

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 9935

The criteria for the initial classifications are: (1) effective meaning that the drug has the purported therapeutic effect; (2) probably effective meaning that the effectiveness of the drug is probable, but additional evidence is required before it can be declared effective; (3) possibly effective meaning that there is little evidence of effectiveness; and (4) ineffective meaning that there is no acceptable evidence of effectiveness.

On December 11, 1970, the Surgeon General requested all agencies within HEW to establish procedures within 45 days to prohibit the use of Federal funds for the purchase of drug products classified as ineffective or possibly effective by FDA. Two exceptions were noted:

- Ineffective and possibly effective drugs could be purchased for use in approved clinical research projects.
- Possibly effective drugs could be purchased when no alternative means of therapy with drugs in the probably effective or effective categories is available.

On October 8, 1971, HEW issued a regulation prohibiting expenditure of Federal funds under its direct care programs for ineffective and possibly effective drugs except under the two conditions listed above. However, regulations prohibiting such purchases under Medicaid have not been issued.

PRIOR GAO REPORT ON EFFECTIVE DRUGS

On May 9, 1972, we issued a letter report to the Administrator, Social and Rehabilitation Service, HEW, in which we recommended that regulations to preclude the purchase of ineffective and possibly effective drugs under Medicaid be issued without further delay. We stated that about \$196,000 had been expended in Ohio during January, April, July, and October 1970, for 38,000 prescriptions for 106 ineffective drugs, and that about \$99,000 had been expended in Illinois and New Jersey in July and October 1970, for 21,000 prescriptions for 16 ineffective drugs.

In his reply, dated June 13, 1972, the Administrator stated that a regulation precluding expenditures for ineffective and possibly effective drugs under Medicaid was being prepared for transmittal to the Office of the Secretary, HEW, for publication as a proposed rule. The proposed regulation has not yet been published.