

most of these countries require registration and licensing of all drugs during definite periodic intervals, which in my opinion is a more stringent type of control than we have in the United States today.

A third dimension to be considered in evaluating the effectiveness of the present drug system is the climate of attitudes toward the regulation of drug production and distribution. It seems to me that there is a growing recognition among drug manufacturers that strict compendial standards and active governmental enforcement of these standards—measures intended primarily to protect the consumer—also benefit the drug industry itself.

I base this statement on the observation that many quality control scientists employed by industry now collaborate actively on a voluntary basis in helping to improve the standards and specifications of the USP for use as regulatory measures by the enforcement agency. Such an attitude not only reflects an awareness among enlightened members of the industry that these endeavors are necessary to ensure the quality of drug products in the market and to protect the good health of both the consumers and the producers. It also results in adherence to good manufacturing practices within the factory, and the establishment of strict internal quality controls.

Please note that I have referred to enlightened members of the industry, for it must be admitted that the laudable attitude I have described does not command a unanimous consensus. In my ministrations as Director of the USP Drug Standards Division, I have sensed a reluctance on the part of some few companies to release scientific information necessary to the progressive development of sound public standards for drugs. Previously, as an official of the Food and Drug Administration, I had reason to believe that more than a few companies were oblivious to the principles of good manufacturing practices and quality control.

At USP we rely exclusively upon voluntary cooperation and the assessment of empirical scientific evidence by peer group review. Withholding of significant new data would result in the persistence of mediocre, archaic standards and analytical tests, unless the missing information can be developed by more cooperative scientists elsewhere in industry, or by research laboratories in the academic or Governmental sectors. Fortunately, we have been able to enlist the aid of several interested research laboratories in this enterprise, particularly those of the Food and Drug Administration.

Another avenue for eliciting information leading to the revision of tests and standards is a new USP publication entitled "Comment Proof". This periodical, circulated on subscription, shows the tentative monographs for drug articles and the chapters on general tests proposed for adoption in forthcoming USP issuances, after deliberations by panels of USP advisers.

The USP Committee of Revision receives comments and recommendations for changes in these proposals from representatives of trade associations and of individual manufacturers; from Government officials, including those from the Defense Personnel Supply Center, the National Institutes of Health, the Veterans Admin-