Statement of Paul W. Schmidt
Pharmaceutical Liability Subcommittee
Judiciary Committee I
North Carolina Senate

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My name is Paul Schmidt, and I am a partner with the law firm of Covington & Burling LLP. I have spent my career litigating pharmaceutical cases in both state and federal courts across the country, including in states -- like New Jersey -- with the type of rebuttable FDA defense that this Committee is considering. I am here today on behalf of PhRMA, the Pharmaceutical Research & Manufacturers of America, a nationwide association of the country's leading pharmaceutical manufacturers. I appreciate the opportunity to speak in support of Bill Draft 2011-TG-14A.

There are numerous pharmaceutical product liability cases in North Carolina and nationwide. As of 2006, these lawsuits made up more than one-third of *all* product liability lawsuits filed in federal court.[1] More than 71,000 drug lawsuits were filed in federal courts between 2001 and 2006.[2]

Like any type of lawsuit, not all of these pharmaceutical liability cases have merit. And the volume of litigation alone, regardless of the validity of the claims, can have significant negative consequences. It can have a serious impact on an industry that has important ties to this State, in terms of innovation occurring here and jobs being created here, and it can also impact broader public health concerns. For example, it can deter innovation in certain areas: many manufacturers have stopped researching and producing crucial products like vaccines and medications for pregnant women, which are particularly vulnerable to lawsuits.

The FDA defense is intended to help companies defend the lawsuits that do not have merit by recognizing the crucial role that the Food and Drug Administration plays in studying the science of medicines and ensuring that medicines have appropriate warnings. The bill would do this by saying that, when a company follows the rules, it is entitled to a defense in these lawsuits. That defense can be overcome in appropriate circumstances, and it would not be available at all where a company does not follow the rules.

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[1] Lisa Girion, State Vioxx Trial Is Set as Drug Suits Boom; An Explosion in Litigation Spurs Calls for Legal Reform and Regulatory Changes, L.A. Times, June 27, 2006.

[2] *Id.*

The defense is based on the fact that these lawsuits ask juries to determine whether the manufacturer of a medicine properly described complex scientific information about its medicine in its warning labeling. Juries often struggle with determining what the correct standard is on these issues. The FDA defense would guide juries by attaching importance to the fact that the FDA considers these very same questions and approves safety labeling for medicines based on its monitoring of safety information.

The FDA spends a great deal of time examining safety data and making sure that that information is appropriately described in each medication's labeling. The FDA must approve this labeling word-for-word before the drug can come to market at all, and changes to the labeling must also be approved by the agency. In fact, Congress has made a point over the past several years to ensure that the FDA explicitly has the power to order label changes and to gain full access to the most up-to-date safety information. There are severe criminal and civil penalties for a company that misbrands a drug, markets it without approval, or withholds information from or misleads the FDA.

The FDA defense would rely on this extensive FDA oversight. It would not bar plaintiffs from bringing lawsuits against pharmaceutical manufacturers. Instead, it would increase the level of proof required when the company has followed the FDA's rules. The bill provides that, when the FDA's process works the way that it is supposed to, a company should receive a measure of protection from lawsuits by following that process.

Under such circumstances, a presumption arises that the drug is "safe and effective for its approved use." A plaintiff has to prove otherwise by "clear and convincing evidence." This is the same standard that North Carolina law uses in several other areas.[3] It is a stronger standard than the "more than half" implied by preponderance of the evidence, but it is by no means impossible to show.

This defense would not apply at all if the company did not follow FDA rules in a way that impacts the case. Specifically, a plaintiff can show that the presumption does not apply by proving that the manufacturer participated in one of several types of misconduct that undermine the integrity of the FDA process: (1) it disregarded an FDA order removing the drug from the market; (2) it was found to have withheld from or misrepresented to the FDA information material to the approval of the drug; (3) it made an illegal payment to a government employee to secure approval; or (4) it promoted the drug for off-label use. If a plaintiff can prove that one of these types of activities occurred, the defendant would not get the benefit of the FDA defense.

[3] *See* N.C. Gen. Stat. § 7B–805 (child neglect); *Upchurch v. Upchurch*, 128 N.C.App. 461, 464 (1998) (trusts & estates law).

Several other states have similar FDA defenses that have worked well in practice. For example, the Committee heard last month about New Jersey's FDA defense, which is actually stronger than the presumption that Bill Draft 2011-TG-14A would provide. The New Jersey law provides a rebuttable presumption that FDA-approved warnings are adequate, but New Jersey courts have interpreted this defense as being "virtually dispositive" in the absence of "deliberate" misconduct.

Even with this defense, lawsuits regularly proceed to trial and verdict in New Jersey. There are presently fourteen mass tort and coordinated proceedings that deal with pharmaceuticals in New Jersey, with well over 17,000 plaintiffs between them. Trials are regularly ongoing in these cases, and they include the very same medications that this Committee has heard about, meaning that these plaintiffs in New Jersey are not being denied their day in court. New Jersey has simply adopted a means of identifying those cases which should or should not go forward, and those cases where the company is entitled to a defense based on following the FDA's rules.

The North Carolina FDA defense would serve the same purpose. It would not "immunize" defendants generally from liability. Instead, it would simply help identify the cases that should move forward by imposing a higher standard when a drug meets FDA's rigorous safety requirements and when the company follows the FDA's rules.

When the regulatory system works, the defense provides protection to manufacturers who are following the safety rules. This screens out cases where the FDA has ensured that a proper warning was given or that the science does not support a warning. But the presumption also provides a straightforward avenue for plaintiffs to allege that those safety requirements were inadequate for a given drug and that the FDA's process was compromised -- those cases can go forward. This screening process is good not only for pharmaceutical companies that innovate and create jobs in the State, but also for the other parties, like doctors and other health care professionals, who are often dragged into lengthy and complicated litigations with little basis either as witnesses or even, for strategic reasons, as co-defendants. It is not designed to immunize bad actors; it is designed to reward good actors. As such, it would promote fairness in these cases and further the public health. Thank you.