North Carolina Legislature, Senate Subcommittee Meeting
Thursday, March 29th, 2:00 p.m.

Dr. Wayne Welsher

My name is Dr. Wayne Welsher. I am a cardiovascular surgeon, now retired. Before I retired I was a heart surgeon for over 25 years, serving as Chief of the Department of Cardiovascular Surgery at Cape Fear Valley Medical Center in Fayetteville, North Carolina. I'm also a life-long Republican, and I consider myself to be very conservative. I'm here to urge you to vote against this proposed bill to give drug companies immunity from lawsuits in North Carolina because, based on what I've seen in my own practice in recent years, I think it's a very bad idea.

The rationale of this bill seems to be that if the FDA approves a drug as safe and effective…then it probably is. I'd like to believe that's the case, and it may have been true in the past, maybe back in the 1950's. But today – with drug companies paying millions of dollars in fees to "fast track" drug approval, and with drugs that were once approved by FDA being pulled off the market every year, it's simply naïve to believe that FDA approval is a guarantee of safety. My experience with the drug Trasylol is a good example, and it's a story that's very relevant to the decision you're about to make.

Trasylol was used for years in open heart surgery because it was believed to reduce the risk of bleeding and to improve patient outcomes. It was approved by the FDA as being "safe and effective," in the mid-1990's. I didn't start using the drug myself until the early 2000's and, in my patients, it was effective to do what it was approved for – to help reduce bleeding. But then we started to notice that a lot of our patients were developing kidney failure after their surgery. Now that's a very serious complication of open heart surgery, and it's often a fatal complication. At first, we didn't connect these cases of kidney failure with the drug itself because FDA had nothing to say about kidney failure as a possible side effect of the drug, and the manufacturer, Bayer, was telling us flatly – through its sales reps – that the drug *didn't* cause kidney failure.

I only found out that wasn't true after I was drawn into the Trasylol litigation as a fact witness. I had prescribed the drug for several patients of mine who then developed kidney failure and died. These were North Carolina citizens whose families filed wrongful death claims, and in the course of those cases, I was deposed by representatives of the defendant, Bayer. Over the course of those depositions, I learned that – despite what its sales reps were telling me – Bayer had known for years that their drug caused kidney failure and increased the risk of death. Bayer had conducted studies in-house – like the Kress study, which they finished in 2003 – that reported Trasylol tripled the risk of kidney failure after heart surgery. But Bayer didn't publish those studies, and didn't report them to the FDA and certainly didn't tell us, the doctors who were using the drug. So we were completely in the dark about that risk for years…and so was the FDA.

The problem didn't really become public knowledge until 2006 when an independent researcher, Dennis Mangano, published an article in the *New England Journal of Medicine*. Later that year the FDA convened an Advisory Committee meeting to re-examine the safety

record for the drug. And after that meeting it was learned that Bayer had conducted another major study, involving some 80,000 patients, which again confirmed the risk of kidney failure and death associated with this drug. Bayer didn't publish that study, either, and they didn't report it to FDA until the lead author of the study, Dr. Alexander Walker, threatened to blow the whistle. When it learned about the Walker study, the FDA finally asked Bayer to withdraw the drug from the market in November of 2007 and at that point, the FDA was quoted in the New York Times as saying this drug, Trasylol, was so dangerous that there was "no class of patients for whom the benefits outweighed the risks." So that's what FDA thought in 2007, about a drug they had been approving as safe and effective for the past 13 years.

So: it's naïve to assume that a drug is safe, simply because it's approved by FDA – and unfortunately, it's also naïve to assume that drug companies share all the safety data they have with the FDA, when they have a multimillion dollar incentive not to do so. And when they don't do that, when a drug company makes hundreds of millions of dollars, like Bayer did, selling a drug that they know has safety problems they're not telling doctors about, then it just seems to me, as a matter of what's right, the drug company ought to bear responsibility for that. At a minimum, they ought to be required to refund the money the taxpayers spent for medical bills. I can tell you that in each of the Trasylol cases where I testified, my patients' families received at least a modest recovery and in every case, the Medicare program got reimbursed for the medical bills they had paid. If this bill passes – if this bill had been in effect last year – that simply wouldn't have happened. The burden of paying those medical bills would have been shifted from the drug company that was at fault – to the taxpayers of North Carolina.

As a Republican and as a physician, I just don't think that's right. It offends my sense of fairness. That's why I've taken the time to come talk to you today, and that's why I respectfully urge you to vote this bill down. Thank you.