say that the process was objective. Furthermore it did involve the firms and their body of information to as great a degree as the firm chose to involve themselves.

May I continue, Mr. Chairman?

Senator NELSON. Let me say this. I understand each one of these distinguished panels offered to the company whose product was involved the full opportunity to prove the case with demonstrated examples of scientifically controlled studies pursuant to the standard established in the statute under the Kefauver-Harris amendments; is that correct?

Dr. LEY. That is absolutely correct.

Senator NELSON. And these companies 5 and 6 years after the law was passed, and in some cases 10 and 15 years after they started marketing the drug, were unable to produce for the panels, for their review, scientifically controlled studies; is that not the fact?

Dr. LEY. This is correct with many of the drugs considered. With other drugs the panels did reach the judgment that the data presented supported efficacy. But in speaking of the combination antibiotics, the panel, after reviewing all the material that the manufacturer had been able to collect over this period from 1962 until roughly 1966, when it was submitted to the Academy——

Senator NELSON. My question was addressed only to those fixed combinations that the National Academy concluded did not meet the statutory standard of efficacy. And as to that, adequately controlled studies were not produced.

Dr. LEY. Adequately controlled studies were not produced.

Senator NELSON. And as I understand it, the recommendation of each of the five panels on the fixed combination antibiotics was unanimous?

Dr. LEY. That is correct.

Senator NELSON. Isn't it also correct that the scientific community, involving those who were expert on the use of these various drugs, concluded a good many years ago that fixed combinations were not efficacious?

Dr. LEY. There were many members of the scientific community who concluded and spoke very vigorously that fixed combination antibiotics were an illogical and irrational therapeutic tool as early as 1952.

Senator NELSON. Do you recall a 1957 article by Dr. Dowling, who is past chairman of the AMA Council on Drugs, in which he took this position?

Dr. LEY. Yes, sir.

Senator NELSON. I think I have already put this in the record. But are you aware that the AMA Journal itself has editorialized very strongly against fixed combinations over a period of years?

Dr. LEY. I am aware of that.

Senator NELSON. I think this would be an appropriate place to put in the record a memorandum by Dr. Max B. McQueen of the FDA. This point was made before the Fountain committee on May 13, and presented to the Fountain committee at that time, but it did not receive much notice. Are you familiar with the memorandum from Dr. McQueen, to Dr. Paul Bryan respecting the studies that your inspector, Roy Sanberg, obtained from the Upjohn Co. files on March 7, 1969?

Dr. LEY. Yes, sir.