



Department of Justice

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NATION'S LARGEST NURSING HOME PHARMACY AND PHARMACEUTICAL MANUFACTURER PAY \$112 MILLION TO SETTLE FALSE CLAIMS ACT CASES

U.S. PROCEEDS WITH RELATED ACTION AGAINST TWO NURSING HOME CHAINS AND THEIR PRINCIPALS

BOSTON, MA - Acting United States Attorney Michael K. Loucks and Tony West, Assistant Attorney General for the Justice Department's Civil Division announced today the Government has reached settlements of \$98 million with Omnicare, Inc. ("Omnicare"), of Covington, Kentucky, and \$14 million with IVAX Pharmaceuticals, Inc. ("IVAX"), of Weston, Florida, to resolve the allegations of multiple whistleblowers that Omnicare engaged in kickback schemes with several parties, including IVAX. At the same time, the United States announced the unsealing of its Complaint against two large nursing home chains, Mariner Health Care, Inc. ("Mariner"), SavaSeniorCare Administrative Services, LLC ("Sava"), both of Atlanta, Georgia, and their principals, Leonard Grunstein, Murray Forman and Rubin Schron.

The settlement with Omnicare, the nation's largest pharmacy that specializes in dispensing drugs to nursing home patients, resolves allegations that the company solicited and/or paid four different types of kickbacks:

First, the United States contends that Omnicare solicited and received kickbacks from Johnson & Johnson (J&J), a pharmaceutical manufacturer, in exchange for agreeing to recommend that physicians prescribe Risperdal, a J&J antipsychotic drug, to nursing home patients. The Government contends that J&J's kickbacks to Omnicare took multiple forms, including: market share rebates that were conditioned on Omnicare engaging in an "Active Intervention Program" for Risperdal; payments disguised as fees for the purchase of data; payments disguised as educational grants; and fees to attend Omnicare meetings. Omnicare then used its consultant pharmacists to encourage physicians to prescribe Risperdal for their nursing home patients, but failed to disclose to physicians that the recommendations were a condition of Omnicare receiving the rebate payments from J&J. After the conduct at issue, the Food and Drug Administration mandated that the label for Risperdal carry a "black box" warning that "Elderly Patients with dementia-related psychosis treated with atypical antipsychotic drugs [including Risperdal] are at an increased risk of death compared to placebo."

Second, the United States contends that Omnicare regularly paid kickbacks to nursing homes by providing them with consultant pharmacist services at rates below Omnicare's cost and below the fair market value of such services when they are provided independently of dispensing pharmacy services. By law, nursing homes must retain consultant pharmacists to review patients' drug regimens at least once a month. This requirement arose from a Congressional mandate that nursing homes "protect and promote the rights of each resident, including . . . the right to be free from . . . chemical restraints imposed for purposes of discipline or convenience and not required to treat the resident's medical symptoms." The Government contends that Omnicare offered its consultant pharmacist services to nursing homes at below cost and below fair market value in order to induce the homes to refer their patients to Omnicare for dispensing pharmacy services.

Third, the United States has alleged that Omnicare solicited, and IVAX paid, \$8 million in kickbacks in exchange for Omnicare's agreement to purchase \$50 million in drugs from IVAX. In soliciting the kickbacks, Omnicare touted its ability to drive utilization of IVAX drugs through drug-switching programs. Omnicare's regular outside counsel on healthcare regulatory matters advised both Omnicare and IVAX against proceeding with the transaction, but Omnicare and IVAX went forward after Omnicare secured a more favorable opinion from a second attorney who was unaware of the first attorney's warnings to the parties. The Government's allegations against Omnicare and IVAX, now a subsidiary of Teva Pharmaceuticals Industries, Ltd., are further detailed in a separate Complaint that was unsealed today.

Finally, the United States has alleged that Omnicare, Mariner, Sava, Grunstein, Forman, and Schron conspired to arrange for Omnicare to pay the nursing home chains \$50 million in exchange for the right to continue providing pharmacy services to the nursing homes, which together constituted one of Omnicare's largest customers. The Government alleges that the parties attempted to disguise the \$50 million kickback as a payment to acquire a small Mariner business unit that had only two employees and no tangible assets apart from accounts receivable valued at less than \$3 million. The Government further alleges that, after the parties became aware of the government's investigation, Grunstein, Forman, and Schron created backdated documents in a further attempt to hide the kickback. The Government's allegations against Omnicare and the Mariner defendants are further detailed in a separate complaint that was unsealed today. Today's settlement resolves the allegations against Omnicare. The Government will proceed with its case against the Mariner defendants.

"Nursing home pharmacies specialize in providing drugs to elderly patients who are often suffering from Alzheimer's Disease or dementia, and who have little or no control over the drugs they receive. Today's settlement provides a strong message to these pharmacies, as well as to pharmaceutical companies and nursing homes, that the Government will not tolerate the payment of kickbacks which can distort proper medical judgment and put profits ahead of good medical care," said Loucks.

"These types of arrangements can subvert the medical judgment of health care professionals and result in patients being provided medications they neither need nor benefit from. They also drive up the costs of health care at a time when those funds are sorely needed to

provide care to our nation's most vulnerable populations – the elderly and the poor,” said Tony West, Assistant Attorney General for the Justice Department's Civil Division.

As part of the settlement, Omnicare has agreed to enter into an amended and restated corporate integrity agreement with the Office of Inspector General of the Department of Health and Human Services, while IVAX also has agreed to enter into a corporate integrity agreement. Those agreements provide for procedures and reviews to be put in place to avoid and promptly detect conduct similar to that which gave rise to this matter.

Whistleblower lawsuits filed under the *qui tam* provisions of the False Claims Act that are pending in the District of Massachusetts triggered this investigation. The payments to the whistleblowers from the federal share of the civil recovery have not been finalized yet.

The cases were investigated by the Chicago, St. Louis and Boston units of the Office of Inspector General of the Department of Health and Human Services, the Chicago unit of the Food and Drug Administration Office of Criminal Investigations and the Federal Bureau of Investigation. The cases are being handled by Gregg Shapiro and Christine Wichers in Loucks' Civil Division and Laurie Oberembt in the Justice Department's Civil Division.

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