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STATE OF NORTH CAROLINA JUSTICE	IN THE GENERAL COURT OF
WAKE COUNTY	SUPERIOR COURT DIVISION.
	FILE NO.
STATE OF NORTH CAROLINA ex rel.) ROY COOPER, ATTORNEY GENERAL,)	
Plaintiff,	COMPLAINT
v .	COMPLAINT
ASTRAZENECA) PHARMACEUTICALS, LP and) ASTRAZENECA LP)	
Defendants.)	
<u>INTRODU</u>	in the second se

Plaintiff State of North Carolina, by and through its Attorney General, brings this action against Defendants ASTRAZENECA PHARMACEUTICALS, LP and ASTRAZENECA LP, Delaware corporations, pursuant to North Carolina's Unfair and Deceptive Trade Practices Act, N.C.G.S. §§ 75-1.1, et seq. Plaintiff seeks a permanent injunction, statutory civil penalties, costs, and other appropriate relief.

PLAINTIFF COMPLAINS OF DEFENDANTS AND ALLEGES AND SAYS AS FOLLOWS:

PARTIES

1. Plaintiff is the State of North Carolina acting on relation of its Attorney General, Roy Cooper, who brings this action pursuant to authority found in Chapters 75 and 114 of the North Carolina General Statutes.

- 2. The State of North Carolina (hereinafter "the State"), by Roy Cooper, Attorney General of the State of North Carolina, is charged, inter alia, with the enforcement of North Carolina's Unfair and Deceptive Trade Practices Act, N.C.G.S. §§ 75-1.1, et seq.
- 3. Defendants ASTRAZENECA PHARMACEUTICALS, LP and ASTRAZENECA LP (hereinafter "AstraZeneca") are Delaware corporations with their principal place of business at US Corporate Headquarters, AstraZeneca Pharmaceuticals LP, 1800 Concord Pike, Wilmington, DE 19897. AstraZeneca transacts business in North Carolina, but not limited to Wake County, and nationwide by manufacturing, marketing, promoting, selling and distributing prescription drugs, including Seroquel[®].

COMMERCE

4. Defendants at all times relative hereto, engaged in trade or commerce in the State of North Carolina, to wit: selling, promoting and distributing Seroquel.

BACKGROUND

- 5. AstraZeneca manufactures, markets, and promotes Seroquel nationally and in North Carolina. 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. North Carolina 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 specific 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 the FDA-approved indications, including for the treatment of anxiety, depression, sleep disorders, 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.

VIOLATIONS OF LAW

- 18. The allegations contained in paragraphs 1-17 are incorporated herein by reference.
- 19. Defendants, in the course of marketing, promoting, selling, and distributing the prescription drug Seroquel have engaged in a course of trade or commerce which constitutes unfair, deceptive, or misleading practices, and is therefore unlawful under N.C.G.S. § 75-1.1 by promoting Seroquel for uses that have not been shown to be safe or effective and by failing to adequately disclose the risks associated with Seroquel's use.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiff prays for the following relief:

A. That this Court issue a permanent injunction, pursuant to N.C.G.S. § 75-14, prohibiting Defendants, its agents, employees, and all other persons and entities, corporate or otherwise, in active concert or participation with any of them, from engaging in unfair, deceptive or misleading conduct;

B. That this Court fashion equitable relief to cure Defendants' deceptive practices;

C. That this Court order Defendants to pay all costs for the prosecution and investigation of this action, as provided by N.C.G.S. § 75-16.1; and

D. That this Court grant such other and further relief as the Court deems just and proper.

This the 10th day of March, 2011.

ROY COOPER Attorney General

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