

We find it necessary to set up a priority system and pay most attention to those firms that produce most of the drugs in the country. At the top of our list are those large firms that produce 95 percent of the prescription items in the country.

The number of inspections that I mentioned includes inspections of 100 percent of the firms in the country with business over \$10 million a year that produce prescription drugs.

Senator NELSON. What do you mean, inspection 100 percent? The law requires you to inspect them all once every 2 years, does it not?

Dr. SCHMIDT. Yes, sir.

Senator NELSON. Do you meet that requirement?

Dr. SCHMIDT. No, sir, we do not, and I do not think that we ever could for a number of reasons. Certainly, we would miss one firm every 2 years, and, therefore, we would not meet the statutory requirement, by definition.

We must have a flexible policy of priority inspections. When we do identify a very large problem in an important drug, we must be free to make as many inspections of one particular plant or one group of plants in a year as might be needed to correct the problem.

A good example of this, for example, is the large volume parental industry that had a problem with manufacturing sterile products. This is, of course, a critical problem, and we mounted an intensive program in this particular industry. We inspect many of the plants five or six times in 1 year if necessary, and some we do not get to, within the 2-year period.

Senator NELSON. Let me put it another way.

What percentage of the prescription drugs that go into the marketplace, what percentage of those drugs do you inspect once every 2 years?

Is it 95, 98, 90 or some other percentage?

Dr. SCHMIDT. Our best estimate is 95 percent, sir.

Senator NELSON. You are saying that companies producing 95 percent of all of the prescription drugs that go into the marketplace are inspected at least once every 2 years?

Dr. SCHMIDT. Yes, sir.

Senator NELSON. What about that other 5 percent? Are those producers never inspected, or inspected once in 3 or 4 or 5 years? Do you have any figure on it?

Dr. SCHMIDT. Well, they are programed by our field force for inspection as soon as can be done. We have established, partially in response to the GAO report you just heard discussed, a system in which we monitor all firms and notify the field of those that have not been inspected within 1½ years, then 2 years, then about 2½ years, so that when a firm is not inspected within the 2-year period, it will move to the top of the priority listing of our inspectors.

Senator NELSON. So it will get inspected within what period?

Dr. SCHMIDT. Within 2 years.

Senator NELSON. Two years after the expiration of the first 2 years?

If I understood you, you said that when one has not been inspected within the 2 years, they go into top priority.