**April 25, 2012 Statement Before the Pharmaceutical Liability Subcommittee of the Senate Judiciary Committee**

**Kevin Anderson, Senior Deputy Attorney General and Director of the Consumer Protection Division, N.C. Department of Justice**

Thank you, Mr. Chairman. I am Kevin Anderson, the Director of the Consumer Protection Division at the North Carolina Department of Justice. I appreciate the opportunity to speak with you again about the legislative proposal dealing with pharmaceutical cases. Many of my remarks are similar in nature to comments already made by my colleague Eddie Kirby, who heads up the civil part of the Department's Medicaid Fraud Unit, so I will try to keep my remarks short and to the point.

At the outset, I want to provide a brief explanation of what the Consumer Protection Division does. Generally, we bring civil unfair and deceptive trade practice related cases against persons and entities that commit misconduct and violate the law. One point I want to emphasize at the outset, is that the Consumer Protection Division brings cases under Chapter 75 of the North Carolina General Statutes, our unfair and deceptive trade practices statute. Unlike the Department's Medicaid Fraud Unit, we do not bring most of our pharmaceutical cases under North Carolina's False Claims Act. So, while the proposed legislation purports to try to carve out False Claims cases, at least to a certain extent, there is nothing in the bill that attempts to specifically carve out Chapter 75 cases brought by the Consumer Protection Division.

Another point I want to emphasize is that the Consumer Protection Division brings investigations and cases with broad public and state interests in mind, including the consuming public as a whole and state purchasers, and attempts to obtain recoveries and relief that benefit the State of North Carolina. The Federal Drug Administration (FDA) does *not* obtain monetary recoveries for the State of North Carolina; that's not what it does.

As I have said before, the Consumer Protection Division's authority to bring Chapter 75 cases against pharmaceutical companies should be preserved, not diminished. Currently, there is no real debate about our authority to bring these types of cases and obtain recoveries for North Carolina.

However, this bill, if enacted, would, at the very least, cast potential doubt on our authority and put us in the position of possibly having to argue in court about the extent of our authority. While some have said that this bill is not intended to impact the State of North Carolina's authority, there are a number of provisions in the bill that would provide fertile ground for pharmaceutical companies to argue otherwise once an investigation or case was brought. For example, there could be extensive argument and debate about exactly what exactly the "rebuttable presumption" means and how that would impact the burden of proof. There could also be extensive debate about the exceptions in the bill, including when they apply and what would have to be shown for them to apply. There's other language in the bill that could be the subject of debate as well. Different attorneys can argue about what some of this language in the bill means and doesn't mean. Ultimately, however, it would be up to the courts to resolve these

arguments. Again, currently there is not anything that casts much doubt regarding the Consumer Protection Division's authority.

I'd like to briefly address a few points that other parties have made. First, one of the proponents of the legislation has argued that this bill rewards companies that play by the rules and does not inhibit cases against companies that don't play by the rules. However, that argument misses the mark because the overriding framework of this legislation is that a pharmaceutical company really only has to play by one rule – obtain FDA approval of a drug – and then all bets are off because it then becomes much more difficult for enforcement authorities to prove that other rules were broken because of the rebuttable presumption that kicks in.

Another proponent has argued that the bill is merely designed to protect pharmaceutical companies against non-meritorious litigation. I can assure you that the cases that the Consumer Protection Division has brought against pharmaceutical companies are meritorious. In many of the cases we have brought, the federal government also brought criminal charges against the pharmaceutical company (or individuals in the company) for the same type of misconduct. Also, virtually all of our cases are resolved with the consent of the pharmaceutical company, via consent judgments.

It is worth noting that the burden of proof is already on the Consumer Protection Division, as the plaintiff or potential plaintiff, in these cases. Also, current law appears to already allow a company to get into evidence the fact that a drug received FDA approval. So, there is no compelling need for the General Assembly to take an entire industry – the pharmaceutical industry – and now impose a higher than normal burden of proof, this rebuttal presumption, just because a company obtained FDA approval for a drug.

The FDA itself recognizes that its approval process is limited. Here's a quote from the FDA's webpage: "The Food and Drug Adminstration (FDA) approves a drug for marketing after determining that the drug's benefits of use outweigh the risks for the condition that the drug will treat. But even with a rigorous evaluation process, some safety problems surface only after a drug has been on the market and has been used in a broader population."

In sum, it seems to be a matter of common sense that when a pharmaceutical company is violating North Carolina law then the appropriate enforcement authorities should be able to hold that company accountable and obtain appropriate relief for our consumers and state purchasers, without having their hands tied due to a new law that casts any doubt on their enforcement authority. Any legislative effort to curtail our ability to enforce the law and obtain relief for North Carolina would not seem to be in North Carolina's interest.

Thank you again for the opportunity to speak, Mr. Chairman. I'll be glad to answer questions or provide further information.