

Department of Justice

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UNITED STATES FILES SUIT AGAINST DRUG MANUFACTURER JOHNSON & JOHNSON FOR PAYING KICKBACKS TO NATION'S LARGEST NURSING HOME PHARMACY

BOSTON, MA - United States Attorney Carmen M. Ortiz and Tony West, Assistant Attorney General for the Justice Department's Civil Division, announced today that the Government has filed a civil False Claims Act complaint against drug manufacturer Johnson & Johnson (J&J), of New Brunswick, New Jersey, and two of its subsidiaries, Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Johnson & Johnson Health Care Systems, Inc., for paying millions of dollars in kickbacks to Omnicare, Inc. ("Omnicare"), the nation's largest pharmacy that specializes in dispensing drugs to nursing home patients. In November 2009, the United States, numerous states, and Omnicare entered into a \$98 million settlement agreement that, among other things, resolved Omnicare's civil liability under the False Claims Act for taking kickbacks from J&J.

U.S. Attorney Carmen Ortiz said, "Kickbacks in the nursing home pharmacy context are particularly nefarious because they can result in excessive prescribing of strong drugs to patients who have little or no control over the medical care they are receiving. Nursing home doctors should be able to rely on the integrity of the recommendations they receive from pharmacists, and those recommendations should not be a product of money that a drug company is paying to the pharmacy."

"We will pursue those who break the law to take advantage of the elderly and the poor," said Tony West, Assistant Attorney General for the Civil Division of the Department of Justice. "Kickbacks such as those alleged here distort the judgments of health care professionals and put profits ahead of sound medical treatment."

In its complaint against J&J, the United States alleges that J&J paid kickbacks to Omnicare to induce Omnicare to purchase and to recommend J&J drugs, including the antipsychotic drug Risperdal, for use in nursing homes. According to the complaint, J&J understood that Omnicare's pharmacists reviewed nursing home patients' charts at least monthly and made recommendations to physicians on what drugs should be prescribed for those patients. The Government further alleges that J&J knew that physicians accepted the Omnicare pharmacists' recommendations more than 80 percent of the time, and that J&J viewed such pharmacists as an "extension of [J&J's] sales force." The United States alleges that, in order to induce Omnicare and its pharmacists to recommend J&J drugs, J&J paid kickbacks to Omnicare in numerous ways. First, the complaint alleges that J&J entered into agreements with Omnicare pursuant to which Omnicare was entitled to increasing levels of rebates from J&J so long as Omnicare implemented specific "Active Intervention Programs" to drive prescribing of J&J drugs. Second, the complaint alleges that J&J paid Omnicare millions of dollars for "data," much of which Omnicare never provided. According to the complaint, the true purpose of these payments was to induce Omnicare to recommend J&J drugs, and J&J used the disguise of a data purchase arrangement to evade its obligations to disclose the payments to the Government and to pay rebates to state Medicaid programs. Third, the complaint alleges that J&J made various other substantial kickback payments to Omnicare, calling the payments "grants" and "educational funding" even though their true purpose was to induce to Omnicare to recommend J&J drugs.

In response to J&J's kickbacks, according to the complaint, Omnicare undertook various "intervention" programs for J&J drugs. For example, Omnicare engaged in a "Risperdal Initiative" whose purpose, as J&J understood it, was "to persuade physicians to write Risperdal in the areas of Behavioral Disturbances associated with Dementia." After the conduct at issue, the United States 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."

The United States filed its complaint in two consolidated whistleblower lawsuits presently on file in the District of Massachusetts.

This case was 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 case is being handled by Gregg Shapiro and Christine Wichers in Ortiz's Civil Division and Laurie Oberembt in the Justice Department's Civil Division.

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