troduction. The Kefauver-Harris Amendments of 1962 added the pre-marketing requirement of proof of product effectiveness, increase government control of production and quality control procedures, required the registration of all drug manufacturers, increased the inspection powers of FDA and gave FDA greater control of labeling and promotion.

Despite increased legislation and regulation, both the Food and Drug Administration and the industry recognize that the principle of voluntary compliance has remained a key part of the philosophy of federal regulation. This principle gives rise to positive stimulation of responsibility within the industry, so that federal enforcement activities can be held to reasonable, workable limits.

In the field of quality manufacture and control, the techniques and patterns set by pharmaceutical industry leaders have tended over the years to be codified into government regulations. But it is important to recognize that under our system of voluntary compliance, it is neither intended nor practical for a government agency to assume the fundamental responsibilities of production and distribution. For instance, the law calls for inspection of every production facility at least once every two years. Clearly, this infrequency places the greatest share of the burden of maintaining good manufacturing practice upon the producer.

In this area, as in so many others, the competitive nature of American business serves the interests of the public well. For the reliable manufacturer there is a built-in desire to excel in product quality as a competitive measure. The FDA picks up products from distribuiton channels to spot-check contents and labeling. But there are thousands of products in interstate distribution, and hence there is a real responsibility of the manufacturer to guard against the distribution of sub-standard products. Furthermore, spot-checks of product contents and labeling are made after products have been in the channels of distribution for some time. The services performed by brand name manufacturers supplement the regulatory activity of FDA. Their record-keeping, returned goods policies, and inventory checks by their sales representatives help to maintain fresh stocks of quality products on retailers' shelves.

Then too, some FDA powers extend only to products in *inter*state commerce. In many states, separate regulations apply to *intra*state commerce in drugs. Some states have statutes almost identical to the Federal Food, Drug and Cosmetic Act; in others, consideration is being given to laws comparable to federal provisions. Realistically, however, the state rules covering production and sale of drugs within a state's boundaries are, and are likely to remain uncertain and varied for years to come; and the capacity of state governments to carry out an effective enforcement program to back up their laws varies considerably.

Here again, the importance of voluntary compliance is evident. In view of the limitations of enforcement, the public interest is well served by our system of trademark or supplier identification. The well-identified product and producer must excel in product quality as a matter of probity, as well as competitive necessity. By creating a proprietary interest in the performance, reputation, and hence usage of branded products, this system gives a strong stimulus to private responsibility, which together with practical regulation and enforcement, can provide the public with maximum assurance of safe and effective medicines.

III. THERAPEUTIC CONTROL

A fundamental principle enunciated by this paper is that the physician responsible for the care of the patient must determine which drug product is needed in each case. Many important and widely used drug products do not have legal standards. Even when drugs are covered by such standards, there are differences among individual formulations of products of different manufacturers which can be significant for some patients. The physician must decide whether therapeutic precision, reliability, or convenience calls for a particular formulation for a given patient, or the extent to which the selection can be delegated to another member of the health team, e.g., the pharmacist.

Finished pharmaceutical products can differ, even though their principal active ingredients are identical in the generic sense. For some patients these differences can have significant therapeutic consequences.

Under a *compulsory* generic system, which would suggest that all products bearing the same generic designation are equal and could be interchanged, the