

Presentation of F. Edward Kirby, Jr. to the Senate Judiciary I Pharmaceutical Liability

Subcommittee

February 21, 2012

My name is Eddie Kirby. I am the Civil Chief in the Attorney General's Medicaid Investigations Unit. We are responsible for investigating and prosecuting fraud committed by health care providers against the North Carolina Medicaid Program. We have a dedicated group of criminal prosecutors, financial investigators, and SBI agents who focus on Medicaid fraud criminal investigations. In the last federal financial year the Medicaid Investigations Unit recovered over \$9.7 million in criminal restitution and penalties for the taxpayers of North Carolina, and we obtained 22 criminal convictions and pleas.

MIU also has a team of civil attorneys. One of our most powerful tools in combating fraud in the Medicaid program is the North Carolina False Claims Act. Last year, the Medicaid Investigations Unit recovered \$39.5 million in **civil damages** for the State of North Carolina under the **False Claims Act**. Nearly all of the 18 cases we settled last year involved allegations of fraud committed by pharmaceutical manufacturers. Here are two examples:

- We settled with the drug company Novartis for \$6.2 million for alleged payment of kickbacks to doctors to induce the prescription of the company's epilepsy drug for unapproved uses, such as bipolar disorder.
- We settled with the drug company Forest Labs for \$5.3 million for alleged off-label marketing of the anti-depressant drugs Celexa and Lexapro. These drugs were FDA-approved only for adult use, but the company marketed them for unapproved pediatric use.

These settlements illustrate both the enormity of government damages at stake in these cases and the seriousness of the alleged misconduct.

We have concern that the ability of the Attorney General's Office to litigate and recover damages in cases such as these would be largely abrogated under the bill before this Subcommittee. A pharmaceutical products liability statute similar to what is now before you was earlier enacted by Michigan's legislature in the 1990s. Later, the Michigan Attorney General's Office filed a case under the Michigan Medicaid False Claim Act, alleging that the drug company Merck had misrepresented the safety and efficacy of its prescription pain reliever Vioxx in its marketing, which resulted in false claims being submitted to the Michigan Medicaid Program. The drug company moved for summary judgment, arguing that its False Claims Act liability was immunized under the products liability statute. The Michigan Court of Appeals agreed, concluding that the case was a product liability action because it related to the marketing of Vioxx and that the state's fraudulently-induced Medicaid payments were "property damage" under the products liability statute. The state's appeal to the Michigan Supreme Court was denied in a 4 to 3 decision on September 30, 2011.

If the bill before this subcommittee becomes law, we are greatly concerned that the taxpayers of North Carolina could lose millions of dollars in False Claims Act recoveries against pharmaceutical companies. The proposed exception in subsection (c) is **not** effective at carving out the Attorney General's ability to litigate False Claims Act matters, in our opinion. A large number of our recent drug company fraud cases involved allegations that a drug, while safe and effective for its FDA-approved, on-label use, was **not** safe or effective for the off-label use the company illegally promoted. If the bill before you becomes law, we expect that the state of

North Carolina would be forced to litigate whether such cases would be barred under subsection (c), while the federal government and our sister states recover their damages caused by the same fraudulent conduct.

I saw subsection (d) of the latest version of the bill for the first time just a few minutes ago. We would need to consider that language further before we can speak to it. However, I can tell you that off-label marketing is not the only theory of liability in the Medicaid Investigation Unit's civil cases. Just last year we settled a multi-million-dollar case with GlaxoSmithKline in which it was alleged that there were problems in that company's Puerto Rico manufacturing facility, including contamination of drugs by microorganisms. Query whether we would be able to prosecute such a case under this bill.

In conclusion, the Attorney General's Office has concerns about our ability to protect and recover taxpayer dollars lost to Medicaid fraud, along with our ability to protect consumers from unsafe products, under this bill.