

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 10753

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 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 law should be given the needed resources that will enable it to do so effectively. Furthermore, a cadre of