Statement of Douglas W. Kenyon
Pharmaceutical Liability Subcommittee
Judiciary Committee I
North Carolina Senate

April 25, 2012

My name is Doug Kenyon, and I am a partner at the law firm of Hunton & Williams LLP located in Raleigh.

- I am here representing the Pharmaceutical Research and Manufacturers of America ("PhRMA"), the trade association that represents the country's leading pharmaceutical research and biotechnology companies. These companies are devoted to inventing medicines that allow patients to live longer, healthier and more productive lives.
- I have been a commercial litigator for more than 30 years, handling a wide variety of cases affecting the numerous pharmaceutical firms located in our state.
- My practice has included, in recent years, working with the North Carolina Attorney General's office to file a brief with the U.S. Supreme Court in a case about the proper interpretation of the federal False Claims Act.[1]
- I appreciate the opportunity to speak in support of the proposed legislation being considered by this subcommittee.

The proposed legislation, if enacted, **would operate in a straightforward manner**.

- A plaintiff would bring a product liability action against a drug manufacturer or seller "on account of personal injury, death or property damage" suffered by the plaintiff and would allege it was the manufacturer's or seller's drug that "caused the harm."
- If the drug had gone through the rigorous (and long and expensive) regulatory approval process and ultimately been approved by the U.S. Food and Drug Administration ("FDA"), and if "the drug and its labeling were in compliance with" the FDA's approval, there would be "a rebuttable presumption that the drug was safe and effective for its approved use."

In my view, the proposed legislation **strikes an appropriate balance**.

- It recognizes the complex and difficult (and long and expensive) FDA regulatory process to which the many pharmaceutical firms who manufacture and sell drug products in our state are subject.

[1] *Graham County Soil & Water Conservation District, et al. v. United States ex rel. Wilson*, 130 S.Ct. 1396 (2010).

- Conversely, by establishing only a rebuttable presumption, it recognizes the rights of North Carolina consumers as well.
    - By its plain terms, the proposed legislation states that this presumption can be rebutted by the plaintiff. It is not absolute.
    - Plaintiffs can rebut the presumption by showing, for example, that the drug product that allegedly caused the harm did not have the same active ingredient as, or included ingredients different than, the FDA-approved drug; or was manufactured and sold in a different dosage form or strength; or that its labeling did not comply with FDA's approval.
- Because of this rebuttable presumption, the focus of our civil justice system will be on instances where drug manufacturers and sellers are not complying with FDA requirements -- exactly where it should be!
    - Product liability cases against drug manufacturers and sellers will effectively penalize firms that fail to comply with the requirements of the FDA, the federal agency commissioned to assess the safety and effectiveness of drugs and promote the public health.
    - Product liability cases will not burden manufacturers who comply with FDA's stringent requirements.

Contrary to some of the testimony this subcommittee has heard, the proposed legislation **would not grant drug manufacturers immunity** from product liability lawsuits **or deprive North Carolinians access to the courts**.

- First, as already stated, the legislation would merely establish a rebuttable presumption. North Carolinians who believe that they have been injured by a defective drug or a drug with an inadequate warning would have every right to bring an action against the drug's manufacturer or seller and then show that the drug did not comply with the FDA's approval.
- Second, under the proposed legislation, persons who believe they have been injured by a drug can bring an action and show (1) that the manufacturer sold the drug after FDA ordered it removed from the market, or withdrew its approval, or substantially altered its approval; (2) that the manufacturer lied to the FDA in order to get FDA approval for the drug; or (3) that the manufacturer bribed FDA officials in order to obtain approval. In these situations, the presumption does not even apply.
- Third, persons who believe they have been injured by a drug can bring an action and show that the manufacturer or seller marketed the drug for uses not approved in the label and that the off-label use caused the harm to the plaintiff. In this situation, too, the presumption would not apply.

Finally, let me address the concerns raised by the Attorney General's office and say a word about the interaction of the proposed legislation and **North Carolina's ability to participate in state and federal Medicaid fraud actions brought under state or federal False Claims Acts**.

- By its terms, the legislation applies "in any product liability action" involving a "drug that is alleged to have caused the harm." Thus, the legislation (and the rebuttable presumption) would only apply in cases where a drug allegedly caused "personal injury, death or property damage."[2]
- The legislation would not apply in False Claims Act cases where the government alleges that a person "knowingly presents or causes to be presented a false or fraudulent claim for payment or approval" and seeks to recover "three times the amount of damages that the State sustains because of the" false claims.
- Indeed, numerous states (CO, FL, KS, IN, MI, TN, UT and WI) that have statutes with FDA compliance rebuttable presumption provisions like the one under consideration here have recouped millions in Medicaid fraud recoveries.[3]
    - In my view, the legislation will not impede North Carolina's ability to recover from drug manufacturers and sellers any proceeds of Medicaid fraud under state and federal False Claims Acts.

To summarize, the proposed legislation under consideration would, in my estimation, strike an appropriate balance between the pharmaceutical industry and North Carolina consumers; focus the attention of our civil justice system on manufacturer conduct that flouts FDA requirements; and not impede the good work of the Attorney General's office to combat healthcare fraud.

[2] The definition of "product liability action" does not include actions for economic loss. "[A]n action seeking to recover damages for economic loss is not a product liability action governed by the [North Carolina Products Liability] Act." *Atlantic Coast Mechanical, Inc. v. Arcadis, Geraghty & Miller of North Carolina, Inc.*, 175 N.C. App. 339, 623 S.E.2d 334, 339 (2006).

[3] *See* Table, *Medicaid Fraud Recoveries for States with FDA Rebuttable Presumption Provisions*.