Is that a roughly correct statement?

Mr. LOFTUS. I would only qualify it, sir, to say that might, in our judgment, affect the quality of the drug. If it is established that the quality of a drug is affected, there is no question but that we would take action.

Dr. CROUT. May I add one other point that I think we are making. And that is we think that based upon the man effort that goes into an inspection, the DPSC, like everybody else must rely on the FDA inspector for the indepth inspection of plants for GMP's.

Senator NELSON. Because they do not have the personnel to do so?

Dr. CROUT. And simply do not put the time into it, based upon—they have one inspector in a plant for a couple of days. You cannot figure out whether an enormous operation is making drugs by GMP's with one man in a couple of days. It just takes more work than that in a big plant.

Senator NELSON. What is the dimension of this inspection made by FDA? I realize it varies, but one man in 2 days could not inspect a major operation. If it is a major operation, what do you generally consider a necessary commitment of time and personnel to make an adequate inspection?

Dr. CROUT. This has varied from time to time depending on the inspectional program; but let Mr. Loftus speak to that, and I think maybe the IDIP program would be a good model.

Mr. LOFTUS. Yes. It would vary, sir, depending on the size of the firm and the type of the operation. Are they making tablets, are they making a particular type of tablet. For instance, the problem, the GMP problem, the manufacturing quality control problems with regard to meprobamate manufacture or aspirin manufacture would be considerably different from the manufacturing problem involving digoxin or prednisone or something like that, where the ratio of active ingredient to inactive ingredient in the one case is extremely high and in the other case is extremely low.

You would have tablets in both cases, but one inspection you might do in a couple of days, another inspection might take a week.

You get into a manufacturer of parenterals. Whether you are talking about large volume parenterals or small volume parenterals, these are the type of inspections you do not make in a couple of days.

Dr. Crout alluded to what we call the IDIP program. We had a few years ago a program, as we call it, the indepth inspectional program of the entire prescription drug manufacturing industry. I say entire, but I do not deal in absolutes. I think there were a few that we missed, but we got most of them. And some of those inspections lasted as much as 6 months, and we did not leave those firms until—any of those firms—until our district people were satisfied insofar as human beings can be satisfied that those firms were actually producing prescription drugs under proper GMP conditions.

I have years ago been an inspector myself, and it was nothing to spend a week or 2 weeks in a parenteral plant, to spend several days or a week in a tablet plant, depending on the size. You certainly would not spend 2 weeks or a week in a little mom and pop