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**PHARMACEUTICAL COMPANY ASTRAZENECA TO PAY
\$520 MILLION FOR OFF-LABEL DRUG MARKETING**

WASHINGTON – The Department of Justice today announced a \$520 million civil settlement with pharmaceutical company AstraZeneca LP and AstraZeneca Pharmaceuticals, LP (AstraZeneca) to resolve allegations made under the civil False Claims Act that AstraZeneca illegally marketed the anti-psychotic drug Seroquel for uses not approved as safe and effective by the Food and Drug Administration (FDA). Such unapproved uses are also known as “off-label” uses because they are not included in the drug’s FDA approved product label.

United States Attorney General Eric Holder, Assistant Attorney General for the Civil Division Tony West, and United States Attorney Michael L. Levy of the Eastern District of Pennsylvania announced the settlement today. They were joined by Special Agent-in-Charge Nick DiGiulio of the Office of Inspector General of the Department of Health and Human Services.

AstraZeneca, headquartered in Wilmington, Delaware, signed a civil settlement to resolve allegations that by marketing Seroquel for unapproved uses, the company caused false claims for payment to be submitted to federal insurance programs including Medicaid, Medicare, and TRICARE programs, and to the Department of Veterans Affairs, the Federal Employee Health Benefits Program, and the Bureau of Prisons.

The civil settlement agreement provides that AstraZeneca will pay up to \$520 million to the federal government and the states to resolve civil allegations originally brought in a lawsuit under the *qui tam* provisions of the federal False Claims Act and various state False Claims Act statutes. The federal government will receive \$301,907,007 from the civil settlement. The state Medicaid programs and the District of Columbia will share up to \$218,092,993 of the civil settlement, depending on the number of states that participate in the settlement.

Under the Food, Drug, and Cosmetic Act, a company must specify the intended uses of a product in its new drug application to the FDA. Before approving a drug, the FDA must determine that the drug is safe and effective for the use proposed by the company. Once approved, the drug may not be marketed or promoted for off-label uses.

The FDA originally approved Seroquel, also known by the chemical name quetiapine, in September 1997 for the treatment of manifestations of psychotic disorders. In September 2000, 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 (bipolar mania). In October 2006, the FDA approved Seroquel for bipolar depression.

The United States alleges that AstraZeneca illegally marketed Seroquel for uses never approved by the FDA. Specifically, between January 2001 through December 2006, AstraZeneca promoted Seroquel to psychiatrists and other physicians for certain uses that were not approved by the FDA as safe and effective (including aggression, Alzheimer's disease, anger management, anxiety, attention deficit hyperactivity disorder, bipolar maintenance, dementia, depression, mood disorder, post-traumatic stress disorder, and sleeplessness) ("unapproved uses"). These unapproved uses were not medically accepted indications for which the United States and the state Medicaid programs provided coverage for Seroquel.

According to the Settlement Agreement, AstraZeneca targeted its illegal marketing of the anti-psychotic Seroquel towards 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.

In March 2006, AstraZeneca brought certain conduct to the attention of the government and then cooperated in the investigation of the allegations being settled today.

The United States contends that AstraZeneca promoted the unapproved uses by improperly and unduly influencing the content of, and speakers, in company-sponsored Continuing Medical Education programs. The company also engaged doctors to give promotional speaker programs on unapproved uses for Seroquel and to conduct studies on unapproved uses of Seroquel. In addition, the company recruited doctors to serve as authors of articles that were ghostwritten by medical literature companies and about studies the doctors in question did not conduct. AstraZeneca then used those studies and articles as the basis for promotional messages about unapproved uses of Seroquel.

The United States also contends that 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. 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. The United States contends that these payments were intended to induce the doctors to prescribe Seroquel for unapproved uses in violation of the Federal Anti-Kickback Statute.

“Illegal acts by pharmaceutical companies and false claims against Medicare and Medicaid can put the public health at risk, corrupt medical decisions by health care providers, and take billions of dollars directly out of taxpayers’ pockets,” said Attorney General Eric Holder. “This Administration is committed to recovering taxpayer money lost to health care fraud, whether it’s by bringing cases against common criminals operating out of vacant storefronts or executives at some of the nation’s biggest companies.”

“Rooting out health care fraud is a top priority for the Obama Administration, said Kathleen Sebelius, Secretary of the Department of Health and Human Services. “Today’s settlement sends a clear warning to any individual or company seeking to defraud our health care system and returns hundreds of millions of dollars of taxpayer money to the Medicare trust fund where they belong. It reflects the unprecedented energy, resources, and new ideas that this administration has devoted to identifying, prosecuting, and ultimately preventing health care fraud. With the new anti-healthcare fraud resources in the Affordable Care Act, there has never been a worse time to try to steal from our health care system.”

“Consumers are entitled to rely on the claims pharmaceutical companies make about the drugs they sell,” said Tony West, Assistant Attorney General for the Civil Division of the Department of Justice. “Working with our federal and state partners, we will protect the integrity of our public health programs by ensuring that kickbacks from drug companies do not taint the medical decisions of health care professionals.”

“When pharmaceutical companies interfere with the FDA’s mission to insure that drugs are safe and effective, they undermine the doctor-patient relationship and put the health and safety of patients at risk,” said Levy. “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.”

In addition to the civil settlement agreement, resolution of the matter includes a Corporate Integrity Agreement (CIA) between AstraZeneca and the Office of Inspector General of the Department of Health and Human Services. The five-year CIA requires, among other things, that a Board of Directors committee annually review the company’s compliance program and certify its effectiveness; that certain managers annually certify that their departments or functional areas are compliant; that AstraZeneca send doctors a letter notifying them about the settlement; and that the company post on its website information about payments to doctors, such as honoraria, travel or lodging. AstraZeneca is subject to exclusion from Federal health care programs, including Medicare and Medicaid, for a material breach of the CIA and subject to monetary penalties for less significant breaches.

“As a result of this Corporate Integrity Agreement, the actions of AstraZeneca will be more transparent, its Board of Directors held more accountable, and the names of physicians

receiving payments will be disclosed -- all leading to better protection for patients,” said Department of Health and Human Services Inspector General Daniel R. Levinson.

“Today’s disclosures should send a clear message to those doing business with the Government that they will be held accountable for their decisions and actions that have an adverse impact on health care programs, such as Medicare and Medicaid,” said Special Agent-in-Charge Nicholas DiGiulio, HHS, Office of Inspector General, Office of Investigations. “Our office is committed to pursuing those companies and individuals who choose to put profits ahead of the law.”

The government’s investigation was triggered by a whistleblower lawsuit filed under the FCA’s *qui tam* provisions in the Eastern District of Pennsylvania. As part of today’s resolution, James Wetta, the whistleblower in that action, will receive more than \$45 million from the federal share of the civil recovery.

The civil settlement was reached by First Assistant U.S. Attorney Virginia Gibson and Assistant U.S. Attorney Colin Cherico of the United State’s Office for the Eastern District of Pennsylvania and the Commercial Litigation Branch of the Justice Department’s Civil Division. This investigation was conducted by the Department of Health and Human Services Office of Inspector General, U.S. Postal Service’s Office of Inspector General and the FDA’s Office of Criminal Investigations. Assistance was provided by representatives of FDA’s Office of Chief Counsel and the National Association of Medicaid Fraud Control Units.

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