

labels. No penicillin contamination will be permitted in nonpenicillin products and we have a new section on sanitation.

The Food and Drug is also giving priority to the development of separate Good Manufacturing Practices regulations for specific processes such as the production of large volume paranterals, tablets, or capsules, medicinal gases, and radiopharmaceuticals.

Specific GMP regulations are also being drafted for manufacturers of bulk drugs and for repackers and relabelers.

Our plant inspection activities have been excellent. There have been about 8,000 drug firms registered with FDA, but fortunately the number of prescription drug manufacturers is much lower. There are approximately 400 basic manufacturers of prescription drugs in the country, and each of these is inspected at least every 2 years. The larger manufacturers are inspected much more frequently, as they should be, in view of their market impact. That occurs when new products come on the market and things of that kind.

Mr. GORDON. Mr. Secretary, may I interrupt for just a moment?

Secretary WEINBERGER. Yes.

Mr. GORDON. I would like to go back to page 6 for a moment. I missed something there.

Secretary WEINBERGER. Page 6?

Mr. GORDON. Yes.

You referred to the difficulty of ascertaining the true acquisition cost of drugs. Would this difficulty not be eliminated, and would more money be saved, if the government itself bought the drugs and distributed them through the regular commercial channels?

For example, the druggist orders whatever he needs from a manufacturer for his government account, and the bill is sent to the government buying agency. The cost of the drug would be lower because the government buying agency can buy drugs for its depots on an open-ended basis. The government will pay for the drug plus the pharmacists' fee for the reimbursement program.

Have you given any thought to this kind of a tie-in?

Secretary WEINBERGER. Yes, but we have rejected it, Mr. Gordon, because we do not want to interfere with the basic market system to that extent. We do not want to expand the government's activities. There are problems with this that a lot of people have raised as to the enormous cost that is involved in it. Those considerations or those criticisms are wrong, but they might be perilously close to being right if we got into this kind of a large governmental activity of buying all the drugs and shipping them and doing all of that that I think should properly be done by the private sector.

Mr. GORDON. Thank you.

Secretary WEINBERGER. The basic problem of quality is, as I said, something that underlies all of this. Therefore, I think it is important to note what FDA is doing to insure that—and we have mentioned that we have the every-2-year inspection in the larger manufacturers because applications for new drugs for other reasons are inspected more frequently than that. And that is proper because they have a greater impact on the market.

Another thing we are doing is the surveillance of marketed drugs to determine whether they are adhering to compendial standards