ORLANDO DIVISION	
In Re:	§ Case No. 6:06-md-1769-ACC-DAB
SEROQUEL PRODUCTS	§ § ALL CASES
LIABILITY LITIGATION	s ALL CASES
LIABILITTELITIGATION	8
MDL 1769	ş
	§
	8
ALL UNNAMED PLAINTIFFS	9 8
v.	§ JURY TRIAL DEMANDED
	§
ASTRAZENECA PHARMACEUTICALS,	§
LP, ASTRAZENECA, LP,	§
ASTRA USA, INC., KBI SUB INC.	§
ASTRAZENECA, AB,	§
ASTRAZENECA, PLC and	§
ASTRAZENECA, UK LIMITED	§

UNITED STATES DISTRICT COURT

### SEROQUEL MASTER COMPLAINT

# I. INTRODUCTION

 This Master Complaint is submitted to serve the administrative functions of efficiency and economy and to present certain common facts and claims in the context of this Multidistrict proceeding. This Master Complaint is filed with Plaintiffs' full reservation of their right to amend same in accordance with the rules of procedure or with leave of Court. This Master Complaint does not include claims asserted in putative class actions that have been transferred to this Court under <u>28 U.S.C. § 1407</u>, nor does it constitute a waiver or dismissal of said actions or the claims asserted therein.

# **II. JURISDICTION AND VENUE**

2. The Court has jurisdiction over this lawsuit under 28 U.S.C. §1332(a)(1) as the amount in controversy exceeds \$75,000, excluding interest and costs. This Federal Court sitting in diversity may exercise personal jurisdiction over Defendants under the Florida long-arm statute, § 48.193(1)(b) & (f)(2), Fla. Stat., which permits jurisdiction over a person to the full extent of the

due process clause of the United States Constitution. Venue is proper in this Court pursuant to the July 6, 2006, Transfer Order of the Judicial Panel on Multidistrict Litigation, under 28 U.S.C. §1391(a)(1) because all Defendants "reside" in this judicial district as that term is defined in 28 U.S.C. §1391(c), under 28 U.S.C. §1391(a)(2) in that a substantial part of the events or omissions giving rise to these claims arose in this judicial district, and/or, under 28 U.S.C. §1391(a)(3) because there is no district in which the action may otherwise be brought and at least one Defendant is subject to personal jurisdiction in this district.

### III. PARTIES

- Plaintiffs are individuals who ingested Seroquel, suffered injuries as a result thereof and currently
  reside in, and are citizens of, most or all of the states in the United States.
- 4. Defendant, AstraZeneca Pharmaceuticals LP, is a Delaware limited partnership doing business in the State of Delaware, and the United States. AstraZeneca Pharmaceuticals LP, is the United States Subsidiary of AstraZeneca PLC, and was created as a result of the union of Zeneca Pharmaceuticals and Astra Pharmaceuticals LP in the U.S. after the 1999 merger. AstraZeneca Pharmaceuticals LP's principal place of business is in Delaware1800 Concord Pike, PO Box 15437,Wilmington, DE 19850. Upon Information and belief AstraZeneca Pharmaceuticals LP's general and limited partners are: AstraZeneca AB, a Swedish corporation with its principal place of business in Sweden; Zeneca Inc., a Delaware corporation with its principal place of business in Delaware; Astra USA Inc., a New York corporation with it's principal place of business in Delaware; and Astra US holdings Corporation, a Delaware corporation with it's principal place of business in Delaware. Therefore AstraZeneca Pharmaceuticals LP is a citizen of Delaware, New York and Sweden.
- 5. Defendant, AstraZeneca LP, is a Delaware limited partnership doing business in the State of Delaware, and the United States. AstraZeneca LP's principal place of business is in Delaware. Upon information and belief AstraZeneca LP's general partner is AstraZeneca Pharmaceuticals LP, which as stated above is a citizen of Delaware, New York, and Sweden. AstraZeneca LP's

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sole limited partner, KBI Sub Inc., is incorporated in the state of Delaware and its principal place of business is in New Jersey. Therefore, AstraZeneca LP is a citizen of Delaware, New York, New Jersey and Sweden.

- 6. Defendant, Astra USA, Inc. is a New York corporation duly organized and existing under the laws of New York, doing business in the State of New York and the United States. Astra USA, Inc.'s principle place of business is in Delaware. Astra USA, Inc. is a limited partner of AstraZeneca Pharmaceuticals LP. Therefore, Defendant, Astra USA Inc. is a citizen of the State of New York and Delaware.
- Defendant, KBI Sub Inc., is incorporated in the state of Delaware and its principle place of business is in New Jersey. KBI Sub Inc. is AstraZeneca LP's sole limited partner. Therefore, Defendant KBI Sub Inc. is a citizen of the State of Delaware and New Jersey.
- 8. Defendant AstraZeneca AB, is the general partner of AstraZeneca Pharmaceuticals LP, and is a foreign company with its principal place of business at SE-151 85, Södertälje, Sweden. Lacking an agreed appearance, this Defendant 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.
- 9. Defendant AstraZeneca PLC, is the ultimate parent company of all Defendants, and is a foreign company with its principal place of business at 15 Stanhope Gate, London, W1K 1LN, England, United Kingdom. Lacking an agreed appearance, this Defendant 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.
- 10. Defendant AstraZeneca UK Limited is a company incorporated under the laws of England and Wales and has a registered office in London, England. Defendant AstraZeneca UK Limited is the holder of the New Drug Application by which the U.S. Food and Drug Administration first

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granted approval for Seroquel. Lacking an agreed appearance, this Defendant 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.

11. AstraZeneca Pharmaceuticals LP, AstraZeneca LP, Astra USA, KBI Sub Inc., AstraZeneca AB, AstraZeneca PLC AND AstraZeneca UK Limited shall be collectively referred to as "AstraZeneca" or the "Seroquel Defendants"). At all times relevant herein, the Seroquel Defendants were in the business of designing, testing, monitoring, manufacturing, labeling, advertising, marketing, promoting, selling and distributing pharmaceuticals, including Seroquel, for use by the mainstream public, including Plaintiffs.

# IV. FACTUAL BACKGROUND

- 12. Seroquel (chemically referred to by its active ingredient, quetiapine fumarate) is among a group of drugs known as "atypical antipsychotics" or "second generation antipsychotics". Seroquel was initially approved in September 1997 by the U.S. Food and Drug Administration (hereinafter the "FDA"). Both first and second generation antipsychotics are often referred to as *neuroleptic drugs* as they are believed to produce a sedating or tranquilizing effect, decreased delusions, hallucinations and psychomotor agitation. They are also sometimes referred to as *major tranquilizers*.
- 13. Other second generation antipsychotics include:
  - clozapine (Clozaril) Novartis approved 9/89;
  - risperidone (Risperdal) Janssen- approved 12/93;
  - olanzapine (Zyprexa) Eli Lilly approved 9/96;
  - ziprasidone (Geodon) Pfizer approved 2/01; and
  - aripiprazole (Abilify) Ortho McNeil approved 11/02.

Accordingly, Seroquel was at least the fourth "me too", "copy cat" atypical antipsychotic on the market.

- 14. "First generation", "conventional" or "typical antipsychotics" (another subclass of neuroleptic drugs) include chlorpromazine (Thorazine), fluphenazine (Prolixin), haloperidol (Haldol, Halperon), mesoridazine (Serentil), perphenazine (Trilafon), thioridazine, and trifluoperazine (Stelazine). They also produce significant extrapyramidal symptoms such as dystonic reactions, Parkinsonism, akathisia (restlessness and agitation), and tardive dyskinesia. Further, they have been associated to a lesser degree than the second generation drugs with the development of metabolic side effects like diabetes.
- 15. The initial indication for Seroquel approved by the FDA was solely for treatment of adults with schizophrenia, a relatively rare condition that affects less than one percent of the population of the United States.
- 16. The pharmacologic action of Seroquel is thought to be dependent on its ability to block or moderate the level of dopamine, a chemical found in the brain that in excessive amounts is believed to cause abnormal thinking and hallucinations. Likewise, all neuroleptic drugs act as inhibitors of the dopamine-2 (D2) receptor. First generation antipsychotics bind tightly to the receptor to produce a prolonged duration of effect but also increased side effects. Second generation antipsychotics, it was originally theorized, would bind more loosely producing fewer side effects.
- 17. Medical literature dating back to the 1950s, demonstrated that conventional antipsychotics had the potential to cause diabetes, diabetes-related injuries (e.g. severe weight gain, hyperglycemia, diabetic ketoacidosis), pancreatitis, cardiovascular complications, and other severe adverse effects. The medical reports describe cases of sudden onset hyperglycemia after the initiation of chlorpromazine treatment which resolved upon withdrawal of the drug. Additionally, patients with existing diabetes had a notable worsening of symptoms with antipsychotic treatment. Hiles, BW, *Hyperglycemia and Glycosuria Following Chlorpromazine Therapy*. JAMA 1956;162:1651.

- 18. In another 1950's study, all patients were given a measured dose of glucose (assimilating the same amount of food intake), however, the group that was pretreated with a conventional antipsychotic (chlorpromazine) showed a markedly slower drop in blood sugar levels in three hours of blood tests thereafter. Charatan, FBF, *The effect of Chlorpromazine ("Largactil") on Glucose Tolerance*, J. Ment. Sci. 1956;101:351-3. Because of these studies and significant other medical evidence, since 1979 the use of conventional antipsychotics has been listed as a diabetic risk factor by the National Diabetes Data Group. National Diabetes Data Group; *Classification and diagnosis of diabetes mellitus and other categories of glucose intolerance*. Diabetes 1979; 28:1039-57.
- AstraZeneca's own pre-clinical studies regarding Seroquel confirmed the propensity of its atypical antipsychotic to cause diabetes and related life threatening and deadly conditions - just like conventional antipsychotics.
- 20. Shortly after AstraZeneca's September, 1997, approval and sales of Seroquel began, reports of U.S. consumers using Seroquel suffering from hyperglycemia, acute weight gain, diabetes mellitus, pancreatitis, and other severe diseases and conditions associated began to surface. AstraZeneca knew, or was reckless in not knowing, of these reports.
- 21. Based on decades old confirmation of the association between conventional antipsychotics and diabetes and its lethal side effects, AstraZeneca, a manufacturer of an atypical antipsychotic, had every reason to be vigilant in identifying a signal and an association that atypicals would result in diabetes just like conventional antipsychotics. AstraZeneca was aware of studies and journal articles in 1998 and 1999 confirming the link between atypicals, new onset diabetes and permanent hyperglycemia-related adverse events. Wirshing, DA, *Novel Antipsychotics and new onset diabetes*. Biol. Psychiatry, 1998:15;44:778-83; Allison, DB, *Antipsychotic-Induced Weight Gain: A Comprehensive Research Synthesis*. Am. J. Psychiatry, 1989:156:1686-96. Despite this

knowledge, AstraZeneca never attempted to provide an adequate warning label – at least to Americans - until they were ultimately forced to do so by the FDA.

- 22. Seroquel's worldwide sales in 1998, its first full year on the market, were a modest \$63 million. According to AstraZeneca's 2005 Annual Report, worldwide Seroquel sales exceeded \$2.76 billion. Restated, sales increased 4,280% in seven years.
- 23. Critical to this blockbuster success was AstraZeneca's aggressive marketing of Seroquel, which consisted chiefly of overstating the drug's uses and benefits (including massive off-label promotion), while understating and consciously concealing its life-threatening side effects. Seroquel, upon information and belief, was promoted, off-label for the treatment of depression, anxiety, childhood Tourette's Syndrome, autism, obsessive compulsive disorder (OCD), alcoholism, treatment of tardive dyskinesia, treatment-resistant major depressive disorder, Parkinson's disease symptoms and/or insomnia. As part of the aggressive marketing of Seroquel, sales representatives actively detailed and promoted the drugs to physicians, pharmacists and other health care providers by understating, denying and or trivializing risks, overstating benefits, promoting indications outside of the label, and generally diluting the import of the label with aggressive promotion techniques to gain market share.
- 24. Shortly after Seroquel's product launch and first widespread usage, the number of adverse event reports involving diabetes-related illnesses associated with Seroquel, spiked. These promotional efforts were made, while fraudulently, willfully and wantonly withholding important safety information from the physicians, the FDA, and the public, specifically, that AstraZeneca was aware of numerous reports of diabetes associated with the use of these drugs, well beyond the background rate and well beyond the rate for other antipsychotic agents.
- 25. In December 2000, an article published in the *British Medical Journal* concluded that "[t]here is no clear evidence that [Risperdal or other atypical anti-psychotics like Seroquel] are more effective or are better tolerated than conventional antipsychotics [including Haldol and

Thorazine]". Geddes, J, et al., *Atypical antipsychotics in the treatment of schizophrenia:* systematic overview and meta-regression analysis. Br. Med. J., 2002; 321:1371-76.

- 26. By July 2001, Defendant AstraZeneca had received at least 46 reports of diabetes mellitus in patients taking Seroquel, including reports in the medical literature, and including at least 21 cases of ketoacidosis or acidosis and 11 deaths, and, by the end of 2003, AstraZeneca had received at least 23 more. Most cases appeared within 6 months of initiating Seroquel therapy.
- 27. Upon information and belief, prior to and during the time most Plaintiffs ingested Seroquel, the Japanese label for Seroquel provided a detailed warning regarding the risks of diabetes associated with Seroquel, and specifically informed physicians regarding the necessity of medical monitoring of patients on Seroquel. At the time the Plaintiff ingested Seroquel, Defendant AstraZeneca had not adopted this safer, more accurate label for the U.S. distribution of Seroquel.
- 28. Upon information and belief, prior to and during the time of use of Seroquel by most Plaintiffs, the Japanese label warned specifically of the diabetes risk, prominently in the beginning of the package label stating:
  - Quetiapine fumarate is contraindicated for use in patients with diabetes or a history of diabetes.
  - b. Quetiapine fumarate should be used with caution in patients with risk factors for diabetes, including hyperglycemia, obesity or a family history of diabetes.
  - c. Patients receiving quetiapine fumarate should be carefully monitored for symptoms of hyperglycemia, and the drug should be discontinued if such symptoms occur. The symptoms of severe hyperglycemia include weakness, excessive eating, excessive thirst, and excessive urination.
  - d. Physicians should educate patients and their family members about the risk of serious hyperglycemia associated with quetiapine fumarate and how to identify the symptoms of hyperglycemia. In April 2002, the Japanese Health & Welfare Ministry issued emergency safety information regarding the risk of diabetes, diabetic ketoacidosis, and hyperosmolar coma for patients prescribed Seroquel. On information and belief, prior to that time, Defendant AstraZeneca was involved in discussions with the Japanese agency regarding labeling changes for Seroquel and other atypicals.

- 29. While warning of the association of Seroquel with diabetes, glucose dysregulation, ketoacidosis, weight gain and the need for medical monitoring in Japan, AstraZeneca failed to provide the same or similar warnings to the public and prescribing physicians in the United States.
- 30. In April 2002, the British Medicines Control Agency warned about the risk of diabetes for patients prescribed the atypical antipsychotic Zyprexa in its newsletter *Current Problems in Pharmacovigilance*. This newsletter reported forty (40) reports of diabetes, hyperglycemia, diabetic ketoacidosis, diabetic coma, and one death among users of Zyprexa. Subsequently, the British government required Lilly to warn consumers about the risk of diabetes and diabetic ketoacidosis, and further required Lilly to instruct patients who were using Zyprexa to monitor their blood sugar levels. AstraZeneca knew or should have known that these dangerous side effects were common to all drugs of the class known as atypical antipsychotics.
- 31. In September, 2002 a population of over 20,000 neuroleptic drug users from the U.K. General Practice Research database were followed (19,102 using atypicals and 958,453 using conventional). 424 cases of new onset diabetes were identified and matched to 1,522 controls (about 4 per case) by age, gender, general practice and index date. The adjusted OR for current use of any antipsychotic was 1.7 (95% CI = 1.3-2.3) and for current use of atypical antipsychotic was 4.7 (95% CI = 1.5-14.9). Kornegay CJ, Vasilakis-Scarmozza C, Jick H; *Incident Diabetes Associated with Antipsychotic use in the United Kingdom General Practice Research Database*. J Clin Psychiatry 2002; 63:758-62.
- 32. On September 11, 2003, the FDA informed all manufacturers of atypical antipsychotic drugs, including AstraZeneca, that due to an increasing prevalence of diabetes-related illnesses associated with this class of drugs, all labeling must bear the following language in the Warnings section:

Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given these confounders, the relationship between atypical antipsychotic use and hyperglycemiarelated 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.

- 33. Despite the FDA action, AstraZeneca waited until January 30, 2004 to send out a "Dear Doctor" letter attempting to advise treating physicians of the new warnings. On April 22, 2004 AstraZeneca was forced to send out a revised "Dear Doctor" letter due to the fact that the first one was misleading, as it potentially downplayed the need to continually monitor a patient's blood sugar levels while on the drug. This critical information did not make it into the *Physicians' Desk Reference* until the 2005 edition.
- 34. Seroquel may be the least potent atypical antipsychotic from an efficacy standpoint but not a risk standpoint in the atypical subclass. Seroquel likely requires more milligrams to be effective than more potent drugs like risperidone or ziprasidone. Seroquel is available in 25mg, 100mg, 200mg, and 300mg dosages. The total daily dose for the first four days of therapy is 50 mg (Day 1), 100 mg (Day 2), 200 mg (Day 3) and 300 mg (Day 4). From Day 4 onwards, the dose is often titrated to an effective dose in the range of 300-450 mg/day or less. That is,

Seroquel is usually given once daily, with the dose often adjusted upward until an optimal dose is found.

- 35. In a case-control study of 13,611 inpatients in facilities operated by the New York State Office of Mental Hygiene, rates of diabetes were compared in patients taking first and second generation antipsychotics. New cases of diabetes were identified by a new prescription for an anti-diabetic medication. 8,461 patients met the inclusion criteria of being hospitalized for more than 60 days and not using antidiabetic medications in the past. 1,539 of these patients received a prescription for antidiabetic medication for a prevalence rate of 11.31%. Of these, 181 were new prescriptions. Eight controls were matched to each case by year, length of observation period, race, age, and diagnosis for a total of 1,448 controls. Of the 24 cases and 112 controls who took Seroquel, the odds ratio (OR) of developing diabetes was 3.09 (95% Cl = 1.59-6.03) compared to taking a first generation antipsychotic. There was also a statistically significant elevation in risk for those patients taking more than one second generation antipsychotic (OR = 2.86, 95% CI = 1.57-5.2). 42 of the 181 cases of treatment emergent diabetes developed in the group taking more than one second generation antipsychotic. 20 of those 42 cases of new onset diabetes (47%) were taking Seroquel as one of two atypicals. Citrome L, Jaffe A, Levine J, Allingham B, Robinson J: Relationship between antipsychotic medication treatment and new cases of diabetes among psychiatric inpatients. Psychiatric Services 2004; 55:1006-13.
- 36. The marketing and promotion efforts of AstraZeneca, through its advertisers and sales force, overstated the benefits of Seroquel and minimized, downplayed and concealed the risks associated with this drug. Despite the fact that AstraZeneca knew or should have known that Seroquel was associated with the aforesaid adverse effects, including diabetes mellitus, it recklessly, negligently, and with willful and wanton indifference to the health and safety of consumers, failed to include any warning regarding hyperglycemia, diabetes mellitus, or related conditions until on or after January 2004.

- 37. Recently, researchers at the National Institute of Mental Health published a report on atypical antipsychotics, including Seroquel, which found that the majority of patients in each group discontinued their assigned treatment owing to inefficacy or intolerable side effects or for other reasons and that the atypicals, including Seroquel, were no more effective than the older, cheaper, and still available conventional antipsychotic perphenazine. This report echoes the conclusions reported in the *British Medical Journal* in 2000.
- 38. In January 2006, AstraZeneca was notified that the U.S. Attorney's Office in Los Angeles, California, had commenced an investigation of AstraZeneca's promotional activities related to its products, including Seroquel.
- 39. Despite AstraZeneca's knowledge regarding the safety risks its drug posed, they continued to ignore, downplay, sidestep, and delay the dissemination of open and frank information that patients and physicians needed to avoid the life-threatening injuries that Seroquel could cause. As a result of this callous disregard for human safety in the name of profits, Plaintiffs have suffered the injuries, damages, and losses complained of herein.

# V. FRAUDULENT CONCEALMENT AND APPLICATION OF THE DISCOVERY RULE

- 40. The nature of Plaintiffs' injuries and their relationship to Seroquel use were inherently undiscoverable; and, consequently, the discovery rule should be applied to toll the running of the statute of limitations until Plaintiffs knew or through the exercise of reasonable care and diligence should have known of the existence of their claims against AstraZeneca. Plaintiffs did not discover, and through the exercise of reasonable care and due diligence, could not have discovered, their injuries earlier.
- 41. Further, Plaintiffs did not have knowledge of facts that would lead a reasonable, prudent person to make inquiry to discover Defendants' tortious conduct. Under appropriate application of the "discovery rule," Plaintiffs' suit was filed well within the applicable statutory limitations period.

42. AstraZeneca affirmatively and intentionally lulled, induced, and otherwise prevented Plaintiffs from discovering the existence of their various causes of action against AstraZeneca through its fraudulent acts, omissions, concealments, and suppression of the dangers associated with its drug and other information necessary to put Plaintiffs on notice. Plaintiffs have therefore been kept in ignorance of vital information essential to the pursuit of their claims, without any fault or lack of diligence on their part. Plaintiffs could not reasonably have discovered the fraudulent nature of AstraZeneca's conduct. Accordingly, AstraZeneca is estopped from relying on any statute of limitations to defeat any of Plaintiffs' claims.

### VI. CAUSES OF ACTION

# FIRST CLAIM FOR RELIEF

### NEGLIGENCE

- 43. Plaintiffs hereby incorporate by this reference all other paragraphs of this Complaint as if fully set forth herein at length.
- 44. AstraZeneca is the designer, manufacturer, and seller of the drug Seroquel.
- 45. When placed in the stream of commerce in 1997, Seroquel was not accompanied by adequate warnings regarding the significant blood sugar related risks associated with the ingestion of Seroquel, particularly diabetes mellitus. The warnings given by the Seroquel Defendants did not accurately reflect the existence of the risk, let alone the incidence, symptoms, scope, or severity of such injuries.
- 46. AstraZeneca failed to perform adequate testing concerning the safety of the drug Seroquel in that adequate testing would have shown that Seroquel poses serious risk of blood sugar related problems which would have permitted adequate and appropriate warnings to have been given by AstraZeneca to prescribing physicians, health insurance companies, the various states' formularies, and the consuming public.
- 47. AstraZeneca had a duty to exercise reasonable care in the design, manufacture, sale, and distribution of the drug, Seroquel, including a duty to assure that the product did not cause users to suffer from unreasonable, dangerous side effects when used alone or in foreseeable combination with other drugs.
- 48. AstraZeneca was negligent in the design, manufacturing, testing, advertising, marketing, promotion, labeling, warnings given, and sale of Seroquel in that, among other things, the Seroquel Defendants:
  - failed to provide Americans a warning for diabetes that AstraZeneca concluded the Japanese were entitled to;
  - b. failed to use reasonable care to design an atypical anti-psychotic that was safe for its intended and foreseeable uses, not defective, and not unreasonably dangerous;
  - failed to use reasonable care in designing and manufacturing Seroquel as to make it safe for its intended uses, not defective, and not unreasonably dangerous;
  - recklessly, falsely, and deceptively represented or knowingly omitted, suppressed, and/or concealed material facts regarding the safety and efficacy of Seroquel from

prescribing physicians, the medical community at large, health insurers and state formularies;

- negligently marketed Seroquel despite the fact that risks of the drug were so high and the benefits of the drug were so speculative that no reasonable pharmaceutical company, exercising due care, would have done so;
- f. failed to use reasonable care to make reasonable tests, inspections, drug trials, and/or evaluations necessary to discover such defects and unreasonably dangerous conditions associated with AstraZeneca's drug, Seroquel;
- g. failed to use reasonable care to investigate and/or use known and/or knowable reasonable alternative designs, manufacturing processes, and/or materials for Seroquel;
- h. failed to use reasonable care to warn plaintiffs of dangers known and/or reasonably suspected by AstraZeneca to be associated with Seroquel;
- failed to timely use reasonable care to discover the dangerous conditions or character of AstraZeneca's drug, Seroquel;
- j. failed to use due care in the design, testing and manufacturing of Seroquel so as to prevent the aforementioned risks, including, *inter alia*, diabetes mellitus, and the serious complications stemming therefrom including seizures, coma, death, liver disease, kidney disease, blindness, and other serious side effects including rapid weight gain, pancreatitis, urinary frequency and hyperglycemia;
- k. failed to issue proper warnings regarding important possible adverse side effects associated with the use of Seroquel and the comparative severity and duration of such adverse effects, despite the fact that the Seroquel Defendants knew, or should have known, that numerous cases reports, adverse event reports, and other data that associated Seroquel with diabetes mellitus, and the serious complications stemming therefrom including seizures, coma, death, liver disease, kidney disease, blindness, and other serious side effects including rapid weight gain, pancreatitis, urinary frequency and hyperglycemia;
- failed to conduct adequate pre-clinical testing and post-marketing surveillance to determine the safety of Seroquel;
- failed to provide adequate training and information to medical care providers for the appropriate use of Seroquel;
- n. failed to warn plaintiffs and healthcare providers, prior to actively encouraging and promoting the sale of Seroquel, either directly, or indirectly, orally, in writing, or other media about the following:
  - The need for a battery of diagnostic tests to be performed on the patient prior to ingesting Seroquel to discover risk factors and help prevent potentially fatal side effects;

- (2) The need for comprehensive, regular medical monitoring to ensure early discovery of hyperglycemia, diabetes, weight gain, hyperlipidemia, hypertriglyceridemia, pancreatitis, and other potentially fatal side effects;
- (3) The adverse side effects associated with the use of Seroquel, including, but not limited to, diabetes mellitus; and/or
- (4) The possibility of becoming disabled as a result of using Seroquel; and,
- r. failed to timely develop and implement a safer, alternative design of Seroquel, which would meet the same need without the known risks associated with Seroquel and which would not have made the product too expensive to maintain its utility; and
- s. failed to carry out the ongoing duty of pharmacovigilance, including, to continually monitor, test, and analyze epidemiology and pharmacovigilance data regarding safety, efficacy and prescribing practices; to review worldwide adverse event reports, worldwide medical literature and to monitor the Seroquel Defendants own warnings in other countries (including Japan) and learning of or failing to learn of a signal and an association between Seroquel and diabetes, and related health problems, and failing to inform doctors, regulatory agencies, and the public of new safety and efficacy information it learns, or should have learned, about Seroquel once that information becomes available to it.
- 49. Despite the fact that the Seroquel Defendants knew or should have known that Seroquel caused unreasonable, dangerous side effects which many users would be unable to remedy by any means, the Seroquel Defendants continued to market Seroquel to consumers, including plaintiffs, when there were safer alternative methods available.
- 50. AstraZeneca knew or should have known that consumers such as plaintiffs would foreseeably suffer injury as a result of AstraZeneca's failure to exercise ordinary care as described above.
- 51. As a direct and proximate result and legal result of the AstraZeneca's failure to supply appropriate warnings for the drug, Seroquel, and as a direct and legal result of the negligence, carelessness, other wrongdoing and action of the Seroquel Defendants described herein, the Plaintiffs ingested Seroquel and suffered significant injury.
- 52. AstraZeneca's negligence was a proximate cause of the harm suffered by the plaintiffs.
- 53. As a direct and proximate cause and legal result of the AstraZeneca's negligence, carelessness, and the other wrongdoing and actions of the Seroquel Defendants as described herein, plaintiffs

have suffered physical injury, medical expense, future medical expense, and have incurred financial expenses and have suffered economic losses.

## SECOND CLAIM FOR RELIEF

### STRICT PRODUCTS LIABILITY - FAILURE TO WARN

- Plaintiffs hereby incorporate by this reference all other paragraphs of this Complaint as if fully set forth herein at length.
- 55. Seroquel was marketed to physicians and was marketed and advertised directly to the consuming public. Seroquel, as manufactured and supplied to healthcare professionals and the general public, was unaccompanied by proper warnings regarding the serious risks of ingesting the drug. The information provided to consumers did not reflect Defendants' knowledge that Seroquel was not safe and effective as indicated in its aggressive marketing campaign, nor were consumers made aware that ingesting the drug could result in serious injury, pain and diabetes and/or death. Additionally, Defendants committed overt acts and issued doublespeak in order to downplay the truth which began to surface. This information began to emerge in the form of adverse event reports, medical studies, and the 2003 FDA labeling change mandate. Any attempts by Defendants to satisfy its duty to warn were compromised by the backdrop of the Seroquel Defendants' actions, including but not limited to its 2002 diabetes warning in Japan. As part of the aggressive marketing of Seroquel, sales representatives actively detailed and promoted the drug to physicians, pharmacists and other health care providers by understating, denying and or trivializing risks, overstating benefits, promoting indications outside of the label, and generally diluting the import of the label with aggressive promotion techniques to gain market share. Moreover, defendant improperly misinformed the medical community by intentionally disseminating false and misleading information into the medical literature that understated or minimized the risks and over-stated benefits, and promoted the product for offlabel use.

- 56. Full and proper warnings that accurately and fully reflected the risks of serious injury and/or sudden death due to the ingestion of Seroquel should have been disclosed by Defendants. Plaintiffs were prescribed Seroquel by physicians who utilized the drug in a manner reasonably foreseeable by Defendants. Seroquel was expected to and did reach Plaintiffs without substantial change in its condition as tested, manufactured, designed, labeled, packaged, marketed and distributed. Plaintiffs were not aware of, and could not have reasonably discovered, the unreasonably dangerous nature of Seroquel.
- 57. The marketing defect resulting from such inadequate and improper warnings, instructions and dissemination of information to the medical community and plaintiffs directly, was the producing cause and legal and direct result of the failure to warn consumers of the defective condition of Seroquel, as manufactured and/or supplied by the Seroquel Defendants and its representatives, Plaintiffs have suffered severe, permanent and disabling injuries and related damages.

### THIRD CLAIM FOR RELIEF

#### STRICT PRODUCTS LIABILITY - DESIGN DEFECT

- 58. Plaintiffs hereby incorporate by this reference all other paragraphs of this Complaint as if fully set forth herein at length.
- 59. Seroquel was placed into the stream of commerce by the Seroquel Defendants, acting through authorized agents, servants, employees and/or representatives. Plaintiffs were prescribed Seroquel by Plaintiffs' physicians and used the drugs in a manner normally intended, recommended, promoted and marketed by the Seroquel Defendants. Seroquel failed to perform safely when used by ordinary consumers including plaintiffs, even when used as intended or in a reasonably foreseeable manner. Accordingly, Seroquel was defective in its design and was unreasonably danger in that its foreseeable risks exceeded the benefits associated with its design or formulation.
- 60. The Seroquel ingested by Plaintiffs was expected to and did reach Plaintiffs without substantial change in its condition as tested, manufactured, designed, labeled, packaged, marketed and distributed and plaintiff could not through the exercise of reasonable care, have discovered Seroquel's defects or perceived the danger of its use. Seroquel was defective in design or formulation in that its use posed a greater likelihood of injury than other available antipsychotic medications and was more dangerous than an ordinary consumer could reasonably foresee. As a result of their use of Seroquel, Plaintiffs suffered severe, permanent and disabling injuries and related damages.

## FOURTH CLAIM FOR RELIEF

### FRAUD AND INTENTIONAL MISREPRESENTATION

 Plaintiffs hereby incorporate by this reference all other paragraphs of this Complaint as if fully set forth herein at length.

- 62. AstraZeneca through advertising, labeling, direct product detailing by sales representatives to the medical community, and other communications including letters to medical community, and medical literature disseminated made misrepresentations to physicians and the public, including Plaintiffs, about the safety and efficacy of Seroquel. Physicians and their patients, including Plaintiffs, justifiably relied on AstraZeneca's misrepresentations, and Plaintiffs were harmed as a result. Plaintiffs are entitled to recover damages for their injuries produced by AstraZeneca's misrepresentations. Physicians and their patients, including the Plaintiffs, relied on AstraZeneca's misrepresentations are entitled to recover actual damages for their injuries as a result. Plaintiffs are entitled to recover as a result. Plaintiffs are entitled to recover damages are harmed as a result. Plaintiffs are entitled to recover damages for their injuries produced by AstraZeneca's misrepresentations. Physicians and their patients, including the Plaintiffs, relied on AstraZeneca's misrepresentations are entitled to recover actual damages for their injuries as a result of the AstraZeneca's misrepresentations and fraud.
- 63. Defendants are in the business of manufacturing, marketing, distributing and/or selling these drugs. Through their advertising and through labels on their products, Defendants made misrepresentations to the public at large and specifically to Plaintiff and her physician.
- 64. Defendants breached their duty to Plaintiff under the RESTATEMENT (SECOND) OF TORTS § 402(B)(1965) regarding the misrepresentations set out above. Defendants represented the product to be safe to use. These were material misrepresentations of fact concerning the character, nature and dangerous propensities of the product manufactured, sold, and marketed by Defendants.
- 65. Plaintiff and their physicians justifiably relied upon the misrepresentations made by the Seroquel Defendants. Such conduct by the Seroquel Defendants proximately caused injuries and damages to Plaintiffs for which Plaintiffs now seek to recover damages.

# FIFTH CLAIM FOR RELIEF

# NEGLIGENT MISREPRESENTATION

66. Plaintiffs hereby incorporate by this reference all other paragraphs of this Complaint as if fully set forth herein at length.

- 67. The Seroquel Defendants, in addition to knowing misrepresentations, made misrepresentations without any reasonable grounds for believing its statements to be true to Plaintiffs, other patients, and the medical and psychiatric communities.
- 68. The Seroquel Defendants, through its misrepresentations, intended to induce justifiable reliance by Plaintiffs, other patients, and the medical and psychiatric communities.
- 69. The Seroquel Defendants, through its marketing campaign and communications with treating physicians or psychiatrists, was in a relationship so close to that of Plaintiffs and other patients that it approaches and resembles privity.
- 70. The Seroquel Defendants owe a duty to the medical and psychiatric communities, Plaintiffs, and other consumers, to conduct appropriate and adequate studies and tests for all its products, including Seroquel, and to provide appropriate and adequate information and warnings.
- 71. The Seroquel Defendants failed to conduct appropriate or adequate studies for Seroquel. The Seroquel Defendants failed to exercise reasonable care by failing to conduct studies and tests of Seroquel.
- 72. As a direct and proximate result of the Seroquel Defendant's negligent misrepresentations, Plaintiffs developed diabetes, pancreatitis and/or life threatening complications therefrom and were caused to suffer severe and permanent injuries, pain, and mental anguish, including diminished enjoyment of life, and fear of developing other harmful conditions including, but not limited to, pancreatitis, diabetic ketoacidosis, and diabetic coma. The Seroquel Defendants are liable to Plaintiffs jointly and severally for all general, special and equitable relief to which Plaintiff is entitled by law.

# SIXTH CLAIM FOR RELIEF

# BREACH OF EXPRESS WARRANTY

73. Plaintiffs hereby incorporate by this reference all other paragraphs of this Complaint as if fully set forth herein at length.

- 74. The Seroquel Defendants are merchants and/or sellers of Seroquel. Defendants sold Seroquel to consumers, including Plaintiffs, for the ordinary purpose for which such drugs are used by consumers. The Seroquel Defendants made representations to Plaintiffs about the quality or characteristics of Seroquel by affirmation of fact, promise and/or description.
- 75. The representations by the Seroquel Defendants became part of the basis of the bargain between Defendants and Plaintiffs. Seroquel did not comport with the representations made by Defendants in that it was not safe for the use for which it was marketed. Plaintiffs have notified Defendants that Defendants has breached its express warranties. This breach of warranty by Defendants was a proximate cause of the injuries and monetary loss suffered by Plaintiffs.

# SEVENTH CLAIM FOR RELIEF

# BREACH OF IMPLIED WARRANTY

76. Plaintiffs hereby incorporate by this reference all other paragraphs of this Complaint as if fully set forth herein at length.

# 1. Warranty of Merchantability

77. The Seroquel Defendants are merchants and/or sellers of Seroquel. Plaintiffs purchased Seroquel as placed in the stream of commerce by the Seroquel Defendants and used it for the ordinary purpose for which such drugs are used by consumers. At the time it was purchased by Plaintiffs, Seroquel was not fit for the ordinary purpose for which such drugs are used because it was not manufactured, designed or marketed in a manner to accomplish its purpose safely. The Seroquel Defendants' breach of its implied warranty of merchantability was a direct and proximate cause of Plaintiffs' injuries, diseases, and damages complained of herein.

### 2. WARRANTY OF FITNESS

- 78. The Seroquel Defendants placed Seroquel into the stream of commerce with the knowledge that Plaintiffs were purchasing said drugs for a particular purpose. Further, Defendants knew, or should have known, that Plaintiffs were relying on Defendants' skill or judgment to select goods fit for Plaintiffs' purpose.
- 79. The Seroquel Defendants delivered goods that were unreasonably dangerous and unfit for Plaintiffs' particular purpose, in that they were defectively designed and did not come with adequate warnings.
- 80. The Seroquel Defendants' failure to select and sell a product which was reasonably safe for its intended use was a direct and proximate cause of Plaintiffs' injuries, diseases, and damages complained of herein.

## **EIGHTH CLAIM FOR RELIEF**

### UNJUST ENRICHMENT

- 81. To the detriment of Plaintiffs the Seroquel Defendants have been, and continue to be, unjustly enriched as a result of the unlawful and/or wrongful collection of, inter alia, payments for Seroquel.
- 82. Plaintiffs were injured by the cumulative and indivisible nature of the Seroquel Defendants' conduct. The cumulative effect of the Seroquel Defendants' conduct directed at physicians and consumers was to artificially create demand for Seroquel at an artificially inflated price. Each aspect of the Seroquel Defendants' conduct combined to artificially create sales of Seroquel.
- 83. The Seroquel Defendants have unjustly benefited through the unlawful and/or wrongful collection of, inter alia, payments for Seroquel and continue to so benefit to the detriment and at the expense of Plaintiffs.
- 84. Accordingly, Plaintiffs seek full disgorgement and restitution of the Seroquel Defendants' enrichment, benefits and ill-gotten gains acquired as a result of the unlawful and/or wrongful conduct alleged herein.

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### NINTH CLAIM FOR RELIEF

#### VIOLATION OF STATE CONSUMER PROTECTION LAWS

85. Plaintiffs hereby incorporate by this reference all other paragraphs of this Complaint as if fully set forth herein at length.

86. The Seroquel Defendants' actions, as complained of herein, constitute unfair competition or

unfair, unconscionable, deceptive or fraudulent acts or practices in violation of various state

consumer protection statutes that allow consumers to pursue claims. Plaintiffs assert this claim on

behalf of the Plaintiffs whose claims arise in the states identified below and pursuant to the

statutes identified below:

(a) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of <u>Alaska Stat. Code § 40.50.471</u>, et seq.;

(b) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of <u>Ariz. Rev. Stat. § 44-1522</u>, et seq.;

(c) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of <u>Ark. Code § 4-88-101</u>, et seq.;

(d) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of <u>Cal. Bus. & Prof. Code § § 17200</u>, et seq. and the Consumer Legal Remedies Act, <u>Civ.</u> <u>Code § 1750</u> et seq. ("CLRA");

(e) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of <u>Colo. Rev. Stat. § 6-1-105</u>, et seq.;

(f) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of <u>Conn. Gen. Stat. § 42-110b</u>, et seq.;

(g) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of <u>6 Del. Code § 2511</u>, et seq.;

(h) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of <u>D.C. Code § 28-3901</u>, et seq.;

(i) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, et seq.;

 (j) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of <u>Haw. Rev. Stat. § 480</u>, et seq.;

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(k) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of <u>Idaho Code § 48-601</u>, et seq.;

(l) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of <u>815 ILCS § 505/1</u>, et seq.;

(m) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. § 24-5-0.5.1, et seq.;

 (n) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of <u>Kan. Stat. § 50-623</u>, et seq.;

(o) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. § 367.110, et seq.;

(p) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of <u>5 Me. Rev. Stat. § 207</u>, et seq.;

(q) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of <u>Md. Com. Law Code § 13-101</u>, et seq.;

(r) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, et seq.;

(s) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of <u>Mich. Stat. § 445.901</u>, et seq.;

(t) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 325F.67, et seq.;

(u) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vernon's Mo. Rev. Stat. § 407.010, et seq.;

(v) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code § 30-14-101, et seq.;

(w) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of <u>Neb. Rev. Stat. § 59-1601</u>, et seq.;

(x) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of <u>Nev. Rev. Stat. § 598.0903</u>, et seq.;

 (y) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of <u>N.H. Rev. Stat. § 358-A:1</u>, et seq.;

(z) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of <u>N.J. Stat. Ann. § 56:8-1</u>, et seq.;

(aa) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. Ann. § 57-12-1, et seq.;

(bb) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349, et seq.;

(cc) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, et seq.;

(dd) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of <u>N.D. Cent. Code § 51-15-01</u>, et seq.;

(ee) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of <u>Ohio Rev. Stat. § 1345.01</u>, et seq.;

(ff) Defendants have engaged in unfair competition or unfair or deceptive acts or practices or made representations in violation of Okla. Stat. tit. 15 § 751, et seq.;

(gg) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, et seq.;

(hh) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of <u>73 Pa. Stat. § 201-1</u>, et seq.;

 (ii) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of <u>R.I. Gen. Laws. § 6-13.1-1</u>, et seq.;

 (jj) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of <u>S.C. Code Laws § 39-5-10</u>, et seq.;

(kk) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of <u>S.D. Code Laws § 37-24-1</u>, et seq.;

(ll) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of <u>Tenn. Code § 47-18-101</u>, et seq.;

(mm) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of <u>Tex. Bus. & Com. Code § 17.41</u>, et seq.;

(nn) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of <u>Utah Code Ann. § 13-1 1-1</u>, et seq.;

(oo) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vt. Stat. Ann. tit. 9, § 245 1, et seq.;

(pp) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of <u>Va. Code § 59.1-196</u>, et seq.;

(qq) Defendants have engaged in unfair competition or unfair, deceptive acts or fraudulent acts or practices in violation of <u>Wash. Rev. Code § 19.86.010</u>, et seq.;

(IT) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of <u>W. Va. Code § 46A-6-101</u>, et seq.; (ss) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of <u>Wis. Stat. § 100.20</u>, et seq.; and

(tt) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of <u>Wyo. Stat. § 40-12-100</u>, et seq.

# TENTH CLAIM FOR RELIEF

# GROSS NEGLIGENCE/MALICE

- 87. Plaintiffs hereby incorporate by this reference all other paragraphs of this Complaint as if fully set forth herein at length.
- 88. The wrongs done by the Seroquel Defendants were aggravated by the kind of malice, fraud and reckless disregard for the rights of others, the public and Plaintiffs for which the law allows the imposition of exemplary damages, in that the Seroquel Defendants' conduct:
  - was specifically intended to cause substantial injury to Plaintiffs;
  - when viewed objectively from the Seroquel Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and the Seroquel Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or
  - included a material representation that was false, with the Seroquel Defendants knowing that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that the representation be acted on by Plaintiff. Plaintiff relied on the representation and suffered injury as a proximate result of this reliance.
- 89. Plaintiffs therefore seek exemplary damages in an amount within the jurisdictional limits of the court. Plaintiffs also allege that the acts and omissions of named AstraZeneca, whether taken singularly or in combination with others, constitute gross negligence which proximately caused the injuries to Plaintiffs. In that regard, Plaintiffs seek exemplary damages in an amount that would punish Defendants for their conduct and which would deter other manufacturers from engaging in such misconduct in the future.

90. AstraZeneca's actions, described above, were performed willfully, intentionally, with malice and/or with reckless disregard for the rights of Plaintiffs and the public. At a minimum, AstraZeneca's acts and omissions were (a) specifically intended to cause substantial injury to Plaintiffs and/or (b) when viewed objectively from the standpoint of the Seroquel Defendants at the time of their occurrence, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others. AstraZeneca had actual and subjective awareness of the risk involved but nevertheless proceeded with conscious indifference to the rights, safety or welfare of others, including Plaintiffs. As such, Plaintiffs are entitled to punitive damages against AstraZeneca.

# VII. DAMAGES

- 91. By reason of the foregoing, Plaintiffs, demand judgment for damages against the Seroquel Defendants including compensatory damages, costs of the prosecution of this action, and further, demands trial by jury of all issues so triable, and for such other and further relief as this Court deems just and proper.
- 92. As a direct and proximate result of Plaintiffs ingestion and use of AstraZeneca's defective product, Seroquel, Plaintiffs injuries include, but are not limited to the following damages and seek recovery thereon:
  - 1. Disability:
  - 2. Onset of Stage II Diabetes;
  - Diabetic coma;
  - Past and future emotional distress including, without limitation, justifiable fear of disease;
  - 5. Loss of Enjoyment of Life;
  - 6. Physical and Mental Pain and Suffering;
  - 7. Inconvenience;

- 8. Past and future mental anguish;
- 9. Physical Pain and Suffering;
- 10. Increased risk of debilitating disease;
- 11. Medical Monitoring through their lifetime;
- Plaintiffs' spouses, where named, also seek damages for loss of consortium, services, love and affection;
- 13. Past and future medical expenses;
- 14. Physical impairment; and
- 15. Physical disfigurement.
- 16. Death.

# VIII. WRONGFUL DEATH & SURVIVAL DAMAGES

- 93. In the case where Plaintiffs have suffered a wrongful death due to The Seroquel Defendants' acts and omissions complained of herein, Plaintiffs' heirs and representatives seek compensation for the following general and special damages including, but not limited to, damages for survival and wrongful death claims that Plaintiffs have sustained both in their individual capacity and as personal representatives of the estate:
  - a. The conscious physical pain and suffering sustained by Decedent prior to their death;
  - b. The mental anguish sustained by Decedent prior to their death;
  - c. The physical impairment suffered by Decedent prior to their death;
  - d. The disfigurement suffered by Decedent prior to their death;
  - e. Reasonable and necessary medical expenses incurred by Decedent prior to their death;
  - f. Reasonable funeral and burial expenses incurred by Decedent and their estate;
  - g. Decedent's lost earning capacity;
  - h. The loss of household services, consortium, pecuniary loss, companionship and society which Plaintiffs received from Decedent prior to their last illnesses and death; and

 The mental anguish suffered by Plaintiffs as a consequence of the last illnesses and death of Decedent.

# VIII. PUNITIVE DAMAGES

- 94. Plaintiffs hereby incorporate by this reference all other paragraphs of this Complaint as if fully set forth herein at length.
- 95. At all times relevant hereto, Defendants had actual knowledge of the defective and dangerous nature of Seroquel as set forth herein and continued to design, manufacture, market, promote, distribute and sell it so as to maximize sales and profits at the expense of the public's health and safety and in conscious disregard for the foreseeable serious harm caused by the drug. The Seroquel Defendants' conduct exhibits such an entire want of care as to establish that its actions were a result of fraud, ill will, recklessness, gross negligence, malice and/or willful and intentional disregard for the safety and rights of consumers of its drugs such as Plaintiffs. Plaintiffs therefore seek to recover punitive and exemplary damages to the fullest extent permitted by law.

#### IX. COUNT

### LOSS OF CONSORTIUM

- 96. Plaintiffs hereby incorporate by reference all other paragraphs of this Complaint as if fully set forth and further allege as follows:
- 97. In cases where Plaintiffs were married at the time of their respective injuries, the spouses of such plaintiffs were entitled to their comfort, care, affection, companionship, services, society, advice, guidance, counsel and consortium.
- 98. As a direct and proximate result of one or more of those wrongful acts or omissions of the Defendants described above, Plaintiffs' spouses have been and will be deprived of their

comfort, care, affection, companionship, services, society, advice, guidance, counsel and consortium.

# XI. STATE STATUTORY PRODUCT LIABILITY LAW

99. To the extent any of the states where given plaintiffs reside have statutory product liability law in addition or in lieu of the common law allegations set forth above those plaintiffs hereby plead and incorporate by reference those statutory allegations.

# X. DEMAND FOR JURY TRIAL

100. Plaintiffs hereby demand trial by jury in this action of all issues so triable.

# PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against the Seroquel Defendants as follows:

- (a) compensatory damages on each cause of action;
- (b) punitive damages on all counts as permitted by applicable law;
- (c) awarding reasonable attorneys' fees, expert fees, costs of prosecution and costs of court;
- (d) prejudgment and post-judgment interest at the highest legal rate, and
- (e) granting such additional and further relief as the Court deems just and proper.

Respectfully submitted,

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