

take a sampling of a class of drugs from the market, analyze it and find problems that way. What we do not have is the mechanism we have in antibiotics where every batch produced must be cleared by us before it is marketed. Other drugs can be marketed and then we have to find the problem after the fact. And this is what we are referring to.

Senator NELSON. What kind of mechanical problem does it present to the FDA to batch-test all anti-infectives?

Dr. SIMMONS. Well, we do 21,000 a year here in Washington and we are able to handle that quite expeditiously. It works quite well.

Senator NELSON. That also applies to all imported anti-infectives, too?

Dr. EDWARDS. Right.

Senator NELSON. Go ahead, Doctor.

Dr. EDWARDS. The Food and Drug Administration's drug sampling and testing programs constitute another effort to find out just how well this system of quality assurance is working. While we appreciate that no monitoring system is without deficiencies, we are seeking the best approach, both medically and statistically, in this important part of the program of quality assurance.

Our National Center for Drug Analysis (NCDA) located at St. Louis, plays an important role in our total effort to assure the quality of drugs. We are very hopeful that this center can be significantly expanded in the months ahead.

At this center we have a modern, sophisticated, facility equipped with automated analytical instrumentation to which we are adding computerization. This will enable us to conduct a large-scale national drug surveillance program.

This program is already underway and we hope to expand it for use in conjunction with our new formulator oriented drug analysis program.

What this is in fact, Mr. Chairman, is that heretofore we in our drug analysis have gone to the retail level to get our drug samples. Under this new program we are going straight to the manufacturer to obtain our sampling materials.

Compliance operations continue to encourage industry cooperation to the maximum extent possible. Voluntary recalls have been the most commonly used method for removing defective or mislabeled drugs from the market and usually the quickest and most effective way to protect the public. There were some 951 recalls during the current fiscal year, some 707 in 1969, and some 711 in 1968. Every recall is reviewed to see how it could have been prevented. When one is found that illustrates an important problem, a recall case is prepared and distributed throughout the country. Drug firms have welcomed such guidance and 40 case studies were available at the end of fiscal 1969, 46 at the end of fiscal 1970. The very important drug, digoxin, has presented an interesting problem that I think gives you some idea how our drug surveillance and National Center operate. Digoxin tablets, an important pharmaceutical drug, are manufactured by some 37 firms. For more than a year content uniformity difficulties resulted in many recalls. Nearly all the manufacturers of this product were having serious difficulty meeting product uniformity specifications.