

State of North Carolina

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November 2, 2009

North Carolina Senate President Pro Tempore Marc Basnight North Carolina House of Representatives Speaker Joe Hackney Co-Chairs, Joint Legislative Commission on Governmental Operations

Senator John Snow
Senator Ellie Kinnaird
Representative Alice Bordsen
Representative Jimmy Love
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 Pfizer, Inc.

Dear Members:

G.S. §114-2.5 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.

On August 31, 2009, a Settlement Agreement was executed between Pfizer, Inc. and the State of North Carolina. Pfizer, Inc. is a Delaware corporation with its principal place of business in New York. Pfizer, Inc. manufactures, distributes, markets, and sells pharmaceutical products in the United States, including drugs sold under the names of Bextra, Geodon, Zyvox, Lyrica, Aricept, Celebrex, Lipitor, Norvasc, Relpax, Viagra, Zithromax, Zoloft, and Zyrtec. The settlement resolved allegations that Pfizer, Inc. and its subsidiaries paid kickbacks and engaged in off-label marketing campaigns that improperly promoted numerous drugs that Pfizer manufactures. It was alleged that Pfizer engaged in a pattern of unlawful marketing activity to promote multiple drugs for certain uses which the Food and Drug Administration ("FDA") had not approved. While it is not illegal for a physician to prescribe a drug for an unapproved use,

federal law prohibits a manufacturer from promoting a drug for uses not approved by the FDA. This promotional activity allegedly included the following:

- From February 2002 through April 2005, Pfizer marketed Bextra for conditions and dosages other than those for which it was approved.
- From January 2001 through December 2007 Pfizer promoted the use of the antipsychotic drug Geodon for a variety of off-label conditions such as attention deficit disorder, autism, dementia and depression for patients that included children and adolescents.
- From January 2001 through February 2008 Pfizer promoted the sale of Zyvox, an antibiotic only approved to treat certain drug resistant infections, for a variety of off-label conditions.
- From September 2005 through October 2008, Pfizer promoted the sale of the pain medication Lyrica for a variety of off-label conditions.

In addition, from January 2001 through December 2004 Pfizer allegedly paid illegal remuneration to health care professionals to induce them to promote and prescribe Bextra, Geodon, Lyrica, Zyvox, Aricept, Celebrex, Lipitor, Norvasc, Relpax, Viagra, Zithromax, Zoloft and Zyrtec. Payments allegedly included entertainment, cash, travel and meals.

Under the terms of North Carolina's settlement, the State of North Carolina recovered \$25,516,752.14. Of that amount, the federal government received \$15,856,782.07 to satisfy North Carolina's obligation to return the federal portion of Medicaid recoveries to the federal government. The North Carolina Medicaid Program received \$4,852,738.58 as restitution and interest. In addition, pursuant to Article IX, Section 7 of the North Carolina Constitution and G.S. § 115C-457.1, the penalty portion of the settlement in the amount of \$4,532,639.29 will be paid to the Civil Penalty Forfeiture Fund for the support of North Carolina public schools. Pursuant to G.S. § 115C-457.2 and G.S. § 108A-70.12(b)(3), the North Carolina Department of Justice will receive \$274,592.20 for investigative and collection costs.

As part of the settlement, Pfizer, Inc. will enter a Corporate Integrity Agreement with the United States Department of Health and Human Services, Office of the Inspector General which will closely monitor the company's future marketing and sales practices.

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

Very truly yours,

Kristi Hyman Chief of Staff

KH:kds

cc: Jean Sandaire, NCGA Fiscal Research Division Greg McLeod, NCDOJ, Legislative Counsel Nels Roseland, NCDOJ, Deputy Chief of Staff