Mr. GORDON. Doctor, can you give us the names of those companies, and also the drugs involved?

Dr. GODDARD. Yes. I can give you those now or for the record.

Mr. GORDON. Could you read them, and then we will put them in the record, also.

Dr. GODDARD. S. E. Massengill, three products: Predsem, Salcort, Salcort-Delta; Organon: Cortrophin Gel, Cortrophin-zinc, Hexadrol phosphate injection, Hexadrol phosphate tabs and elixir; Lakeside Labs, Norparmin. Armour has not been issued, and I would prefer not to mention the drug yet.

(The information referred to follows:)

STATEMENT OF THE FDA CONCERNING COMPANIES REQUESTED TO CORRECT PDR MONOGRAPHS

The three pharmaceutical companies requested to issue "Dear Doctor" letters to correct misinformation occurring in the *Physicians' Desk Reference,* and the specific drugs involved are:

S. E. Massengill Company: Predsem; Salcort; Salcort-Delta.

Lakeside Laboratories: Norparmin.

Organon, Inc.: Cortrophin Gel; Cortrophin Zinc; Hexadrol Phosphate Injection; Hexadrol Tablets and Elixer.

Senator NELSON. Is there approval required by FDA of advertising put in the Physicians' Desk Reference?

Dr. GODDARD. No. That is, of course, a form of labeling, and we review it. And if we find flaws there, we then direct the firms to take remedial action.

Senator NELSON. But you do not review it prior to publication?

Dr. GODDARD. I do not think we should. I think the burden is on the firms. We have explained what the 1962 amendments meant. We are now prepared to explain in even further detail the regulations that we have issued as proposed regulations. And so I do not believe we should have to assume the burden of reviewing prepublication copy. It is quite clear what is required. It should be in fair balance. Physicians should be warned of the bad effects of the drugs as well as told of the good effects.

This type of surveillance of advertising coupled with our administrative action will, I believe, substantially increase the quality of such promotions. Nevertheless, advertising will remain advertising.

The information contained in package inserts is essential to counterbalance the claims made in many drug promotions. As I have pointed out, these inserts are not accomplishing this function, primarily because it does not reach the physician; secondarily, because it is not in readable form.

Now, the compilation of a drug compendium will be a difficult task. The central issue, from FDA's standpoint, is how to abbreviate the package insert material without compromising the public health protection that full information can provide. If we are to condense such labeling, it will still have to adequately reflect current knowledge about the drug. However, we believe that an objective summary, approved by FDA, would be preferable to a package insert which is never read. Also, we believe it will be possible to group several drugs into one category with a general summary covering all the drugs included in the group.