



## State of North Carolina

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ATTORNEY GENERAL

October 27, 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  
Nichols Institute Diagnostics and Quest Diagnostics Incorporated

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 3, 2009, a Settlement Agreement was executed between Quest Diagnostics Incorporated and Nichols Institute Diagnostics and the State of North Carolina. Nichols Institute Diagnostics is a wholly owned subsidiary of Quest Diagnostics Incorporated. The settlement covered the time period of May 2000 through April 30, 2006 and resolved allegations that Nichols Institute Diagnostics and Quest Diagnostics Incorporated engaged in the manufacturing, marketing and selling Intact and Bio-Intact PTH Kits despite knowing that some kits produced results that were materially inaccurate and unreliable, thereby causing some clinical laboratories that purchased and used the Intact and Bio-Intact PTH Kits to submit false claims for

reimbursement to the Medicaid Program. The Advantage Intact PTH and Bio-Intact PTH kits were used by laboratories to measure parathyroid hormone levels in blood samples, the Advantage 25 OH-D kit was used by laboratories to measure hydroxyvitamin D levels in blood samples, the Advantage ACTH kit was used to measure adrenocorticotrophic hormone levels in blood samples and the Advantage DHEA-S Kit was used by laboratories to measure dehydroepiandrosterone sulfate levels in blood samples.

Under the terms of North Carolina's settlement, the State of North Carolina recovered \$337,236.38. Of that amount, the federal government received \$218,305.69 to satisfy North Carolina's obligation to return the federal portion of Medicaid recoveries to the federal government. The North Carolina Medicaid Program received \$120,353.69 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 \$6,433.12 will be paid to the Civil Penalty Forfeiture Fund for the support of North Carolina public schools. Pursuant to § 115C-457.2, the North Carolina Department of Justice will receive \$194.86 for collection costs.

As part of the settlement, Quest Diagnostics Incorporated and Nichols Institute Diagnostics 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 product reliability.

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