Remarks by Mary Bethel
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Senate Judiciary 1 Pharmaceutical Liability Subcommittee
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Good afternoon Mr. Chairman and members of the Subcommittee. I am Mary Bethel, Associate State Director for Advocacy for AARP North Carolina. I have worked with programs for older adults in North Carolina for over 36 years.

AARP is a nonprofit, nonpartisan social welfare organization with a membership and offices in all 50 states as well as the District of Columbia, Puerto Rico, and U.S. Virgin Islands. The mission of AARP is to help people 50+ have independence, choice and control in ways that are beneficial and affordable to them and society as a whole. We seek to help older Americans live long and healthy lives.

Although I was not present for the Subcommittee meetings on February 21 and March 29, I have gone back and read the comments of the persons who made presentations at the meeting. Since no group relies more on medication than seniors, after reading the comments, I felt that it was important that AARP North Carolina take this opportunity to relay our position on the proposed bill.

It is very important to AARP, and our over 1 million members in North Carolina, that the pharmaceutical industry be accountable for the manufacture and quality of the medications it produces. Liability lawsuits against manufacturers provide a vital check to protect consumers and should be preserved.

Older adults are the largest per capita users of prescription drugs, therefore they are the most likely to be at risk. One in three older adults uses 5 or more prescription medications regularly (JAMA 12/24/2008 "Use of Prescription and Over-the-Counter Medications and Dietary Supplements Among Older Adults in the United States"). This is a key reason AARP is particularly interested about this proposal to grant immunity for drug manufacturers. The safety of drugs, their interaction with other medications, and their effect on seniors who are more vulnerable must be examined rigorously and understood.

The proposed legislation would grant a special immunity in cases where federal approval is granted. This would ignore the reality that the federal resources for approval are limited and the adverse effects of drugs are often discovered only after approval. A study in the Journal of the American Medical Association in 2002 found that only half of newly discovered adverse drug reactions are detected and documented within seven years of a drug's approval.

Previous speakers have already shared examples of consumers harmed by "approved" prescription drugs that were unsafe or marketed without adequate warnings. I will offer another example - a drug prescribed for type-2 diabetes, a condition that impacts many seniors. The drug is Actos, manufactured by Takeda Pharmaceuticals. The FDA approved the drug for market even though initial clinical tests showed an increase in bladder tumors in male rats. Today, hundreds of patients have filed suit against the company after a study showed patients taking the drug for more than a year have a 40 percent increased risk of bladder cancer.

AARP's interest in protecting consumers in this area is also reflected in its endorsement of the Patient Safety and Drug Labeling Improvement Act in the U.S. Congress. This bill would address the issue of whether generic drug manufacturers have a duty to include new warnings about potentially serious side effects on their labels as they become known. This bill is needed to give consumers of generic drugs greater protection.

Because new knowledge can require new warnings, drug manufacturers must take reasonable steps to ensure that their drugs are adequately labeled. They should not be immune from liability under state law if they fail to take reasonable steps to ensure that consumers are properly warned about risks from their products.

In closing, many of the citizens of our State, including older adults, depend on medications to live better, fuller lives. We ask this Subcommittee and the General Assembly to not expose them to the risk that this legislation represents - the risk that drug companies will not be held accountable when people suffer harm, or worst yet, die. To protect the citizens of North Carolina, please do not move forward with this bill.

Thank you for this opportunity to address you today.