well as the promotional literature, there wouldn't be a rational doctor in America who would prescribe it. That strikes me as a shocking situation in the practice of medicine, and the promotion of drugs. It isn't the doctor's fault. He believes that this drug has been proven. But the fact is that it not only has not been proven, but there would appear to be no doubt in where a combination of studies indicated that the blood level dropped to zero, where a doctor is prescribing for a patient with the expectation that this drug will do even more than tetracycline and novobiocin in combination, there would appear to be no doubt that he is not giving his patient the best medical care; isn't that correct?

Dr. LEY. One could draw that conclusion.

Senator NELSON. There has been testimony before the committee that because of this product, because of the way the investigations of this kind are done for drug companies, that the companies ought to be required to have the investigator, who did their study, send a copy of his study to the FDA. Do you think that would serve a useful purpose?

Dr. LEY. At this time, Mr. Chairman, I do not believe that this type of loophole exists to any significant degree. It may remain for certain products which have been marketed prior to the 1962 amendments. I do not believe it is present now.

We investigated as well as we could the reason why these data had not been formally provided to the agency before hand. In 1964, as I recall, the firms were requested, as Mr. Goodrich indicated earlier, to summarize all existing material on the older products marketed before 1962, and provide a summary to the agency for review.

Now, as nearly as we can determine, these studies conducted in 1959 and 1960 by Upjohn were not summarized in the material they provided us in 1964. So that we are faced with the fact that these studies should have been provided to us in 1964. They were not, as nearly as we can determine. I believe they should have been at that time.

Senator NELSON. What makes you so confident, then, that it isn't still occurring?

Dr. LEY. I believe that firms doing investigational studies on drugs after 1962 have been far more careful and trustworthy in providing data to us. The 1962 law makes this compulsory for all firms developing new drug products. Since I have been commissioner I have yet to find an example where a firm has not been most proper in providing investigational data to us.

I think the Senator should recognize that we are speaking about a class of drugs marketed between 1938 and 1962 where FDA and industry have had strong differences of opinion. The matter was finally taken to court. Industry questioned the Agency's right to require efficacy data for this group of drug products. Mr. Goodrich can provide the background information on the various legal cases that were raised in the early days of implementating the Kefauver-Harris amendment. This particular group of drugs marketed between 1938 and 1962 has been the subject of very serious discussion and argument, concerning the extent of our authority.