

GOVERNMENT OF THE DISTRICT OF COLUMBIA
Office of the Inspector General

Inspector General
February 23, 2012



ST. LOUIS – BASED KV PHARMACEUTICAL TO PAY \$17 MILLION
TO SETTLE FALSE CLAIMS ALLEGATIONS

Inspector General Charles J. Willoughby announced today that the District of Columbia has joined other states and the federal government in reaching an agreement in principle with KV Pharmaceutical Company to settle allegations that the company failed to advise the Centers for Medicare and Medicaid Services (CMS) that two unapproved products did not qualify for coverage under federal and state health care programs. KV Pharmaceutical Company, which was the St. Louis-based parent company of now-defunct Ethex Corporation, will pay the states and the federal government a total of \$17 million dollars to compensate Medicaid and various federal healthcare programs for its conduct. Ethex is alleged to have submitted false quarterly reports to the government related to a pair of drugs, Nitroglycerin Extended Release Capsules (Nitroglycerin ER) and Hyoscyamine Sulfate Extended Release Capsules (Hyoscyamine ER).

Nitroglycerin ER is a single entity coronary vasodilator containing controlled release nitroglycerin that was used for treating angina pectoris (chest pain due to lack of oxygen supply to the heart muscle). Hyoscyamine Sulfate ER is an antispasmodic medication that has been used to treat various stomach, intestinal, and urinary tract disorders that involve cramps, colic, or other painful muscle contractions. While the active ingredients in Nitroglycerin and Hyoscyamine Sulfate ER had been in products on the market for many years, the Food and Drug Administration (FDA) made determinations in the late 1990s that resulted in the drugs being ineligible for reimbursement by government health care programs such as Medicaid.

The settlement resolves allegations that Ethex misrepresented the regulatory status of both drugs and failed to advise CMS that these unapproved drugs did not

qualify for coverage under federal health care programs. As a result, the government contends, Ethex knowingly caused false claims to be submitted for Nitroglycerin ER and Hyoscyamine Sulfate ER. Ultimately, neither drug ever received full regulatory approval for safety and effectiveness, and neither product is currently on the market.

The federal share of the settlement is \$10,158,695, and the state Medicaid share of the settlement is \$6,841,305. The lawsuit was brought under the qui tam, or whistleblower, provisions of the False Claims Act, which allow private parties with knowledge of fraud to sue on behalf of the United States and share in any recovery.

The D.C. Department of Health Care Finance provided data, and Mr. Willoughby recognized Medicaid Fraud Control Unit Auditors LaShawn Brooks and E-Rika Sellers for their work on analyzing the data and working with the National Association of Medicaid Fraud Control Units team that participated in the investigation and conducted settlement negotiations with KV on behalf of the settling states. Team members included representatives from New York, South Carolina, Texas and Maine.