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FOR IMMEDIATE RELEASE
WEDNESDAY JUNE 4, 2008
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WALGREENS TO PAY $35 MILLION TO UNITED STATES, 42 STATES AND PUERTO RICO TO SETTLE MEDICAID PRESCRIPTION DRUG FRAUD CLAIMS

CHICAGO – The United States, 42 states and Puerto Rico will receive $35 million from Walgreen Co., of Deerfield, Illinois, to settle Medicaid prescription-drug-fraud claims initiated by a whistleblower, federal and state officials announced today. Walgreens, a nationwide pharmacy chain with more than 5,000 stores in 48 states and Puerto Rico, allegedly substituted different versions of prescribed drugs (such as tablets for capsules) solely to significantly increase the cost and profit rather than for any legitimate medical reason. The settlement covers Walgreens' submission of reimbursement claims to Medicaid programs in 42 states and Puerto Rico for three prescription drugs from July 2001 through 2005: Ranitidine (generic Zantac), Fluoxetine (generic Prozac) and Eldepryl or Selegiline (generic Eldepryl).

The settlement, which was filed today in U.S. District Court in Chicago, was announced by Patrick J. Fitzgerald, United States Attorney for the Northern District of Illinois; Daniel R. Levinson, Inspector General, U.S. Department of Health and Human Services; Michael Cleary, Special Agent-in-Charge of the U.S. Food and Drug Administration, Office of Criminal Investigations, in Chicago;

and Robert D. Grant, Special Agent-in-Charge of the Chicago Office of the Federal Bureau of Investigation. The whistleblower lawsuit that initiated the case was unsealed at the same time.

The settlement with Walgreens is similar to previous settlements with CVS Caremark Corp., which agreed to pay $36.7 million in March of this year, and a $49.5 million settlement with Omnicare, Inc., that was reached in November 2006.

During the investigation, the United States Attorney's Office joined forces with the National Association of Medicaid Fraud Control Units (NAMFCU), to conduct a joint health care fraud investigation. NAMFCU is an organization of 49 state Medicaid Fraud Control Units and provides a forum for sharing information and improving the quality of investigations

"Switching between tablets and capsules to deliver medications might seem harmless, but when that is done solely to increase profit and in violation of federal and state regulations that are designed to protect patients, pharmacies must know that they are subjecting themselves to the possibility of triple damages, civil penalties and legal fees," Mr. Fitzgerald said. "These significant penalties, combined with the willingness of insiders to report fraud, should deter such misconduct, but when it doesn't, companies that manipulate the system should know that we will aggressively pursue all available legal remedies."

Inspector General Levinson, of HHS, said: "The Office of Inspector General is committed to working with our state and federal partners to fight prescription drug fraud." Noting that the Corporate Integrity Agreement with Walgreens includes comprehensive oversight of the company's federal health care program business, he added "let this serve as a reminder of our priority to investigate and prevent illegal schemes that abuse Medicaid programs at the expense of taxpayers and vulnerable recipients."

The officials noted that Walgreens did not admit liability as part of the settlement.

Under the agreement, within 10 business days Walgreens will pay the United States $18,584,972.62 as the federal share of settlement and it will pay a total of $16,415,027.37 to be apportioned among the participating state Medicaid programs. Separate settlement agreements establish the amounts owed to each state. The State of Illinois, for example, will receive approximately $1.25 million.

The only states not participating in the settlement are Alaska, California, Delaware, Hawaii, Maine, North Dakota, Vermont and West Virginia, as well as the District of Columbia.

The universal federal settlement covers allegations that, for each of the three drugs, Walgreens improperly switched Medicaid patients from a cheaper version of the drug to a more expensive version solely to increase its reimbursement rate. Medicaid patients who were prescribed 150 mg or 300 mg tablets of Ranitidine were switched instead to more expensive capsules; prescriptions for 10 mg or 20 mg capsules of Fluoxetine were switched to more expensive tablets; and prescriptions for 5 mg tablets of Eldepryl were switched to more expensive capsules.

While capsules and tablets generally function in the same way when they enter the body, both federal Food and Drug Administration law and state statutes provide that the different dosage forms of the same compound are not considered the same. Therefore, pharmacists cannot switch customers between capsule and tablet forms of a medication without a direct order from a physician. State and federal regulations permit a pharmacist to switch between medications (such as from a name brand to a similarly formulated, equally effective generic drug) for a Medicaid beneficiary only if two conditions are met: first, that the replacement drug is considered therapeutically and pharmaceutically equivalent, and secondly, that the unit price for the replacement drug is *less* than the unit price for the medication originally prescribed.

Medicaid is a joint federal–state program that provides health care benefits for certain groups, primarily low-income and disabled persons. The federal involvement in Medicaid includes providing matching funds and ensuring that states comply with minimum standards in the administration of the program. The federal share of states' Medicaid payments, known as the Federal Medical Assistance Percentage (FMAP), is based on each individual state's per capita income compared to the national average. Among the states, the FMAP is at least 50 percent, and in some instances, as high as 83 percent. In Illinois, the FMAP or federal share is 50 percent.

As part of the settlement, Walgreens has also entered into a compliance agreement with the Department of Health and Human Services that is designed to prevent this type of drug switch in the future. The compliance agreement will be in effect for five years.

The individual, or so-called "relator," who initiated the case by filing his own separate lawsuit, will receive a share of the settlement from both the United States and the states that have their own whistleblower statutes. Relator Bernard Lisitza will receive a total of just over $5 million, comprised of $3,159,445 as his share of the federal settlement and $1,844,377 from the state settlements.

Mr. Lisitza, a licensed pharmacist, is represented by Michael Behn, of Behn & Wyetzner, Chartered, in Chicago.

The United States was represented by Assistant United States Attorney Linda A. Wawzenski, deputy chief of the U.S. Attorney's Office Civil Division. Walgreens was represented by Frederick Robinson, of Fulbright & Jaworski.

The case is *United States et al., ex rel. Bernard Lisitza v. Walgreen Co.* , 03 C 744 (N.D. Il.).

Under the federal False Claims Act, defendants may be liable for triple the amount of actual damages and civil penalties between $5,500 and $11,000 for each violation. Individual whistleblowers may be eligible to receive between 15 and 30 percent of the amount of any recovery.

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