ment to the effect that we haven't any right to examine the effectiveness of this class of drugs.

Senator NELSON. This is a prescription drug?

Mr. GOODRICH. No.

Senator NELSON. And they are contesting the legal authority of the FDA to act in this?

Mr. GOODRICH. Yes.

Let me go back. It is an over-the-counter drug for so-called capillary fragility, for bleeding states. The contention is that since the product became generally recognized as safe some years ago—it is essentially innocuous—that it is not subject to have the effectiveness review that is now going on. We, of course, are contesting that issue in the district court in Alexandria.

Senator NELSON. Under the law, if the drug is one of that class of drugs involved here and is found to be ineffective, does FDA have the authority to require its removal from the marketplace?

Mr. GOODRICH. We think so. The drug industry is contending in a suit that has been pending in Wilmington, Del., since soon after the enactment of the 1962 amendments that they have certain protections under the grandfather clause of the 1962 amendments. That case has never been pressed on to trial because of the pendency of the NAS–NRC review, and the plaintiff has been reporting to the court that it wishes to await further process in that review before deciding what to do about that pending action in Wilmington.

Senator NELSON. The National Academy is doing the review?

Mr. GOODRICH. Yes.

Senator NELSON. And they, I assume, are using consulting clinicians around the country?

Dr. LEE. Yes, sir, the Academy set up a number of panels with a chairman of each panel. They review all the data that is available, evaluate it and make their recommendations.

Senator NELSON. And on this drug they came to the conclusion it was ineffective?

Mr. GOODRICH. Yes.

Senator NELSON. Is the company contesting that conclusion?

Mr. GOODRICH. No, they are contesting our right to subject the article to administrative procedures of requiring proof of effectiveness. They would, of course, I think contend that they have some evidence that the product is effective. They have submitted that evidence to the Food and Drug Administration, and it has been reviewed and found to be wholly inadequate.

Senator NELSON. So what they would like is a chance to sell placebos at high prices?

Mr. GOODRICH. Right.

Senator NELSON. Please go ahead.

Dr. LEE. To return to my statement, Mr. Chairman, and to focus on the adverse drug reaction reporting system available to the Food and Drug Administration, we are trying to improve this system. And I would just like to cite a recent example in an article which revealed that among a group of patients hospitalized for chronic illness, 35 percent had at least one reported adverse drug reaction. Eighty percent of these reactions were either moderate or major in their severity. Only 20 percent were described as minor.