United States Attorney Northern District of Illinois

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FOR IMMEDIATE RELEASE TUESDAY NOVEMBER 14, 2006 www.usdoj.gov/usao/iln PRESS CONTACTS: AUSA Linda Wawzenski (312) 353-1994 AUSA/PIO Randall Samborn (312) 353-5318

OMNICARE, INC. TO PAY \$49.5 MILLION TO UNITED STATES AND 43 STATES TO SETTLE MEDICAID PRESCRIPTION DRUG FRAUD ALLEGATIONS

CHICAGO – The United States and 43 states will receive \$49.5 million from Omnicare, Inc., of Covington, Kentucky, to settle Medicaid prescription-drug-fraud claims initiated by two whistleblowers, federal and state officials announced today. Omnicare, the largest provider of pharmacy services to skilled nursing facilities and assisted living communities in the United States, 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 Omnicare's submission of reimbursement claims to Medicaid programs in 43 states for three prescription drugs from April 2000 through 2005: Ranitidine (generic Zantac), Fluoxetine (generic Prozac) and Buspirone (generic Buspar).

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 Agentin-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. Also today, one of the two whistleblower lawsuits that initiated the case was unsealed, and, together, the cases yielded the largest-ever settlement of a federal health care fraud case in the Northern District of Illinois.

The case also marks the first time that a United States Attorney's Office has 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. In this case, agents from the FBI, the FDA Office of Criminal Investigations, and the Health and Human Services Department's Office of Inspector General joined forces with state attorneys general and investigators from Illinois, Massachusetts, Ohio, Pennsylvania, North Carolina, and Florida. In addition, each of the 43 states in which Omnicare operated during the relevant time period provided electronic claims data and other information to the investigative team.

"The health care industry should be wary of manipulating federal and state programs in this manner because, under the federal False Claims Act and its state counterparts, those who are caught face the prospect of triple damages plus significant additional penalties and attorneys fees," Mr. Fitzgerald said. "With significant civil deterrents such as these, and the increasing willingness of corporate insiders to report fraud, companies that cheat federal and state governments risk, at a minimum, potentially crippling financial losses."

Inspector General Levinson, of HHS, said: "Investigating Medicaid prescription drug fraud is a top priority for the U.S. Department of Health and Human Services, Office of Inspector General. We will continue to work closely with Medicaid Fraud Control Units around the country to investigate and prosecute those who engage in schemes to illegally profit from and defraud the Medicaid program at the expense of vulnerable beneficiaries."

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

Under the agreement, within 10 business days Omnicare will pay the United States slightly more than \$29,641,000 as the federal share of settlement and it will pay a total of approximately \$19,858,782 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 a net of \$2,568,762.

The universal federal settlement covers allegations that, for each of the three drugs, Omnicare improperly switched Medicaid patients from a cheaper version of the drug to a more expensive version solely to increase its reimbursement rate. Medicaid patients were given Ranitidine capsules instead of the cheaper tablets, Fluoxetine tablets instead of the cheaper capsules, and two 7.5-mg. tablets of Buspirone instead of the cheaper, single 15-mg. tablet. Those switches increased prices substantially while adding no medical benefit and violating federal and state regulations. For example, by substituting Ranitidine capsules for the 150-mg. tablets that were prescribed between December 15, 2000 and April 1, 2001, Omnicare was able to charge Illinois Medicaid \$79.80 instead of \$17.10 per 60 tablet prescription for a difference of \$62.70.

Omnicare made some of these switches without specifically informing the prescribing doctor of the change in drug form, sometimes falsely telling the physician that the new version of the drug would be cheaper for the payer, and other times suggesting some undefined patient benefit from the new form of the drug. Nevertheless, according to the allegations, Omnicare's sole reason for each switch was to increase the amount of reimbursement it would receive from Medicaid for each prescription.

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, Omnicare 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.

Both individuals, or so-called "relators," who initiated the case by filing their own separate lawsuits, will receive a share of the settlement from both the United States and the states that have their own whistleblower statutes. One relator, Bernard Lisitza, will receive \$6,443,204, and relator David Kammerer will receive \$792,593 as their respective shares of the federal and state settlements.

Mr. Lisitza, a licensed pharmacist who worked as a supervisor at Jacobs HealthCare Systems, an Omnicare facility in Des Plaines, Illinois, is represented by Michael Behn, of Behn & Wyetzner, Chartered, in Chicago. Mr. Kammerer, the former director of Medicaid reimbursement at Omnicare's headquarters in Kentucky, is represented by Charles Atkins, of Weisser & Wolf in Cincinnati, and Shelley Slade, of Vogel & Slade in Washington, D.C.

The United States was represented by assistant United States attorney Linda A. Wawzenski, deputy chief of the U.S. Attorney's Office civil division. Omnicare was represented by Sanford Teplitzky, of Ober, Kaler, Grimes & Shriver in Baltimore, Maryland.

The case is *United States et al., ex rel. Bernard Lisitza v. Omnicare, Inc.*, 01 C 7433, and *United States et al., ex rel. David Kammerer v. Omnicare, Inc.*, 04 C 2074 (N.D. II.). The Lisitza case was unsealed today, while the Kammerer case remains under seal.

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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