Senator NELSON. Well, as I understood your testimony, you requested the companies to summarize the data that had on all their drugs that came under the purview of the law. What was the status of that request?

Mr. GOODRICH. That was a record and reporting requirement that they were to report to us an initial report certifying that the clinical claims as they appeared at that time, 1964, in the promotional material were supported by the clinical information known to the company, and that if the company had any clinical reports that did not support the claim, they were to submit the report together with a revision of their label.

And an initial report was made on this drug which certified that the claims were supported.

There were no reports of this negative finding as we look at the files today. We only received these reports through an inspection conducted earlier—just a short time ago.

Senator NELSON. And do I understand it to be your interpretation of the law that concerning the requests that the FDA made of the companies to supply them with the summary—or whatever they had—that the FDA had authority under the law to require them to do so.

Mr. GOODRICH. Yes, sir. And the failure to make a report is both a ground for suspending the product from the market and for regulatory action of a criminal nature if the report was not made as required.

Now, as Dr. Ley pointed out, with many drugs, but not with the antibiotics—there was a contention that about a thousand drugs were exempt from the recordkeeping and reporting requirements, because they had become old drugs prior to the enactment of the 1962 amendments, and that the 1962 amendments only required records and reports for those products that remained new drugs as of 1962. We contested that issue. The PMA sued us in Delaware. And the case is still pending there. And PMA has notified the court that it does not wish to press on with the case until it can learn more about the NAS–NRC study which is now underway.

Senator DOLE. Mr. Chairman.

Senator NELSON. Senator Dole.

Senator DOLE. I am still learning about all the drugs and terms, as a freshman member of this committee. But I am wondering, what is the role of FDA in determining the relative efficacy with reference to fixed combinations, with specfic reference to the letter, the report by Dr. McQueen? Is this responsibility you have in fixed combinations to determine the relative efficacy or not? Is this the matter in question.

Dr. LEY. Let Mr. Goodrich, if he will, speak to the legal aspects and then let me speak to the medical aspects.

Mr. GOODRICH. The issue no doubt that you are addressing yourself to, Senator, is the testimony of Senator Ribicoff when he was Secretary of Health, Education, and Welfare supporting the Kefauver bill when he said that we did not seek control over relative efficacy. However, where promotional material makes a relative efficacy claim, then that claim has to be supported by substantial evidence. In this case Upjohn has claimed that Panalba, the combination