

Maker Had Issued Warnings on Diet Drug

By Milt Freudenheim

The New York Times, September 17, 1997, Wednesday, Late Edition

Redux, the diet drug that was withdrawn from sale Monday after 15 meteoric months, was a problem product virtually from the start. In that short time, the American Home Products Corporation, the big pharmaceuticals and health care company, repeatedly issued warnings of rare but dangerous side effects for Redux and sent 950,000 cautionary letters to doctors and pharmacists.

American Home Products suspended Redux and an older drug, Pondimin, after Federal regulators told the company on Friday about a significant number of reports indicating heart-valve problems.

Nearly all occurred with people who used the American Home drugs in a combination known in the trade as fen-phen—fenfluramine (or Pondimin) and phentermine, which is marketed by SmithKline Beecham and other companies.

The manufacturers said they never promoted the combined use. American Home warned against the combination as early as last winter.

Securities analysts said that American Home Products would write down \$200 million to \$300 million to cover the withdrawal of Redux and Pondimin. The drugs' combined sales were \$360 million in 1996, but have sharply fallen this year.

The write-down does not include any legal liability in dozens of suits filed across the country. "It is too early to assess the potential legal liability created by this issue," said Steven C. Tighe of Merrill Lynch.

Investors evidently discounted the legal threat, noting that the loss of diet-drug sales would translate into less than 10 cents' profit a share in a company with 1996 sales exceeding \$13 billion. American Home Products shares rose 93.75 cents yesterday, to \$74.1875.

The Food and Drug Administration had narrowly approved Redux in July 1996 after previously rejecting it. Sales took flight and some Wall Street analysts rhapsodized about the next billion-dollar drug.

But by June of this year, after damaging reports appeared in medical journals, newspapers and on the Internet, sales sagged and American Home called in a crisis manager, Robinson, Lerer & Montgomery, a New York public relations firm, to address the diet drug's problems.

American Home, based in Madison, N.J., had previous experience with a problem product. The company has paid \$2.4 billion into trusts to compensate users of the Dalkon Shield, a birth-control device that was blamed for pelvic injuries. American Home inherited the Dalkon liability when it acquired A. H. Robins, a health care company that took refuge in bankruptcy proceedings after a deluge of lawsuits.

Dr. Marc Deitch, medical director of Wyeth-Ayerst Laboratories, the pharmaceutical unit of American Home Products, said the company rewrote the Redux warnings for the first time after The New England Journal of Medicine reported in August 1996 on increased blood pressure in the lungs of some patients who used Redux.

American Home acquired rights to sell Redux in the United States from its maker, Interneuron Pharmaceuticals of Lexington, Mass. It had been sold in Europe by a French drug company for nearly a decade.

Dr. Deitch said the company added another warning last winter stating that Redux was approved only for short-term use and that results of using it in combination with other drugs, "especially phentermine," had not been studied.

Robert Essner, president of Wyeth-Ayerst, said there was "no data at that point to suggest any problem," even though Pondimin had been on sale since 1973. But in March, American Home got the first word of heart-valve problems from a cardiologist at the Mayo Clinic, Dr. Deitch said. The company "followed up with Mayo in March, April and May," he said, "to define the problem and understand it better."

In July, it met with F.D.A. officials and changed the label again, adding a box warning about heart-valve complications and giving more prominence to the possibility of high blood pressure in the lungs.

The Mayo heart-valve findings were published on the Internet and in The New England Journal. The company said it had heard of 100 patients with problems of various kinds, including 24 studied by Mayo.

American Home said it had asked Mayo and 10 other centers to study

the drug to try to nail down whether the obese patients had heart-valve problems before taking Redux and whether the problems disappeared when they stopped taking it.

Yesterday, American Home said that Dr. Arthur Weyman, a professor at Harvard University Medical School, would head a panel of cardiologists and epidemiologists to review the new information.

The company bought full-page newspaper ads to publicize the withdrawal of the drugs.

[Correction: This article about the American Home Products Corporation's problems with two diet drug misidentified the one that the company warned last winter was approved only for short-term use. It was Pondimin. Redux was approved for longer-term use.]