

IN THE CIRCUIT COURT OF PULASKI COUNTY, ARKANSAS
Znl DIVISION

STATE OF ARKANSAS *ex rel.*

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Pat O'Brien Circuit Clerk

DUSTIN MCDANIEL, ATTORNEY GENERAL

PLAINTIFF

vs.

CASE NO. CW8-5448

ASTRAZENECA
PHARMACEUTICALS LP,
ASTRAZENECA LP,
ASTRAZENECA PLC,
ASTRAZENECA AB, and
ASTRAZENECA UK LIMITED

DEFENDANTS

COMPLAINT

Plaintiff, State of Arkansas *ex rel.* Dustin McDaniel, Attorney General, for its Complaint against the Defendants, states and alleges as follows:

The State brings this action on behalf of the Divisions of Behavioral Health Services ("DBHS") and Medical Services ("Medicaid") of the Arkansas Department of Human Services ("DHS"), and the Arkansas Department of Finance and Administration ("DFA"), specifically its Employee Benefits Division ("DFAEBD"), as injured purchasers and/or reimbursers of prescription drugs, and as representative of, and as *parens patriae* on behalf of the citizens of Arkansas. Under the Arkansas Constitution and other positive law of the State, including Arkansas's common law and including, among other laws, Ark. Code Ann. §§ 25-16-702, *et seq.*, 4-88-104, 4-88-201 *et seq.*, and 20-77-901, *et seq.*, the State is responsible for, and has a duty to protect, the health, safety and welfare of its citizens.

The State seeks to obtain compensatory, punitive and other damages, restitution, civil penalties, injunctive and other equitable relief against Defendants AstraZeneca Pharmaceuticals

LP, AstraZeneca LP, AstraZeneca PLC, AstraZeneca AB and AstraZeneca UK Limited (“Defendants”), as more fully set forth below and, in support thereof, avers as follows:

I. PARTIES

1. The Plaintiff is the State of Arkansas, with this suit being brought by its Attorney General, Dustin McDaniel, in the State’s capacity as sovereign and in its proprietary capacity on behalf of the DHS, DFA and as representative of, and as *parens patriae* on behalf of, Arkansas citizens.

2. AstraZeneca Pharmaceuticals LP is a limited partnership organized and existing under the laws of the state of Delaware with its principal place of business in Delaware. AstraZeneca Pharmaceuticals LP is authorized to conduct business in Arkansas, and its registered agent for service of process is The Corporation Company, 425 West Capitol Avenue, Suite 1700, Little Rock, Arkansas 72201.

3. AstraZeneca LP is a limited partnership organized and existing under the laws of the state of Delaware with its principal place of business in Delaware. AstraZeneca Pharmaceuticals LP is authorized to conduct business in Arkansas, and its registered agent for service of process is The Corporation Company, 425 West Capitol Avenue, Suite 1700, Little Rock, Arkansas 72201.

4. AstraZeneca AB is a Swedish company. AstraZeneca AB may be served with process via Registered, Return Receipt Requested, International Mail to its principal place of business pursuant to Articles 10(a) and 15 of the Hague Convention on the Service Abroad of Judicial and Extrajudicial Documents in Civil or Commercial Matters.

5. AstraZeneca UK Limited is a wholly owned subsidiary of AstraZeneca AB. AstraZeneca UK Limited is a foreign company. AstraZeneca UK Limited may be served with

process via Registered, Return Receipt Requested, International Mail to its principal place of business pursuant to Articles 10(a) and 15 of the Hague Convention on the Service Abroad of Judicial and Extrajudicial Documents in Civil or Commercial Matters.

6. AstraZeneca PLC is a foreign company with its principal place of business at 15 Stanhope Gate, London, W1K 1LN, England, United Kingdom. AstraZeneca PLC may be served with process via Registered, Return Receipt Requested, International Mail to its principal place of business pursuant to Articles 10(a) and 15 of the Hague Convention on the Service Abroad of Judicial and Extrajudicial Documents in Civil or Commercial Matters.

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

II. JURISDICTION & VENUE

8. This Court has jurisdiction over this matter pursuant to Ark. Code Ann. § 4-88-104, § 20-77-908, § 16-4-101 and the common law of the State of Arkansas. Venue is proper pursuant to Ark. Code Ann. § 16-106-101, § 16-106-102, § 16-60-103, § 20-77-908, § 4-88-104, § 4-88-112, and the common law of the State of Arkansas. The Defendants have transacted business in the State of Arkansas.

9. Defendants did, individually or in conjunction with others, research, develop manufacture, create, design, test, label, sterilize, package, distribute, supply, market, sell, promote, advertise, warn and otherwise distribute Quetiapine Fumarate ("Seroquel") in Arkansas and specifically in Pulaski County.

III. INTRODUCTION

10. This is an action to recover funds expended by the State in providing medical treatment to Medicaid, DBHS and DFAEBD participants suffering from Seroquel-related illnesses and to recover funds expended in purchasing Seroquel or the reimbursement of Seroquel prescriptions for uses that were not medically necessary. Many of the details and critical facts related to Defendants' scheme are exclusively known by Defendants.

11. The DFAEBD is a State-sponsored program that administers prescription drug benefits for the State's active and retired employees. The DFA oversees the DFAEBD. The DFAEBD reimburses pharmacies, physicians and hospitals for prescriptions written for and dispensed to participants in the State's employee health insurance program.

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

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

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

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

16. Defendants manufacture Seroquel and promote the drug to physicians in Arkansas through their representatives. For years, the State has incurred significant expenses associated with the provision of necessary health care and other assistance necessary under its Medicaid, DBHS and DFAEBD programs to citizens who suffer, or who have suffered, from Seroquel-related injuries, diseases or sickness.

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

18. Defendants have recognized and aggressively exploited this loophole in two ways. First Defendants have engaged in a direct, illegal, nationwide program of promotion of the use of Seroquel for non-medically necessary uses. Defendants have conducted this program of promotion knowing that prescriptions for Seroquel are generally reimbursed by the State Medicaid, DBHS and DFAEBD programs even though such prescriptions may be written for non-medically necessary uses of Seroquel.

19. Second, since the inception of their promotion of Seroquel, Defendants have falsely represented to the State, and to the public in general, that Seroquel is safer and more effective than less expensive, first generation antipsychotics.

20. Finally, Defendants' failure to provide an adequate warning of the risks of using Seroquel has compromised the general health and welfare of Arkansas citizens. The State, in its common law duty to act as *parens patriae*, thus has standing to recover its necessary costs of treatment of Arkansas citizens resulting from Seroquel-related injuries for which Defendants are liable.

SEROQUEL'S CLINICAL PROFILE

21. Defendants 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.

22. 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.

23. A troubling side effect of all antipsychotics is that the blockage of dopaminergic neurotransmission in the basal ganglia causes extrapyramidal syndromes (EPS), such as parkinsonian effects. A long-lasting movement disorder, tardive dyskinesia, also occurs with prolonged treatment.

SEROQUEL'S SAFETY PROFILE

24. During the 1990's pharmaceutical companies, acting on the "atypical" hypothesis, introduced newer drugs attempting to capture the enhanced therapeutic effect of clozapine without its toxicity and without the increased EPS caused by traditional antipsychotics. Before 1993, the only atypical antipsychotic in the United States market was clozapine, and due to its toxicity it had very little market share. Ten years later, atypical antipsychotics such as Seroquel account for over 90% of all antipsychotic drugs prescribed for all psychiatric purposes, regardless of whether they were approved for those indications.

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

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

27. Medical literature dating as far back as the 1950s, and Defendants' own pre-clinical studies of Seroquel, demonstrated that Seroquel, like older antipsychotic medications, had the potential to cause diabetes, diabetes-related injuries (e.g. weight gain and hyperglycemia), cardiovascular and cerebrovascular complications, and other severe adverse effects. By the time Seroquel was first marketed, the neurochemical bases for the efficacy and side-effects were generally known to Defendants, i.e., effects on dopamine, serotonin, and histamine systems in the brain. Therefore, prior to marketing Seroquel, Defendants should have been concerned about Seroquel causing neurological problems, weight gain, diabetes, pancreatitis, hyperglycemia, cardiovascular complications, and metabolic syndrome. And yet

Seroquel's original label, and all label changes until 2004, did not adequately warn of these adverse effects.

28. Seroquel's pre-marketing clinical trials did not support an assertion that it was less likely to cause extra pyramidal symptoms ("EPS") than traditional antipsychotics. Upon information and belief, Defendants' trials were designed to produce similar rates of EPS in patients sorted into placebo groups and those taking Seroquel.

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

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

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

32. Defendants did not entirely ignore the reports of adverse events concerning diabetes and elevated glucose levels. Rather, they implemented marketing strategies that blamed diabetes and hyperglycemia on the schizophrenic population at large, rather than on Seroquel. Thus, upon information and belief, despite the fact that Defendants' own internal studies and

adverse event data revealed that Seroquel increased the risk of diabetes, even among schizophrenics, Defendants refused to adequately warn patients of this known risk. At the same time, Defendants affirmatively misrepresented that the incidence of diabetes associated with Seroquel was due only to background incidence inherent in the schizophrenic population.

33. On September 26, 1997 Seroquel became the fourth atypical antipsychotic to receive FDA approval. During the next several years, Defendants heavily marketed and promoted Seroquel for its approved indication, treatment of adults with schizophrenia, and for multiple non-medically necessary uses of the drug, for example, sleeplessness, attention deficit-hyperactivity disorder (ADHD), depression, anxiety, mood disorder, bipolar disorder, and aggression associated with late-onset dementia. By late 2000, Defendants had significant market share for United States antipsychotic drug use, and demonstrated the sales potential of marketing atypical antipsychotic drugs for non-medically necessary uses.

34. The FDA reprimanded Defendants for making false statements in their 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.

35. Among the statements contained in Defendants' promotion of Seroquel found to be false and misleading were:

- Defendants' claims that Seroquel is effective in a broader range of mental conditions, including bipolar disorder and schizoaffective disorder;
- Defendants' claims as to how Seroquel "works" (the mechanism of action of antipsychotic drugs is unknown); and
- Defendants' claims that Seroquel had been proven safer and more effective than first generation antipsychotics.

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

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

38. Despite Defendants' knowledge that Seroquel causes weight gain, which significantly increases a patient's risk of contracting diabetes, Defendants failed to provide a prominent warning of the increased risk of diabetes and hyperglycemia and the need to provide patients with baseline diabetes screening and glucose monitoring. A warning, though still inadequate, did not appear until it was forced by the FDA.

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

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.

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

41. Among these goals were plans to create a series of studies designed to illustrate Seroquel'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.

42. Seroquel is the fastest growing atypical antipsychotic, in terms of sales. Crucial to this blockbuster success was Defendants' aggressive marketing of Seroquel, which consisted chiefly of overstating the drug's uses, while concealing its life-threatening side effects.

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

44. Defendants' decision to target the State's elderly had two results. Medically unnecessary claims for Seroquel were submitted to Medicaid, DBHS and DFAEBD for reimbursement, and the drugs caused disastrous health consequences for geriatric patients.

45. 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.

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

47. 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*.

48. Upon information and belief, despite the foregoing, Defendants continue to promote Seroquel as safe and effective treatment for dementia in elderly patients.

49. In October of 2006, the FDA was required to admonish Defendants for false and misleading acts associated with the promotion of Seroquel. The FDA found that Defendants' promotions misrepresented Seroquel's risk profile. According to the FDA, Defendants' marketing of Seroquel "raises significant public health and safety concerns through its minimization of the risks associated with Seroquel." Among Defendants' false and misleading statements regarding Seroquel's safety were the following:

- Failing to warn physicians of the increased risk of treatment-emergent hyperglycemia-related adverse events in patients treated with Seroquel in their 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 physicians 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 physicians 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.

50. There is no valid scientific evidence that Seroquel is safe and effective for treatment of any off label indication, including any use in children. There is no valid scientific evidence concerning the therapeutic equivalence of Seroquel for any off label indication, including any use in children.

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

IV. ALLEGATIONS

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

53. From the 1997 product launch of Seroquel to the present, Defendants engaged in widespread fraudulent statements and conduct, and pervasive false and misleading marketing, advertising and promotion of Seroquel. Defendants deceived physicians, consumers, the State, and others regarding the comparative efficacy of Seroquel to other traditional and atypical antipsychotics. Defendants failed to warn – and affirmatively misled – physicians, consumers, the State, and others in the medical community regarding Seroquel's association with diabetes, diabetes-related conditions, EPS and other adverse effects.

54. Defendants actively marketed and promoted Seroquel for use in several populations where the efficacy and safety of the drug had yet to be established – marketing Seroquel for the treatment of various conditions or symptoms in children, marketing Seroquel for

treatment in the elderly for dementia, and marketing Seroquel for treatment of patients who experience depressive or other physiological conditions.

55. After achieving FDA approval of Seroquel, Defendants sought to increase the sales of Seroquel while avoiding the substantial expense and delay of petitioning the FDA for approval of expanded or additional uses of Seroquel. Their scheme consisted of elaborate and clandestine promotion of non-medically necessary uses of Seroquel.

56. Upon information and belief, this scheme was carried out by: employing the illegal direct solicitation of physicians to prescribe Seroquel for non-medically necessary uses; the making of false statements to physicians and pharmacists concerning the efficacy and safety of Seroquel for non-medically necessary uses; and the use of active concealment to avoid the utilization policies of Medicaid, DBHS and DFAEBD, which are intended to ensure reimbursement or purchase for medically necessary uses only.

57. The State spends millions of dollars each year to provide or pay for health care and other necessary facilities and services on behalf of indigents and other eligible citizens whose said health care costs are directly caused by Seroquel-induced injuries.

58. Defendants collectively sold or aided and abetted in the sale of Seroquel which was and is defective and unreasonably dangerous for all but a limited segment of the State's adult schizophrenic and bipolar population.

59. Upon information and belief, at all pertinent times, Defendants knew, or should have known, that Seroquel was and is unreasonably hazardous to human health for all but a limited segment of the State's adult schizophrenic and bipolar population.

60. Defendants, through their funding and control of certain studies concerning the effects of Seroquel on human health, their control over trade publications, promoting, marketing,

and/or through other agreements, understandings and joint undertakings and enterprises, conspired with, cooperated with and/or assisted in the wrongful suppression, active concealment and/or misrepresentation of the true relationship between Seroquel and various diseases, all to the detriment of the public health, safety and welfare and thereby causing harm to the State.

61. Seroquel is inherently, abnormally, and unreasonably dangerous for all but a limited segment of the State's adult schizophrenic and bipolar population. The health risks and costs of Seroquel to the citizens of the State and to the State greatly outweigh any claimed utility of Seroquel for all but a limited segment of the State's adult schizophrenic and bipolar population. Defendants knew or should have known of the dangers inherent in the use of Seroquel, and that the public and the State would be harmed by Defendants' intended and foreseeable use of Seroquel.

62. As a direct and proximate result of the deceptive marketing practices of Defendants, Seroquel was and is defective and unreasonably dangerous.

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

64. The defective condition of Seroquel directly and proximately caused Arkansas public assistance participants to suffer various Seroquel-induced diseases, injuries and sicknesses, and directly and proximately caused the State to expend millions of dollars in order to provide necessary health care to these citizens through its Medicaid, DBHS and DFAEBD programs, thereby directly damaging the State.

65. At all pertinent times, it was foreseeable by Defendants that certain of the Arkansas Medicaid, DBHS and DFAEBD participants who used Seroquel would become ill and suffer injury, disease and sickness as a result of using Seroquel as Defendants intended, and it was further foreseeable by Defendants that the State would be required to expend millions of dollars each year in order to provide necessary medical treatment and facilities to those citizens.

66. Defendants individually, and through their representatives, fraudulently misled the public, physicians treating Medicaid, DBHS and DFAEBD participants and the State, with regard to the health risks of Seroquel, all for the purpose of increasing Defendants' profits from the sale of Seroquel.

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

68. At all pertinent times, Defendants purposefully and intentionally engaged in these activities, and continue to do so, knowing that when the State's Medicaid, DBHS and DFAEBD participants use Seroquel as it was and is intended to be used, that the State's Medicaid, DBHS

and DFAEBD participants would be substantially certain to suffer disease, injury and sickness, including diabetes, stroke, pancreatitis, seizures and other illnesses, and that the State would be directly injured thereby, all as described above.

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

70. Upon information and belief, the statements, representations and promotional schemes publicized by Defendants were deceptive, false, incomplete, misleading and untrue. Defendants knew, or should have known, that their statements, representations and advertisements were deceptive, false, incomplete, misleading and untrue at the time of making such statements. Defendants had an economic interest in making such statements. Neither the State nor the physicians in Arkansas who prescribed Seroquel had knowledge of the falsity or untruth of Defendants' statements, representations and advertisements when Medicaid, DBHS and DFAEBD claims for Seroquel were submitted; moreover, the State had a right to rely on Defendants to act honestly when dealing with the State. Each of the Defendants' statements, representations and advertisements were material to the State's purchase or reimbursement of Seroquel in that the State does not intentionally cover drugs for non-medically necessary uses.

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

72. Upon information and belief, a significant percentage of Arkansas Medicaid, DBHS and DFAEBD participants, believed to number in the hundreds, if not thousands, suffered serious diseases and/or potentially life-threatening medical conditions after taking Seroquel. Such risks of use were known, or should have been known, to Defendants who failed to warn Arkansas physicians treating Medicaid, DBHS and DFAEBD participants of those risks.

V. CAUSES OF ACTION

COUNT I

VIOLATION OF THE ARKANSAS MEDICAID FRAUD FALSE CLAIMS ACT

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

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

75. As entities providing goods to providers under the Arkansas Medicaid Program, Defendants are persons within the meaning of Ark. Code Ann. § 20-77-901(6).

76. Submission of Seroquel prescriptions to Medicaid for reimbursement constitute claims within the meaning of Ark. Code Ann. § 20-77-901(2).

77. Defendants' purposeful false statements and representations regarding the safety and efficacy of Seroquel for non-medically necessary uses violate the Medicaid Fraud False Claims Act. Defendants' purposeful false statements and representations regarding Seroquel caused the submission of claims for Seroquel to Medicaid for reimbursement. Defendants' conduct constitutes Medicaid fraud within the meaning of Ark. Code Ann. § 20-77-902(1)-(3), (10).

78. Upon information and belief, Defendants have purposely offered to pay remuneration, including kickbacks, bribes and rebates, both directly and indirectly, in cash and in kind, to physicians and pharmacists participating in the Medicaid program. These payments caused the submission of non-medically necessary claims for Seroquel to Medicaid. Defendants' conduct constitutes Medicaid fraud within the meaning of Ark. Code Ann. § 20-77-902(7)(A)(i)-(ii).

WHEREFORE, pursuant to Ark. Code Ann. § 20-77-903, the State respectfully requests that this Honorable Court enter judgment in its favor and against Defendants and that the State be awarded reimbursement for all expenditures made for non-medically necessary prescriptions of Seroquel, three (3) times the amount Defendants knowingly caused to be submitted for wrongful reimbursement of Seroquel, ten thousand dollars per false claim, the State's reasonable expenses in enforcing the Medicaid Fraud Act and such other relief as justice and equity may require.

COUNT II

VIOLATIONS OF THE ARKANSAS MEDICAID FRAUD FALSE CLAIMS ACT

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

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

81. As entities providing goods to providers under the Arkansas Medicaid Program, Defendants are persons within the meaning of Ark. Code Ann. § 20-77-901(6).

82. Submission of Seroquel prescriptions to Medicaid for reimbursement constitute claims within the meaning of Ark. Code Ann. § 20-77-901(2).

83. Since the inception of their marketing of Seroquel, Defendants knowingly misrepresented that Seroquel is more effective in the treatment of the negative symptoms of schizophrenia and less likely to produce certain adverse events involving involuntary movement disorders, which are commonly associated with antipsychotics. Defendants knew these representations were unsubstantiated and false at the time they were made and that Seroquel is no more effective than appropriate doses of first generation antipsychotic drugs and no less likely to produce these adverse events. Defendants touted Seroquel's added efficacy dimension and the reduction of these adverse events as justification for its higher cost. As a result of these representations, and in an effort to spare their patients from experiencing these adverse effects, Arkansas physicians treating Medicaid participants opted for Seroquel instead of less expensive first generation antipsychotics.

84. Defendants' purposeful false statements and representations regarding the safety and efficacy of Seroquel relative to other antipsychotics violate the Medicaid Fraud False Claims Act. Defendants' purposeful false statements and representations regarding Seroquel caused the submission of claims for Seroquel to Medicaid for reimbursement. Defendants' conduct constitutes Medicaid fraud within the meaning of Ark. Code Ann. § 20-77-902 (1)-(3), (10).

85. Upon information and belief, Defendants have purposely offered to pay remuneration, including kickbacks, bribes and rebates, both directly and indirectly, in cash and in kind, to physicians and pharmacists participating in the Medicaid program. These payments were in exchange for the recipients' submission to Medicaid of claims for Seroquel instead of claims for less expensive antipsychotics. Defendants' conduct constitutes Medicaid fraud within the meaning of Ark. Code Ann. § 20-77-902 (7)(A)(i)-(ii).

WHEREFORE, pursuant to Ark. Code Ann. § 20-77-903, the State respectfully requests that this Honorable Court enter judgment in its favor and against Defendants and that the State be awarded reimbursement for the amount of the incremental cost of reimbursement for Seroquel instead of available first generation antipsychotics, three (3) times the amount Defendants knowingly caused to be submitted for wrongful reimbursement of Seroquel, ten thousand dollars per false claim, the State's reasonable expenses in enforcing the Medicaid Fraud Act and such other relief as justice and equity may require.

COUNT III

RECOVERY OF THE COST OF TREATMENT FOR INJURIES CAUSED BY SEROQUEL

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

87. The method by which Seroquel was marketed in Arkansas rendered it defective and unreasonably dangerous.

88. The design and/or manufacture of Seroquel rendered it a dangerously defective drug in that its use causes dangerous, and potentially life-threatening, medical conditions when taken as recommended by Defendants and such risks were not generally known by Arkansas physicians, the State and/or Arkansas Medicaid, DBHS and DFAEBD participants.

89. Seroquel was a dangerously defective drug in that Defendants failed to conduct adequate pre-marketing testing, notwithstanding the known side effects associated with Seroquel and anti-psychotic medications generally.

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

- (a) the lack of an adequate warning caused Arkansas physicians treating Medicaid, DBHS and DFAEBD participants to prescribe Seroquel in inappropriate circumstances and on inappropriate classes of patients;

- (b) Defendants had a duty to warn Arkansas physicians treating Medicaid, DBHS and DFAEBD participants of the risks and potentially life-threatening side effects associated with Seroquel use and failed to do so; and
- (c) the warning and/or labeling provided by Defendants for Seroquel failed to include the risks and or potentially life-threatening side effects associated with Seroquel use that were known to, or readily ascertainable by, Defendants and such risks were concealed from Arkansas physicians treating Medicaid, DBHS and DFAEBD participants.

91. Seroquel is abnormally and unreasonably dangerous as marketed in that the health risks and costs associated with Seroquel greatly outweigh any claimed utility of Seroquel to the State and its Medicaid, DBHS and DFAEBD participants.

92. Seroquel reached the users and consumers thereof in substantially the same condition that it was when originally manufactured, distributed and sold by Defendants. At the time Seroquel was sold or placed on the market, it was in a defective condition and unreasonably dangerous to Arkansas Medicaid, DBHS and DFAEBD participants.

93. Arkansas Medicaid, DBHS and DFAEBD participants, and their physicians, used Seroquel in the manner in which it was intended to be used, without any substantive alteration or change in the product.

94. As a result of Seroquel's defective nature, certain Arkansans whose care is provided by Medicaid, DBHS and DFAEBD were injured.

95. The State was forced to expend significant sums of money, through its Medicaid, DBHS and DFAEBD programs, to treat Medicaid, DBHS and DFAEBD participants who sustained Seroquel-related injuries.

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

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

COUNT IV

VIOLATION OF THE ARKANSAS DECEPTIVE TRADE PRACTICES ACT

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

98. By labeling, distributing, marketing, promoting and selling Seroquel through Arkansas physicians and pharmacies to the State, and Arkansas consumers, Defendants are engaging in trade or commerce directly, or indirectly, affecting the people of the State.

99. Pursuant to the Arkansas Deceptive Trade Practices Act (“DTPA”), Ark. Code Ann. § 4-88-101, the Arkansas Attorney General has the authority to seek restitution and penalties for violations thereof.

100. Defendants have repeatedly and willfully engaged in the following conduct which constitutes a deceptive trade practice and a violation of the DTPA:

- (a) Misrepresenting that Seroquel is safe and effective for indications for which safety and efficacy had not been demonstrated which caused Arkansas physicians treating Medicaid, DBHS and DFAEBD participants to prescribe Seroquel in inappropriate, non-medically necessary circumstances;
- (b) Making false and misleading misrepresentations of fact regarding Seroquel’s risk profile, including but not limited to misrepresenting the likelihood and severity of the side effects associated with Seroquel, including diabetes, stroke, high blood pressure, weight gain and other serious and potentially life-threatening conditions;
- (c) Misrepresenting and concealing material facts and/or failing to inform and educate Arkansas physicians as to the risks and dangers associated with Seroquel use when such facts were well known to, or readily ascertainable by, Defendants;

- (d) Misrepresenting and concealing material facts which were known to Defendants, and unknown to Arkansas physicians, when Defendants knew that Arkansas physicians rely on such facts when deciding whether to prescribe Seroquel to their patients;
- (e) Misrepresenting that Seroquel is safer and more effective than less expensive first generation antipsychotics;
- (f) Misrepresenting Seroquel as being of a particular standard, quality or grade when it is not; and
- (g) Intentionally creating a likelihood of confusion or misunderstanding in the minds of Arkansas physicians as to whether Seroquel was safe or medically necessary for Medicaid, DBHS and DFAEBD participants.

101. Due to the secrecy of the foregoing conduct, the State has only recently been made aware of its actionable nature.

102. Defendants made, and continue to make, orally and in writing, false, misleading or deceptive representations in advertisements, promotions and statements, and otherwise disseminated, and continue to disseminate, false, misleading or deceptive information to the public, including Arkansas citizens, physicians and the State regarding non-medically necessary uses of Seroquel and the health risks and benefits associated with using Seroquel.

103. Moreover, as detailed above, Defendants have violated Ark. Code Ann. § 4-88-201 *et seq.* in that Defendants have targeted “elder or disabled persons,” as such persons are defined in the statute, through Defendants’ violations of the DTPA described above, and have actually committed such DTPA violations against such elder or disabled persons. Defendants knew or should have known that the conduct was directed to elder or disabled persons, such conduct was in disregard of the rights of the elder or disabled persons, the elder or disabled persons were more vulnerable to the Defendants’ conduct because of age, poor health, infirmity, impaired understanding, restricted mobility, and/or disability than other persons, and the elder or disabled persons actually suffered substantial physical, emotional, or economic damage resulting

from the Defendants' conduct. In addition to any civil penalty otherwise set forth or imposed by the Court, the Court should impose an additional civil penalty of ten thousand dollars (\$10,000) for each violation, or such other amount as the Court finds appropriate not to exceed ten thousand dollars (\$10,000).

104. Defendants acted knowingly in committing the violations of the DTPA described herein.

105. Each Seroquel prescription written without an adequate warning, for a non-medically necessary use or where a first generation antipsychotic was available constitutes a separate and distinct violation of the DTPA.

106. As a consequence of Defendants' illegal and deceptive sales and marketing practices, the State made monetary expenditures on behalf of Arkansas Medicaid, DBHS and DFAEBD participants who were prescribed Seroquel for non-medically necessary purposes and/or where a first generation antipsychotic was as safe and effective and less expensive.

107. As a consequence of Defendants' illegal and deceptive sales and marketing practices, Arkansas consumers who were prescribed Seroquel expended money for non-medically necessary uses and/or where a first generation antipsychotic was as safe and effective and less expensive.

108. As a further consequence of Defendants' illegal and deceptive sales and marketing practices, many Arkansas Medicaid, DBHS and DFAEBD participants, including children and elderly, were prescribed Seroquel by their physicians and sustained serious and potentially life-threatening side effects.

109. The State was forced to expend significant sums of money for the treatment of those Arkansas Medicaid, DBHS and DFAEBD participants who sustained serious and potentially life-threatening side injuries as a result of using Seroquel.

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

111. The State seeks the entry of a permanent injunction prohibiting Defendants' unlawful and deceptive conduct and the imposition of all appropriate remedies available under the DTPA.

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

113. The State seeks compensatory damages for all State expenditures resulting from the treatment of those Arkansas Medicaid, DBHS and DFAEBD participants who sustained injuries, side effects and/or adverse medical events after using Seroquel.

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

- (a) a permanent injunction preventing Defendants from deceptively marketing and/or promoting Seroquel as appropriate for non-medically necessary uses;
- (b) restitution of all State expenditures for prescriptions caused by Defendants' deceptive marketing and/or promotion of Seroquel;
- (c) compensatory damages for all expenditures made by the State on behalf of Arkansas Medicaid, DBHS and DFAEBD participants who sustained injuries associated with Seroquel use;

- (d) imposition of \$10,000 civil penalty for each method, act or practice deemed to violate the Act;
- (e) imposition of an additional \$10,000 civil penalty for each DTPA violation committed against an elder or disabled person;
- (f) the State's reasonable expenses in prosecuting the Act; and
- (g) such other relief as justice and equity may require.

COUNT V

NEGLIGENCE

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

115. Defendants owed the State a duty to use reasonable care in the design, manufacture and marketing of their product, Seroquel.

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

- (a) Marketing and/or promoting Seroquel for non-medically necessary uses;
- (b) Failing to adhere to all applicable laws and regulations pertaining to the marketing, promotion and/or labeling of pharmaceutical products, such as Seroquel;
- (c) Marketing and/or promoting Seroquel as appropriate for children;
- (d) Failing to adequately train their sales force so that when Arkansas physicians treating Medicaid, DBHS and DFAEBD participants raised safety concerns regarding Seroquel important safety information was withheld;
- (e) Supplying a product that they knew, or should have known, contained inadequate warnings of side effects and risks that were known to, or based on facts available to Defendants;
- (f) Supplying a product lacking sufficient warnings and/or instructions when they knew, or should have known, the side effects associated with Seroquel were not generally known by Arkansas physicians treating Medicaid, DBHS and DFAEBD participants;

- (g) Representing that Seroquel was safer than less expensive, first generation antipsychotics;
- (h) Continuing to promote, market and/or sell Seroquel after they knew, or should have known, of the serious side effects and risks associated with Seroquel use;
- (i) Allowing Seroquel to be used indiscriminately for uses which are not medically appropriate; and
- (j) Not disclosing data pertaining to such use.

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

118. At all relevant times, Defendants knew, or should have known, that Seroquel was, and is, hazardous to human health.

119. Seroquel is abnormally and unreasonably dangerous as marketed in that the health risks and costs associated with Seroquel greatly outweigh any claimed utility for all but a limited segment of the State's adult schizophrenic and bipolar population.

120. As a direct result of the unreasonable marketing practices of Defendants, Seroquel was, and is, defective and unreasonably dangerous.

121. Seroquel reached the users and consumers thereof in substantially the same condition as when originally manufactured, distributed and sold by Defendants. At the time Seroquel was sold or placed on the market, it was in a defective condition and unreasonably dangerous to all but a limited segment of adult schizophrenic and bipolar Medicaid, DBHS and DFAEBD participants.

122. Arkansas Medicaid, DBHS and DFAEBD participants used Seroquel in the manner in which it was intended to be used, without any substantive alteration or change in the product.

123. Due to the negligent, careless, reckless, willful and/or intentional conduct of Defendants, as set forth above, the State expended millions of dollars of Medicaid, DBHS and DFAEBD funds in purchasing Seroquel prescriptions and was also forced to expend significant sums of money for the care and treatment of Arkansas Medicaid, DBHS and DFAEBD participants injured by Seroquel, all of which was foreseeable to Defendants.

124. The reprehensible nature of Defendants' conduct entitles the State to an award of punitive damages.

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

COUNT VI

BREACH OF WARRANTY

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

126. Through their sales and marketing practices to Arkansas physicians treating Medicaid, DBHS and DFAEBD participants, Defendants warranted that Seroquel was fit and appropriate for patients suffering from conditions for which it was not proven safe and effective.

127. Through their sales and marketing practices to Arkansas physicians treating Medicaid, DBHS and DFAEBD participants, Defendants warranted that Seroquel had no significant risks or side effects that were not identified on its labeling. Defendants further warranted that Seroquel was safer than less expensive, first generation antipsychotics.

128. Arkansas physicians treating Medicaid, DBHS and DFAEBD participants relied on the warranties made by Defendants regarding the appropriate uses and safety profile for Seroquel.

129. Defendants breached the express and implied warranties they made to the State, through Arkansas physicians treating Medicaid, DBHS and DFAEBD participants, since the product was not appropriate for many of the uses for which it was promoted. Also, Seroquel is far less safe than warranted by Defendants.

130. The State expended millions of dollars in Medicaid, DBHS and DFAEBD expenditures for non-medically necessary uses of Seroquel and in purchasing Seroquel when a less expensive, first generation antipsychotic was available. The State also spent significant sums of money, through its Medicaid, DBHS and DFAEBD programs, for medical treatment for those Arkansas citizens who developed serious side effects and/or adverse reactions after using Seroquel. The State's expenses were caused by Defendants' express and implied warranties.

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

COUNT VII

FRAUD & MISREPRESENTATION

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

132. As part of their promotion of Seroquel, Defendants, through their sales representatives and other advertising and promotion, willfully, knowingly and deceptively communicated to Arkansas physicians treating Medicaid, DBHS and DFAEBD participants that

Seroquel was safe and effective for non-medically necessary uses and that it was safer and more effective than less expensive first generation antipsychotics, all of which were knowingly false.

133. Defendants had a duty to disclose the conditions for which Seroquel was arguably proven safe and effective, and not to go beyond those uses in their sales and marketing to Arkansas physicians, the intermediary between Defendants and the State.

134. Defendants intended to induce Arkansas physicians treating Medicaid, DBHS and DFAEBD participants to prescribe Seroquel for Arkansas Medicaid, DBHS and DFAEBD participants for whom Seroquel was not medically necessary.

135. Arkansas physicians treating Medicaid, DBHS and DFAEBD participants as well as the State, were justified in relying on Defendants to educate the physicians as to the appropriate uses and risks of Seroquel.

136. The State, through its Medicaid, DBHS and DFAEBD programs, was forced to expend significant amounts of money for non-medically necessary Seroquel prescriptions which were directly caused by the fraudulent and misleading statements of Defendants.

137. Defendants willfully, knowingly and deceptively withheld material facts regarding the risks and side effects associated with Seroquel use from Arkansas physicians treating Medicaid, DBHS and DFAEBD participants.

138. Defendants had a duty to disclose known risks and side effects associated with Seroquel use, particularly, but not solely, when specifically asked about those risks by Arkansas physicians.

139. Defendants intentionally withheld information regarding the safety risks and side effects associated with Seroquel use with the intention of inducing Arkansas physicians to

prescribe Seroquel for Arkansas Medicaid, DBHS and DFAEBD participants in greater quantities than they otherwise would have, or was otherwise appropriate.

140. Arkansas physicians treating Medicaid, DBHS and DFAEBD participants, as well as the State, were justified in their reliance on Defendants to educate them as to the risks and dangerous and potentially life-threatening side effects associated with Seroquel use.

141. Defendants knew that the State and Arkansas Medicaid, DBHS and DFAEBD participants would not be in a position to discover and understand the true risks of using Seroquel, and the public relied upon the misleading information that Defendants promulgated to Arkansas physicians to the detriment of the State.

142. Defendants knew that the representations that were relied upon by Arkansas physicians treating Medicaid, DBHS and DFAEBD participants were false or were made recklessly without any knowledge of the truth.

143. Each of Defendants' misleading and deceptive statements, representations and advertisements related to non-medically necessary and other inappropriate uses of Seroquel were material to the State's purchase of Seroquel in that the State would not have been required to reimburse pharmacies for many non-medically necessary uses of Seroquel if Defendants had marketed Seroquel legally.

144. The State, through its Medicaid, DBHS and DFAEBD programs, was forced to expend significant amounts of money to treat Arkansas citizens who contracted serious and potentially life-threatening medical conditions resulting from Defendants' deceptive withholding of adequate safety information regarding Seroquel use and/or misrepresenting Seroquel's safety profile.

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

COUNT VIII

UNJUST ENRICHMENT

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

146. Defendants knowingly; willfully and intentionally marketed and promoted Seroquel for conditions and illnesses for which it was not medically necessary.

147. Defendants knowingly, willfully and intentionally withheld information from Arkansas physicians treating Medicaid, DBHS and DFAEBD participants regarding the risks associated with Seroquel use.

148. As a result of the deceptive marketing practices of Defendants, Arkansas physicians treating Medicaid, DBHS and DFAEBD participants prescribed Seroquel in far greater numbers than would have been generated absent Defendants' deceptive and illegal conduct. The inflated levels of Seroquel reimbursement for Medicaid, DBHS and DFAEBD participants resulted in a financial windfall for Defendants.

149. The State paid, reimbursed and/or otherwise conferred a benefit upon Defendants to the extent of the inflated numbers of Seroquel prescriptions that directly resulted from Defendants' fraudulent marketing practices relative to Arkansas Medicaid, DBHS and DFAEBD participants who were not suffering from illnesses for which Seroquel is the medically necessary treatment.

150. Further, Defendants have been unjustly enriched as a result of their false representations that Seroquel is safer and more effective than less expensive, first generation antipsychotics. The State would have purchased far less Seroquel in the absence of Defendants' fraudulent representations.

151. Defendants have been unjustly enriched to the extent of the increased revenue received by Defendants from Seroquel prescriptions that were ultimately reimbursed by the State and resulted from Defendants' deceptive and illegal marketing program.

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

REQUEST FOR JURY TRIAL

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

Respectfully submitted,

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