

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 15431

The regulation of the manufacture, promotion and marketing of drugs is the responsibility of the government in each country where drugs are made, sold and promoted. Drug companies may, and indeed do, adopt standards that exceed the requirements in many countries. The regulation of the drug industry in Mexico, Guatemala or any other country should, however, be a matter of concern for the United States because inadequate regulation poses a hazard both for the citizens of the countries involved, for visitors to those countries and potentially for those who may never travel. In short, inadequate regulation poses a potential threat to world health.

The emergence and widespread prevalence of drug resistant enteric pathogens in two recent Latin American epidemics illustrate these problems. These epidemics were a menace not only to the people of Central America and Mexico, but they were also a potential hazard to all those who visited there.

In order to explain why I believe the development of drug resistant enteric pathogens represents a serious problem, I must review a little history, a little pharmacology and some microbiology.

In the early 1960's, it was found that patients with bacillary dysentery harbored strains of Shigella that were resistant to several antimicrobial drugs. When these resistant strains were cultured in vitro with sensitive strains of Shigella or even other gram negative bacteria, the genes for multiple drug resistance were transferred to the drug sensitive strains without simultaneous transfer of any other genetic marker from the donor strain. The resistance (R) factors have been identified, and resistant strains have been found not only in hospital populations but also in domestic livestock, especially when antibiotics