

Dr. GODDARD. These are individuals who are skilled chemists, let us say, moonlighting.

Mr. GORDON. Commissioner, I notice you referred to the east coast and the west coast. How about the middle?

Dr. GODDARD. We have them in the Middle West, too. They are not devoid of skilled chemists.

Mr. GORDON. I have a couple of questions not related to marihuana but to the FDA.

Next week, some people are going to come to testify before our committee, and in one of the statements I found the following:

Quality firms are well organized to recall with precision—this deals with precision from all commercial channels—any particular lot of a suspected drug product at any time or to provide emergency advice as to where a particular drug product can be obtained when needed.

Now, we have had, in fact we put into the record, considerable information about recalls and I notice that the recovery, especially from the large companies, has been extremely small. For example, we listed a recall from Ayerst Laboratories of 15 million tablets, of which only 30 percent was recovered. Squibb had a recall of Mycostatin. Only 20 percent of the 18 million tablets was recovered. Here is one recalled with 10 percent recovered, another with only 7.9 percent recovered, yet another with only 4 percent recovered.

Now, would you comment on the statement I read in view of the material on recalls that we got from the FDA?

Dr. GODDARD. Let me point out that you want to be careful. A drug company that only recovered 10 percent, this does not necessarily reflect upon their effectiveness in a given recall, but it may more accurately reflect the time period that elapsed between the production and distribution of the drug and the identification of the problem that required the recall. You see what I am driving at?

Mr. GORDON. No.

Dr. GODDARD. If a drug were subpotent, let us say, and batch No. 2,452 was produced on January 5, 1967, and the subpotency was not discovered until September 10, 1967, most of that batch may have been used by the time the recall is identified as being necessary. So there are several things that operate here. One is the elapsed time. Two is the effectiveness of the firm in getting at the batches at the wholesalers and the retailers level. Now, they have control numbers on product. All companies are required to do this. So they do have a precise way of identifying the drug to those who are in the system.

Now, this does not mean that it is not a lot of effort. It is. The wholesalers in meeting with them have expressed their concern about the cost and the effort that they are put to in helping in these recalls, and the local pharmacist is as well. So effectiveness of recall is again a function of several things. You are hard put at times to know just how effective a recall may have been unless there has been a very short period of time between the date of production and its entrance into the system.

Mr. Goodrich may wish to elaborate on this.

Mr. GOODRICH. Simply to say that our good manufacturing practice regulations require that all companies have the capability of recalling from the market drugs that turn out to be subpotent or otherwise in violation. The mechanisms of action are applicable to all drugs. A