

cooperated fully with the enforcement authorities in the investigation, apprehension, and prosecution of those responsible.

Our experience also confirms an observation of Mr. Peter Bensinger, Administrator of the DEA, at the annual meeting of the top executives belonging to the Pharmaceutical Manufacturers Association, held in May of 1976. He noted that there is no reason to believe that industry is responsible for illegal trafficking in amphetamine. Pennwalt knows of no evidence to the contrary.

As this committee may know, allegations were made in January of 1972 that Pennwalt's antiobesity 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. 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.

Senator NELSON. For obesity reasons?

Mr. McGRAW. That is correct, sir.

Mr. BRODERICK. If I may interject, we indicate that we continue to export to Canada, that is wrong.

We should have referred to the fact that we continue to sell to Canada. We did not export to Canada.

Senator NELSON. All right. The record will stand corrected.

Mr. McGRAW. [Reading:]

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 redetermination. Pennwalt therefore discontinued further manufacture of the product and recalled all stocks from the distribution chain, at a cost of approximately \$1 million.

CONCLUSION

On the basis of the evidence which we have summarized today, Pennwalt believes that there is an established medical and social need for its antiobesity products.

We think it important that this committee differentiate between hearsay testimony, utterly unsubstantiated by factual support, and the testimony and documentary evidence available from sources which are recognized to be technically qualified to deal with a complex scientific, social, and medical question.

There remains a population, estimated to be between 30 and 40 million obese Americans, many of whom wish to avail themselves of