We certainly appreciate this opportunity to discuss with you the important issue of safe and effective drugs. These are certainly issues that touch directly on the lives of all of us.

I think no one would question that the discovery and development of new drugs and new antibiotics over the past three decades have contributed enormously to the eradication and control of disease and to the relief of patient suffering.

However, over this same period of time, drug misuse has become a major national problem. I speak not just of drug abuse in the conventional sense, but rather of the promotion, the prescribing, and the use of drugs of limited or no value, and, of course, equally important, the consumption of too many drugs, often for no purpose or for the wrong purpose. I think few things are more tragic than the prescribing and administration of a drug of no proven effectiveness followed by a serious and even sometimes fatal adverse reaction.

We at FDA are concerned first with drug safety, but we must constantly bear in mind that considerations of drug effectiveness and drug safety cannot be separated.

I would like this morning to briefly discuss where we are today, how we arrived at this point and how we plan to proceed in the days ahead.

Our goal is to achieve the objective of excellence in drug quality, honesty in drug promotion, and rationality in drug use at the earliest possible time. We are striving for a uniform and high standard of safety and reliability of all drugs. Of course, this requires us to be concerned with all phases of the drug scene:

We are concerned with all manufacturers large and small;

With the discovery and investigational use and development of all new drugs;

With the evaluation of safety and efficacy of new products offered to the medical profession;

With the quality controls that assure the identity, the strength, the quality, the purity, and the reliability of the product that comes off the production line and into the hospital, and the community pharmacy;

We are concerned with the labeling and promotion of these products;

With the experience of these drugs in the hands of the practicing physician;

And indirectly, of course, with the costs of these products.

Although we have no specific responsibility relating to drug costs, it is well to recall that Senator Kefauver's investigation a decade ago focused attention on the causes of the high cost of prescription drugs. They were poor quality research, excesses, and exaggeration in promotion and the difficulties encountered by prescribers in obtaining reliable information that would facilitate rational drug therapy. All of these important areas are responsibilities of the Food and Drug Administration.

Senator NELSON. May I interrupt a moment? Isn't an additional problem, which relates to costs, the result of brand name prescribing? That is to say, in 40 or more States—the legislatures have passed anti-substitution laws. So then, if you have a situation in which the