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AstraZeneca Is Accused Over Seroquel

By JONATHAN D. ROCKOFF

Plaintiffs lawyers in lawsuits against AstraZeneca PLC plan to hold a news conference Wednesday to release documents they say show executives at the drug maker discussed promoting the antipsychotic drug Seroquel for unapproved uses in children and the elderly.

The documents, which include a public-relations blueprint, strategic plan and other materials, were produced by AstraZeneca during pretrial proceedings in thousands of lawsuits against the company that have been consolidated in U.S. District Court in Orlando, Fla.

Doctors are free to prescribe Food and Drug Administration-approved medications in any way they see fit, but drug makers aren't allowed to promote them for unapproved, or off-label, uses.

There is no evidence the British drug maker actually marketed Seroquel for off-label purposes, and AstraZeneca denies even discussing doing so.

Seroquel, which generated \$800 million in U.S. sales in the first quarter this year, was first approved in the U.S. in 1997 for treating symptoms of psychotic disorders. In 2001, it was designated as a schizophrenia treatment. The FDA extended its use in 2004 to treating bipolar mania and in 2006 to treating bipolar disorder. It hasn't been approved for children or adolescents.

The documents, which were reviewed by The Wall Street Journal, were written by AstraZeneca employees, as well as a consulting firm that plaintiffs lawyers say the company hired. The documents cited plans to "broaden Seroquel use on and off-label," including among adolescents and patients with Parkinson's and Alzheimer's disease, at medical meetings, in sales calls and with patient-advocacy groups.

Tony Jewell, a spokesman for AstraZeneca, denied that the company sought to encourage off-label uses of the drug. "These documents do not advocate the inappropriate promotion of Seroquel," he said. Instead, they "show the company was seeking to explore additional indications for Seroquel and included that in clinical-development plans designed to support efforts to investigate potential additional indications," he added.

In an AstraZeneca public-relations plan dated 2001, one company objective was defined as to "encourage and support" Seroquel's "use outside schizophrenia into a broad range of other patient populations including bipolar disorder and the elderly." The document also said there needed to be "aggressive market penetration" among adolescents, the elderly, patients with bipolar disorder and other groups for Seroquel to grow faster than rivals.

AstraZeneca is currently seeking FDA approval to market the drug for schizophrenia in adolescents and acute treatment of bipolar mania in children and adolescents.

Including those consolidated in Orlando, AstraZeneca says it faces nearly 10,000 lawsuits brought by patients who allege that Seroquel caused diabetes and other health problems. Some of the suits don't involve allegations that AstraZeneca promoted Seroquel for off-label uses. They center instead on claims that the drug had serious side effects the company concealed. AstraZeneca dismisses those allegations as "unproven," pointing to the dismissal of the first

two of those cases to be tried.

The next trial is set to begin in June in Delaware state court, the company reported in a securities filing this month.

Several drug makers have come under fire for allegedly promoting off-label uses of their drugs and have reached settlements with state and federal authorities. In January, [Eli Lilly & Co.](#) agreed to pay \$1.42 billion for alleged off-label promotion of Zyprexa, a Seroquel rival.

Zyprexa and Seroquel both belong to a class of drugs called atypical antipsychotics, which analysts say is widely prescribed off-label. Like its competitors, Seroquel is marketed as a safer alternative to older drugs that caused involuntary tics, heart problems and other side effects.

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