

10542 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

Need for embargo authority

Bureau of Drug officials have expressed a need to have embargo authority--authority to temporarily detain drugs suspected or known to be violative while seizure action is processed and accomplished. Lacking such authority at present, drugs identified for seizure are often shipped to distributors before seizure action is approved. The Associate Commissioner for Compliance stated that FDA is unable to effectively remove a drug from the market after it has been widely distributed since a seizure action would have to be taken through each United States District Court having jurisdiction over the product location. The need for FDA to seek embargo authority is discussed in a previous GAO report to the Congress.¹

Slow judicial process

Some FDA officials consider the effectiveness of injunctions and prosecutions limited because the judicial process is extremely slow, and in the meantime firms continue to produce and market adulterated drugs. During fiscal years 1970 and 1971, FDA approved a total of 51 seizures, 2 injunctions, and 5 prosecutions because of deviations from GMPs. It is evident from the national statistics that, only in a few instances FDA used either an injunction or prosecution to enforce GMPs of the FD&C Act.

One of the few injunction orders processed by FDA took 16 months. Thirteen of the 16 months elapsed while the proposed injunction was being processed through FDA headquarters. By contrast, it took 2 months for the district to prepare the recommendation and 1 month for the United States District Court to approve the injunction after it was filed.

Recent steps toward more aggressive enforcement

In February 1972, FDA's Associate Commissioner for Compliance issued a policy statement which resulted in the following instruction being provided to district offices:

¹"Lack Of Authority Limits Consumer Protection: Problems In Identifying and Removing From The Market Products Which Violate The Law." (B-164031(2), Sept. 14, 1972)