Mr. GORDON. It submitted no data. On what grounds did they want your organization to take a particular action, then?

Dr. PITTMAN. Well, they referred to the published information on bioavailability, and things like that, and implied that such differences might exist with any compound, until it had been tested. The crux of the problem was, if you don't know whether two allegedly identical products are the same, should the burden of proof be on those who say that they are different, or on those who say that they are the same? And we said that if they are in fact the same chemical substance, and particularly if they are manufactured in the same plant, the burden of proof is on the individual who says that they are different. Then the only difference in those would be the price.

A most dramatic example is the 17 different dispensers of brands of chloral hydrate, all made by R. P. Scherer in Detroit, apparently because they have a way to make soft gelatin capsules. And yet the prices on those vary tremendoulsy. If a physician writes a prescription for chloral hydrate, Squibb, which cost $5 per 100 wholesale price, and right next to that bottle on the shelf is Purepak for $1.48 per 100, it is illegal for that pharmacist to pick the cheaper one, even though he knows that they are manufactured in the same vat. And I believe most physicians are not aware of that. However, I think that they are becoming aware of it through articles such as the one I cited here from the *Annals of Internal Medicine.*

Shall I proceed?

The CHAIRMAN. Go ahead.

Dr. PITTMAN. There was another meeting this March with a lot of discussion of this. And a more complete chronology is given in the back in the attachments to the statement.

The data presented at the 21st of June 1974 meeting—let me correct an error in the prepared statement here. On page 4, line 2 of the sec- paragraph, it should read November 30, 1973. It is not 1974, it is 1973.

At the meeting of the 21st of June 1974 the data presented were interesting and are probably unknown to most physicians of the United States. They show that although a given chemical entity, such as chloral hydrate or tetracycline, may be dispensed under the brand name of the major company or by a smaller, less well known company, and although these may vary widely in cost to the customer, these differences do not preclude the fact that all of these can have been made in a single laboratory unidentified to the customer. The data were published in the *California Pharmacist*, and a part, although I don't believe all of them, appeared in your hearing in the past.

The data for chloral hydrate, erythromycin, tetracycline, and some other drugs are given here.

On the other side of the coin, the APhA representatives at the meeting of June 21, 1974, presented data showing a change in active ingredient despite continuation of the same trade name. Thus, "Liquiprin" suspension (Thayer) formerly had salicylamide as the active ingredient; but this was changed to acetaminophen *with no change* in trade name, which remained "Liquiprin" suspension (Thayer). They also presented data showing that the manufacturer of a given drug product might change with no change in the trade name and other data showing that a single manufacturer sometimes marketed a single entity under two trade names.