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State suit targets AstraZeneca over antipsychotic medicine

BY CAROLYNE PARK ARKANSAS DEMOCRAT-GAZETTE

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LITTLE ROCK — Arkansas Attorney General Dustin McDaniel filed suit

Tuesday against drug manufacturer AstraZeneca claiming the company encouraged doctors to prescribe a dangerous drug to children and the elderly for uses beyond its federal approval, harming patients and costing the state millions of dollars.

The suit filed in Pulaski County Circuit Court claims London-based AstraZeneca PLC and four of its related companies in the U.S. and abroad misled doctors and the public to increase sales of the antipsychotic drug Seroquel, even though the company knew people taking it were at risk of injury, disease and sickness.

AstraZeneca is the last of three major drug companies the state is suing with claims they illegally marketed the antipsychotic drugs Zyprexa, Risperdal and Seroquel to be paid for by the state Medicaid and employee health-insurance programs.

McDaniel filed suit against Titusville, N.J.-based Janssen Pharmaceutica of Johnson & Johnson Inc., in November 2006 and Eli Lilly & Co. of Indianapolis on May 1. McDaniel's office is working on the cases with the help of private firm Bailey Perrin Bailey LLP of Houston, which is handling similar suits in at least six other states.

"We want to send a message that these pharmaceutical companies need to walk a straightline when they're dealing with Arkansas and other states because the health and safety of consumers across this country depend on that," said Justin Allen, chief deputy attorney general.

Arkansas is one of several states, including Pennsylvania, Connecticut and South Carolina, suing the companies in hopes of recouping Medicaid payments for the drugs and for treatment of patients who suffered ill effects after taking them.

Eli Lilly settled its case with Alaska in the midst of a jury trial in March for \$15 million.

AstraZeneca spokesman Jim Minnick said Tuesday the company couldn't comment about Arkansas' lawsuit because officials had not been notified of its filing or had a chance to review it.

"Seroquel has helped millions of people suffering from mental illness and has made a meaningful difference in their lives," Minnick said.

Seroquel was approved by the U.S. Food and Drug Administration for treatment of adults with schizophrenia in September 1997. In 2004 it was approved for treatment of adults with acute mania and in 2006 for major depressive episodes associated with bipolar disorder.

Aside from its approved uses, the lawsuit claims the company also marketed the drug for nonmedically necessary uses including sleeplessness, attention deficit-hyperactivity disorder, depression, anxiety, mood disorder, and aggression associated with late-onset dementia.

Seroquel is an atypical antipsychotic, also known as second generation antipsychotics. Such drugs first came on the market in the 1990s as an alternative to "typical" antipsychotics, which cause physical problems, such as spasms or involuntary movement, according to the lawsuit.

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Today atypical antipsychotics account for more than 90 percent of all drugs prescribed for psychiatric purposes, regardless of whether they are approved for those indications.

Seroquel is the fastest-growing atypical antipsychotic in terms of sales, according to the lawsuit.

AstraZeneca failed to properly warn consumers that the drug had the potential to cause diabetes, stroke, pancreatitis, seizures and other illnesses, according to the lawsuit. The FDA reprimanded AstraZeneca in May 1999 and October 2006 for giving misleading information about the drug.

Allen said the state Medicaid program spent about \$200 million on Zyprexa, Risperdal and Seroquel since they came onto the market.

"We believe that the evidence will bear out that a largemajority of that \$200 million was improperly paid for improper prescriptions of those drugs - not based on the fault of the physicians, but based on the off-label marketing efforts of the companies in pushing those drugs to be given to people to whom they shouldn't be given," Allen said.

According to the lawsuit, AstraZeneca violated several state laws by engaging in "a protracted and willful course of corporate misconduct and misrepresentation."

The state is charging Astra-Zeneca with eight counts including Medicaid fraud, which entitles the state to triple damages, and violation of the Arkansas Deceptive Trade Practices Act, for which the state could receive up to \$10,000 for each of "many, many violations," he said.

"Several hundred million webelieve the state could ultimately prove up in damages in trial," Allen said.

Allen said the AstraZeneca filing was delayed because attorneys for the company contacted the state about the case but "that dialogue recently came to a close."

"There were discussions of the issues," Allen said "It's safe to say that given that we're filing suit, certainly no resolution was reached."

Eli Lilly has until early June to respond to Arkansas' lawsuit.

Janssen attempted to move its case with the state to federal court, but it was remanded back to state court about a month ago, Allen said. The case is now undergoing discovery as the company and state exchange information and documents.

It will be at least a year before any of the cases go to trial, Allen said. A trial is expected to take six to eight weeks.

"This is not going to be a quick process. It's going to take time and a lot of work by this office and this office's lawyers, but we're hopeful it will reveal some bad improper behavior by these companies that was injurious not only to the Medicaid program, but potentially to consumers in Arkansas," Allen said.

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