drugs in the whole history of the business so far as anybody has been able to prove. On each occasion, we have had witnesses before the committee from the industry, we have asked for examples of cases where USP standards were met, but the drugs did not have therapeutic equivalency, and the industry has not produced them.

Now, they can produce all kinds of cases where there was bad quality control and the product on the market did not meet USP standards and therefore was not therapeutically equivalent. But it is a rare case so far as this committee can find out, where drugs meet USP standards, but are not equivalent. That is the crux of the whole matter.

As a matter of fact, I am sure you are aware that every formulary in America, both in public programs and private hospitals is based upon the assumption that if drugs meet USP standards, they are therapeutically equivalent. As I am sure you are aware from the testimony in the record, time after time when we asked doctors who practice in hospitals using a formulary, whether the generics included in the formulary produce results equivalent to the brand names, the answer was "Yes, they do."

So what you are arguing against here is the common practice in the whole of the medical profession in the finest of the hospitals in America where formularies are used on the assumption that if drugs meet USP standards, they are equivalent and experience has demonstrated that they are.

Yet the industry has come in today and said, "Well, we have a case here where the standards are met but the generic is not equivalent. There is a problem with this drug, in part because it just came off patent." Your company had the patent and the exclusive control over the production, marketing, and use of this drug for 17 years. When it came on the market, FDA established a standard which your tests prove to be inadequate. But then to proceed, as the industry does, to propagandize the idea that, on the basis of one example, you cannot trust legal standards, seems to me to be a very weak case, frankly. I have said this to every witness who has appeared.

Mr. CUTLER. Mr. Chairman, the next witness, Dr. Slesser, is prepared to testify on the frequency of the occasions in which drugs that contain the same active ingredients have been scientifically demonstrated not to be therapeutically equivalent, and the fact that USP itself specifically disclaims that meeting its standards results in therapeutic equivalency. They specifically deny that in the beginning of their own book.

Dr. Lueck is prepared to testify about chloramphenicol. If we could have Dr. Slesser then discuss with you the frequency with which these occurrences take place I think that might be more orderly.

Mr. GORDON. But, Mr. Cutler, although Dr. Lueck is discussing chloramphenicol, he is drawing broad conclusions, from this one case only.

One other thing, Dr. Lueck, is it not also correct that a patent on the process expired only in July of 1967, only a few months ago.

Dr. LUECK. I can't be sure of that, Mr. Gordon.

Mr. GORDON. Well, the Pink Sheet recently made a statement to the effect that many firms would be unable to manufacture Chloromycetin