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

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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. I spoke at the February 21, 2012 meeting of the subcommittee and I am grateful for the opportunity to speak with you again, with more specificity, about our concerns regarding the draft bill being considered by the subcommittee.

I would like to start with subsection 99B-12(c), which appears at first blush to carve out claims of liability under the North Carolina False Claims Act from the operation of this bill, but actually has the **opposite** effect. In order to see this problem we must read the subsection with the double negative removed: "This section shall bar an action brought pursuant to Article 51 of Chapter 1 of the General Statutes, if the action is based upon allegations that the product was not safe or effective or that the manufacturer failed to provide an adequate warning." It is true that this provision would carve out from the bill's application those False Claims Act cases that are **not** based on allegations that the product was not safe or effective, but that would be a limited number of our cases.

As I stated previously, many of our False Claims Act cases and settlements involve allegations that a pharmaceutical manufacturer has marketed an FDA-approved drug for "off-label" uses. It is implicit in most of these cases, and explicitly alleged in many of them, that the drug at issue is not safe or effective for the off-label use. Our $6.2 million settlement with

Novartis last year to resolve allegations that the company paid kickbacks to doctors to induce prescription of its epilepsy drug for unapproved uses is a prime example of such a case.

To reiterate – if this bill is enacted containing such a narrow carve-out of False Claims Act cases that are **not** based upon allegations that the product was not safe or effective, the implication would be that False Claims Act cases that **are** based upon allegations that the product was not safe or effective **would be subject to the defense under this bill**. Such language is not present in the pharmaceutical product liability provisions that have been enacted by other states. We also see a potential internal conflict between this subsection (c), as it might be applied to off-label marketing cases, and subsection (d) which would create an exception for off-label marketing cases.

We also have concerns about subsection 99B-12(d), because it would require additional proof by the Attorney General's Office beyond the considerable proof the State must already present in its False Claims Act cases in order to establish that the non-liability presumption provision does not apply. Under current law we must prove that the manufacturer engaged in off-label marketing, and that the State paid for use of the drug as a result. Under subsection (d) we also would be required to prove that that the drug was actually used by patients for that particular off-label use, and that the State's injury was caused by the **use** of the drug. Requiring the State to prove that thousands of individual patients actually used their prescribed drugs in specific ways would create an enormous evidentiary burden on the State, above and beyond the considerable burden already placed upon us under the False Claims Act.

Finally, we ask the committee to consider that the MIU has False Claims Act cases that would not be carved out under either subsection (c) or (d) of this bill. In the last several years, we have settled False Claims Act cases against pharmaceutical manufacturers that involved

patient safety allegations, but did not include allegations of off-label marketing. A good example is our $6.4 million settlement in 2007 with the drug company Purdue Pharma, which resolved allegations that the company misbranded the drug OxyContin as being less addictive and less subject to abuse and diversion than other pain medications. The theory of liability in that case was **not** that that OxyContin was marketed for an off-label indication, so subsection (d) of the bill would not apply. But the OxyContin case did involve allegations with respect to the safety of the drug and the adequacy of the warnings the company provided, which would remove it from the operation of subsection (c) in this bill. It would appear that such a case might therefore be subject to the non-liability provision of this bill.

Proponents of the bill have submitted information on Medicaid fraud settlements between pharmaceutical companies and other states that have enacted pharmaceutical non-liability bills containing a rebuttable presumption of non-liability. I see two problems with respect to that:

(1) The emphasis on whether the statute creates a rebuttable or irrebuttable presumption is misplaced. The primary question should be whether these statutes would be applicable to actions under the states' False Claims Acts. We expect the North Carolina Courts would evaluate that question here just as the Michigan Supreme Court did, by looking to the definition of "product liability action" in the products liability statute. The Michigan Court of Appeals decided that the state's False Claims Act damages for Medicaid payments for the drug Vioxx constituted "damage to property" and that Michigan's False Claims Act case against Merck was therefore barred. Subsection 99B-1(3) of this bill contains the virtually identical language, "property damage" – which is a concern. Furthermore, the limited False Claims Act carve-out in subsection 99B-12(c) of the draft bill, which is not present in the other

states' pharmaceutical product liability statutes, would suggest to the North Carolina Courts that this bill **would** be applicable to claims under the North Carolina False Claims Act except as limited by subsections 99B-12(c) and (d). This would invite litigation and it has the potential to limit our ability to settle North Carolina False Claims Act cases, in my view.

(2) The settlements identified by the bill's proponents are nationwide, global settlements by consent of the parties, not judgments of a court. It is important to note that at any point a defendant in a state False Claims Act matter in any of these states may elect not to settle its liability but rather to defend on the basis of a non-liability provision, as in the Michigan v. Merck case. It is small comfort to the Attorney General's Office that the bill now before the Subcommittee would establish a rebuttable presumption, rather than an absolute bar, where our burden would be to rebut the presumption by clear and convincing evidence. That would be a high hurdle for us to clear.

In conclusion, the Attorney General's Office continues to be concerned that the bill before this subcommittee could result in the loss of millions of dollars in False Claims Act recoveries against pharmaceutical companies. The bill also would severely impact the Attorney General's Office's ability to protect consumers, since there is no carve-out for our Consumer Protection Division. The need for this bill, in our view, has not been demonstrated, but its potential harmful impact on the work of the Attorney General's Office is clear.