

fore, it has a social use. For clarification of the record, I am assuming you do not mean to say they have any constructive social uses.

Dr. GODDARD. I hope my remark would not be interpreted that it did; no. I tried to say that it is a social phenomenon that we have to contend with. It is a bad one.

Senator NELSON. I knew you intended to say that, and I did not want to leave the record open to an incorrect interpretation.

Dr. GODDARD. There are those who disagree.

Mr. GORDON. I have one more question. This is a quote from someone else's statement which we will hear next week:

Recent figures of FDA inspections, for example, do little to encourage optimism in this regard. The agency made 3,651 inspections of drug plants in 1966. Impressive as that figure may seem, it is 150 inspections less than the 1965 figure and 34 less than the number for 1964. I do not recite these figures to criticize the FDA, Mr. Chairman. Their inspections, of necessity, are becoming more complex and time consuming and FDA personnel shortages are persistent. Nevertheless, fewer inspections are being made, not more. It seems to me, therefore, it would be imprudent to rely heavily or solely on this mechanism as the method of assuring drug quality.

The import of this whole thing is that you cannot rely on the FDA, but rather you have to rely on the reputation and fame of the manufacturer to insure good quality drugs. Since you are here, I think it might be a good idea for you to comment on this.

Dr. GODDARD. We are taking steps to make certain that you can rely on the FDA. We are going to have two different approaches. One is carrying out more selective kinds of inspections. Working with Booz, Allen and Hamilton, we are identifying the critical areas of an inspection, those parts of the inspection that most frequently reveal flaws in the system. So our inspectors will do more partial inspections, but more target kinds of inspections.

Secondly, we are going to select 300 pharmaceutical firms next year for special attention, and add 300 more pharmaceutical firms for special attention the next year. That second year, we will have 600 of the 900 that produce prescriptions under very close surveillance, and the third year, all 900.

Now, let us not misunderstand what I am saying to mean that this will provide complete assurance of quality of drugs. It will not. Most of the responsibility still is and probably belongs on the manufacturer who enters commerce and produces these drugs. Concomitantly, we are operating and will be expanding the National Center for Drug Analysis, where we hope to get up to the analysis of several hundred thousand samples of drugs purchased at the retail level. Thus we will be able to act as a further step in the manufacturer's own quality control program with respect to those features that can be seen in the laboratory.

Now, I would like to make the point that companies, large and small, require surveillance. You look at the recall list and it is not uniquely the property of the small company. Companies constantly make this claim, "Our drugs are better, higher quality, they are guaranteed," these kinds of things. I would like to see the evidence that their drugs are therapeutically more effective than small companies. They point to some isolated episodes that have occurred. We know these, too, and we have taken steps to correct them, such as the sugar-coated tetracycline episode several years ago.