STATEMENT OF THE FOOD AND DRUG ADMINISTRATION REGARDING COST OF BATCH CERTIFICATION OF ALL DRUGS

Assumptions:

(a) The number of batches of drugs started in a day in a medium and large plants does not vary greatly with the size of the plant. The size of the batch will vary greatly with the size of the plant. Starting as many as 10 batches in one day would be unusual. The figure, 5 batches, started in one day is more probable. For small plants (less than 20 employees), the figure one batch started per day may be used.

(b) 1500 manufacturers of Rx drugs.

(c) Batch certification cost $90.

(d) Working days per annum—250.

Estimates	Number of firms	Batches per day	Batches
Large (12 percent, over 100 employees)	180	8	1,440
Medium (19 percent, 20 to 99 employees)	285	5	1,425
Small (69 percent, 1 to 19 employees)	1,035	1	1,035
Total			3,900

On the basis of 250 working days per annum, the number of batches started in a year is 975,000.

Cost of batch certification at $90 ea. equals $88,000,000.

Mr. GORDON. Have there ever been occasions when detail men have made claims to doctors which the FDA has subsequently found out were false and misleading? If so, could you furnish us with a list of some representative examples?

Dr. GODDARD. I do not know of any examples of that kind. First of all, we have no way of monitoring what the detail man tells the physician. I think the physician does that himself and that is why we think the drug advertising controls that we exert are important. Further, that is why I think a good compendium is important, it sort of puts a fence around what can be said about a drug. And a proper kind of fence, too. I do not think we should unduly restrict firms but rather proper scientific restrictions should be imposed.

Now, we cannot monitor what detail men say. I know of one instance—a physician brought to our attention a telegram that was being—had been sent to him and his conferees in that area urging the doctors to prescribe on that day a given product which was entering the marketplace. The company did not even know when we checked with them that their salesman in that area had done this.

I think the companies are anxious to have their 6 minutes of a doctor's time used well, without getting involved in things that are questionable, and excessive claims are questionable. They tell me this, and I have no reason to doubt it. But, we have no way of knowing how often this occurs and no other examples of it having occurred.

Mr. GORDON. Well, since you cannot monitor what the detail man says, a large part of the advertising cannot be supervised by the FDA, is that not correct?

Dr. GODDARD. That is true, except in the sense that I mentioned before: the journal advertising, the printed advertising that goes out in the form of labeling, direct mail pieces, and other forms that are produced, do place certain constraints around the detail man. And the compendium would put another constraint around him as well.

Now, beyond that I see no practical way of carrying this any further, nor do I necessarily think it has to be done in any other fashion.