

companies by virtue of their past record, recalls, their inspections, quality of the plant with respect to our previous inspections, all the factors that relate, in our opinion, to how well a company is meeting the good manufacturing practices.

So we rank ordered the drug companies. We will take the first 300 this coming year, provided we get the manpower, and subject these to intensive scrutiny. The second year, an additional 300. Again, Congress willing and the Bureau of the Budget permitting, the third year we will inspect the last 300.

Now, in addition to that we are stepping up our quality control valuations through the National Center for Drug Analysis in St. Louis, a newly established facility, where we ultimately hope to be able to draw more than 100,000, perhaps as many as 300,000 samples from the retail level each year.

These steps, I believe, are necessary to assure a high quality of drug products in the marketplace. They aren't inexpensive, let me point out. This activity bears substantial cost figures. But I think these steps are desirable and necessary.

So with respect to this specific example, it's quite possible that this could happen again tomorrow. I can't speak to the point of whether DSA can make any modifications or is planning any in their program, but we find this kind of thing occurring in our routine work.

This problem with drugs is no different than those encountered in producing automobiles where a third of them come off the production line with defects that the manufacturer has to call back and correct. We are trying to get the defect rate down to 1 percent in the drug industry. Most good companies, I believe, agree with this. They too have problems on their quality control line because the list of those involved in drug recalls, in labeling mixups, is not exclusively made up of the small manufacturers. It includes large manufacturers as well.

Mr. GALLAGHER. About what percentage would you say now would be defects?

Dr. GODDARD. I would really hesitate to offer a guess.

Mr. GALLAGHER. But you are aiming to get down to a 1 percent level?

Dr. GODDARD. Less than 1 percent. We plan a periodic review of the 20 major categories of the drugs in the marketplace. Thus, when we see a product line, let's say, 40 manufacturers are usurping, and all that usurping stays within the bounds of potency, solubility, dissolution rates, and so forth, we can decrease our sampling on that and pay more attention to a product beyond the 1 percent level.

We must do this with a 95 percent confidence level, so it gets to be a difficult sampling program. It is feasible because of the development of the new automated testing equipment which we have installed in our St. Louis facility. We are developing new testing methods and adapting them to work out a program of this type.

Now that kind of information, incidentally, will also be made available to State purchasing agents as well as other Federal procurement activities. I think it would be extremely valuable information for all those involved in the purchase of drugs.

Mr. GALLAGHER. Doctor, you say there is a one-third recall on automotive, and you're aiming for a 1 percent. I'm just wondering—