



State of North Carolina

ROY COOPER
ATTORNEY GENERAL

Department of Justice
PO Box 629
Raleigh, North Carolina
27602

Phone: (919) 716-6400
Fax: (919) 716-6750

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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

RE: G.S. §114-2.5; Report on Settlement Agreement for Dava Pharmaceuticals, Inc. (Cefdinir, Clarithromycin, Methotrexate, and Rheumatrex)

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 Dava Pharmaceuticals, Inc. ("Dava") and the State of North Carolina. Dava is a Delaware corporation headquartered in Fort Lee, New Jersey. Dava markets and sells pharmaceutical products throughout the United States. Dava distributed, marketed and sold pharmaceutical products in the United States, including the drugs Clarithromycin, Cefdinir, Methotrexate, and Rheumatrex. The settlement resolves allegations that from October 1, 2005 through September 30, 2009, Dava misrepresented Clarithromycin, Cefdinir, Methotrexate as non-innovator drugs when the drugs should have been classified as innovator products in its rebate submissions. Dava also used incorrect

methodologies in calculating average manufacturer prices for its drugs Clarithromycin, Cefdinir, Methotrexate, and Rheumatrex.

Under the terms of North Carolina's settlement, the State of North Carolina will recover \$818,490.47. Of that amount, the federal government will receive \$475,999.27 to satisfy North Carolina's obligation to return the federal portion of Medicaid recoveries to the federal government. The North Carolina Medicaid Program will receive \$334,907.51 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 \$7,583.69 for investigative costs. The settlement proceeds will be paid in quarterly installments which have already commenced and will conclude in November 2016.

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

Very truly yours,


Kristi Hyman
Chief of Staff

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