



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 Otsuka America
Pharmaceutical, 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 November 12, 2009, a Settlement Agreement was executed between Otsuka America Pharmaceutical, Inc. ("Otsuka") and the State of North Carolina. Otsuka is a Delaware corporation headquartered in Rockville, Maryland that marketed and sold pharmaceutical products in the United States including the atypical antipsychotic drug Abilify (aripiprazole) which is approved for the treatment of adult schizophrenia and bipolar disorder. The settlement resolves allegations that from January 2002 through December 2005, Otsuka promoted the sale and use of Abilify for pediatric use prior to the approval for these uses by the Food and Drug Administration ("FDA") and to treat dementia-related psychosis, a use for which FDA has not

approved Abilify, that these uses were not medically-accepted indications, and that the Medicaid Program did not cover Abilify dispensed for these uses. This settlement is related to an earlier settlement with Bristol-Myers Squibb ("BMS"). Otsuka Pharmaceuticals, Inc. developed the drug Abilify in Japan and licensed it to BMS which marketed the drug in the United States. An earlier settlement with BMS to resolve allegations regarding the marketing of Abilify and other products was reached and reported to this Subcommittee in 2008. This settlement resolves Otsuka's more limited involvement in marketing the drug Abilify.

Under the terms of North Carolina's settlement, the State of North Carolina recovered \$138,176.68. Of that amount, the federal government received \$78,769.87 to satisfy North Carolina's obligation to return the federal portion of Medicaid recoveries to the federal government. The North Carolina Medicaid Program received \$29,069.21 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 \$28,799.40 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 \$1,538.20 for investigative and collection costs.

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:ng

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