

10600 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

A further difficulty concerns data for formulating a drug. Even when the proper ingredients and quantities to be used are known, a product having a therapeutic effect different from that desired may be manufactured.

Thus, because of inadequate or incomplete data or the existence of patents, specifications are issued for many drugs that the Government buys which do not increase competition. Frequently, only one source can provide what the Government wants.

The degree of competition obtained in procuring drugs is less than that obtained for many other Government supply items. In fiscal year 1970 only about 7 percent of VAMC and DPSC dollar procurements for central stocks were made under formal advertised procedures. Much of the balance was procured under contracts negotiated with the sole source of supply or under contracts negotiated and awarded after proposals were solicited.

The primary reasons for the lack of competition are the large number of patented drugs and the Food and Drug Administration's (FDA's) requirements for approving drugs for manufacture. Some manufacturers have difficulty meeting these requirements because of the technical requirements and costs involved.

AVAILABILITY AND USE OF SPECIFICATIONS

DPSC generally will not approve a drug for central management unless (1) data sufficient to develop a competitive procurement specification is available or (2) all three military services concur in designating a single procurement source. Consequently DPSC has prepared specifications for nearly all the 1,100 drugs it manages. Only 1 percent of these items are intentionally bought noncompetitively from preselected sources.

Although DPSC attempts to buy competitively virtually all the drugs it manages, it has been successful only for about 51 percent of 1,100 items and the degree of competition on many of them is quite limited. The remainder, about 535 items, is supplied by single sources. FDA regulations, which disallow marketing without approved new drug applications or antibiotic certificates, or patents preclude or