

State of North Carolina

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North Carolina Senate President Pro Tempore Phil Berger North Carolina House of Representatives Speaker Thom Tillis Co-Chairs, Joint Legislative Commission on Governmental Operations

Senator Harry Brown
Senator Thom Goolsby
Representative James L. Boles, Jr.
Representative N. Leo Daughtry
Representative Pat B. Hurley
Representative Shirley B. Randleman
Co-Chairs, Appropriations Subcommittees on Justice and Public Safety

North Carolina General Assembly Raleigh, North Carolina 27601-1096

RE: G.S. §114-2.5; Report on Settlement Agreement for K-V Pharmaceutical Company (Nitroglycerin Extended Release Capsules & Hyoscyamine Sulfate Extended Release Capsules)

Dear Members:

Section 114-2.5 of the North Carolina General Statutes requires the Attorney General to report to the Joint Legislative Commission on Governmental Operations and the Chairs of the Appropriations Subcommittees on Justice and Public Safety regarding all settlements and court orders which result in more than \$75,000.00 being paid to the State. Pursuant to that statute, I am writing regarding the settlement of claims for Medicaid reimbursement to the state and federal governments in the above-referenced matter. Pursuant to federal law (42 C.F.R. § 433.320) recoveries in these cases are shared on a pro rata basis by the state and federal governments.

A Settlement Agreement has been executed between K-V Pharmaceutical Company ("K-V") and the State of North Carolina. K-V is a Delaware corporation headquartered in St. Louis, Missouri and was the parent of Ethex Corporation ("Ethex"), a company that was dissolved in December 2010. K-V markets and sells pharmaceutical products throughout the

United States. Ethex distributed, marketed and sold pharmaceutical products in the United States, including the drugs Nitroglycerin Extended Release Capsules, used for treating angina pectoris, and Hyoscyamine Sulfate Extended Release Capsules, an antispasmodic drug used to treat various stomach, intestinal, and urinary tract disorders. The settlement resolves allegations that from April 1999 through December 31, 2007, Ethex submitted to the Centers for Medicare and Medicaid Services ("CMS") false quarterly reports that misrepresented the regulatory status of Nitroglycerin Extended Release Capsules and Hyoscyamine Sulfate Extended Release Capsules and failed to advise CMS that both drugs no longer qualified as covered outpatient drugs.

Under the terms of North Carolina's settlement, the State of North Carolina recovered \$341,123.09. Of that amount, the federal government will receive \$180,508.93 to satisfy North Carolina's obligation to return the federal portion of Medicaid recoveries to the federal government. The North Carolina Medicaid Program received \$156,957.93 as restitution and interest. Pursuant to G.S. § 115C-457.2 and G.S. § 108A-70.12(b)(3), the North Carolina Department of Justice will receive \$3,656.23 for investigative costs.

We will be happy to respond to any questions you may have regarding this report.

Very truly yours,

Wust hy Kristi Hyman Chief of Staff

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cc: Kristine Leggett, NCGA Fiscal Research Division Nels Roseland, NCDOJ, Deputy Chief of Staff