciting, receiving, offering or paying any kickback, bribe or rebate" in connection with a PACE claim. *Id.* The statute provides a penalty up to $10,000 for each violation of the foregoing provisions. *Id.* at (b).

35. The Commonwealth of Pennsylvania relies on persons causing claims to be submitted to Medicaid and PACE to recognize and honor the permissible scope of reimbursement and to obey the governing law and regulations in activities that cause such claims.

36. Defendants have aggressively exploited their position, their superior knowledge of their products' characteristics and their knowledge that payers such as Plaintiff relied on suppliers and sellers to comply with governing regulations, by means of direct, illegal programs of promotion of use of their antipsychotic drugs for non-medically accepted indications and non-medically necessary uses. Defendants have conducted this program of promotion knowing that the majority of prescriptions for their antipsychotic drugs are reimbursed by state public assistance programs even though prescriptions for non-medically accepted indications and non-medically necessary uses of drugs fall outside the coverage of Commonwealth formularies.

37. In Pennsylvania, Lilly, AZ and Janssen have each marketed their respective antipsychotic drugs, Zyprexa, Seroquel and Risperdal, for non-medically accepted indications and non-medically necessary uses including use for the treatment of general mood and behavior disorders, attention deficit disorder, attention deficit hyperactivity disorder, schizo-affective disorder, depression not associated with psychosis, sleeplessness, autism, dementia and for use on Pennsylvania children.

38. Further, each Defendant has intentionally misrepresented to prescribers who treat Medicaid and PACE participants that their respective antipsychotic drugs are safer than less expensive, generic antipsychotics. To the extent the Plaintiff has reimbursed pharmacies for Zyprexa, Seroquel or Risperdal prescriptions when a first generation antipsychotic was available

and appropriate, those prescriptions were medically unnecessary and resulted in an unnecessary and improper expenditure of millions of Medicaid and PACE dollars.

SCHIZOPHRENIA AND ITS TREATMENT

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

40. There are many clinical presentations of schizophrenia. Despite common misconceptions of schizophrenia as a "split-personality", schizophrenia is a chronic disorder of thought and affect. The Diagnostic and Statistical Manual of Mental Disorders, 4th edition, (DSM-IV) assigns a diagnosis of schizophrenia when a patient suffers two or more of the following characteristic symptoms: delusions, hallucinations, disorganized speech, grossly disorganized or catatonic behavior and negative symptoms.[2]

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

42. Since the discovery of the effects of antipsychotics, 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.

---

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

43. 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.

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

45. By the 1980s, clozapine was being investigated for the treatment of schizophrenia on the theory that it might be more effective and cause less movement disorder than other antipsychotics. Clozapine was termed an atypical antipsychotic because it had an "atypical index" when measuring its effect on brain activity in different parts of the brain. It was hypothesized that the different effects by clozapine on the areas of the brain that control movement would cause less movement disorder than other antipsychotics. However, the potential of clozapine to cause toxic side effects, including agranulocytosis, limited its prescription to about 10 percent of persons with schizophrenia.

EMERGENCE OF THE ATYPICAL ANTIPSYCHOTICS OR SECOND GENERATION ANTIPSYCHOTICS

46. During the 1990's pharmaceutical companies, acting on the "atypical" hypothesis, introduced newer drugs attempting to capture the enhanced therapeutic effect of clozapine without its toxicity and without the increased extra pyramidal symptoms ("EPS") caused by traditional antipsychotics. Before 1993, the only atypical antipsychotic in the United States market was clozapine. Due to its toxicity, clozapine had very little market share. Ten years

later, atypical antipsychotics would account for about 90% of all antipsychotic drugs prescribed for all psychiatric purposes, regardless of whether they were approved for those indications. The atypical antipsychotics include clozapine (Clozaril), olanzapine (Zyprexa), quetiapine (Seroquel), risperidone (Risperdal), aripiprazole (Abilify), and ziprasidone (Geodon), and are considered the second-generation antipsychotics (SGA). This lawsuit arises from Defendants' strategy, through a series of unlawful acts and practices, to obtain the largest United States market shares for atypical antipsychotics.

ADVERSE EVENTS COMMON TO ANTIPSYCHOTIC DRUGS

47. Medical literature dating as far back as the 1950s demonstrates that antipsychotic drugs have the potential to cause diabetes, diabetes-related injuries (e.g. weight gain and hyperglycemia), cardiovascular and cardiovascular complications, and other severe adverse effects. The prevalence of diabetes in patients with schizophrenia increased from 4.2% in 1956 to 17.2% in 1968 due to the introduction of antipsychotics.

48. All antipsychotics now bear a warning regarding the risks of treatment-emergent hyperglycemia and diabetes associated with their usage.

49. Another traditional and troubling side effect of antipsychotics is that the blockage of dopaminergic neurotransmission in the basal ganglia causes EPS such as parkinsonian effects. A long-lasting movement disorder, tardive dyskinesia ("TD"), also occurs with prolonged treatment. TD is potentially irreversible and affects all patient populations. The risk of TD and the likelihood that it will become irreversible increase as the duration of treatment and the total cumulative dose of antipsychotic drugs administered to a patient increase. However, TD can develop after relatively brief treatment periods at low doses. There is no known treatment for

TD, although it has been observed to remit, on occasion, upon the cessation of antipsychotic drug therapy.

50. Due to the implications of triggering TD, the FDA advises that antipsychotic treatment should be reserved for patients who suffer from a chronic illness that (1) is known to respond to antipsychotic drugs, and (2) for whom alternative, equally effective, but potentially less harmful treatments are not available or appropriate.

51. Further, a potentially fatal symptom complex referred to as Neuroleptic Malignant Syndrome ("NMS") is associated with use of antipsychotic drugs, including Zyprexa, Seroquel and Risperdal. Clinical manifestations of NMS are hyperplexia, muscle rigidity, altered mental status, and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmia). According to the FDA, the management of NMS symptoms should include: 1) immediate discontinuation of antipsychotic drugs; 2) intensive symptomatic treatment and medical monitoring; and3) treatment of any concomitant serious medical problems for which specific treatments are available.

52. Although it is not known how Zyprexa, Risperdal or Seroquel work, all three drugs have demonstrated a propensity to cause weight gain, movement disorders and other very serious health problems to different degrees, as explained herein.

RISPERDAL'S MEDICALLY ACCEPTED INDICATIONS

53. Janssen obtained approval from the FDA to market Risperdal oral tablets for the treatment of schizophrenia in adults on December 29, 1993. On June 10, 1996, the FDA approved Risperdal oral solution for the treatment of schizophrenia in adults. On April 2, 2003, the FDA approved Risperdal M-Tab for the treatment of adults with schizophrenia. On October 29, 2003, the FDA approved Risperdal Consta for the treatment of schizophrenia in adults. On

December 4, 2003, the FDA approved Risperdal oral tablets, Risperdal oral solution and Risperdal M-Tab as monotherapy for the short-term treatment of acute manic or mixed episodes associated with Bipolar I Disorder, and as combination therapy, with lithium or valproate, for the short-term treatment of acute manic or mixed episodes associated with Bipolar I Disorder.

54. The United States Pharmacopeia-Drug Information and the DRUGDEX Information System support the use of Risperdal for the indications approved by the FDA. The American Hospital Formulary Service Drug Information ("AHFS") supports the use of Risperdal for the indications approved by the FDA and, in 2003, initiated support for the use of Risperdal to treat behavioral problems in children 5-17 years old with autistic disorder. The AHFS noted that it did not support the use of Risperdal to treat the core symptoms of autism, but only manifestations of moderate to severe behavioral problems associated with autistic disorder. Prior to 2003, the compendia supported only the uses of Risperdal approved by the FDA. The uses supported by these three Compendia and the FDA-approved labeling are collectively defined as Risperdal's "Medically Accepted Indications" in the Federal Medicaid Act, 42 U.S.C.A. §1396r-8.

55. Neither the Compendia cited above nor the FDA-approved labeling support any use of Risperdal by children, other than a narrow indication, for autism, or adults with depression, anxiety, ADD, ADHD, sleep disorders, anger management, mood enhancement or mood stabilization.

SEROQUEL'S MEDICALLY ACCEPTED INDICATIONS

56. AstraZeneca obtained approval from the FDA to market Seroquel tablets for treatment of adults with schizophrenia in September 1997. On January 12, 2004 the FDA approved Seroquel tablets for treatment of adults with acute mania associated with Bipolar I

Disorder and combination therapy with lithium or divalproex for acute manic episodes associated with bipolar I disorder. On October 20, 2006, Seroquel tablets were approved for treatment of adults with major depressive episodes associated with bipolar disorder.

57. The AHFS, United States Pharmacopeia-Drug Information and the DRUGDEX Information System support the use of Seroquel in adult schizophrenic patients only. The uses supported by these three Compendia and the FDA-approved labeling are collectively defined as Seroquel's "Medically Accepted Indications" in the Federal Medicaid Act, 42 U.S.C.A. §1396r-8.

58. Neither the Compendia cited above nor the FDA-approved labeling support any use of Seroquel by children or for treatment of adults with anxiety, ADD, attention deficit hyperactivity disorder, sleep disorders, anger management, mood enhancement or mood stabilization.

ZYPREXA'S MEDICALLY ACCEPTED INDICATIONS

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

60. The AHFS, United States Pharmacopeia-Drug Information and the DRUGDEX Information System support the use of Zyprexa in adult schizophrenic patients only. The uses

supported by these three Compendia and the FDA-approved labeling are collectively defined as Zyprexa's "Medically Accepted Indications" in the Federal Medicaid Act, 42 U.S.C.A. §1396r-8.

61. Neither the Compendia cited above nor the FDA-approved labeling supports any use of Zyprexa by children or for treatment of adults with depression, anxiety, ADD, ADHD, sleep disorders, anger management, mood enhancement or mood stabilization.

DEFENDANTS' PRE-MARKETING PLANNING

62. From their respective product launches to the present, Defendants engaged in wide-spread fraudulent statements and conduct, and pervasive false and misleading marketing, advertising and promotion of their antipsychotic drugs. Defendants deceived physicians, consumers, the Commonwealth, and others regarding the comparative efficacy of their antipsychotic drugs to other atypicals and traditional antipsychotics. Defendants failed to warn – and affirmatively misled – physicians, consumers, the Commonwealth, and others in the medical community regarding their antipsychotic drugs' association with diabetes, diabetes-related conditions, movement disorders, NMS and other adverse effects.

63. Further, even though Zyprexa, Seroquel and Risperdal are limited in their FDA-approved indications, Defendants actively marketed and promoted their respective antipsychotic drugs for unapproved uses in several populations where the efficacy and safety of the drug had not been established – each marketing their drugs for the treatment of various conditions or symptoms in children, for treatment in the elderly for dementia, and for treatment of patients who experience depressive or mood disorders.

64. Upon information and belief, Defendants' schemes to increase the sales of their antipsychotic drugs consisted of elaborate and clandestine promotions of non-medically accepted

indications and non-medically necessary uses as well as deliberate misrepresentations regarding, and omissions of, critical information related to the drugs' risk profiles.

65. Upon information and belief, this scheme was carried out by: employing the illegal direct solicitation of physicians to prescribe their respective antipsychotic drugs for non-medically accepted indications and non-medically necessary uses; the making of false statements to physicians and pharmacists concerning the efficacy and safety of their respective antipsychotic drugs for non-medically accepted indications and non-medically necessary uses; the use of active concealment to avoid the policies of Medicaid and PACE, which are intended to refuse payment for uses of drugs which are not medically necessary; and the active training of Defendants' employees in methods of avoiding detection of their activities by the Commonwealth.

66. Among the tactics employed by Defendants were plans to create studies designed to illustrate their antipsychotic drug's superior profile to both (a) placebo and (b) a representative conventional antipsychotic while providing funding to engage "key opinion" and "thought" leaders in publication worthy trials.

67. Upon information and belief, Defendants sought out, and provided incentives and funding to, doctors and researchers prior to their respective launches to develop deceptive and misleading medical literature for use in marketing.

68. Defendants each set out to fund specious scientific literature capable of significantly growing the market potential of their respective drugs in suspected areas of high non-medically accepted utilization.

69. In this regard, it was Defendants' strategy well before the launch of their respective antipsychotic drugs to market the drugs not only for use with children and the elderly but also for a variety of symptoms in the broad realm of mood and thought disorders, a strategy

that gave rise to an ongoing pattern of false and misleading conduct. This conduct resulted in both the submission of claims for non-medically accepted indications and non-medically necessary uses of Zyprexa, Seroquel and Risperdal to Medicaid and PACE as well as adverse health effects among Medicaid and PACE participants.

70. Despite being on notice of the potential for deadly diabetes-related side effects, Defendants each opted for the bare minima of well-tailored clinical trials, of limited duration, such that no side effects were likely to be revealed.

71. Further, neither Zyprexa's, Seroquel's nor Risperdal's pre-marketing clinical trials support an assertion that they are less likely to cause EPS than traditional antipsychotics. Upon information and belief, Defendants' trials were specifically designed to produce similar rates of EPS in patients sorted into control groups and those taking each Defendant's drug. In order to produce such a result, Defendants selected patients for the placebo groups that were in the course of treatment with high doses of typical antipsychotics or populated control groups with patients taking high doses of conventional antipsychotics known to be associated with high incidences of adverse events, such as Haldol.

72. The manifestation of EPS in a patient taking antipsychotics is largely dose-dependent. In other words, patients become more likely to manifest EPS as the antipsychotic dose is titrated up. Further, patients that develop EPS generally continue to experience EPS for months after discontinuing antipsychotic treatment. Because of this, patients in Defendants' control groups continued to experience EPS at the rate at which they had been experienced while on antipsychotic treatment. Meanwhile, patients in the atypical antipsychotic groups predictably developed EPS at the rate to be expected in a population taking antipsychotic medication, a rate which essentially matched the control group.

73. Based on similar or elevated levels of EPS in the control and atypical antipsychotic groups, Defendants each claimed, in their marketing, that patients taking their drug were less likely to develop EPS than patients taking traditional antipsychotics.

74. Nevertheless, because the mechanisms of action for Defendants' atypicals were fundamentally the same as other antipsychotics the FDA required warnings for Defendants' drugs that included NMS and TD.

75. From the outset, Defendants recognized the need to promote non-medically accepted indications and non-medically necessary uses as the key to blockbuster success for their respective antipsychotic drugs. They continue to promote non-medically accepted indications and non-medically necessary uses for their drugs today.

76. Defendants' "studies" of their respective drugs were, in reality, devices created to position their drugs against each other and traditional antipsychotics. Defendants circulated only studies that would reflect positively on their drug, or negatively on each other. This publication strategy entailed having individual medical marketing affiliates identify key influencers in their market and generate research designed to increase market share in non-medically accepted indications and non-medically necessary uses.

77. Thus, instead of conducting true scientific research in good faith to legitimately test the efficacy and safety of their antipsychotic drugs, Defendants focused on creating narrowly tailored studies specifically designed to enhance commercial value.

78. Upon information and belief, Defendants' clear aim from the outset was to expand non-medically accepted and non-medically necessary usage for their respective drugs. Defendants had this aim despite the fact that they were aware of numerous problems associated with their drugs, including:

- absent to limited treatment response in a significant number of patients;
- no demonstrable long term benefit in so-called negative symptoms;
- no effect or exacerbation of co-morbid mood symptoms; and
- an equivalent incidence of movement disorders compared with traditional antipsychotic drugs

79. Defendants' pre-launch marketing strategy for their respective drugs is summarized as follows: result-driven study designs supported by result-driven selection of paid consultants and researchers, narrowly tailored such that they "should" only provide support for the efficacy and safety of their respective drugs as an agent capable of combating as wide a variety of disease states and symptoms as possible so that Defendants could sell as much of their respective drug to as many patients at the maximum price possible, despite the known problems with the drug.

SPECIFIC ASPECTS OF DEFENDANTS' MARKETING EFFORTS

80. Upon information and belief, Defendants created complicated marketing structures that appeared independent from their proprietary promotion forces. Defendants did so to avoid regulations concerning off-label promotion and also to create the facade of independence to hide the misleading messages of safety and efficacy related to non-medically accepted and non-medically necessary usage.

81. In order to successfully execute their marketing strategies, Defendants generated favorable articles that appeared to emanate from independent physicians and continuing legal education programs to inundate the information market and give scientifically baseless and unsafe uses of their drugs an appearance of independent peer-to-peer credibility.

82. Finally, given the predominant usage of antipsychotics in the public sector Defendants sought to exploit the Commonwealth's Medicaid and PACE programs.

Defendants' Peer Selling Efforts

83. Upon information and belief, Defendant's peer-to-peer marketing scheme centered on hosting numerous events where doctors selected, trained and approved by Defendants would falsely oversell the efficacy and safety of their respective antipsychotic drugs. Defendants provided participants with favorable information on the non-medically accepted indications and non-medically necessary uses of their respective drugs, and regularly paid doctors for their attendance. Defendants funded scores of such events from their respective launches to present.

84. Because Defendants are prohibited from directly producing such events, they created and controlled peer-selling enterprises composed of medical marketing firms and several dozen physicians who routinely promoted their respective drugs to other physicians in the Commonwealth. Defendants maintained control over these events. They selected and approved the content of the supposedly independent programs as well as the doctors who participated in the promotion of their respective drugs. The events were designed to give doctors the false impression that the events were educational in nature and independent from the control of the Defendants.

85. Defendants employed improper and unlawful sales and marketing practices, including: (a) deliberately misrepresenting the safety and medical efficacy of their respective drugs for a variety of non-medically accepted and non-medically necessary uses; (b) knowingly misrepresenting the existence and findings of scientific data, studies, reports and clinical trials concerning the safety and medical efficacy of their respective drugs for both medically accepted

indications as well as a variety of non-medically accepted indications and non-medically necessary uses; (c) deliberately concealing negative findings or the absence of positive findings relating to their respective drugs and/or their non-medically accepted indications and non-medically necessary uses; (d) wrongfully and illegally compensating physicians for causing the prescribing of their respective drugs; (e) knowingly causing the publication of articles, studies and reports misrepresenting the scientific credibility of data and touting the medical efficacy of their drugs for non-medically accepted indications and non-medically necessary uses; (f) intentionally misrepresenting and concealing their role and participation in the creation and sponsorship of a variety of events, articles and publications used to sell their respective drugs for treatment in non-medically accepted and non-medically necessary situations; and (g) intentionally misrepresenting and concealing the financial ties between themselves and their affiliates responsible for deceptively promoting their respective drug.

86. Defendants' schemes were highly successful. Upon information and belief, well over half of all dollars spent on atypical antipsychotic drugs are spent on non-medically accepted or non-medically necessary uses.

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

88. Risperdal is the most widely used atypical antipsychotic in the world. Risperdal has gone from annual sales of zero on 1/1/94 to over $3,500,000,000 in 2005. Crucial to this blockbuster success was Janssen's aggressive marketing of Risperdal, which consisted chiefly of overstating the drug's efficacy, while concealing its propensity to cause diabetes, EPS, stroke and other injuries.

89. Seroquel is the fastest growing atypical antipsychotic, in terms of sales. In 2005, AZ's Seroquel sales were $2,761,000,000, which constituted a 35% increase over 2004 sales. Like Risperdal and Zyprexa, Seroquel's success was directly caused by AZ's aggressive promotion of Seroquel for non-medically accepted indications and non-medically necessary uses and misrepresentations regarding Seroquel's risk profile.

90. Upon information and belief, Defendants controlled all aspects of their respective drug's promotion. Defendants compensated marketing affiliates for their efforts and controlled compensation to vendors and physicians participating in marketing events. Defendants closely monitored all events to insure that the misleading representations related to non-medically accepted indications and non-medically necessary uses of their respective drug were made to physicians attending the events.

Role of Medical Marketing Firms in Defendants' Promotions

91. Upon information and belief, third party medical marketing firms were critical to Defendants' schemes to promote their respective antipsychotic drug for non-medically accepted indications and non-medically necessary uses. Defendants' marketing strategy called for information about non-medically accepted indications and non-medically necessary uses of their respective drug to be widely disclosed in continuing medical education programs, consultants' meetings, and other programs where physicians could relay information regarding unapproved and non-medically necessary usage to other doctors.

92. Bona fide continuing medical education programs and similar educational events are exempt from FDA rules prohibiting off-label promotion because the sponsoring organization—which is often a nonprofit, such as a medical school, is theoretically independent and responsible for controlling the programs' content. In practice, however, these programs are produced with the assistance of third party medical marketing firms, working at Defendants' behest, which supplied content and controlled the selection of presenting physicians.

93. Defendants' marketing strategies intentionally corrupted the educational purpose of these events. Upon information and belief, instead of accredited institutions planning independent programs and approaching third party vendors and financial sponsors, Defendants created turnkey medical programs, with financing already included, and sought "independent" institutions that would promote their respective drugs in the manner Defendants instructed.

94. Upon information and belief, among the information the Defendants, through their supposedly independent vendors and paid physicians, deliberately omitted from events they sponsored was the following:

- the lack of clinical trial evidence to support their respective drugs' non-medically accepted and non-medically necessary uses;
- clinical trial results that demonstrated that their respective drugs were no more safe or effective than less costly, first generation antipsychotics;
- negative evidence that their respective drugs did not work for non-medically accepted indications or non-medically necessary uses;
- information that virtually all publications and studies that allegedly supported their respective drugs' non-medically accepted or non-medically necessary use had been initiated and funded by Defendants;
- information that the doctors who were involved in peer selling had been paid substantial subsidies to use Defendants' respective antipsychotic drugs on their patients for non-medically accepted or non-medically necessary purposes;
- that the information regarding non-medically accepted and non-medically necessary uses of their respective drug was baseless;

- information that the events were not funded, as advertised, by an "unrestricted" grant from the Defendants, but that the grants were conditioned upon the participating vendors and sponsoring institutions making presentations that presented the non-medically accepted and non-medically necessary uses of Defendants' respective drug in the most favorable light; and

- information related to dangerous side effects revealed through Defendants' internal research, adverse event reports, and independent research.

95. Defendants' medical marketing efforts include third party advertisers, proliferation firms and outside consultants such as Creative Street, Inc; Marketplace Management; Lewis & Gore; Harper; Aldephi Research, Millward-Brown Research; GSW; Pramaton, Inc.; Martin Hamblin; Cohn & Wolfe; and Grey Strategic Marketing/Grey Healthcare Group.

Role of Physicians

96. Upon information and belief, one of Defendants' principal strategies for marketing their respective antipsychotic drug was to target key physicians to influence the prescribing practices of their peers. These doctors would promote Defendants' drugs to their peers by (i) falsely touting the safety and efficacy of Defendants' respective drug for non-medically accepted indications and non-medically necessary uses; (ii) claiming that Defendants' respective drug was being appropriately used by other physicians for non-medically accepted indications and non-medically necessary uses; (iii) suggesting mechanisms of action that could explain Defendants' respective drug's efficacy, safety profile and use for non-medically accepted and non-medically necessary purposes, even though the mechanisms of action of Zyprexa, Seroquel and Risperdal are not understood; and (iv) falsely claiming that they were privy to non-existent clinical data that would support non-medically accepted and non-medically necessary use.

97. Upon information and belief, to recruit physicians, including Pennsylvania physicians, to participate in fraudulent peer-selling, Defendants identified specific doctors and informed them of the Defendants' interest in funding research opportunities and clinical trials at their institutions. Doctors who were willing to speak favorably about Defendants' respective drug often received substantial funds in the form of research grants. Defendants recruited doctors at major teaching hospitals to deliver Defendants' respective marketing message to other physicians. This practice is critical and highly successful because doctors, unlike Defendants themselves, can communicate formally to other physicians at marketing events or informally to colleagues within a hospital or medical practice without concern for FDA regulation and without the commercial appearance of formal drug company marketing.

98. Upon information and belief, Defendants created an explosion in the non-medically accepted and non-medically necessary usage of their respective drug with this practice. Defendants did so by creating the false perception that physicians were using their respective drug and investigating its efficacy in non-medically accepted and non-medically necessary uses on their own initiative, and not as a result of Defendants' respective marketing activities. Defendants each developed a stable of physicians to create this perception.

99. Defendants, principally through their respective medical marketing affiliates, paid these physicians to write journal articles and letters to the editor that favorably discussed non-medically accepted and non-medically necessary uses of their respective antipsychotic drug. In addition to providing free travel to resorts, free lodging and free meals, Defendants also paid these physicians to give talks at medical education seminars, advisory boards, consultants' meetings, speakers bureaus and similar events that favorably discussed non-medically accepted and non-medically necessary uses of their respective drug.

100. Physicians were absolutely critical to Defendants' respective marketing schemes. The participation of physicians allowed Defendants and their respective medical marketing affiliates to disguise promotional events as educational events or consultants' meetings. Moreover, as noted above, Defendants and their medical marketing affiliates knew that peer-to-peer selling was far more effective than traditional detailing. By channeling payments to physicians through medical marketing firms, the physician-speakers' financial ties with the Defendants were hidden from prescribers treating Medicaid and PACE participants. Defendants were thus able to mislead prescribers about the promotional nature of the events. The large amounts of money physicians received from the Defendants, for speaking and other purposes, were hidden from the physicians who attended events at which Defendants' respective drug was marketed.

101. Some physicians participated in this scheme by publishing favorable journal articles and letters to the editor about non-medically accepted and non-medically necessary uses of Defendants' respective drug. Defendants paid large sums of money, often in the form of research grants, to induce doctors to publish such articles. In most cases, the purported physician-author was not required to perform any research or even write the article. Marketing firms who were financed by the Defendants ghostwrote articles under the physician participants' names. Physicians merely had to "lend" their names to the articles, in exchange for a payment. The purpose of recruiting physicians as authors in this manner was to hide the fact that the articles were no more than promotional literature.

102. The more favorable a physician's statements about Defendants' respective drug, the more he or she could expect in the form of speaker fees and research grants. Physicians who refused to deliver a favorable message did not receive additional payments.

103. Plaintiff does not at this time know the identity of all of the physicians that participated in this scheme. The Defendants' unlawful marketing operations sponsored events in Pennsylvania from their respective launches to present. Upon information and belief, certain Pennsylvania physicians, received cash payments for participating in the Defendants' unlawful marketing operations for the time period indicated (not counting travel, food, lodging and entertainment benefits they also received).

Role of Pharmacies

104. Upon information and belief, Defendants set up separate sales divisions to service long term care facilities. Long term care facilities were critical to Defendants because they treat the elderly population, which includes many Medicaid and PACE participants, as well as children being treated for behavioral symptoms, many of whom are also Medicaid participants. Both populations were considered essential markets for Zyprexa's, Seroquel's and Risperdal's growth in non-medically accepted and non-medically necessary sales. The growth of sales in the long-term sales division was heavily weighted to pediatric use and to non-medically accepted and non-medically necessary uses in the elderly population.

105. Long term care facilities are not serviced by traditional retail pharmacies. Instead they are serviced by "closed end" pharmacies. The long term care pharmacy market is dominated by a few companies, including Omnicare, Pharmerica, and Neighbor Care. Defendants' long term care sales representatives work closely with long term care pharmacies in marketing their respective drug to physicians for non-medically accepted indications and non-medically necessary uses. Defendants' sales representatives often provided unrestricted educational grants to effectuate their schemes to expand their respective drug's use.

Ghostwritten Publications

106. Defendants also sought to generate favorable, seemingly independent articles related to non-medically accepted indications and non-medically necessary uses of their respective drug.

107. Upon information and belief, Defendants hired non-physician technical writers to create articles related to non-medically accepted indications and non-medically necessary uses of their respective drug and the safety and efficacy of their drug compared to first generation antipsychotics and other atypicals. Defendants then paid reputable physicians to serve as the articles' "authors." This practice is referred to as "ghostwriting."

108. Defendants also recruited medical marketing firms to monitor the status of publications and to coordinate and execute the ghostwriting plan. The role played by the marketing firms in assisting the Defendants in creating ghostwritten publications was very similar to the role played by marketing firms in the coordination of peer-to-peer marketing events.

109. Publications that Defendants distributed as part of their publication strategy intentionally misrepresented Defendants' 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 Defendants 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 their respective drug.

110. Even in cases where physician-"authors" drafted the articles themselves, they did so under the same system of direction and control through which Defendants controlled speaker content generally. Upon information and belief, physicians were promised grants and other gifts

if they wrote favorable articles. If a physician attempted to write a negative article, Defendants would intervene and have a more favorable draft written. If this failed, Defendants would suppress the article or restrict its dissemination.

111. Upon information and belief, the final method by which Defendants controlled the content of published information related to their respective drug was through their policies of publishing only favorable results of their own internal trials and suppressing results that were unfavorable.

112. Although Plaintiff is aware of the policy of suppressing unfavorable studies, all information regarding negative studies funded by Defendants remains in the sole possession of Defendants and/or members of the their respective unlawful marketing operations. Defendants have never produced the results of these studies to the public or to the Plaintiff and its attorneys. Plaintiff believes that generally, these studies either did not support, or directly contradicted, the Defendants' repeated and sustained representations which are summarized below.

Fraudulent and Unlawful Acts Regarding Safety and Efficacy

113. When presenting information about their respective drug to physicians in response to unsolicited requests for information on non-medically accepted indications or non-medically necessary uses, Defendants had a duty to provide fair and balanced information. Defendants were also required to provide fair and balanced information whenever they engaged in promotional activities. Fair balance is not limited to written materials but all presentations. Defendants knew that whenever they were required to provide fair and balanced information, Pennsylvania law and industry standards required that they provide any negative information as well as positive information about their drug.

114. Within the medical community, in the context of describing properties of approved prescriptions drugs, the terms "effective" and "efficacy" have specific and well

understood meanings. 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.

115. Although Defendants have extensively promoted their respective drug for non-medically accepted indications and non-medically necessary uses, few placebo-controlled, clinical studies have been conducted on non-medically accepted indications or non-medically necessary uses of their drug. The results of most studies that have been conducted are negative or inconclusive. Placebo controlled clinical trials for Zyprexa's, Seroquel's or Risperdal's use for bipolar disorder, unipolar disorder, dementia, essential tremor, spasticity, controlled diabetic pain, and panic disorder have all failed to show that any of the three drugs is safe and effective for those conditions.

116. Any presentation concerning Defendants' respective drug's use for indications other than those approved by the FDA that purports to rely on clinical or published evidence must also describe those countervailing clinical studies that have found that the drug is not effective for off-label uses. Where such information is not provided, any statements about Defendants' respective drug's efficacy in treating off-label use is false, misleading, distorted, inaccurate, unfair, imbalanced and omits material facts necessary to be disclosed.

117. Pennsylvania law and industry standards also prohibit Defendants from misrepresenting scientific evidence that supports (or fails to support) claims that their respective 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. Failure to comply with these standards violated the Defendant's legal duty to provide accurate and non-misleading information.

118. In addition to their failure to warn of the serious and life-threatening illnesses associated with their respective drug, Defendants also undertook, through the use of intermediary marketing firms, to promote the use of their respective drug for uses for which they were never approved by the FDA and for which they have never been proven to be safe or effective.

119. These unlawful marketing operations routinely and knowingly provided false, inaccurate, misleading, distorted, unfair and imbalanced information about the use of Zyprexa, Seroquel and Risperdal for non-medically accepted indications and non-medically necessary uses.

FRAUDULENT AND UNLAWFUL ACTS REGARDING PROMOTIONS FOR NON-MEDICALLY ACCEPTED ELDERLY USAGE

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

121. Defendants' respective decision to target the Commonwealth's elderly had two results. Non-medically accepted and medically unnecessary claims for Zyprexa, Seroquel and Risperdal were submitted to Medicaid and PACE for reimbursement, and the drugs caused disastrous health consequences for geriatric patients.

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

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

123. Although the atypical antipsychotics are FDA-approved for the treatment of schizophrenia, none has been approved for the treatment of behavioral disorders in patients with dementia. As a result of the findings, the FDA required Defendants to include a Boxed Warning or "black box warning" in their respective labeling describing this risk and emphasizing that the drugs are not approved for this indication.

124. Upon information and belief, despite the foregoing, Defendants continue to promote their respective drug as safe and effective treatment for dementia in elderly patients.

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

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

126. With respect to Lilly, such promotion is particularly sinister given the results of a study it performed in 1995, before Zyprexa was initially approved by the FDA. Upon

information and belief, Lilly learned that olanzapine, the active ingredient in Zyprexa, was ineffective in treating such conditions as dementia and Alzheimer's. Nevertheless, from the inception of marketing, Lilly promoted Zyprexa for symptoms of dementia and Alzheimer's in the elderly.

127. In 1999, Janssen was reprimanded by the FDA for promoting Risperdal for the treatment of the elderly. In a letter from the FDA to Todd McIntyre, Janssen's Director of Regulatory Affairs, the agency took issue with certain promotional materials that it had acquired as part of its monitoring and surveillance program. According to the FDA, Janssen engaged in a false and misleading campaign to promote Risperdal to geriatric patients. Among the items found by the FDA to be **false and misleading** were:

- Janssen's claims in its promotions that Risperdal was safe and effective for elderly patients, despite little or no data to support such claims;
- Janssen's claims that Risperdal has a low incidence of movement disorders;
- Janssen's claims that Risperdal has a low incidence of sedation;
- Janssen's claims that Risperdal has a low incidence of anticholinergic effects (variety of movement disorder);
- Janssen's claims that Risperdal treatment is associated with a low incidence of adverse events coupled with presentations of adverse events associated with Risperdal's discontinuation because such presentations imply that the only adverse events associated with Risperdal result from a patient being taken off the drug;
- Janssen's claims that Risperdal is safer or more effective than other antipsychotics;
- Janssen's claims that Risperdal "enhances daily living" or that it offers "quality control of symptoms for daily living";

- Janssen's claims that Risperdal can "control health-related quality of life";
- Janssen's failure to warn that the use of Risperdal by healthy elderly patients created a greater potential for hepatic and renal dysfunction and cardiovascular sensitivity;
- Janssen's marketing Risperdal outside its education by representing that Risperdal is a safe and effective treatment for hostility in the elderly; and
- Janssen's claims that Risperdal is a safe and effective treatment for "psychotic symptoms associated with a broad range of disorders," including schizophrenia, schizophreniform disorder, schizoaffective disorder, bipolar disorder and elderly psychosis.

128. The FDA further found that Janssen's promotion of Risperdal lacked fair balance because:

- The risk information in its promotional literature "appears in pale and tiny font at the bottom or back of a journal ad or other presentation, or after the closing of a letter", thus lacking the "prominence and readability that is reasonably comparable to the presentation of efficacy information"; and
- It minimized important information related to TD and EPS.

129. Upon information and belief, despite studies and data that confirm the lack of efficacy and significant health and safety risks associated with the promotion of each of the three drugs for the elderly, Defendants continue this practice.

FRAUDULENT AND UNLAWFUL ACTS REGARDING PROMOTIONS FOR NON-MEDICALLY ACCEPTED PEDIATRIC USAGE

130. To generate additional sales, Defendants each undertook schemes to market and promote their respective drug for use in the treatment of children suffering from disorders such as depression, anxiety, Attention Deficit Disorder (ADD), Attention Deficit Hyperactivity

Disorder (ADHD), sleep disorders and generally as a mood stabilizer. Zyprexa, Seroquel and Risperdal are not now and have never been approved by the FDA for any use in children[3]. Further, the Plaintiff's programs' policies have never intended reimbursement for non-medically accepted indications or non-medically necessary uses.

131. Upon information and belief, this lack of approval did not restrain Defendants from marketing their respective drug for treatment of children and adolescents. Upon information and belief, Defendants each sponsored several studies in the 1990s to determine the effects of their respective drug on a variety of symptoms in children and adolescents.

132. Zyprexa, Seroquel or Risperdal have never been proven safe or effective for non-medically accepted or non-medically necessary, pediatric uses promoted by Defendants and their respective intermediary marketing firms. As a result of Defendants' marketing, children participating in Medicaid in Pennsylvania 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 movement disorders, diabetes and diabetes-related complications.

133. The children and adolescents of Pennsylvania remain a considerable market segment for Zyprexa, Seroquel and Risperdal. Pediatric sales of Zyprexa totaled approximately $500 million between 1999 and 2005. On November 1, 2005 Leila Abboud of The Wall Street Journal 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 & Co.'s Zyprexa and Johnson & Johnson's Risperdal that aren't well studied in children." Upon information and belief, Defendants continue to promote their respective drug for the treatment of children participating in the Medicaid

[3] Risperdal received a narrow indication from the FDA for the treatment of children exhibiting certain types of behavior associated with autism in late 2006.

program, despite knowledge that usage of antipsychotics by children is unsafe and not demonstrably effective.

ONGOING REFUSAL TO DISCLOSE KNOWN ADVERSE EFFECTS

Lilly

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

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

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

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

> as being part of a therapeutic recovery rather than an adverse event. That data I think was fairly compelling because it was included in our labeling.

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

138. Moreover, the FDA complained that the October 1, 1996 teleconference had "presented a misleading impression of Zyprexa as a superior, highly effective, virtually free of side effects, easy to use product." Dr. Tollefson had said that olanzapine had no Parkinsons-like side effects: "We're very pleased that the labeling in the U.S. will show by objective rating scales that both Parkinsons like side effects and restlessness or Acathisia, the incidence across all doses of Zyprexa was comparable to placebo. That is essentially this drug did not induce persistent Parkinsonian problems." And: "[W]e've been able to show that there is a statistically and significantly lower incidence of this neurological [Tardive Diskinesia] side effect with Zyprexa than with conventional drugs." Not only was this a clearly deceptive analysis of the

clinical trial results, years later Lilly admitted on its "Patient Information Sheet Revised 04/2005" for Zyprexa that it could "cause serious problems such as . . .A movement problem called tardive dyskinesia (TD)."

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

140. Upon information and belief, Lilly believed, as early as 1996, that blood glucose monitoring should be recommended for patients on Zyprexa. Nevertheless, they allowed their spokesman, Dr. Tollefson, to distinguish Zyprexa from its competitors as a treatment option that did not require monitoring, leaving the impression that Zyprexa was less expensive to prescribe than other antipsychotics because it did not require blood monitoring.

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

start with the therapeutically effective does [sic] on day one." By contrast, however, Lilly's official label says that patients should commence with 2.5 to 5 mg on day one.

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

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

AZ

144. The FDA reprimanded AZ for making false statements in its promotion of Seroquel immediately after launch. In a May 1999 letter from the FDA to Anthony Rogers, Director of Marketed Products Group, the agency referenced its November 24, 1998 Warning Letter requesting information about statements that the FDA found to be false and misleading.

145. Among the statements contained in AZ's promotion of Seroquel found to be false and misleading were:

- AZ's claims that Seroquel is effective in a broader range of mental conditions, including bipolar disorder and schizoaffective disorder;

- AZ's claims as to how Seroquel "works" (the mechanism of action of antipsychotic drugs is unknown); and
- AZ's claims that Seroquel had been proven safer and more effective than first generation antipsychotics.

146. Further, the FDA found that AZ's promotion of Seroquel lacked fair balance because it failed to disclose risks and important warnings including NMD, TD, orthostatic hypotension and seizures.

147. The FDA's 1999 letter did not deter AZ, however. In October of 2006, the FDA was again required to admonish AZ for essentially identical false and misleading acts. In 2006, the FDA found that AZ had again made presentations in its promotions related to Seroquel's risk profile that were false and misleading. According to the FDA, AZ's marketing of Seroquel "raises significant public health and safety concerns through its minimization of the risks associated with Seroquel." Among AZ's false and misleading statements regarding Seroquel's safety were the following:

- Failing to warn doctors of the increased risk of treatment-emergent hyperglycemia-related adverse events in patients treated with Seroquel in its promotions, thus undermining the FDA-approved labeling;
- Misrepresenting the incidence of diabetes in post-marketing adverse event reports;
- Failing to include relevant risk information about Seroquel;
- Failing to warn doctors of the irreversibility of TD as treatment continues and the fact that the condition may remit if treatment is interrupted;

- Failing to reveal that NMS is a potentially fatal symptom complex associated with Seroquel;
- Failing to inform doctors of the symptoms of NMS and that treatment with Seroquel should be immediately ceased upon the observance of such symptoms; and
- Failing to reveal material facts about the risk of seizures, orthostatic hypotension and cataract development associated with Seroquel usage.

Janssen

148. Janssen was admonished by the FDA in 1999 for disseminating false and misleading information regarding the adverse events associated with Risperdal use. Among the items found by the FDA to be false and misleading were:

- Janssen's claims that Risperdal has a low incidence of movement disorders;
- Janssen's claims that Risperdal has a low incidence of sedation;
- Janssen's claims that Risperdal has a low incidence of anticholinergic effects (variety of movement disorder);
- Janssen's claims that Risperdal treatment is associated with a low incidence of adverse events coupled with presentations of adverse events associated with Risperdal's discontinuation because such presentations imply that the only adverse events associated with Risperdal result from a patient being taken off the drug;
- Janssen's failure to warn that the use of Risperdal by healthy elderly patients created a greater potential for hepatic and renal dysfunction and cardiovascular sensitivity;

149. The FDA further found that Janssen's promotion of Risperdal lacked fair balance because:

- The risk information in its promotional literature "appears in pale and tiny font at the bottom or back of a journal ad or other presentation, or after the closing of a letter", thus lacking the "prominence and readability that is reasonably comparable to the presentation of efficacy information"; and
- It minimized important information related to TD and EPS.

FRAUDULENT AND UNLAWFUL ACTS REGARDING THE SUPPRESSION OF THE SPECIFIC RISK OF HYPERGLYCEMIA AND DIABETES

150. While Zyprexa, Seroquel and Risperdal sales continued to escalate exponentially each year, Defendants continued to hide the adverse effects their respective drug was having on the elderly, children, those diagnosed with schizophrenia and others.

151. 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, since the 1940's, chlorpromazine and similar conventional antipsychotics have been known to impair glucose metabolism, which can lead to weight gain. Nevertheless, Defendants each went to great lengths to conceal this potentially sales-crushing side effect until confrontation of the weight gain issue became unavoidable.

152. Prior to the launch, Defendants each knew or should have known that their respective drug causes weight gain. Upon information and belief, long before case reports in peer-reviewed medical literature became known to the general medical public, Defendants were each aware of large numbers of diabetes-related adverse events associated with their respective drug.

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

These AERs were reported to the FDA and known to Lilly. Both AZ and Janssen were also aware of mounting diabetes-related AERs regarding their respective antipsychotic drug.

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

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

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

157. Defendants did not entirely ignore the reports of adverse events concerning diabetes and elevated glucose levels. Rather, they each implemented marketing strategies that blamed diabetes and hyperglycemia on the schizophrenic population at large, rather than on their respective drug. Thus, upon information and belief, despite the fact that each Defendant's own internal studies and adverse event data revealed that its respective drug increased the risk of diabetes, even among schizophrenics, Defendants each refused to adequately warn patients of

this known risk. At the same time, Defendants were each affirmatively misrepresenting that the incidence of diabetes associated with their respective drug was due only to background incidence inherent in the schizophrenic population.

IN LATE 2003, THE FDA REQUIRED DEFENDANTS TO WARN OF TREATMENT-EMERGENT DIABETES AND HYPERGLYCEMIA

158. On September 11, 2003, the FDA advised Defendants of what they had each known for years: that "epidemiological studies suggest an increased risk of treatment-emergent hyperglycemia-related adverse events in patients treated with atypical antipsychotics." The FDA's conclusions were based on "an extensive review of data available for patients treated with atypical antipsychotics over a number of years." The FDA requested class-labeling for all atpyical antipsychotics to include a warning about hyperglycemia-related adverse events. The FDA concluded that atypicals create a risk of hyperglycemia, in spite of Defendants' repeated claims to the contrary.

159. The FDA included its "[m]onitoring recommendations" as follows:

- 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; and patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing.

160. The FDA required Defendants to adopt the following "WARNING" about hyperglycemia and diabetes mellitus in their respective labels:

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

161. Despite the FDA's mandate that Defendants immediately warn of the dangers described above, Janssen waited two months, until November of 2003, to send prescribing physicians a "Dear Doctor Letter" advising of the new warnings.

162. On April 19, 2004, Janssen's November letter was chastised by the FDA for being brazenly "false" and "misleading."

163. According to the FDA, Janssen's letter misled doctors by failing to disclose the addition of information relating to hyperglycemia and diabetes mellitus to the labeling, minimizing the risks of potentially fatal hyperglycemia-related adverse events, failing to recommend regular glucose control monitoring to identify diabetes mellitus as soon as possible and misleadingly claiming that Risperdal is safer than other atypical antipsychotics.

164. The FDA demanded that Janssen immediately cease the dissemination of promotional materials for Risperdal containing claims similar to the foregoing and that it provide a plan of action to correct the effects of its false and misleading letter.

165. Finally, the FDA admonished Janssen that the violations detailed above did not constitute an exhaustive list, and that it was continuing to "evaluate other aspects" of Janssen's promotional campaign for Risperdal and could determine that "additional measures" would be necessary to "fully correct the false or misleading messages resulting from your [Janssen's] violative conduct."

166. Months later, in July of 2004, Janssen finally sent a "Dear Healthcare Provider Letter", that was acceptable to the FDA, containing the new warnings.

167. Lilly's "Dear Doctor Letter" did not go out until March 1, 2004, over two months after the FDA's deadline.

168. The "Dear Doctor Letter" discussed the "increased risk of hyperglycemia and diabetes in patients taking" atypical antipsychotics. The letter said:

> Eli Lilly and Company would like to inform you of important labeling changes regarding Zyprexa (olanzapine). The Food and Drug Administration (FDA) has asked all manufacturers of atypical antipsychotic medications, including Lilly to add a Warning statement describing the increased risk of hyperglycemia and diabetes in patients taking these medications, including Zyprexa.

169. The letter came from Dr. Paul Eisenberg, Vice President, Global Product Safety of Lilly. Again, Lilly hid itself among its competitors and reminded physicians that "all manufacturers" had to adopt the same warning. Lilly's letter made no mention of the increased and unique risks posed by Zyprexa.

2004: Diabetes Consensus Statement

170. 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 treatment with atypical antipsychotics can cause a rapid increase in body weight. 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, including Zyprexa, Seroquel and Risperdal.

171. The Consensus Statement acknowledged that diabetes is a very serious disease that afflicts millions of Americans. Some of the more common complications of diabetes are heart disease, stroke, circulatory problems, leading to amputation of limbs, neuropathy, and retinopathy. Because of the grave prognosis associated with diabetes, atypical antipsychotics that both cause the onset of diabetes and exacerbate the complications associated with diabetes in those predisposed to its development pose very serious public health risks-particularly when the medical community is not adequately warned of these side effects.

172. 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]."

CATIE Results

173. In September of 2005, the public perception of atypical antipsychotics created by Defendants was dealt a crushing blow when the results of the first phase of the Clinical Antipsychotic Trials of Intervention Effectiveness ("CATIE") study were published in the New England Journal of Medicine. The CATIE study was initiated by the National Institute of Mental Health ("NIMH") to compare the relative safety and efficacy of second generation (atypical) antipsychotic drugs to first generation antipsychotics. The study was conducted between January 2001 and December 2004 at multiple clinical sights across the United States. Critically, the CATIE study was not financed by the pharmaceutical industry.

174. The CATIE study grew out of concerns that had emerged regarding the SGAs' value and safety.

175. Earlier clinical trials had indicated that Clozapine was more effective than first-generation drugs. However, the issue of whether the other atypicals were more effective than older, cheaper drugs remained largely unanswered.

176. Therefore, the NIMH undertook a multi-site, double-blind comparison between an older drug, perphenazine, and the newer drugs, including Zyprexa, Seroquel and Risperdal; clozapine was omitted because it had already been observed to have superior efficacy.

177. The CATIE results were revolutionary. Regarding efficacy, the study's authors concluded that Zyprexa, Seroquel and Risperdal were no more effective than the first generation antipsychotic, perphenazine, in treating schizophrenia. Further, about two thirds of the Zyprexa patients discontinued their medication prior to the end of the 18 month study period because of intolerable side effects. In addition, the times to discontinuation because of intolerable side effects, including movement disorders, were similar among all the groups. In other words, the

CATIE study proves what Defendants each knew since launching their respective drug: that Zyprexa, Seroquel and Risperdal are no more effective in treating schizophrenia, and no safer, than first generation antipsychotics.

Summary

178. On information and belief, as a result of the manufacturing, marketing, selling and distributing of Zyprexa, Seroquel and Risperdal, the Defendants have reaped millions of dollars in profits at the expense of the Plaintiff's Medicaid and PACE programs and the health of individuals participating in Medicaid and PACE.

179. The Plaintiff and the participants in Medicaid and PACE were injured as a direct and proximate result of Defendants' schemes to market their respective antipsychotic drug for non-medically accepted indications and non-medically necessary uses. As a result of Defendants' actions and those of the intermediary marketing firms, the Plaintiff paid all or part of the cost of Zyprexa, Seroquel and Risperdal for non-medically accepted indications and non-medically necessary uses for which they would not have paid absent Defendants' illegal conduct.

180. Pennsylvania physicians who treat, and prescribe medications for, Medicaid and PACE participants necessarily act as the intermediary between Defendants and the Plaintiff.

181. Further, upon information and belief, Defendants carried out their deceptive marketing plan in the following manner: by directly, and falsely, promoting their respective drug as safe and effective for non-medically accepted indications and non-medically necessary uses; thereby influencing the Preferred Drug List and other policies of the Pennsylvania Medicaid and PACE programs, which are intended to refuse payment for drugs when submitted for uses which are not medically accepted or are medically unnecessary; and, by actively training their respective sales forces to avoid alerting the FDA to their activities and teaching representatives how to dismiss any safety concerns raised by physicians without addressing same.

182. There is no valid scientific evidence to support the contention that Zyprexa, Seroquel or Risperdal is safe and effective for the treatment of any non-medically accepted indication.

183. The Plaintiff was forced to spend significant sums of money on the reimbursement of Zyprexa, Seroquel and Risperdal prescriptions for those Pennsylvania Medicaid and PACE participants who were treated with Zyprexa, Seroquel and Risperdal for non-medically accepted indications and non-medically necessary uses.

184. Many Pennsylvania Medicaid and PACE participants were, in fact, injured after taking Zyprexa, Seroquel or Risperdal. Many contracted diabetes, pancreatitis and other serious diseases and potentially life-threatening medical conditions.

185. The Plaintiff spends millions of dollars each year to provide or pay for health care and other necessary facilities and services on behalf of participants whose health care costs are directly attributable to Zyprexa, Seroquel or Risperdal.

186. Had Defendants adequately warned Pennsylvania physicians of the risks and serious side effects associated with their respective drug, physicians could have made informed choices when prescribing medications to Pennsylvania Medicaid and PACE participants. As a result, the Plaintiff would not have incurred the level of expenditures necessary to treat the illnesses caused by Defendants' respective drug that were sustained by Pennsylvania Medicaid and PACE participants.

COUNT I

SUBMISSION OF FALSE & FRAUDULENT CLAIMS UNDER MEDICAID PROGRAM

187. The Plaintiff incorporates by reference the foregoing allegations as if set forth at length herein.

188. A significant percentage of patients who use or have used Zyprexa, Seroquel or Risperdal for non-medically accepted indications and non-medically necessary uses are persons whose prescriptions are paid for in whole or in part by Medicaid.

189. Defendants' aggressive, illegal promotions have induced a misallocation of Commonwealth Medicaid funds through a pattern of fraudulent conduct by causing the Commonwealth to pay out sums for prescriptions for which reimbursement was not intended. Defendants' conduct constitutes Medicaid fraud within the meaning of 62 P.S. §1407.

190. Defendants have, as alleged, actively concealed their promotion of their respective drug for non-medically accepted indications and non-medically necessary uses from the Commonwealth's regulatory authorities. Said active concealment is motivated by the desire to, and has had the effect of, preserving the flow of Commonwealth funds to reimburse Zyprexa, Seroquel and Risperdal prescriptions for non-medically accepted indications and non-medically necessary uses. Said active concealment constitutes a pattern of fraudulent conduct through which Commonwealth payments are derived, and constitutes Medicaid fraud within the meaning of 62 P.S. §1407.

191. Defendants have knowingly caused false claims for payment to be submitted to the Commonwealth's Medicaid program 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 legally entitled, with the costs ultimately being borne, in whole or in part, by the Commonwealth 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 of Zyprexa, Seroquel or Risperdal.

192. Defendants entered into separate agreements to obtain or aid others in obtaining reimbursement or payments for which there was no entitlement under the Commonwealth's Medicaid program.

193. Violation of the Public Welfare Code entitles the Commonwealth to reimbursement of all funds for which payment should not have been made, including but not limited to all funds paid by the Commonwealth for reimbursement of non-medically accepted indications and non-medically necessary uses of Zyprexa, Seroquel and Risperdal.

194. Further, Defendants caused the foregoing false claims to be submitted with knowledge that they were not within the scope of Medicaid coverage. Such conduct entitles the Commonwealth to two times the amount wrongfully reimbursed.

WHEREFORE, the Commonwealth respectfully requests that this Honorable Court enter judgment in its favor and against Lilly, AZ and Janssen and that the Commonwealth be awarded reimbursement for all expenditures made for non-medically accepted indications or non-medically necessary uses of Zyprexa, Seroquel and Risperdal and two times the amount Defendants knowingly caused to be submitted for wrongful reimbursement of their respective drug and such other relief as justice and equity may require.

COUNT II

SUBMISSION OF FALSE & FRAUDULENT CLAIMS UNDER PACE PROGRAM

195. The Plaintiff incorporates by reference the foregoing allegations as if set forth at length herein.

196. A significant percentage of patients who use or have used Zyprexa, Seroquel and Risperdal for non-medically necessary indications are persons whose prescriptions are paid for in whole or in part by PACE.

197. Defendants' aggressive, illegal schemes have induced a misallocation of Commonwealth PACE funds through a pattern of fraudulent conduct by causing the Commonwealth to pay out sums for prescriptions for which reimbursement was not intended. Defendants' conduct constitutes PACE fraud within the meaning of 72 P.S. §3761-521.

198. Defendants have, as alleged, aided pharmacies in the submission of false or fraudulent claims or applications for reimbursement to PACE. Further, Defendants have paid or offered to pay kickbacks or bribes, in cash or in kind, to physicians and pharmacies in connection with the rendition of PACE services.

199. Defendants have knowingly caused false claims for payment to be submitted to the Commonwealth's PACE program by intentionally promoting non-medically necessary uses of their respective drug to prescribing physicians for the purpose of receiving greater compensation than that to which they are legally entitled, with the costs ultimately being borne, in whole or in part, by the Commonwealth through its PACE reimbursement to pharmacies. These prescriptions constitute false claims because PACE reimbursement is not intended for non-medically necessary uses of Zyprexa, Seroquel or Risperdal.

200. Violation of the PACE statute entitles the Commonwealth to $10,000 per act.

WHEREFORE, the Commonwealth respectfully requests that this Honorable Court enter judgment in its favor and against Lilly, AZ and Janssen and that the Commonwealth be awarded $10,000 for each medically unnecessary claim for Zyprexa, Seroquel and Risperdal that Lilly, AZ and Janssen caused to be submitted to PACE and such other relief as justice and equity may require.

COUNT III

RECOVERY OF THE COST OF TREATMENT FOR INJURIES CAUSED BY ZYPREXA, SEROQUEL AND RISPERDAL

201. The Plaintiff incorporates by reference the foregoing allegations as if set forth at length herein.

202. The method by which Zyprexa, Seroquel and Risperdal were marketed rendered them defective and unreasonably dangerous to Pennsylvania Medicaid and PACE participants.

203. Zyprexa, Seroquel and Risperdal are dangerously defective drugs in that Defendants failed to conduct adequate pre-marketing testing, notwithstanding the known side effects associated with antipsychotic medications.

204. Zyprexa, Seroquel and Risperdal are dangerously defective because they lacked a sufficient warning of the risks related to diabetes-related injuries, cardiovascular injuries movement disorders and NMS and also because:

(a) the lack of an adequate warning caused Pennsylvania physicians treating Medicaid and PACE participants to prescribe Zyprexa, Seroquel and Risperdal in inappropriate circumstances and for inappropriate classes of patients;

(b) Defendants had a duty to warn Pennsylvania physicians treating Medicaid and PACE participants of the risks and potentially life threatening side effects associated with the use of their respective drug and failed to do so; and

(c) the warning and/or labeling provided by Defendants for their respective drug failed to include the risks and or potentially life threatening side effects associated with their drug that were known to, or readily ascertainable by, Defendants and such risks were concealed from the Commonwealth and Pennsylvania physicians treating Medicaid and PACE participants.

205. Zyprexa, Seroquel and Risperdal are abnormally and unreasonably dangerous as marketed in that the health risks and costs associated with their usage in all but certain adult patients with schizophrenia or bipolar disorder greatly outweigh any claimed utility to the Commonwealth and its Medicaid and PACE participants.

206. Zyprexa, Seroquel and Risperdal reached Medicaid and PACE participants in substantially the same condition as when originally manufactured, distributed and sold by Lilly, AZ and Janssen, respectively. At the time Zyprexa, Seroquel and Risperdal were sold or placed

on the market, they were in a defective condition and unreasonably dangerous to all but certain adult Pennsylvania Medicaid and PACE participants with schizophrenia or bipolar disorder.

207. Pennsylvania Medicaid and PACE participants, and their physicians, used Zyprexa, Seroquel and Risperdal in the manner in which they were intended to be used, without any substantive alteration or change in the products.

208. As a result of Zyprexa's, Seroquel's and Risperdal's defective nature, certain Pennsylvanians whose care is provided by Medicaid and PACE, were injured.

209. The Plaintiff was forced to expend significant sums of money, through its Medicaid and PACE programs, to treat Pennsylvania citizens who sustained diabetes-related injuries, cardiovascular injuries, NMS or movement disorders caused by Zyprexa, Seroquel or Risperdal.

210. The Commonwealth is entitled to recover the costs of such treatment as *parens patriae*.

WHEREFORE, the Plaintiff respectfully requests that this Honorable Court enter judgment in their favor and against Lilly, AZ and Janssen and award the Plaintiff compensatory damages and any other relief as justice may require.

COUNT IV

NEGLIGENCE

211. The Plaintiff incorporates by reference the foregoing allegations as if set forth at length herein.

212. Defendants owed the Plaintiff a duty to use reasonable care in the marketing of their respective antipsychotic drug. Specifically, Defendants owed the Plaintiff a duty to not cause Medicaid and PACE to reimburse pharmacies for prescriptions of Zyprexa, Seroquel or Risperdal that were not for medically accepted indications or medically necessary uses. Further,

Defendants owed the Plaintiff a duty to accurately disclose known risks associated with their respective antipsychotic drug.

213. Defendants negligently, carelessly, recklessly, willfully and/or intentionally engaged in the following conduct in violation of their respective duties:

(a) Marketing and/or promoting their respective drug for non-medically accepted indications and non-medically necessary uses, including use by children;

(b) Improperly training their respective sales forces so that when Pennsylvania physicians treating Medicaid and PACE participants raised safety concerns regarding Zyprexa, Seroquel or Risperdal, important safety information was withheld;

(c) Supplying products they knew, or should have known, contained inadequate warnings of side effects and risks that were known to, or readily ascertainable by them;

(d) Continuing to deceptively promote, market and/or sell their respective antipsychotic drug well after they knew, or should have known, of the serious side effects and risks associated with the use of their drug; and

(e) Allowing their respective drug to be used indiscriminately for uses far beyond its respective indications.

214. Defendants' negligent, careless, reckless, willful and/or intentional conduct was the proximate cause of injuries and damages sustained by the Commonwealth.

215. At all relevant times, Defendants knew, or should have known, that their respective drug was, and is, hazardous to human health.

216. Zyprexa, Seroquel and Risperdal are abnormally and unreasonably dangerous as marketed in that the health risks and costs associated with Zyprexa, Seroquel and Risperdal greatly outweigh any claimed utility to the Plaintiff or all but certain of its adult Medicaid and PACE participants with schizophrenia or bipolar disorder.

217. As a direct result of the respective unreasonable marketing practices of Defendants, Zyprexa, Seroquel and Risperdal were, and are, defective and unreasonably dangerous.

218. Zyprexa, Seroquel and Risperdal reached the users and consumers thereof in substantially the same condition as when originally manufactured, distributed and sold by Lilly, AZ and Janssen, respectively. At the time Zyprexa, Seroquel and Risperdal were sold or placed on the market, they were in a defective condition and unreasonably dangerous to many Pennsylvania Medicaid and PACE participants.

219. Pennsylvania Medicaid and PACE participants, and their physicians, used Zyprexa, Seroquel and Risperdal in the manner in which they were intended to be used, without any substantive alteration or change in the products.

220. Due to the negligent, careless, reckless, willful and/or intentional conduct of Defendants, as set forth above, the Plaintiff expended millions of dollars of Medicaid and PACE funds in reimbursing for non-medically accepted indications and non-medically necessary uses of Zyprexa, Seroquel and Risperdal prescriptions and was also forced to expend significant sums of money for the care and treatment of Pennsylvania Medicaid and PACE participants injured by Zyprexa, Seroquel or Risperdal, all of which was foreseeable to Defendants.

221. The reprehensible nature of Defendants' conduct entitles the Plaintiff to an award of punitive damages.

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

COUNT V

BREACH OF WARRANTY

222. The Plaintiff incorporates by reference the foregoing allegations as if set forth at length herein.

223. Through their labeling, as well as their sales and marketing practices to Pennsylvania physicians treating Medicaid and PACE participants, Defendants each warranted that their respective drug was fit and appropriate for patients suffering from conditions less serious than schizophrenia and bipolar disorder, the only conditions for which the drugs were arguably proven safe and effective.

224. Through their labeling, as well as their sales and marketing practices to Pennsylvania physicians treating Medicaid and PACE participants, Defendants warranted that their respective drug was fit and appropriate for pediatric use.

225. Through their labeling, as well as their sales and marketing practices to Pennsylvania physicians treating Medicaid and PACE participants, Defendants warranted that their respective drug had no significant risks or side effects that were not identified in their respective labeling.

226. Pennsylvania physicians treating Medicaid and PACE participants relied on the warranties made by Defendants regarding the appropriate uses and safety profile for their respective antipsychotic drug.

227. Defendants breached the express and implied warranties they made to the Commonwealth, through physicians treating Medicaid and PACE participants, since the products were not appropriate for use in children, or for adults with conditions less serious than schizophrenia and bipolar disorder and because each of the drugs was far less safe than warranted by Defendants.

228. The Plaintiff expended millions of dollars in Medicaid and PACE funds in reimbursing pharmacies for non-medically accepted indications and non-medically necessary uses of Zyprexa, Seroquel and Risperdal based on Defendants' express and implied warranties and also spent significant sums of money, through its Medicaid and PACE programs, for medical treatment for those Pennsylvania citizens who developed serious side effects and/or adverse reactions after using Zyprexa, Seroquel or Risperdal.

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

COUNT VI

FRAUD & MISREPRESENTATION

229. The Plaintiff incorporates by reference the foregoing allegations as if set forth at length herein.

230. As part of their promotion of their respective drug, each of the Defendants, through its sales representatives and other advertising and promotion, willfully, knowingly and deceptively communicated to Pennsylvania physicians that its drug was safe and effective for patients with conditions for whom the drug was not medically accepted or not medically necessary, not approved for usage, and not proven to be effective or beneficial. Each Defendant knew that the Pennsylvania physicians treated Medicaid and PACE participants.

231. Defendants each had a duty to disclose the conditions for which their respective drug was not legitimately proven safe and effective, and not to promote the use of their respective drug for those indications to Pennsylvania physicians, the intermediary between Defendants and Medicaid and PACE.

232. Defendants knew and intended that Pennsylvania physicians would rely on their representations and promotions, including the "peer to peer" schemes described above, and Defendants intended to induce Pennsylvania physicians to prescribe their respective drug for Medicaid and PACE participants for whom the use of their drug was not medically accepted or medically necessary. By so doing, Defendants expected and intended that the Plaintiff would incur expenses for the purchase of their products, as a result of their representations and omissions.

233. Pennsylvania physicians treating Medicaid and PACE participants, as well as the Plaintiff, justifiably relied on Defendants to present accurate information to physicians as to the appropriate uses, indications, and contraindications for their respective drug.

234. The Plaintiff, through its Medicaid and PACE programs, was forced to expend significant amounts of money for non-medically accepted and non-medically necessary Zyprexa, Seroquel and Risperdal prescriptions which were directly caused by the fraudulent and misleading statements of Defendants respectively.

235. Defendants each willfully, knowingly and deceptively withheld material facts regarding the risks and side effects associated with their respective drug use from Pennsylvania physicians treating Medicaid and PACE participants.

236. Defendants each had a duty to disclose known risks and side effects associated with the use of their respective drug, particularly, but not solely, when specifically asked about those risks by Pennsylvania physicians.

237. Defendants each intentionally withheld information regarding the risks and side effects associated with their respective drug with the intention of inducing Pennsylvania physicians treating Medicaid and PACE participants to prescribe their respective drug for

Pennsylvania Medicaid and PACE participants in greater quantities than they otherwise would have, or was otherwise appropriate.

238. Pennsylvania physicians treating Medicaid and PACE participants as well as the Plaintiff, justifiably relied on Defendants to provide fair, accurate, and complete information, and to refrain from misleading them or concealing information about the risks and side effects associated with the use of their respective drug.

239. Defendants knew that the Plaintiff and Pennsylvania Medicaid and PACE participants, particularly children and the elderly, would not be in a position to discover and understand the true risks of using their respective drug, and that the public relied upon the misleading information that Defendants promulgated to Pennsylvania physicians treating Medicaid and PACE participants, to the detriment of the Plaintiff.

240. Defendants knew that the representations that were relied on by Pennsylvania physicians treating Medicaid and PACE participants were false or were made recklessly without any knowledge of the truth.

241. Each of Defendants' misleading and deceptive statements, representations and advertisements related to dangerous, non-medically accepted and non-medically necessary uses of their respective drug were material to the Plaintiff's purchase of Zyprexa, Seroquel and Risperdal in that the Plaintiff would not have been required to reimburse pharmacies for non-medically accepted or non-medically necessary uses of Zyprexa, Seroquel or Risperdal, if Defendants had marketed their respective drug legally.

242. The Plaintiff, through its Medicaid and PACE programs, was forced to expend significant amounts of money to treat Pennsylvania Medicaid and PACE participants who contracted serious and potentially life threatening medical conditions resulting from Defendants'

deceptively withholding adequate safety information regarding the use of their drug and/or misrepresenting their respective drug's safety profile.

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

COUNT VII

MISREPRESENTATION UNDER RESTATEMENT (SECOND) OF TORTS §402B

243. The Plaintiff incorporates by reference the foregoing allegations as if set forth at length herein.

244. Defendants, through their advertising, labeling, sales representative contacts with Pennsylvania physicians, and otherwise, have misrepresented material facts about their respective drug's appropriateness as a treatment for non-medically accepted indications and non-medically necessary uses.

245. Defendants, through their advertising, labeling, sales representative contacts with Pennsylvania physicians, and otherwise, have misrepresented material facts about the risks and harms associated with using their respective drug.

246. The Plaintiff and Pennsylvania physicians treating Medicaid and PACE participants justifiably relied on Defendants' misrepresentations regarding the appropriateness and safety of their respective drug for use by Pennsylvania Medicaid and PACE participants who suffered from conditions other than schizophrenia and/or bipolar disorder.

247. The Plaintiff, through its Medicaid and PACE programs, was forced to expend significant sums of money to treat those Pennsylvania Medicaid and PACE participants who

sustained illnesses caused by Defendants' respective drug based on Defendants' misrepresentations of their respective product's safety.

248. The Defendants are subject to strict liability for the damages resulting from their misrepresentations about the safety and efficacy of their respective product, pursuant to Restatement (Second), of Torts §402B.

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

COUNT VIII

UNJUST ENRICHMENT

249. The Plaintiff incorporates by reference the foregoing allegations as if set forth at length herein.

250. Defendants knowingly, willfully and intentionally marketed and promoted their respective drug for treatment of conditions and illnesses for which they were not medically accepted or medically necessary.

251. Defendants knowingly, willfully and intentionally withheld information from Pennsylvania physicians treating Medicaid and PACE participants regarding the risks associated with the use of their respective drug.

252. As a result of the deceptive marketing practices of Defendants, Pennsylvania physicians treating Medicaid and PACE participants prescribed Zyprexa, Seroquel and Risperdal in far greater numbers than would have been generated absent the deceptive and illegal conduct of Defendants. Defendants received a financial windfall from Medicaid and PACE as a result of their deceptive conduct.

253. Medicaid and PACE paid, reimbursed and/or otherwise conferred a benefit upon Defendants to the extent of the increased numbers of Zyprexa, Seroquel and Risperdal prescriptions that directly resulted from Defendants' deceptive marketing practices relative to Pennsylvania Medicaid and PACE participants.

254. Defendants have been unjustly enriched to the extent of the increased revenue received from prescriptions for their respective drug that were ultimately reimbursed by Medicaid or PACE and resulted from Defendants' deceptive and illegal marketing efforts.

WHEREFORE, the Plaintiff respectfully requests that this Honorable Court enter judgment in its favor against Defendants and that Defendants be required to make restitution to Medicaid and PACE for all expenditures made for non-medically accepted or non-medically necessary prescriptions of Zyprexa, Seroquel and Risperdal and such other relief as justice and equity may require.

Respectfully submitted,

COHEN, PLACITELLA & ROTH, P.C.

By: _____
STEWART L. COHEN
WILLIAM D. MARVIN

Counsel for Plaintiffs:
Of Counsel:
BAILEY, PERRIN BAILEY
Michael W. Perrin
Texas Bar No. 15797500
Fletcher V. Trammell
Texas Bar No. 24042053
440 Louisiana, Suite 2100
Houston, Texas 77002
ftrammell@bpblaw.com
(713) 425-7100
(pro hac admission will be requested)

Robert E. J. Curran
ID #08620
8 West Front Street
Media, PA 19063
rejcurransr@yahoo.com
(610) 565-0505

VERIFICATION

FLETCH TRAMMELL, ESQUIRE, hereby states that as a result of my investigation and research into the conduct of the defendants, described in the foregoing Complaint, I am in a better position than any individual officer or employee of the agencies of the Commonwealth Plaintiff to present this Verification, that I am authorized to present this Verification, that the statements made in the foregoing Complaint are true and correct to the best of my knowledge, information and belief, and that I understand that the statements therein are made subject to the penalties of 18 Pa. C.S. Section 4904 relating to unsworn falsification to authorities.

Feb. 23, 2007
DATE

FLETCH TRAMMELL, ESQUIRE
Attorney for Plaintiffs