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For \$520 Million, AstraZeneca Settles Case Over Marketing of a Drug

By **DUFF WILSON**

AstraZeneca has completed a deal to pay \$520 million to settle federal investigations into marketing practices for its blockbuster [schizophrenia](#) drug, Seroquel, the Attorney General, [Eric Holder](#), said at a news conference Tuesday afternoon.

"AstraZeneca paid kickbacks to doctors as part of an illegal scheme to market drugs for unapproved uses," [Kathleen Sebelius](#), secretary of health and human services, said at the event in Washington. She said the company promoted drugs for unapproved uses by children, the elderly, veterans and prisoners.

Glenn Engemann, AstraZeneca's U.S. general counsel, released a statement saying the company denies the allegations but settled the investigation with the payment.

"It is in the best interest of AstraZeneca to resolve these matters and to move forward with our business of discovering and developing important, life-changing medicines — while avoiding the delay, uncertainty, and expense of protracted litigation," Mr. Engemann said.

AstraZeneca becomes the fourth pharmaceutical giant in the last three years to pay to settle federal investigations into illegal marketing of antipsychotic drugs, a lucrative category of medications that have quickly risen to the top of United States sales charts.

AstraZeneca agreed to sign a corporate integrity agreement with the federal government over its marketing of Seroquel for unapproved uses, but will not face criminal charges, company and federal officials said.

The company, based in London, has been accused of misleading doctors and patients by playing up favorable research and not adequately disclosing studies that show Seroquel increases the risk of [diabetes](#).

AstraZeneca still faces more than 25,000 civil lawsuits filed on behalf of patients contending that the company did not disclose the drug's risks.

The deal would make formal an [agreement in principle](#) the company reached last October with the United States attorney in Philadelphia. At that time, AstraZeneca said in a filing with the [Securities and Exchange Commission](#) that it had set aside \$520 million in respect to the investigation.

The company was facing two federal investigations and two whistle-blower lawsuits involving Seroquel sales and marketing practices. One of the investigations related to physicians who had participated in clinical trials. The other inquiry involved sales staff.

As a result of aggressive marketing, Seroquel has been increasingly used for children and elderly people for indications not approved by the [Food and Drug Administration](#). The drugs have caused rapid weight gain in children, and side effects including deaths have prompted warnings against giving the drugs to elderly patients for [dementia](#).

Although doctors are permitted to prescribe any approved drug for off-label uses, it is illegal for drug makers to promote medications for any purpose not specifically approved by the F.D.A.

AstraZeneca, which reported \$4.9 billion in Seroquel sales in 2009, plans to report its first-quarter financial results on Thursday.

The company will join a series of American pharmaceutical companies that have paid to settle federal investigations into illegal marketing.

In the largest such case, [Pfizer](#) paid \$2.3 billion last September, including \$1.3 billion in the biggest criminal fine of any type in United States history, for off-label marketing of the painkiller [Bextra](#) and other drugs. Bextra was withdrawn from the market in 2005. The Pfizer fine included \$301 million for off-label marketing of its antipsychotic drug Geodon.

[Eli Lilly](#) paid \$1.4 billion in January 2009 to settle investigations into illegal marketing of its

antipsychotic drug Zyprexa. Lilly's settlement included a \$515 million criminal fine, which until the Pfizer case was the largest such fine ever imposed on a corporation.

In 2007, [Bristol-Myers Squibb](#) and a subsidiary paid \$515 million to settle federal and state investigations into marketing of its antipsychotic drug Abilify.

The newer generation of antipsychotics has surpassed [cholesterol](#)-lowering drugs to become the nation's top-selling category of medications, accounting for \$14.6 billion of the nation's \$300 billion in drug spending last year, according to the research firm IMS Health.

Seroquel, a pill usually taken once or twice a day that sells for more than \$4 each, was the fifth-best-selling drug in the United States last year, IMS said. As with other antipsychotics, much of that spending is by the federal government, through the [Medicaid](#) and [Medicare](#) programs.

AstraZeneca, with American headquarters in Wilmington, Del., has previously denied wrongdoing in the Seroquel investigations. It has paid \$656 million to defend itself in court against more than 25,000 civil lawsuits, the company said in an S.E.C. filing in January. Those cases are only recently beginning to reach trial.

The company has argued that people who were found to have diabetes after taking Seroquel already had diabetes or had existing conditions that made them at high risk of the disease.

According to company e-mail messages unsealed in civil lawsuits, AstraZeneca "buried" — a manager's term — a 1997 study that showed Seroquel users gained 11 pounds a year, while publicizing a study that asserted users lost weight. Company e-mail messages also refer to doing a "great smoke-and-mirrors job" on unfavorable studies.

Gardiner Harris contributed reporting.