

Mr. GORDON. Mr. Stetler, pursuing the problem of content rather than format, the article, "The Anonymous Drug That Hospitalized a Patient," which is part of the advertisement is based on a letter which was sent to the Canadian Medical Journal on January 12, 1963, on tolbutamide. The chairman referred to it a while ago.

The article in the PMA ad does not include the fact that the generic product used was outside the limits set by the Food and Drug regulations of Canada as the chairman stated. Don't you think that was a very important piece of information that should have been included?

Mr. STETLER. No, I do not.

Mr. GORDON. In other words, you are comparing a brand name drug with a generic named drug that was on the market illegally?

Mr. STETLER. Well, I suppose all of them that after the fact are determined not to meet standards are on the market illegally. But they are on the market to be used to fill prescriptions that are written generically at that time. That is the point that is being made here. It is very easy after the fact to say it is an illegal drug—it does not meet the standards. But who knows that when the prescription is presented and it is on the shelf of the drugstore, and it is used—this is basically one of our points. That merely an indication on a label that it allegedly meets USP or NF standards is not the beginning and the end of the story.

Mr. GORDON. But we are dealing with the problem of equivalency, or at least clinical effectiveness of drugs that meet USP standards—not drugs that do not.

Mr. STETLER. I suppose the person that got this, and the pharmacist that dispensed this assumed it met USP standards, or it would not have been on the market to be available to fill that prescription.

Senator HATFIELD. Mr. Chairman, I would like to interrupt here. Mr. Gordon brings up something I have found over the hearings to be difficult to comprehend and a lot of discussion but little fact.

Is there in your opinion any kind of scientific data which shows therapeutic equivalency between generic and brand names, or a differential?

Mr. STETLER. It is not a matter of opinion of mine, Senator. We have had concrete, specific, scientific documented evidence that was presented to the committee on Monday of this week, which we are prepared to present today——

Senator HATFIELD. You have it with you?

Mr. STETLER. We have it.

Senator HATFIELD. Could we have it?

Mr. STETLER. This is from Parke, Davis. Dr. Lueck is here prepared to discuss it if he is permitted to.

Senator HATFIELD. Mr. Chairman——

Senator NELSON. When did we receive that testimony?

Mr. STETLER. Monday of this week—the first chance we had to give it to you. But on the 6th of this month, when we presented my statement and Dr. Lueck's statement we said "We have preliminary information and we will have more, and we will get it to you as soon as we can." That was delivered on Monday of this week, 3 or 4 days ago, in full detail, with all the charts to document the material in the statement, and Dr. Lueck is here prepared to talk about it today.