

zation and centralization has markedly improved the efficiency of the FDA analytical drug laboratories during recent years. A similar regrouping of its drug inspection capabilities should likewise result in more efficient operations.

I believe that the measures proposed for strengthening the drug control apparatus of FDA, together with our own progress in strengthening USP will eventually permit an unreservedly affirmative answer to your original question—that the system for monitoring and protecting the quality of the Nation's drug supply is working very well indeed.

If you have any questions, Mr. Chairman and staff, I should be pleased to respond. Thank you.

Senator NELSON. As I recall, yesterday—and the record will speak for itself—that the testimony of Dr. Schmidt was that there was about 800 inspectors in the FDA. I believe that he said about 800 or a few more. And that wherever problems arise they will have inspectors there as long as is necessary to solve the problem, that many of the companies producing a substantial percentage of the drugs in the country are inspected much more frequently than the statutory requirement of once every 2 years. But they have now a computerized system whereby any company that has not been inspected within the 2-year period, the computer kicks out the names and that they are all then inspected within the next 6 months. They go to the top of the list.

I have no notion of what may be required. I suppose if a company has a good quality control system, once every 2 years may be perfectly adequate. If it does not, once a month may not even be adequate. But the system they described rather impressed me as a pretty efficient, effective system, though I have no basis for making a judgment as to what the optimum or ideal frequency of inspection would be.

Do you?

Dr. BANES. No, sir. I do not. And I would leave that to the administrative judgment of those responsible for it. In the past I believe that these inspectors available to the Food and Drug Administration were assigned to all of the problems that come under its purview, and one of the difficulties there is that when you have a crisis hazard due to food problems there are no inspectors available for a steady continuous attention to drug problems.

The point of my discussion, Senator, was that in my opinion there ought to be a group of highly trained specialized drug inspectors who are continuously assigned to these drug problems, and when crises arise on the drug side the attention should be given. But this of course is the responsibility of the officials who are charged with that responsibility.

I note that the President in his health message has requested an augmented staff of inspectors for FDA, because I am sure they could use a far greater component of inspection force than they now have.

Mr. GORDON. Dr. Banes, with respect to the use of these large machines you mentioned to perform unnecessary assaying or testing,