So it refers entirely to the standards in the antibiotic regulations.

Senator NELSON. In this case, you had both a product patent and a process patent, is that correct?

Dr. LUECK. I am sorry, I cannot comment on the process patent with certainty at the moment.

Senator NELSON. I am reading from the Pink Sheet, April 25, 1966:

Parke, Davis Chairman Harry Loynd at April 19 stockholders meeting predicted another $70 million Chloromycetin year for 1966 despite the expiration in October of the product patent, the first basic one on the drug. Even after October, it will be illegal for anyone to manufacture Chloromycetin in the U.S. A key process patent doesn't expire until July, 1967.

Is that an accurate statement from the Pink Sheet?

Dr. LUECK. I would have to presume, Mr. Chairman, that it is an accurate statement.

Senator NELSON. So the record is clear, we have a case here which does not involve standards set by the U.S. Pharmacopeia at all.

Dr. LUECK. Yes, sir.

Senator NELSON. We have a case here in which the FDA set the standards under law.

Dr. LUECK. Yes, sir.

Senator NELSON. Do you know whether or not your experts from Parke, Davis were consulted by FDA as to what those standards ought to be?

Dr. LUECK. Yes, sir.

Senator NELSON. And they agreed with the standards that the FDA established?

Dr. LUECK. Well, the normal procedure, Mr. Chairman, was followed in the case of Chloromycetin, where the drug was discovered and researched and our information supplied to the Food and Drug Administration requesting permission to distribute the product for certain medicinal needs.

Senator NELSON. No; I mean when the patent ran out.

Dr. LUECK. Oh, no; when the patent ran out, there was no communication between Parke, Davis and the Food and Drug Administration on changing standards.

Senator NELSON. Did the FDA then just adopt the standards that had been agreed upon between the FDA and Parke, Davis up until the expiration of the patent?

Dr. LUECK. Yes; the same standards that applied before the patent ran out still applied after the patent ran out. They still prevail.

Senator NELSON. Were the experts in Parke, Davis aware that if only those standards were met, the drug manufactured by another firm would not be therapeutically effective?

Dr. LUECK. No, sir; we were not. We were only aware of the therapeutic equivalency of our own product.

Senator NELSON. Therapeutic effectiveness, you mean?

Dr. LUECK. That is right.

Senator NELSON. Because you did not have any equivalency test.

Dr. LUECK. I am sorry, I used the wrong word. Thank you for correcting me.

Senator NELSON. So even the best experts in Parke, Davis that had been manufacturing this drug on an exclusive basis for 17 years did