Dr. BANES. Continuing on page 5:

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 the 19th revision of the USP now in preparation will contain 38 percent 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 has the requisite information and resources.

We are aware of charges that FDA does not inspect drug factories frequently enough to determine whether good manufacturing practices are in fact observed, or has failed to take notice of defective manufacturing practices known to officials from other agencies.

In regard to the latter charge, it would be well to ascertain whether the alleged violations were indeed called to the attention of the responsible agency in a timely manner, and if not, why not. Unless the Food and Drug Administration has authenticated information, it cannot be expected to initiate punitive or corrective action.

It is our impression at USP that FDA does react rapidly to rectify problem situations. Under a recently instituted project, USP has been in a position to bring certain drug product problems to the attention of both FDA and the drug industry. To our knowledge, FDA has moved promptly to investigate these problems and to deal with them.

The other charge, relating to a low frequency of factory inspections, is far more serious in its implications. If it is true that FDA cannot investigate and correct poor manufacturing conditions among unenlightened producers because it does not have an adequate force of trained drug inspectors, then there is indeed a deficiency in the present enforcement of drug control standards.

If this deficiency exists, it must be eliminated as rapidly as possible. It seems to me that if there is a group of trained drug inspectors elsewhere in Government agencies, they should be transferred to the Food and Drug Administration forthwith, in accordance with the principle that the agency responsible for enforcing the laws should be given the needed resources that will enable it to do so effectively.

Furthermore, a cadre of inspectors within FDA should be trained intensively for drug work and centralized under the direction of the agency unit responsible for monitoring drug quality. Speciali-