



State of North Carolina

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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
Eli Lilly and Company

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 May 4, 2009, a Settlement Agreement was executed between Eli Lilly and Company and the State of North Carolina. Eli Lilly and Company is a pharmaceutical manufacturer located in Indiana. The settlement covered the time period of September 1999 through December 31, 2005 and resolved allegations that Eli Lilly engaged in the off-label marketing of the drug Zyprexa, which is one of a newer generation of antipsychotic medications (called atypical antipsychotics) used to treat certain psychological disorders. Eli Lilly was alleged to have willfully promoted the sale and use of Zyprexa, primarily through a marketing campaign called "Viva Zyprexa," for certain uses which the Food and Drug Administration had not

approved. The promotional activities undertaken by Eli Lilly in the "Viva Zyprexa" campaign promoted Zyprexa not only to psychiatrists, but also to primary care physicians, for such unapproved uses as the treatment of depression, anxiety, irritability, disrupted sleep, nausea and gambling addiction. In implementing the campaign, Eli Lilly also provided remuneration and other things of value to physicians and other health care professionals. As a result of these promotional activities, Eli Lilly caused physicians to prescribe Zyprexa for children and adolescents, dementia patients in long term care facilities, and in unapproved dosage amounts, all of which are uses that were not medically accepted indications for which state Medicaid programs would approve reimbursement.

Under the terms of North Carolina's settlement, the State of North Carolina recovered \$21,591,105.34. Of that amount, the federal government received \$13,248,896.17 to satisfy North Carolina's obligation to return the federal portion of Medicaid recoveries to the federal government. The North Carolina Medicaid Program received \$3,930,143.35 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 \$3,890,711.05 will be paid to the Civil Penalty Forfeiture Fund for the support of North Carolina public schools. Pursuant to § 115C-457.2 and G.S. § 108A-70.12(b)(3), the North Carolina Department of Justice will receive \$144,247.18 for investigative and collection costs.

As part of the settlement, Eli Lilly 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,

A handwritten signature in black ink, appearing to read "Kristi Hyman", with a long horizontal flourish extending to the right.

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