

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 10751

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 advisors. 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 Administration and the Food and Drug Administration; from scientists in schools of pharmacy and medicine; from scientists associated with foreign pharmacopeias, foreign companies and foreign governments; and from unaffiliated scientists writing as private individuals. It is my responsibility to review these comments, in concert with the responsible