(The letter referred to follows:)

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SUBSTITUTION FOR BRAND-NAMED DRUGS

To the EDITOR:

The serious consequences of a request by one of my diabetic patients that his druggist be allowed to supply a cheaper drug to refill my prescription for a brand-name tolbutamide prompts this communication. I believe it has a significant bearing on the present controversy about generic drug prescribing and might well alert some of my fellow physicians to hazards inherent in this practice.

This patient who had been controlled for 11 months on diet and 1 g. daily of tolbutamide (Mobenol) inexplicably went out of control recently, his fasting blood sugar rising rapidly to 287 mg. %. At that time the patient noted tolbutamide tablets intact in his stools and brought one tablet in to me. He was then asked to bring in the remainder of his prescribed tablets, and since his case record still specified that he was taking Mobenol, these were forwarded to the manufacturer, together with the passed tablet. At the same time the patient was hospitalized and his diabetes mellitus was controlled on the former dosage of tolbutamide.

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 distintegrate 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."

In other words, although these tablets contained the labelled quantity of drug, they were to all intents and purposes quite useless.

This episode has, therefore, resulted in temporary lapse in control of the patient's diabetes, and also necessitated the expense and inconvenience of a period of hospitalization in order to regain control. It has also resulted in subsequent investigation of the pharmacy concerned by the Ontario College of Pharmacy inspector which revealed a notation on the prescription concerned that permission to substitute a cheaper brand had been obtained from myself by telephone through my nurse.

This case, which has been a traumatic experience for the patient and myself, of course, does not necessarily indict all or even the majority of unbranded drugs as being suspect. However, since diabetes is one of the few areas of therapeutics where failure of response to a drug can be observed clinically and measured objectively, I consider this instance most significant and revealing. It makes one wonder how many product failures occur in other circumstances where results are less obvious or dramatic.

Until existing regulations allowing the import into Canada, distribution and sale at discount prices, of unassayed drugs are altered, I will henceforth not prescribe any drug without specifying a brand or manufacturer.

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Senator NELSON. Senator Hatfield.

Senator HATFIELD. Mr. Chairman, I would like to pursue this for just one or two moments, because as I understand, Mr. Stetler, you said earlier that the Reader's Digest approached you on this possible advertisement, and that it was drawn then in conjunction with an advertising company?

Mr. STETLER. Yes, sir.

Senator HATFIELD. Mr. Chairman, I suggest that perhaps you have focused upon something that might involve even the Reader's Digest, that perhaps we might have them before our committee—for the simple reason that if you look a few pages later, you will find another advertisement, a single-page advertisement which is not perforated, but purely a part of the magazine—it is not listed with a page number, because it, like this particular advertisement that we are talking