

Mr. STETLER. When they did the excess run, they took that off.

Senator NELSON. Well, can you believe there was any intent on the part of whoever did it, other than to mislead the public as to what it was?

Mr. STETLER. I can tell you with assurance there was no intent on my part. And I am responsible for the PMA's part of it. It was their recommended format. I accepted it. And I do not attribute deception to them, and certainly there was none on our part.

Senator, could I begin on this statement?

Senator NELSON. I just have one other item here, and then Senator Hatfield has a question.

I think with regard to this ad I ought to put something in the record at this stage. It is a letter from Wolins Pharmaceutical, and I quote:

As a follow-up to our report to you of October 19, 1967, we enclose the November issue of Reader's Digest.

This issue, as you no doubt know, contains an 8-page advertising section placed by the Pharmaceutical Manufacturers' Association. We offer it as additional and continuing evidence that the PMA is going out of its way to malign generic name drugs and undermine public confidence in them.

We draw your particular attention to page M-4, second column, to the article's reference to tolbutamide. We were not aware that tolbutamide was available under its generic name. The patent is owned by Upjohn, circa 1957, and the drug is produced and sold in the United States only by Upjohn under the name Orinase. It is one of the fifty most prescribed drugs. Wolins has no knowledge of it ever being offered in this country under its generic name; in fact, we believe that we are safe in saying that no other brand name manufacturer in the U.S. produces it either.

We wonder why the PMA has to go all the way to Canada to find an example of an unsatisfactory generic name drug? Canada, of course, does not impose the strict manufacturing controls in operation in the United States. Yet 50 million people were exposed to this distorted presentation.

Mr. STETLER. We are prepared to illustrate in our testimony some very specific examples in the United States.

Senator NELSON. All right.

One more thing about the example of tolbutamide. I want to put in a letter in the record to the Canadian Medical Journal by Arnold K. Carter, M.D., of Windsor, Ontario, in which he comments on the case of tolbutamide used as an example in the Reader's Digest article:

The firm replied at once that the tablets submitted were not of their manufacture, as judged by physical appearance, but that they would analyze them and report. The findings, which I received shortly, were as follows:

These tablets contained 500 mg. of tolbutamide but did not disintegrate after 45 minutes in gastric juice followed by 63 minutes in intestinal juice. They are completely outside the limits set by the food and drug regulations for tablets sold in Canada.

This is the exact example you are using—then the drug being used manufactured in Canada did not meet Canadian standards, and certainly did not meet ours, so it certainly cannot be an indictment of generic drugs as such.

Mr. STETLER. Senator, this drug was sold in Canada. Whether it met standards or not, it was available as a generic product. I am sure it is easy after it passed through the patient for somebody to say it did not meet standards.