

(2) They create a practicable procedure for applying to pharmaceuticals the authority for product prequalification contained in Section 604(f) of the Foreign Assistance Act of 1968. In other words, Mr. Chairman, we can now apply our price tests before rather than after delivery.

Formulation of the new standards with their more stringent criteria enables us to continue to finance pharmaceuticals with some assurance that the interests of all parties in procuring essential and suitable items at reasonable costs are safeguarded. With this assurance, we are continuing to finance pharmaceuticals—products of American industry that are considered vital to health and population control programs supported by AID.

I wish to make it clear that AID does not find fault with any of the drugs we discuss today except for their prices. We ourselves do not evaluate the relative efficacy of drugs or the cost-benefit ratio of one drug compared to another since we have no special expertise in this area. Rather we rely on the advice and guidance of recognized experts.

It would be helpful to us if there were official cost-benefit studies of drugs which we could consult. In the absence of such studies, we must rely on the best published expert information available from semiofficial or private sources. We will continue to make decisions as to the ineligibility of specific drugs whenever experts indicate excessively high prices for drugs for which equally satisfactory lower cost substitutes are available.

The Agency also has under review a relatively new problem in the pharmaceutical area—the status of drugs declared “possibly effective” by the FDA as a result of NAS-NRC findings. These are drugs for which there is little evidence that they are effective for any of their claimed indications. Drugs in this category have not been taken off the U.S. market. We note, however, that the Surgeon General has announced a policy for HEW that no Federal funds be expended for purchasing drug products classified “possibly effective.” By memorandum of December 11, 1970, all department agencies of the HEW were so notified.

Our Agency now is reviewing the action that it should take to complement actions of other U.S. Government agencies, such as HEW, to bar the financing of any bulk ingredient which is virtually synonymous with a dosage brand designated as “possibly effective” by the NAS-NRC.

The work we have done on pricing standards for pharmaceuticals since the hearings of last August provides a foundation for future activities that may encourage increased participation in our programs by the small business community. I would like to be a little more specific on this point. All 16 drugs which have been referred to and which have been declared ineligible under our new price rules are the exclusive products of large companies. The lower priced drugs of choice that are logical replacements are generally made by small business firms. These small business firms now have increased prospects that their products will be considered for purchase by importers.

As a second example, we already have evidence that at least one large company finds it unattractive to sell some of its products at