

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 10749

I am grateful for your invitation to discuss with you the question proposed by your Subcommittee, namely, how well is the quality of the nation's drug supply being monitored and protected by our system of compendial specifications and standards coupled with FDA's enforcement of them? My answer, in brief, is that the system is working quite well, comparatively speaking, but that it could and should be working much better. I should like to enlarge upon that response in several dimensions.

In the first instance, if we consider progression on a time-scale, there can be no doubt that the standards and specifications of the United States Pharmacopeia are far more perceptive and more demanding than they were thirty-five years ago. Similarly, the potentialities of the Food and Drug Administration in monitoring the quality of our drug supply have been considerably extended during that time. The regulatory powers of the Food and Drug Administration have been significantly strengthened by several amendments to the Federal Food, Drug and Cosmetic Act of 1938 -- most notably the Kefauver-Harris Amendments of 1962, and the Good Manufacturing Practice provisions of that Amendment. Furthermore, the remarkable advances in all of the pharmaceutical sciences during the past three decades and particularly in drug analysis and biopharmaceutics, have stimulated the adoption of more exacting requirements in governmental and pharmacopeial standards and in manufacturers' drug quality control programs.

Second, if we compare the quality of the drug supply and the effectiveness of drug regulation in the United States with those encountered elsewhere, we can again affirm that we have much to which we can point with pride. The drug industry of the United States, the U. S. Food and Drug