

14902 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

"In all of those sixteen years, Pennwalt has learned of no deaths or any serious physical or mental injury or damage attributable to the drug. In addition, Pennwalt is not aware of any significant instances of phentermine abuse, and its product liability experience with the drug Ionamin reflects but one payment, in the amount of \$3,500., to settle one suit brought by a patient who alleged she had used Ionamin (on prescription) as well as several other drugs manufactured by other defendants in her case."

The DEA Monitors and Audits the Distribution of Anti-Obesity Drugs

The Drug Enforcement Administration plays a very active role in monitoring and auditing our scheduled substances. It requires that all manufacturers of all Schedule II products submit monthly DEA-222-C forms. These reports require Pennwalt, for example, to list each purchase or sales transaction involving Biphentamine, as a Schedule II substance, by date, amount, and identity and location of purchase.

The DEA also requires the quarterly filing of ARCOS computer tapes recording each controlled substance transaction under Schedule II and all transactions involving narcotic drugs in any schedule exclusive of those on Schedule V. These computer tapes show the movement of the drug both within the plant and in distribution, again showing date, amount and recipient.

For Ionamin, a Schedule IV product, the DEA requires that we record the name and location of each purchaser, its registration number, and the quantity, identity, and strength of the product by package unit. These same standards apply to our purchase of Ionamin's raw material, phentermine.