or to the standards that are established in new drug applications. This analytical work is carried out in St. Louis in our National Center for Drug Analysis—we have 19 field laboratories. Drugs of similar composition—whenever we can—are assigned to a single laboratory for analysis so we can get automated testing and standardized procedures.

During 1975, we will analyze over 20,000 human drug samples and that requires about 250,000 individual assays. We found that only a very small percentage of drugs are not in compliance with official standards andn require regulatory action.

The CHAIRMAN. May I interrupt you there a moment, Mr. Secretary?

Dr. Henry Simmons, in an article in the March 1973 issue of FDA Consumer—I just wanted to read a couple of excerpts into the record—stated that:

> Each year our National Center for Antibiotics Analysis receives approximately 20,000 samples for examination. The rejeciton rate is approximately 1 percent. These rejects cannot be marketed. Based on many years of experienc with this program, we are confident there is no significant difference between so-called generic and brand name antibiotic products on the American market. Any antibiotic offered for sale in the United States, regardless of whether it is brand or generic, has met the same high FDA standards.[1]

And at another point in the statement he states:

> Since 1970, our St. Louis lab has completed the study of 19 classes of drugs, including adrenocorticosteroids, major and minor tranquilizers, urinary antibacterial agents, central nervous system depressants, antihyroid agents, cardiac glycosides coronary vasodilators, anticoagulants, oral contraceptives, and others, and we have found no significant differences between them. On the basis of the data we have accrued to date, we cannot conclude there is a significant difference in quality between the generic and brand name products tested.

Do you agree with the conclusions reached by Dr. Simmons in that article?

Secretary WEINBERGER. Yes.

Generally, I do not think it is a matter of brands or generics. A great many of the generics are marketed by brand name manufacturers, and many are made by the same people. In the last analysis, I think, the quality comes down to the individual drug itself. We are trying to assure through our monitoring programs that we have uniform quality.

For some drugs we need somewhat more sophisticated methods, but generally, we are trying to make sure that we have such things as dissolution rates and bioavailability testing. And that is why we have said that before a drug is put into this program—this Maximum Allowable Cost—we will have to have those tests and be sure that the quality is the same, whether it is a generic or method of marketing. I do not think there is any significant dfference. There are significant differences in the quality of some drugs and when we find those—we know some of them already—we would not put them on the list.

The CHAIRMAN. Perhaps you would want Dr. Schmidt or Dr. Cooper to respond to this, but in any event, you mentioned bioavailability. And as you are aware, there are lots of arguments around the country about this subject. My query is this: Therapeutic equivalence and bioavailability are not necessarily the same, are they?

[1] See article by Dr. Simmons, page 11841.