Remarks of David R. Work to North Carolina Senate Subcommittee on Pharmaceutical Liability, March 29, 2012

I am David Work, Executive Director Emeritus of the North Carolina Board of Pharmacy. I served as Executive Director of the Pharmacy Board for over 30 years until April 30, 2006. The Pharmacy Board is the state agency charged with regulating the practice of pharmacy through the adoption and application of rules, issuing licenses after examination, and conducting disciplinary actions for misconduct. I served as President of the National Association of Boards of Pharmacy in 1993-1994.

I hold a pharmacy degree from the University of Iowa and a law degree from the University of Denver. I received the Order of the Long Leaf Pine in 1981, and a Doctor of Humane Letters (Hon.) from Wingate University in 2007.

This Subcommittee is considering a bill to create a "Product Liability Defense" in litigation involving drugs approved by the federal Food and Drug Administration (FDA).

I believe it would be unwise to adopt this legislation for several reasons. First, the proposed bill is bad for consumers. The federal Food, Drug and Cosmetic Act was never intended to be part of a system to convey immunity from litigation against any business, profession or group of providers. It was directed at protecting the public, not special interest groups. Granting immunity to manufacturers, based on the FDA drug approval process, would remove a crucial incentive for drug companies to take prompt remedial action when they discover adverse events.

Second, the proposed bill is bad for pharmacists. As practicing professionals, many of whom own or operate small businesses, pharmacists necessarily depend on drug manufacturers to provide accurate and timely information about pharmaceuticals on a continuing basis. Many adverse side effects are first discovered in the marketing phase, after the FDA has issued its approval. Typically the drug manufacturer learns about these adverse events long before the FDA, while the physician, pharmacist and consumer remain in the dark. If a consumer is injured and the drug company has immunity, the pharmacist will face an increased risk of liability.

The FDA relies on the manufacturer to provide data on safety and effectiveness for any drug being considered for approval. In the typical case the manufacturer enters into a contract with a Clinical Research Organization (CRO) to conduct research and obtain the information requested by FDA. The normal clinical trial compares the new product with a placebo for effectiveness. This means that the new compound must be better than nothing -- not a high standard.

The FDA issues multiple warning letters each year to drug companies that have withheld information, submitted false information or have problems with the integrity of their data. The examples below illustrate that dangerous drugs with fraudulently obtained FDA approval can remain on the market for years, increasing the drug companies' profits and harming the unsuspecting public, without resulting in any "final agency action" by the FDA.

THE KETEK DEBACLE

In 2000 the drug manufacturer Aventis submitted fraudulent and fabricated data and misled the FDA into approving the drug Ketek used to treat sinus infections. Aventis's clinical investigator in charge of the

study necessary for approval had fabricated 350 patients, forged consent forms and faked results. The clinical investigator pleaded guilty to fraud in 2003 and was sentenced to 57 months in prison.

An external auditor under contract with Aventis testified at a Congressional hearing that Aventis had concrete knowledge of the blatant fraud and forgery. The auditor repeatedly told officials at Aventis about the numerous problems until Aventis fired him with a warning not to speak to the FDA . In addition to the evidence from the criminal case and the congressional hearing, two FDA special agents concluded in separate investigations that Aventis knowingly submitted fraudulent data to the FDA. Nonetheless, in 2008, the FDA closed the case against Aventis with just a warning letter.

Aventis misled the FDA, and Ketek should never have been approved. People who took Ketek for a common cold died of liver failure. Yet by the time FDA withdrew approval of Ketek in 2007, the dangerous drug had been on the market for almost three years, doctors had written over five million prescriptions for Ketek, and Aventis had made over $400 million. There was never a final agency determination of fraud.

METABOLIFE HIDES DRUG SIDE EFFECTS

Metabolife International, Inc. was one of the largest sellers of dietary supplements in the United States. The drug company specialized in an ephedra-based diet pill that generated hundreds of millions of dollars in annual sales. In 1997, the FDA was concerned about the safety of ephedra and considering stricter regulation. Metabolife vigorously opposed stricter regulation and submitted documents to the FDA claiming there had been no adverse drug events associated with Metabolife's diet pill. In fact, Metabolife knew of over 10,000 adverse events, including heart attacks, strokes, seizures, psychosis and death.

Metabolife and its founder were indicted on eight counts of making false, fictitious and fraudulent representations to the FDA. Ultimately Metabolife entered a confidential plea agreement and Metabolife's founder paid $20,000 and pled guilty to one count of providing false information to the FDA. The FDA never made a determination by final agency action that the drug company had intentionally withheld information or submitted false information related to receiving or maintaining drug approval. In 2004, the FDA withdrew approval for ephedra because it was too dangerous, after the deadly diet pill had been on the market as an FDA-approved drug for eight years.

FDA approval should never relieve the drug manufacturer of its continuing duty to exercise reasonable care. Because clinical trials include only a limited number of patients in a limited span of time, they cannot prove that a drug is safe. The real test of safety occurs after FDA approval, when the drug has been used by tens of thousands or millions of patients, and enough time has elapsed to see the long-term side effects.

As Executive Director of the Pharmacy Board, my primary mission was to protect the public. The proposed bill allows negligent drug companies to avoid responsibility for their conduct, and puts innocent consumers at risk. To protect public health and safety, I urge you to reject this bill.