

10750 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

Administration and the United States Pharmacopeia are generally cited as the hallmarks of preeminence in pharmaceutical circles throughout the world. Only Canada, Scandinavia, and Western Europe approach or equal the levels of excellence that we have established; none surpass them to a significant degree.

A third dimension to be considered in evaluating the effectiveness of the present 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 assure 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