An increased sense of responsibility by drug makers that quality assurance is essential to continued industry growth, and corresponding efforts on their part to catch their own defective products.

The introduction of new methodology and new technology to accomplish more sample tests in less time than before, thus increasing the identification of products warranting action.

When all of these things are considered, we find that the record of drug recalls in recent months shows that the drug industry—large companies as well as small—has much to do before we can conclude that the drug supply is what the Nation deserves. We hope to see the time when it is rare indeed that we must ask a company to remove a drug from the market.

Your staff already has a print-out showing drug recalls by company during this past year.

One of the questions you have raised with me and my staff, Senator Nelson, is the therapeutic equivalency of identical drugs. All of our efforts in St. Louis and in production control are aimed at making every drug available today a drug which the doctor, the pharmacist, and the patient may trust to achieve the desired results. As a preface, I must stress, Senator Nelson, that drugs are intended to affect physiological functioning of the body. Thus, the values of the effect of a drug must be weighed against the dangers of the disease or condition being attacked. No drug can ever be guaranteed to be completely safe. You do not have "safe drugs" on the one hand and "unsafe drugs" on the other. When we talk about drug safety, we are talking about relative safety.

The Secretary of Health, Education, and Welfare has appointed a task force which is studying the problems of including prescription drugs in the medicare program. This study, among other things will of necessity cover in depth the areas of relative drug safety and of relative therapeutic equivalency.

Here, as you know, Senator Nelson, certain guidelines are available for our use. The U.S.P. and the N.F. have for many years set standards for laboratory examination in the expectation that every drug conforming to these standards will produce the required results in patients. The manufacturing and testing procedures contained in NDA's and the test procedures in antibiotic and insulin regulations also constitute such standards.

In large measure, we believe that these standards serve their intended purposes. This appears to be particularly true for most antibiotics and insulin; as you are aware, the FDA certifies each batch of antibiotics and insulin to be marketed to see that each meets the appropriate standards, but, as noted before, are not necessarily full guarantees.

However, the science of drug production and formulation is becoming increasingly complex. The establishment of standards adequate to meet our increasingly complicated needs is a continuing process in which the private organizations maintaining the U.S.P. and the N.F., and the Government working with them, are constantly striving to keep ahead.

I think it is important, Senator Nelson, to keep this question of therapeutic equivalency in perspective. There are some who would