

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 10615

Officials of DOD and VA have reservations, however, and stated that it would be imperative that such a program (1) be at least as effective as their present programs and (2) fully recognize the agencies' special requirements; for example, shelf life and packaging of items for military use.

The FDA Commissioner testified on January 19, 1971, before the Subcommittee on Monopoly, Senate Select Committee on Small Business, that drug inspection by three Federal agencies was duplicative and that the resources used by other agencies for drug inspection should be allocated to FDA.

CONCLUSIONS

The present DSA, VA, and FDA drug inspection systems are not as efficient as they could be, because several Federal agencies survey the plants and inspect the products of the same vendors and sometimes the same items. Also the agencies differ in their degrees of inspection for both plants and products.

DSA makes preaward surveys and in-plant product inspections for the majority of the drugs bought for military use--those items that are centrally managed. However, military hospitals make substantial procurements commercially, either under FSS contracts or from local vendors, of which no inspections are made, other than those by FDA. VA augments FDA inspection to a lesser degree than DSA does and still seems to obtain satisfactory results.

RECOMMENDATION

Advantages should stem from having a single agency responsible for quality assurance activities pertaining to purchases of drugs by Federal agencies. Since FDA has statutory responsibilities pertaining to the manufacture of drugs, it seems to be the logical choice for this centralized responsibility. The additional responsibility should facilitate the performance of its other responsibilities relating to drug manufacturers.

Accordingly, we recommended that the Secretary of HEW; the Secretary of Defense; and the Administrator, VA, review the frequency and type of inspections required and the related staffing, organization, and administration changes