Mr. GROSSMAN. I want you to say that if you believe that the U.S.P. standards are not adequate, and that we should increase the minimum quality standards, why isn't the PMA pressuring the U.S.P. to do it. You have people on the U.S.P. that are members of PMA.

Mr. CUTLER. Mr. Grossman, what we have tried to say, and what the U.S.P. itself says, and the publisher, the editor of the N.F. himself says, is that laboratory tests of the type that those two formularies or documents prescribe will not determine pharmacological availability or therapeutic effectiveness.

Now, we cannot conjure up a test that will determine that in the laboratory. What we are trying to say is you can only determine that by clinical testing of the drug product itself.

Mr. GROSSMAN. And the U.S.P. does not at present——

Mr. CUTLER. The U.S.P. does not purport to establish clinical testing. It attempts to establish certain laboratory tests to detect the presence of an active ingredient in a drug.

Mr. GROSSMAN. Do you, as a consumer, feel safe when you take a drug that has a U.S.P. standard?

Mr. CUTLER. The consumer does not select his drug. He goes to a doctor.

Mr. GROSSMAN. You, yourself, sir—are you concerned when you take a drug that has supposedly met U.S.P. standards, that you are not getting the proper quality control?

Mr. CUTLER. I don't have an idea in the world whether it met U.S.P. standards. I do not know how I would know. I get a prescription from a doctor on whom I depend, I go to a pharmacy that he recommends, and I get a drug.

Mr. GORDON. On page 3 you discuss the great care exercised by manufacturers in insuring that the correct amount of ingredients is in each tablet. This is your statement.

At this point I would like to insert into the record a list from the latest issue of Clin-Alert on recalls of products from major companies. I might mention Diamox Sustets, put out by Lederle Laboratories; Coumadin, put out by Endo Laboratories; Panwarfin, Abbott Laboratories. These are all members of the PMA that produced drugs which could not meet U.S.P. standards.

(The document referred to follows:)

[From Clin-Alert, Nov. 3, 1967]

DRUG RECALLS

LABELING ERRORS

A. *Diamox Sustets (acetazolamide-Lederle Laboratories)*: Approximately 700 bottles of 500 mg. Diamox Sustets (the export name for Diamox Sequels) were recalled due to a labeling error. According to FDA's weekly report of drug recalls (Sept. 27 thru Oct. 3), the recall was initiated September 27, 1967 by telephone.

B. *Coumadin (warfarin sodium-Endo Laboratories)*: Approximately 30 million tablets recalled nationally. Tests showed that the tablets were above, and in some cases, below the stated potency levels on the labels. Variations were greater than those permitted to ensure safety. According to news releases (public announcement of the recall was made by FDA's New York Office) a spokesman for the food and drug agency warned that the overstrength tablets could be fatal to some patients. Later, Dr. Goddard, Commissioner of the U.S. Food and Drug Administration, was quoted as stating that lives would not be imperiled by taking the drug.