2418 Longworth House Office Building
Washington, D.C. 20515
(202) 225-3976

District Office
3435 West 3d Street
Los Angeles, California 90020
(213) 651-1040

Congress of the United States
House of Representatives
Washington, D.C. 20515

HENRY A. WAXMAN
24TH DISTRICT, CALIFORNIA

COMMITTEES:
INTERSTATE AND FOREIGN COMMERCE
CHAIRMAN, SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT
GOVERNMENT OPERATIONS

December 1985

Dear Friend,

As this year comes to an end, I thought you might be interested in reviewing some articles that touch on some of my legislative activities. I look forward to further progress on these issues, and hope you will stay in touch with me on other matters of interest to you.

Best regards,
Henry Waxman

The Washington Post January 25, 1985

Carbide Was Told Of Hazards

Company Inspectors Faulted Procedures Before Bhopal Leak

By Donald P. Baker
Washington Post Staff Writer

Nearly three months before leaking methyl isocyanate killed at least 2,000 people at Union Carbide Corp.'s plant in Bhopal, India, inspectors at Carbide's sister plant in Institute, W.Va., warned that "a real potential for a serious incident" existed there in the way the company handled the deadly chemical.

The internal report, made public yesterday by a congressional subcommittee, warned that "a runaway reaction could occur" in the storage tanks at Institute and that "the planned response . . . would not be timely or effective enough to prevent catastrophic failure of the tank."

The Carbide team also reported several incidents of water contamination of the Institute tanks. An Indian scientist said earlier this month that he believes that water entering an underground storage tank at the Bhopal plant set off a violent runaway reaction, spewing clouds of poison gas into the air.

The Bhopal plant was modeled after the West Virginia facility. The investigation into the Bhopal disaster has not been completed.

Rep. Henry A. Waxman (D-Calif.), chairman of the House Energy and Commerce subcommittee on health and environment, said the company document "completely discredits" a report by the Environmental Protection Agency Wednesday that, despite 28 instances of leaking MIC over a five-year period, safety at the West Virginia plant was "above average."

Rep. Robert E. Wise Jr. (D-W.Va.), whose district includes Institute, said Carbide board chairman Warren M. Anderson told him that the report was a "worst-case scenario" and that some of the remarks in it were "taken out of context."

Dick Henderson, a Carbide spokesman at Institute, said the Carbide safety audit team "plays the role of a devil's advocate."

EPA said yesterday that while it "shares many of the concerns regarding worker and plant safety" raised by Waxman, plant safety is regulated by the Occupational Safety and Health Administration. An OSHA spokesman said that agency's report on MIC handling at Institute and at plants to which it is shipped will be completed next month.

J.M. Poulson, the Carbide employe in charge of the July 9-13 plant inspection, wrote that although "no imminent hazards requiring immediate correction were noted, two concerns classified as major were identified by the team."

Poulson wrote that while the incidents of contamination were handled without problems, they "may have created a degree of confidence or lack of concern that could allow a situation to proceed to the point where it is not controllable." The report added that "incidents of water contamination may be warnings, rather than examples of successfully dealing with problems."

Waxman said the Carbide memorandum "raises serious questions" about the corporation's conduct.

"Why did Union Carbide conclude that the possibility of a runaway reaction that would be catastrophic was not something that should be dealt with immediately?" he asked. "Did anyone in Union Carbide communicate this information to Bhopal prior to the largest air pollution disaster in history? Was the document ever given to EPA or state officials?"

Waxman yesterday contacted Anderson, who was on Capitol Hill meeting with the West Virgnia delegation, and told him that the report "raises all sorts of questions" about safety measures at the plant.

REP. HENRY A. WAXMAN
. . . memo "raises serious questions"

"We need answers from you about what Union Carbide has done" in response to the report, said Waxman, who asked Anderson to testify before a special meeting of his subcommittee next week.

Waxman recalled that Anderson, in testimony before his subcommittee at a hearing Dec. 14 at Institute, said, "It never entered my mind" that an accident such as Bhopal could happen.

Jackson Browning, who is in charge of health, environment and safety affairs for Carbide, testified at that hearing that the Institute and Bhopal plants "both respond to the same process safety standards."

Waxman called the EPA report released Wednesday "disgraceful." He said the EPA did not uncover the Carbide document "because they didn't ask the right questions" and added, "The fallacy of EPA is that it thinks the industry should regulate itself."

Waxman said it may be necessary for Congress to set standards for the hundreds of life-threatening chemicals used by the nation's 5,000 chemical plants and to require strict safety standards.

The Washington Post July 16, 1985

Drug Industry Accused Of Gouging Public

Waxman Attributes Price Hikes to Greed

By Sari Horwitz
Washington Post Staff Writer

Rep. Henry A. Waxman (D-Calif.) lashed out at the U.S. drug industry yesterday, charging that they are "gouging the American public" with "outrageous" price increases for prescription drugs.

Prescription drug prices, the fastest-growing component of U.S. medical costs, have risen at more than twice the rate of inflation since 1981, while the industry's profit rate was nearly triple the average for all manufacturers, said Waxman, chairman of the House subcommittee on health and the environment.

"Without adequate explanation, one can only conclude that what is going on in this industry is greed on a massive scale," Waxman said at an overflow hearing on drug price increases. "This is an industry that insists on increasing its profits at the expense of the sick, the poor and the elderly."

From January 1981 to June 1985, the CPI rose 23 percent while prescription drug prices shot up 56 percent, according to a congressional staff report. The study also said that during the past four years, pharmaceutical companies had an average after-tax profit rate of 12.7 percent, while the figure for all manufacturers was 4.2 percent.

Drug industry officials defended soaring pharmaceutical prices by stressing that, while they have risen in the last few years, drug prices climbed only slightly in previous years, resulting in an overall growth since 1967 that was below the inflation rate.

Drug company executives added that prices have climbed recently to cover accelerated investment in researching and developing new and better medications to protect Americans.

R&D investment by pharmaceutical firms will exceed $4 billion worldwide, about four times the amount spent 10 years ago, said Gerald J. Mossinghoff, president of the Pharmaceutical Manufacturers Association.

"The increased investment in pharmaceutical R&D has contributed to higher drug prices today, but certainly will lead to better, even more cost-effective medicines tomorrow," Mossinghoff said. "New drugs developed by our industry are among the principal reasons that the death rate for heart disease declined by 40 percent and the rate for strokes 55 percent over the past 20 years."

However, when Waxman asked for the percentage of consumer drug price increases that is allotted to research and development, Mossingoff and officials of three drug companies—Hoffman-La Roche Inc., Merck & Co. Inc. and the American Home Products Corp.—could not produce a figure.

"One should not be fooled into thinking that most of the dollars pouring in from these price increases are going into R&D," Waxman said. "For every additional dollar of sales, the industry is immediately setting aside 13 cents for profit and large amounts for marketing and advertising."

Senior citizens, who consume roughly 30 percent of prescribed drugs, are often the hardest hit by soaring prescription drug prices. About 80 percent of the elderly, most of whom are living on fixed incomes, must pay out-of-pocket since neither Medicare nor most private insurers reimburse for prescription drugs consumed outside of hospitals.

Anne Witoff, a 75-year-old Alexandria woman who testified yesterday, said that since January she has been charged more than $1,000 for prescription drugs that she has to take every day for her heart condition. "I have to take this medicine in order to survive," said Witoff, whose bills aren't covered by Medicare or her private insurer. "And every time I go to renew a prescription, there's a new price."

The Wall Street Journal July 12, 1985

Program to Spur 'Orphan' Drugs Proves a Success

By Carol Winn
Staff Reporter of The Wall Street Journal

WASHINGTON—As a young stockbroker, William Baird had a major problem. Mr. Baird says he recalls listening to a client and "I slowly slipped off to sleep."

Mr. Baird has narcolepsy, a rare disease in which sleeping can be triggered by laughter, anger or the slightest bit of elation. A second rare disorder robs him of muscle control. Until nearly two years ago, "I simply had to avoid emotions or feeling really good about anything," the 46-year-old Mr. Baird says. No effective medicine was available for his disease.

Today, Mr. Baird, now president of the American Narcolepsy Association in San Carlos, Calif., can work effectively for 10 to 12 hours a day. He has benefited—as have thousands in the past 2½ years—from the testing and production of so-called orphan drugs.

Such drugs are the fruit of the Orphan Drug Act, which took effect in January 1983. The act provides federal aid for the development and marketing of drugs that otherwise may not be commercially feasible because of the relatively small number of potential users. Mr. Baird, for example, is one of only 40,000 to 70,000 people in the U.S. who are afflicted with narcolepsy.

Successful Legislation

Although many associations like Mr. Baird's say more funds are needed, most such groups and most officials say the legislation has been a success. Since the law was enacted, 61 products have been designated as orphan drugs and are now being tested or are already approved for sale.

The program "is giving new hope to people who have given up hope," says Democratic Rep. Henry Waxman of California, a leading sponsor of the act.

To quality for an orphan drug, a disease must affect fewer than 200,000 people. The law authorizes grants to pay researchers and drug companies for the costs of animal and human clinical research, awards companies a seven-year exclusive marketing license to sell the drug if a patent can't be acquired and provides them with tax incentives.

Most grants range from $15,000 to $128,000, according to the Orphan Products Development Office, a division of the Food and Drug Administration. Recently, the House voted 413-0 to fund the program for three more years at a rate of $4 million each year. Senate action is pending.

The law has benefited 28-year-old Lowell Handler of Cold Spring, N.Y. He didn't respond well to a drug he previously used to treat Tourette's Syndrome, a degenerative, neurological disease characterized by involuntary muscular movements and uncontrollable vocal sounds. The drug caused lethargy, deep depression, restlessness and other side effects. He now takes the orphan drug Pimozide which, while not a cure, has less-serious side effects.

While taking the orphan drug during its experimental stage, Mr. Handler had to pay for expensive blood and urine tests. Now, because of the law, the drug is marketed nationally, and he simply goes to the drugstore and pays $40 a month for the medication he takes every day.

Limited Funds

The program has also led to treatments of such diseases as postanoxic myoclonus, an uncontrollable muscle contraction; acute intermittent porphyria, characterized by severe abdominal pain; and pneumocystitis carinii pneumonia, a lung infection.

The limited amount of federal aid, however, means that some companies still might find developing such drugs is too costly. Paula Harbison, a physician in San Diego, has interstitial cystitis, a painful bladder disease that she says provokes frequent urination—sometimes 60 times a day—and often keeps her from working. Because of the Orphan Drug Act, she was once able to obtain the drug Elmiron for her pain. But the drug is no longer being tested in the U.S. by Pharmacia, AB, of Sweden, which has international distribution rights.

William Murphy, vice president of regulatory and quality systems at Pharmacia Inc., the U.S. distributor, says supplies were discontinued because of a corporate decision to "shift . . . research priorities." He adds that Elmiron has been used for almost 15 years in Germany and "without a question the drug is safe." But further testing is required to meet U.S. safety requirements. The company is considering resuming research in the U.S.

Despite such setbacks, the program is providing some money—and hope—where little existed before. Says Rep. Waxman, "The facts of the matter were and are that they (pharmaceutical companies) are in the business to make a profit. . . . It seemed to me this was a problem we had to deal with in some constructive way." He adds, "I wish we could put more money into it."