

Mr. DWINELL. We do, sir.

Senator NELSON. Go ahead.

Mr. DWINELL. As was indicated at the earlier hearing, we have had pricing problems under our general price rules with the pharmaceutical industry. Relatively more claims have been issued for overcharges in pharmaceutical transactions as a result of our postaudit review than for any other commodity we finance.

Mr. GORDON. Why is that? Why the drug industry? Why do you have more problems with the drug industry than with any other industry?

Mr. DWINELL. Because it is a unique industry, unique in that it has—pricing policies quite different from those of many other industries.

Also, I might say that of all the pharmaceuticals that we finance, a large percentage is rather standard, highly competitive pharmaceuticals where we have very little problem with pricing. We have had problems, as was brought out in the previous hearing, with regard to certain patented items. It is to try to control the pricing in that area that we have instituted these new rules which I am about to explain to the committee.

Relatively more claims, as I have indicated, have been issued for overcharges than for any other commodity we finance. Now, this review is a continuous process and more claims on past transactions will be issued if warranted. Details on our claims and refunds received were submitted to the committee previously.

As I have said, pharmaceuticals are products of an industry which is unique in its character and pricing practices. We have, therefore, established for this industry specific pricing rules to govern the eligibility of pharmaceuticals for AID financing. These were published in the Federal Register of December 31, 1970. They are contained in an appendix to this statement.

(The appendix referred to follows:)

APPENDIX—DEPARTMENT OF STATE, AGENCY FOR INTERNATIONAL DEVELOPMENT

NOTICE—DETERMINATION OF COMMODITY ELIGIBILITY FOR BULK PHARMACEUTICAL PRODUCTS

Pursuant to § 604(f) of the Foreign Assistance Act of 1961, as amended by § 301(a) of the Foreign Assistance Act of 1968, AID has stated in § 201.11(k) of Regulation 1, 22 CFR § 201.11(k), that each commodity "shall be approved in writing by AID for each sale transaction as eligible for AID financing." The statutory language in § 604(f) requires AID to approve each commodity "as eligible and suitable for financing."

It is current AID policy not to finance pharmaceutical products in finished dosage form. The Agency has, however, been financing most bulk (i.e. not in finished dosage form) pharmaceutical products. By means of this announcement, AID advises parties who may be interested in participating in sale transactions of bulk pharmaceutical products under AID financing that henceforth AID will apply the following criteria in determining whether, under regulatory and statutory standards, this Agency should find a product described on the Commodity Approval Application, AID Form 11, to be "eligible and suitable" for AID financing:

(1) AID will not finance from an authorized source country a bulk pharmaceutical product at an FAS price which exceeds by more than 10% the FAS price at which the product, by whatever description, is generally available from any other free world country. With respect to a product patented in the U.S., AID will compare FAS prices between the U.S. product and the