C. *Panwarfin (warfarin sodium-Abbott Laboratories)*: Approximately 4 million, 5 and 10 mg. subpotent tablets recalled. This FDA-initiated action was announced to retail pharmacists by letter dated October 10, 1967.

Mr. GORDON. Also you remember that some time ago we put into the record a list of major recalls, some of them including millions of tablets, from Squibb, Abbott, Roche, Pfizer. I cannot understand why you are making such a big deal about going beyond U.S.P. standards, when many of your own companies cannot even meet U.S.P. standards.

Dr. SLESSER. Dr. Scheele, are you going to talk about recalls?

Mr. GORDON. Also, I would like to call attention to a list of recalls, which I will put in the record, where the following companies, members of the PMA, could not even meet the current good manufacturing practices provisions of the Kefauver-Harris Amendment of 1962. For example, Squibb & Sons, "Various drugs manufactured without satisfactory controls." Abbott Laboratories, "Various drugs manufactured without satisfactory controls." Wyeth Laboratories, "Aludrox manufactured without satisfactory controls." Charles Pfizer & Co., Inc., "Several drugs mislabeled because of inadequate controls."

(The document referred to follows:)

[From the Pink Sheet, July 26, 1965]

(Excerpts—Drug Recalls—Oct. 1, 1962, to June 30, 1965, p. 18)

ACTIONS INVOLVING "CURRENT GOOD MANUFACTURING PRACTICE"—SECTION CITATION CASES

Firm	Charges	Present status or case
E. R. Squibb & Sons, New York, N.Y.	Various durgs manufactured without satisfactory controls.	Hearing held. Case placed in permanent abeyance by FDA Headquarters on Mar. 11, 1965.
Abbott Laboratories, Inc., North Chicago, Ill.	----do----	Hearing held. Case placed in permanent abeyance by FDA's district office on Mar. 16, 1965.
Wyeth Laboratories, Inc., Philadelphia, Pa.	"Aludrox" manufactured without satisfactory controls.	Hearing held. Case placed in permanent abeyance by FDA's district office on Dec. 1, 1964.
Chas. Pfizer & Co., Inc., New York, N.Y.	Several drugs mislabeled because of inadequate controls.	Hearing held. Case placed in permanent abeyance by FDA's district office on May 25, 1965

Mr. CUTLER. Mr. Gordon, you are only proving our point—that even the best companies make mistakes occasionally. If you go over those drug recall lists, you will find that the frequency of drug recalls for the non-PMA member companies that make only 5 percent of the drugs is far higher for any volume unit of production you want to take than the frequency of recalls of the PMA members who make 90 to 95 percent of the drugs.

The fact that even the best companies are not perfect helps to establish our point—that doctors simply must use their own experience and their own judgment based on what has happened to their patients when particular drugs of particular manufacturing sources were prescribed.

Now, if, as Senator Nelson indicated earlier, he also favors identifying manufacturing source, I do not suppose we have any disagreement. That is all we are trying to say.

Mr. GORDON. Now, on page 4, you stated:

We all know that effectiveness and safety of a drug product are determined by well-designed, properly controlled and correctly executed clinical tests.