

The Darvon Working Group would meet every Monday at 2 p.m. and every Tuesday at 10:30 a.m. It, in turn, would report to the Darvon Policy Group, composed of Mr. Wood, Dr. Earl B. Herr, president of Lilly Research Laboratories, Mr. Zapapas, Cornelius W. Patinga, an executive vice president, Eugene L. Step, president of the pharmaceutical division, C. Harvey Bradley Jr., the top corporate attorney, and Mr. Davis, who was the link between the two groups. The policy group, meeting every Tuesday at 8:30 a.m., would set strategy and deadlines for the working group.

In business school, such committees are called matrix organizations. Lilly management uses them to tackle temporary problems requiring expertise from several parts of the company. "The problem here is how do you reach out into the corporation and pull together the bits and pieces of information you need to make a solid case?" said Mr. Davis. "This was a major, unfounded threat, with implications for a product and the company," Mr. Davis said. "We knew we were right. And we knew we had to get the data to make that case."

Dr. Wolfe's fatality data, the working group found, were built in part on material gathered for the Drug Enforcement Administration through the Drug Abuse Warning Network, known as DAWN. It collects medical examiners' reports on drug-related fatalities in 23 metropolitan areas. Dr. Wolfe had shown that fatalities involving propoxyphene, of which 95 percent is Lilly's Darvon, had soared 25 percent in 1977 to 590. That put it second only to heroin with 751, and because the network covers only big cities, where heroin use is concentrated, Dr. Wolfe figured that Darvon deaths in smaller communities pushed the Darvon toll above heroin's. He also contended that most of the deaths resulted from accidental overdoses.

WHAT THE TAPES SHOWED

"Our task," said Mr. Luedke, "was to get the DAWN data study," the material from which the D.E.A. compiled the statistics that Dr. Wolfe used. The source was IMS America Ltd., leading experts in pharmaceutical market research and a company that both the Government and the industry consider reliable.

Mr. Luedke asked IMS for the raw material, the 455,000 reports, recorded on 16-track computer tape, showing incidents of drug-related fatalities from 1974 through 1978. The tapes were then turned over to Dr. Redman, who, with a team of five analysts and statisticians, put them through the Lilly computer, updating them as Mr. Luedke obtained 1978 statistics in daily calls to IMS.

The tapes did not exonerate Lilly. They showed hundreds of deaths each year from overdoses of propoxyphene. But DAWN's reports showed only the results for all of 1977, not for each quarter, and Lilly made a happy discovery: "By looking at the tapes," said Mr. Luedke, "we found most of the mentions in the first quarter, and that they then began to drop." The fall of Darvon-related deaths continued from then on, to the end of 1978.

Lilly also went to Dr. Bryan S. Finkle, a toxicologist at the University of Utah, who, in an earlier study, had reported a rise in Darvon-related deaths in the early 1970's. Now he found a decline matching the Lilly analysis. He also found that most deaths resulted from massive overdoses, often in combination with alcohol or other drugs, indicating that many of the fatalities were probably suicides, not accidents. As for the heroin charge, Lilly found that in relation to the number of prescriptions filled, propoxyphene ranked way back in 11th place among all drugs as a cause of death.

Lilly then wanted to see if its own warnings of the hazards of misusing Darvon had had any impact on physicians. They asked IMS to poll them. The sampling of 514 physicians showed that 88 percent were aware of warnings against the abuses of Darvon and that 91 percent considered the drug safe when used as prescribed.

These developments broke in the days just before Christmas. Lilly had still not constructed an airtight case. It was clear that Darvon could at times be lethal with relatively small overdoses, as Dr. Wolfe charged, increasing the risk of accidental fatalities. And data from the IMS tapes still raised questions. Some medical examiners don't file reports on drug-related deaths as promptly as others, so some doubt about the downward trend for 1978 remained. But time was getting short. On Friday, Dec. 29, Lilly would have to answer Dr. Wolfe's petitions in a preliminary submission to the F.D.A. and the D.E.A.

The typists in the Word Processing Center began working right through the night then, cranking out the documents that the working group would assemble