

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 11873

DOD AND VA

Based on our discussions with DOD and VA officials, it is obvious that in the 14 months since we last appeared before this Subcommittee, the two agencies have devoted much effort to achieving the goals of the GSA-led interagency committee and the objectives of the FDA-led effort in the quality assurance area, thereby responding to the recommendations in our report.

For example, in the area of specification development:

- An official of VA's Department of Medicine and Surgery stated that the agency now develops specifications for all new drugs which it decides to manage centrally, except for those which cannot be procured competitively because of patent protection. He said that VA will continue to develop specifications whenever it believes these are required to promote competitive procurement or where the special characteristics of a product must be defined.
- DOD and VA officials stated that information on specification development is currently being exchanged between the two agencies. The VA official stated, for example, that when VA finds it necessary to develop a new specification, it uses that of the military--if one is available--as a basis for its development. Officials of both agencies stated their belief that the development of specifications for products available from only one source of supply is not necessary or desirable.
- The subject of specification development is one of the matters being considered in the FDA-led effort in the quality assurance area. An attempt is being made to establish FDA as a point of contact for review and concurrence in specifications developed by buying agencies so that FDA can adequately plan and carry out its new quality assurance responsibilities.

The issue of how to select items for central management was addressed in one of our recommendations to DOD. This