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Whistleblower Suits Against AstraZeneca Settle for \$520 Mil.

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Drug maker AstraZeneca has agreed to pay \$520 million to settle whistleblower lawsuits filed in federal court in Philadelphia that accused the company of engaging in illegal tactics — including kickbacks to doctors — to promote so-called “off-label” uses for one of its drugs.

The drug, Seroquel, is an anti-psychotic that was approved by the Food and Drug Administration only for narrow uses, such as combating schizophrenia or acute manic episodes in those with bipolar disorder. But prosecutors said AstraZeneca set out to market the drug directly to doctors for a wider range of ailments including Alzheimer’s disease, anger management, depression and sleeplessness.

Among the alleged illegal tactics AstraZeneca used, the suits alleged, were

payments to doctors to pose as authors of articles written by the company, or to deliver lectures encouraging unapproved uses of the drug.

The settlement, announced in Washington, D.C., is the largest amount ever paid by a company in a civil-only settlement of off-label marketing claims. The federal government will receive \$302 million, and states will share up to \$218 million.

“People have a legal right to know that pharmaceutical companies are marketing their drugs only for uses approved by the FDA and that their doctors’ judgment has not been affected by misinformation from a pharmaceutical company trying to boost revenues,” U.S. Attorney Michael L. Levy said.

“When pharmaceutical companies interfere with the FDA’s mission to ensure that drugs are safe and effective, they undermine the doctor-patient relationship and put the health

and safety of patients at risk,” Levy said.

For attorneys Stephen A. Sheller and Brian J. McCormick Jr. of Sheller PC in Philadelphia, the settlement marks the third time in the past 15 months that they have represented a leading whistleblower in a massive pharmaceutical fraud settlement.

Sheller represented whistleblowers in January 2009, when Eli Lilly paid more than \$1.4 billion to settle claims over improper marketing of Zyprexa, and again in September 2009, when Pfizer paid more than \$2.3 billion to settle claims stemming from the marketing of four of its drugs.

In the AstraZeneca case, Sheller’s client,



SHELLER

James Wetta, will be paid a \$45 million reward for his work in exposing the company’s alleged frauds. Serving as co-counsel with Sheller were attorneys Michael Mustokoff, Mark Lipowicz and Teresa Cavenagh of Duane Morris.

Mustokoff said that a second whistleblower, whose suit was filed two years later than Wetta’s, will share in the reward money. Typically, Mustokoff said, the Justice Department strikes a deal with the “first-filer” and encourages settlement with any subsequent filers whose cases are deemed to have contributed to the investigation.

For the U.S. Attorney’s Office in Philadelphia, too, the AstraZeneca settlement caps a string of massive civil settlements in pharmaceutical fraud cases, with Assistant U.S. Attorneys Virginia A. Gibson, the former civil division chief who now serves as first

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assistant, and Margaret L. Hutchinson, the current chief of the civil division, overseeing the investigations.

In the AstraZeneca case, prosecutors alleged that the Wilmington, Del.-based company used illegal tactics to market Seroquel.

In September 2000, the FDA proposed

narrowing the approval for Seroquel to the short-term treatment of schizophrenia only. In January 2004, the FDA approved Seroquel for short-term treatment of acute manic episodes associated with bipolar disorder, and later approved Seroquel for bipolar depression.

But the whistleblower suits alleged that AstraZeneca sales reps were pressing doctors to use the drug for a wide range of less serious disorders and maladies, including aggression, Alzheimer's disease, anger management, anxiety, attention deficit

hyperactivity disorder, bipolar maintenance, dementia, depression, mood disorder, post-traumatic stress disorder and sleeplessness.

Promoting such off-label uses amounts to fraud under the False Claims Act, the suits alleged, because the unapproved uses were not medically accepted indications for which the federal and state Medicaid programs provided coverage for Seroquel.

According to the settlement agreement, AstraZeneca targeted its illegal marketing of Seroquel toward doctors who do not

typically treat schizophrenia or bipolar disorder, such as physicians who treat the elderly, primary care physicians, pediatric and adolescent physicians, and in long-term care facilities and prisons.

Prosecutors also said AstraZeneca violated the federal Anti-Kickback Statute by offering and paying illegal remuneration to doctors it recruited to serve as authors of articles written by AstraZeneca and its agents about the unapproved uses of Seroquel.

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AstraZeneca also offered and paid illegal

remuneration to doctors to travel to resort locations to "advise" AstraZeneca about marketing messages for unapproved uses of Seroquel, and paid doctors to give promotional lectures to other health care professionals about unapproved and unaccepted

uses of Seroquel, prosecutors said.

Under the terms of the settlement agreement, AstraZeneca denied the allegations but agreed to enter into a corporate integrity agreement with the Office of Inspector General of the U.S. Department

of Health and Human Services. The corporate integrity agreement will be in effect for five years.

AstraZeneca was represented in the settlement by attorney John C. Dodds of Morgan Lewis & Bockius.