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MERCER COUNTY
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P.O. Box 45029
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Attorney for Plaintiffs

By: Gina M. Betts
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SUPERIOR COURT OF NEW JERSEY
CHANCERY DIVISION
MERCER COUNTY
DOCKET NO. MER-C- 24-11

PAULA T. DOW, Attorney General of the State of
New Jersey, and THOMAS R. CALCAGNI,
Acting Director of the New Jersey Division of
Consumer Affairs,

Plaintiffs,

v.

ASTRAZENECA PHARMACEUTICALS, LP,
and ASTRAZENECA LP.,

Defendant.

Civil Action

COMPLAINT

Plaintiffs Paula T. Dow, Attorney General of the State of New Jersey ("Attorney General"), with offices located at 124 Halsey Street, Fifth Floor, Newark, New Jersey, and Richard J. Hughes Justice Complex, 8th Floor, West Wing, 25 Market Street, Trenton, New Jersey, and Thomas R. Calcagni, Acting Director of the New Jersey Division of Consumer Affairs ("Director"), with offices located at 124 Halsey Street, Seventh Floor, Newark, New Jersey by way of this Complaint state:

PARTIES AND JURISDICTION

1. The Attorney General is charged with the responsibility of enforcing the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1 et seq. (“CFA”), and all regulations promulgated thereunder, N.J.A.C. 13:45A-1.1 et seq. (“CFA Regulations”). The Director is charged with the responsibility of administering the CFA and the CFA Regulations on behalf of the Attorney General.

2. By this action, the Attorney General and Director (collectively, “Plaintiffs”) seek injunctive and other relief for violations of the CFA. Plaintiffs bring this action pursuant to their authority under the CFA, specifically N.J.S.A. 56:8-8, 56:8-11, 56:8-13 and 56:8-19.

3. Defendant Astrazeneca Pharmaceuticals, LP (“AstraZeneca” or “Defendant”) is Delaware Corporation with its principal place of business located at US Corporate Headquarters, AstraZeneca Pharmaceuticals LP, 1800 Concord Pike, Wilmington, Delaware 19897. AstraZeneca transacts business in the State of New Jersey (“New Jersey”) and nationwide by manufacturing, marketing, promoting, selling and distributing prescription drugs, including Seroquel.®

4. Venue is proper in Mercer County, pursuant to R. 4:3-2, because it is a county in which Defendant has advertised and/or conducted business and is a county in which at least one of the parties resides.

BACKGROUND

5. AstraZeneca manufactures, markets, and promotes Seroquel nationally and in New Jersey. Seroquel is a drug classified as an atypical antipsychotic.

6. While some experts hypothesized, as early as 1993, that atypical antipsychotics may reduce some of the side effects that traditional antipsychotics cause, there were early

signs that these drugs, including Seroquel, produced dangerous side effects, including weight gain, hyperglycemia, diabetes, cardiovascular complications and other severe conditions.

7. Seroquel received approval from the U.S. Food and Drug Administration (hereinafter "FDA") for the treatment of manifestations of psychotic disorders, including schizophrenia, on September 26, 1997.

8. FDA narrowed Seroquel's label to "indicated for the treatment of schizophrenia" on March 27, 2001.

ASTRAZENECA'S MARKETING OF SEROQUEL®

9. New Jersey permits physicians to prescribe FDA-approved drugs for conditions or diseases for which FDA approval has not been obtained when, through the exercise of independent professional judgment, the physician determines the drug in question is an appropriate treatment for an individual patient. This practice is referred to as "off-label prescribing."

10. However, pharmaceutical manufacturers may not promote or market their products for any use not specifically approved by the FDA. This practice is known as "off-label marketing."

11. Before late 2009, Seroquel was approved by the FDA only for the treatment of certain conditions in adults, primarily conditions related to schizophrenia and bipolar mania.

12. Despite having narrow FDA approval for adults only, AstraZeneca promoted and marketed the drug for the treatment of a variety of conditions and to a variety of patient populations not included among FDA-approved indications, including for anxiety, depression and post traumatic stress disorder, and to child and geriatric populations.

13. Through this off-label marketing, AstraZeneca aimed to enhance Seroquel's market penetration across a wide range of diagnoses and patient populations.

14. AstraZeneca promoted Seroquel's use in children and adolescents long before establishing that it was safe or effective for any use in this population.

15. AstraZeneca promoted Seroquel to treat dementia and Alzheimer's Disease in the elderly, even though Seroquel has never been approved for the treatment of these conditions and AstraZeneca has not established that Seroquel is safe and effective for these uses.

16. AstraZeneca also masked, withheld or failed to disclose negative information contained in scientific studies concerning the safety and efficacy of Seroquel.

17. AstraZeneca failed to adequately disclose the risks associated with Seroquel's use by, among other things, minimizing the risk of hyperglycemia and diabetes mellitus and failing to communicate important information regarding neuroleptic malignant syndrome, tardive dyskinesia and the risk of bolded cataracts.

COUNT I

VIOLATION OF THE CFA BY DEFENDANT (UNCONSCIONABLE COMMERCIAL PRACTICES AND/OR MISREPRESENTATIONS)

18. Plaintiffs repeat and reallege the allegations contained in paragraphs 1 through 17 as if more fully set forth herein.

19. The CFA prohibits:

The act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise misrepresentation, or the knowing [] concealment, suppression, or omission of any material fact with intent that others rely upon such

concealment, suppression or omission, in connection with the sale or advertisement of any merchandise....

[N.J.S.A. 56:8-2.]

20. At all relevant times, Defendant was engaged in the advertising, soliciting, selling, promoting and distributing of the prescription drug Seroquel® within New Jersey and elsewhere.

21. In so doing, Defendant has engaged in a course of conduct, trade or commerce which constitutes unconscionable commercial practices and/or misrepresentations in violation of the CFA, among other things, by:

- (a) Marketing Seroquel for a number of uses for which it was not approved by the FDA;
- (b) Marketing Seroquel for use in children and adolescents long before establishing that it was safe or effective for any use in this population; and
- (c) Misrepresenting the characteristics, uses, benefits and qualities of Seroquel.

22. Each unconscionable commercial practice and/or misrepresentation by Defendant constitutes a separate violation under the CFA, N.J.S.A. 56:8-2.

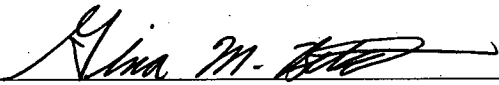
PRAYER FOR RELIEF

WHEREFORE, based upon the foregoing allegations, Plaintiffs respectfully request that the Court enter judgment against Defendant:

- (a) Finding that the acts of Defendant constitute multiple instances of unlawful practices in violation of the CFA, N.J.S.A. 56:8-1 et seq.;
- (b) Permanently enjoining Defendant and its owners, officers, directors, founders, managers, agents, servants, employees, representatives and all other persons or entities under its control, from engaging in, continuing to engage in, or doing any acts or practices in violation of the CFA, N.J.S.A. 56:8-1 et seq., including, but not limited to, the acts and practices alleged in this Complaint;

- (c) Assessing the maximum statutory civil penalties against Defendant for each and every violation of the CFA, in accordance with N.J.S.A. 56:8-13;
- (d) Directing the assessment of costs and fees, including attorneys' fees, against Defendant, for the use of the State of New Jersey, as authorized by the CFA, N.J.S.A. 56:8-11 and 56:8-19; and
- (e) Granting such other relief as the interests of justice may require.

PAULA T. DOW
ATTORNEY GENERAL OF NEW JERSEY
Attorney for Plaintiffs

By: 
Gina M. Betts
Deputy Attorney General
Consumer Fraud Prosecution Section

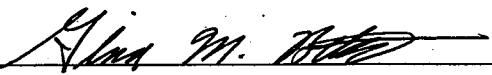
Dated: March 10, 2011
Newark, New Jersey

RULE 4:5-1 CERTIFICATION

I certify to the best of my information and belief that the matter in controversy in this action involving the aforementioned violations of the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1 et seq. ("CFA"), is not the subject of any other action brought by the Attorney General or Director in any other court of this State. I am aware that private actions may have been brought against the Defendant concerning its sale of Seroquel®, but such actions are separate and distinct from this action because private plaintiffs could not seek relief demanded in this action by the Attorney General under the CFA. I further certify that, to the best of my knowledge, the matter in controversy in this action is not the subject of a pending arbitration proceeding in this State, nor is any other action or arbitration proceeding contemplated. I certify that there is no other party who should be joined in this action at this time.

PAULA T. DOW
ATTORNEY GENERAL OF NEW JERSEY
Attorney for Plaintiffs

By: _____

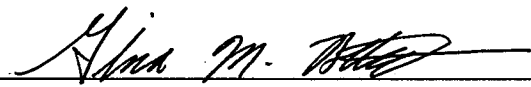

Gina M. Betts
Deputy Attorney General
Consumer Fraud Prosecution Section

Dated: March 10, 2011
Newark, New Jersey

RULE 1:38-7(c) CERTIFICATION OF COMPLIANCE

I certify that confidential personal identifiers have been redacted from documents now submitted to the court, and will be redacted from all documents submitted in the future in accordance with Rule 1:38-7(b).

PAULA T. DOW
ATTORNEY GENERAL OF NEW JERSEY
Attorney for Plaintiffs

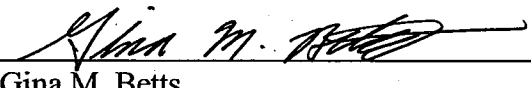
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Newark, New Jersey

DESIGNATION OF TRIAL COUNSEL

Pursuant to R. 4:25-4, Deputy Attorney General Gina M. Betts is hereby designated as trial counsel on behalf of Plaintiffs in this action.

PAULA T. DOW
ATTORNEY GENERAL OF NEW JERSEY
Attorney for Plaintiffs

By: 
Gina M. Betts
Deputy Attorney General
Consumer Fraud Prosecution Section

Dated: March 10, 2011
Newark, New Jersey