SAINT LUKE'S HOSPITAL
OF THE METHODIST CHURCH,
Cleveland, Ohio, November 10, 1967.

Mr. C. JOSEPH STETLER,
President, Pharmaceutical Manufacturers Association,
Washington, D.C.

DEAR MR. STETLER: Your letter to our hospital administrator containing a copy of articles to be published in the November issue of Reader's Digest has been reviewed by myself.

As I am certain that you are interested in the opinions of people concerned with these matters, I do wish to make a few comments. In brief I feel that articles such as "The Anonymous Drug that Hospitalized a Patient" is in poor professional taste. It pictures a dispensing pharmacist as being a part in a medication error. Further it does nothing to instill patient confidence in the physicians and phamacists who care for him since the patient has no idea as to the quality controls of the company manufacturing his drug. To me, the article seems to do little to instill confidence in the patient of American Pharmaceutical Manufacturers.

The increasing frequency of drug recalls from reputable companies is gradually becoming known to the public and may well create doubt in the mind of the patient as to the efficacy of a prescribed drug regardless of its source.

Sincerely yours,

FRANZ W. GEISZ, Pharm. D.,
Director of Pharmacy Service.

Mr. GORDON. Please continue.

Dr. APPLE. We think that the problem of poor quality drugs is diminishing. Legislation in 1962 substantially strengthened regulatory control of the drug supply of this Nation. Added and improved manufacturing standards through regulations and new analytical procedures and equipment are contributing to improved quality. In recent testimony before the Senate Committee on Finance, the president of the Pharmaceutical Manufacturers Association, representing producers of over 95 percent of the brand and generic drug products made and sold in this country, stated:

> We already have, under the Federal Food, Drug and Cosmetic Act, comprehensive mechanisms for assuring that only safe and effective drug products are on the market.

Even if we can prove, with reliable scientific evidence, that a few drugs in final dosage form vary significantly in therapeutic response produced in the patient depending upon which manufacturer made them, this would still not explain why we should not use interchangeably other drug products with insignificant therapeutic differences. The exceptions, if any, should be kept in perspective; they should not govern our entire prescribing and dispensing decisions.

If our drug laws must be strengthened to provide batch certification for clinical effectiveness of every drug product before marketing, then we should be prepared to take this step. We do not believe that this drastic step is either necessary or desirable but will reserve judgment on this point.

This dilemma of duplication of drug products has been solved in hospitals, welfare programs, and elsewhere—such as in some clinic- and physician-owned pharmacies—by establishing formularies. We have not heard evidence that a properly functioning formulary system has had either an adverse effect on patient care, the quality of drug