

subcommittees of the USP Committee of Revision. We then incorporate those changes that are deemed scientifically valid and explain to proponents why certain changes they suggested have not been adopted. In this manner, the USP evolves publicly scrutinized, objective, scientifically verified standards, and practicable tests and assays, through the collaborative efforts of disinterested scientists. Except for their voluntary contributions of time expended in the laboratory and elsewhere, USP receives no financial grants from government, industry or any academic institution. It is entirely self-supporting through the sale of the compendium and related publications, and through the sale of reference materials used in analytical methods.

USP does receive funds for services rendered under not-for-profit contracts with government agencies where these projects bear upon the improvement of standards or test procedures, regardless of whether the drug products involved are USP articles. Although USP is increasing its standards-setting activities and USP XIX now in preparation will contain 38% more monographs for drugs than USP XVIII, the fact is that there will be no public compendial standards for more than half the drug products on the market. We believe that USP could quickly move to fill this void with appropriate support through not-for-profit contracts.

We must recognize, however, that regardless of the virtues written into compendial standards, they will remain meaningless dead letters unless they are effectively enforced. Under delegation of authority from the Secretary of HEW, the Food and Drug Administration is charged with responsibility for enforcing the provisions of the Federal Food, Drug and Cosmetic Act. The agency cannot discharge its responsibilities adequately unless it