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8 **STATE OF WASHINGTON  
KING COUNTY SUPERIOR COURT**

9 STATE OF WASHINGTON,

NO.

10 Plaintiff,

COMPLAINT FOR INJUNCTIVE  
AND OTHER RELIEF

11 v.

12 ASTRAZENECA  
13 PHARMACEUTICALS LP and  
ASTRAZENECA LP,

14 Defendant.

15 Plaintiff, STATE OF WASHINGTON, by ROBERT McKENNA, Attorney General of  
16 Washington and ROBERT LIPSON, Senior Counsel, brings this action complaining of  
17 Defendant ASTRAZENECA PHARMACEUTICALS, LP, a Delaware corporation, and  
18 ASTRAZENECA LP, a Delaware corporation, for violating the Washington Consumer  
19 Protection Act, RCW 19.86 *et seq.* as follows:

20 **I. JURISDICTION AND VENUE**

21 1.1 This action is brought for and on behalf of the STATE OF WASHINGTON, by  
22 ROBERT McKENNA, Attorney General of Washington and ROBERT LIPSON, Senior  
23 Counsel, pursuant to the provisions of the Washington Consumer Protection Act, RCW 19.86  
24 *et seq.*



#### IV. BACKGROUND

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2 4.1 AstraZeneca manufactures, markets, and promotes Seroquel nationally and in  
3 Washington. Seroquel is a drug classified as an atypical antipsychotic.

4 4.2 While some experts hypothesized, as early as 1993, that atypical antipsychotics  
5 may reduce some of the side effects that traditional antipsychotics cause, there were early signs  
6 that these drugs, including Seroquel, produced dangerous side effects, including weight gain,  
7 hyperglycemia, diabetes, cardiovascular complications and other severe conditions.

8 4.3 Seroquel received approval from the U.S. Food and Drug Administration  
9 (hereinafter "FDA"), for the treatment of manifestations of psychotic disorders, including  
10 schizophrenia, on September 26, 1997.

11 4.4 FDA narrowed Seroquel's label to "indicated for the treatment of  
12 schizophrenia" on March 27, 2001.

#### V. ASTRAZENECA'S MARKETING OF SEROQUEL

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14 5.1 Washington permits physicians to prescribe FDA-approved drugs for conditions  
15 or diseases for which FDA approval has not been obtained when, through the exercise of  
16 independent professional judgment, the physician determines the drug in question is an  
17 appropriate treatment for an individual patient. This practice is referred to as "off-label  
18 prescribing."

19 5.2 However, pharmaceutical manufacturers may not promote or market their  
20 products for any use not specifically approved by the FDA. This practice is known as "off-  
21 label marketing."

22 5.3 Before late 2009, Seroquel was approved by the FDA only for the treatment of  
23 certain specific conditions in adults, primarily conditions related to Schizophrenia and Bipolar  
24 Mania.

25 5.4 Despite having narrow FDA approval for adults only, AstraZeneca promoted  
26 and marketed the drug for the treatment of a variety of conditions and to a variety of patient

1 populations not included among the FDA-approved indications, including for the treatment of  
2 anxiety, depression, sleep disorders, and post traumatic stress disorder, and to child and  
3 geriatric populations.

4 5.5 Through this off-label marketing, AstraZeneca aimed to enhance Seroquel's  
5 market penetration across a wide range of diagnoses and patient populations.

6 5.6 AstraZeneca promoted Seroquel's use in children and adolescents long before  
7 establishing that it was safe or effective for any use in this population.

8 5.7 AstraZeneca promoted Seroquel to treat dementia and Alzheimer's Disease in  
9 the elderly even though Seroquel has never been approved for the treatment of these conditions  
10 and AstraZeneca has not established that Seroquel is safe and effective for these uses.

11 5.8 AstraZeneca also masked, withheld, or failed to disclose negative information  
12 contained in scientific studies concerning the safety and efficacy of Seroquel.

13 5.9 AstraZeneca failed to adequately disclose the risks associated with Seroquel's  
14 use by, among other things, minimizing the risk of hyperglycemia and diabetes mellitus and  
15 failing to communicate important information regarding neuroleptic malignant syndrome,  
16 tardive dyskinesia, and the risk of bolded cataracts.

## 17 VI. APPLICABLE STATUTES

18 6.1 AstraZeneca's actions with respect to the marketing and promotion of Seroquel as  
19 outlined in Section V above constitute unfair or deceptive trade practices in violation of  
20 RCW 19.86.020, the Washington Consumer Protection Act.

## 21 VII. PRAYER FOR RELIEF

22 WHEREFORE, the State of Washington respectfully request that this honorable Court  
23 enter an order:

24 7.1 Issuing a permanent injunction prohibiting Defendant, its agents, employees, and  
25 all other persons and entities, corporate or otherwise, in active concert or participation with any of  
26 them, from engaging in unfair, deceptive or misleading conduct;

