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:

    a. 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;

    c. 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;

    d. 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;

e. 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;

i. 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;

l. failed to conduct adequate pre-clinical testing and post-marketing surveillance to determine the safety of Seroquel;

m. 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:

(1) 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

54. 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 off-label 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

61. 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, and were harmed as a result. Plaintiffs 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.