

14910 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

As this committee may know, allegations were made in January of 1972 that Pennwalt's anti-obesity drug product Bifetamina (Biphetamine), in Mexico, was being illegally diverted by purchasers of that drug. Pennwalt was never given evidence of where and how this diversion occurred, nor has Pennwalt been advised of any prosecution with respect to those alleged diversions. Nevertheless, in January of 1972, Pennwalt ceased production and sale of amphetamine products in Mexico and at the same time decided to cease any further export of amphetamine products, except for Canada. These decisions were made to limit our Biphetamine sales to the United States and Canada, in reliance on strict regulatory practices which exist in those two countries. (As this committee knows, in 1973 Canada withdrew its approval of amphetamine products.)

Combination Amphetamine Anorectics

In February of 1973, the FDA published in The Federal Register a finding that all fixed combination amphetamine products were ineffective and unsafe. As a fixed combination, this finding included Biphetamine-T. Although the initial National Academy of Science - National Research Council ("NAS/NRC") finding with respect to Biphetamine-T was that it was "possible effective", Pennwalt elected not to exercise its right to contest the FDA's 1973 re-determination. Pennwalt therefore discontinued further manufacture of the product and recalled all stocks from the distribution chain, at a cost of approximately one million dollars.