

Mr. CAMPBELL. In other words, the money is eventually returned to the country to make a purchase.

Mr. GORDON. How many cases of overcharge did you have last year?

You don't have to tell us now. You can submit it for the record, giving the names of the firms.

Mr. BARONDES. We did submit, I think, last time a list of all companies against whom we had claims where we either collected, or we had not yet collected.

Mr. CAMPBELL. We have a list here that we can submit for the record—it is complete—of the overcharges.

The list of claims previously referred to the Department of Justice is already in the record. Two claims totaling \$343,821.83 are unpaid. Discussions between AID and the two suppliers involved are continuing.

Since pharmaceutical prices charged by AID suppliers must meet both the pricing criteria applicable to all AID financed commodities and the more restrictive criteria of the special pharmaceutical rules which are applied on a preaudit basis, we anticipate that no further refund claims will be required in this product area.

In making our determinations as to the appropriate prices for pharmaceuticals under the current standards we utilize all sources of information available to us. A prime source of information is the pharmaceutical industry itself. Other sources of information are price lists of foreign suppliers, actual export sales from the United States and other countries in which AID restrictions limiting the source of supply do not apply.

No other U.S. Government agency has a concern comparable to that of AID with export prices of unfinished drugs. Price information from other agencies usually does not reflect commercial export prices of drugs and is therefore not particularly helpful to AID. AID has cooperated with other agencies seeking export price information, particularly HEW. We believe that AID financed prices compare favorably with prices in purchases by other agencies.

You also have asked that we describe the actions taken in regard to pronouncements by the FDA and other medical experts on the lack of merit on many drugs.

AID does not finance drugs which the U.S. Food and Drug Administration has found to be either unsafe or ineffective.

In February 1971, we discussed the FDA's authority to approve drugs on the basis of both safety and effectiveness. In exercising this authority, FDA has established four classifications for the drugs it evaluated:

- (1) Drugs classified as "effective" are those which are supported by substantial evidence of effectiveness;
- (2) Drugs classified as "probably effective" are those which are supported by some evidence but additional evidence is required before they can legally be classified as "effective";
- (3) Drugs classified as "possibly effective" are those which are supported by little evidence of effectiveness; and finally,
- (4) Drugs classified as "ineffective" are those drugs which lack acceptable evidence of effectiveness.

Under AID policy, pharmaceuticals in finished dosage form are normally eligible for financing only for use in specific projects in the AID receiving countries. Only unfinished pharmaceuticals, or ingredients,