Senator NELSON. You do not preclear the package insert?

Mr. GOODRICH. We do not. The law exempted—just drew a line—products on the market June 1938 and before. So long as they have the same claim they are not subject to new drug preclearance.

Senator NELSON. Have the same what?

Mr. GOODRICH. Same claims in use as in 1938.

Senator NELSON. Supposing you found out that these claims were not justified. Do you have any authority to require that changes be made?

Mr. GOODRICH. Yes. We would have the authority to proceed through the courts to charge them to be—as being misbranded, and then for us to bear the burden of proving the claims false rather than the burden under the new drug provisions being on the company to prove the drug's effectiveness. That is just a difference in the burden there.

Senator NELSON. Do you know what percentage of the prescription drugs in the marketplace are exempt from your authority to regulate?

Mr. GOODRICH. No; we do not have any reliable figures on that. We are pretty sure that a great majority of the drugs now in use are drugs that have entered the market since the enactment of the new drug law in 1938. There would be a number of oldtimers, of course, that were on the market in 1938, that are still around—phenobarbitol, thyroid, a lot of others. But the great majority of drugs, I think I am correct in saying, now in use are drugs that have been developed between 1938 and the present time. This is why we regard as quite important, our contract arrangement with the National Academy of Sciences, to review the claims of effectiveness for these drugs marketed between 1938 and 1962, enabling us to bring to bear the new requirements of effectiveness on those products. Congress' solution to this in 1962, rather than exempting all those premarketed drugs completely, was to give us the right to, through administrative action—to go back and review the claims, product by product, and to be sure that they were effective as claimed.

Senator NELSON. That authority extends just on drugs marketed from 1938 to 1962?

Mr. GOODRICH. Yes, sir.

Senator NELSON. And you are in the process of reviewing them now?

Mr. GOODRICH. Yes, sir. The contract has been virtually completed, I think. We are getting the reports now, and we have begun to implement the reports by requiring changes in the labeling and packaging.

Senator NELSON. Once the review has been done, do you then, under the law, have the authority to control the package insert?

Mr. GOODRICH. Yes, sir. But we have a dispute with the drug industry about the extent of our authority. But we think we have enough authority to carry this forward.

Senator NELSON. Go ahead, Doctor.

Where were you?

Dr. MCCLEERY. I would like to pick up in the middle of page 8, paragraph c.

We believe that the quotation that we have been talking about misleads in that it is obsolete when used in the ad in 1966, in that it fails to take into account more recent, more scientific, but less salubrious opinions of the same authors available to the firm in medical literature published about a year prior to the ad. The company was aware of the more recent literature, and the facts are that—(1) in 1965 the