Concerns are also mounting on the dangers to the public from "low-level" asbestos contamination of air and water and from asbestos-containing consumer products.

As the realization is dawning that asbestos is too expensive in terms of disease and death to continue using, the industry is beginning to develop the strategies of relocating in lesser developed countries and promoting the use of fiberglass as an asbestos substitute in the United States. There are serious unresolved questions as to the dangers of fiberglass and there are possibilities that it may be no less hazardous than asbestos.

The massive human toll taken by asbestos is probably the single most important incentive to the development of coherent national policies recognizing preventive medicine as a major future component in the delivery of health care.

Vinyl Chloride

One of the most common pejoratives applied to modern times is "the plastic age." And just as age-old natural materials like wood, glass, and metal have been replaced by cheaper synthetic plastics, this seems to imply, so has the value of our lifestyle been degraded. Many things we now touch or use daily are made of plastic. Yet the plastic transformation of our society has only taken place over the last forty years. The consequences to society of its plasticization, in terms both of high energy and health costs, have only recently been appreciated. One of the major costs is from cancer.[1]

Manufacture

Plastics are the leading product of the modern petrochemical industry. This era of plastics dawned in the 1930s with the realization that petroleum was the cheapest and sim-

plest starting material for the synthesis of the vast array of organic chemicals now used by modern industry. Petroleum then gradually replaced coal, which had been previously used for this purpose, and is now almost the exclusive basis of the organic chemical industry.

Vinyl chloride (VC) lies at the heart of the plastics industry. VC was first discovered in 1837. Large-scale production, however, did not start until the 1930s, when it was synthesized from chlorine and ethylene, largely for the manufacture of synthetic rubber.[2] Production levels increased rapidly after World War II at a rate of 15 percent per year, reaching a total of about 7 billion pounds this year.

VC is a simple chemical consisting of a small single molecular unit (a *monomer*) which is normally a gas but can be shipped and stored as a liquid under pressure. VC reacts under conditions of heat and pressure and in the presence of plasticizing chemicals to form large molecular chains (*polymers*) of polyvinyl chloride (PVC) resins. The polymerization of the VC monomer never proceeds to completion, but always leaves some unreacted VC entrapped in the PVC resin. Depending on the production process, this unreacted VC has concentrations ranging as high as 8,000 parts per million (ppm).[3] This residual VC can be dissolved out of the polymer or released by heating it.[4]

PVC resins are molded, injected, and extruded in the fabrication of a wide array of plastic products. These include phonograph records, wire and cable insulation, floor coverings, garden hose, furniture, upholstery fabrics, car bodies, coating of fabrics and wallpaper, containers, bottles, and food wrappings. It is difficult to get an accurate count of the number of U.S. workers involved in all the various stages of PVC production. There are about seventeen VC manufacturing plants, employing about a thousand workers, and forty PVC plants, employing about six thousand workers.[5] There are no figures available,

however, on the number of fabricating plants or on the number of their employees. These must run into the hundreds of thousands.

Suppression by the Industry of Data on the Carcinogenicity of Vinyl Chloride

In May, 1970, an Italian toxicologist, Pierluigi Viola, reported at an international cancer congress in Houston, Texas, that long-term intermittent exposure of a small group of rats to 3 percent of VC in air (30,000 ppm) resulted in the production of cancers in a wide range of organs.[6] Prior to this, there had apparently been no studies in the plastics industry on the possible carcinogenicity of VC, although tens of thousands of workers the world over had been exposed to it for over three decades and at least seven fatal cases of liver cancer had occurred in VC/PVC workers prior to 1970.[7] Disturbed by Viola's public report, a consortium of giant European chemical industries, led by Italy's semi-governmental Montedison, and with contributions from British, Belgian, and French firms, financed a major study initiated in July, 1971, by Cesare Maltoni of the Bologna Cancer Institute.[8] An extensive series of tests were conducted in which adult, infant, and pregnant mice, rats, and hamsters were exposed to VC in inhalation chambers at concentrations ranging from the relatively low 50 ppm level to the toxic 100,000 ppm (10 percent) level. By late 1972, Maltoni had confirmed and extended Viola's results. VC was shown to be a potent carcinogen, inducing a rare type of liver cancer (called angiosarcoma) as well as more common liver cancers (hepatomas) and cancers of other organs, including kidney, brain, and lung. The cancers were subsequently found even at the lowest level tested, 50 ppm.* The overall

*At that time the permissible exposure level for U.S. workers was 500 ppm.

tumor incidence was concentration-dependent, with higher doses increasing the incidence and rate of development of the cancers.[9]

In October, 1972, the Manufacturing Chemists Association, the major trade association of the U.S. chemical industry, entered into an agreement with the European consortium to share their information, but not to disclose it without prior consent.[10] In January, 1973, the U.S. industry representatives visited Maltoni and were given full details of his studies. The Manufacturing Chemists Association (and Maltoni) subsequently failed to disclose this information, in spite of the fact that NIOSH, in the same month, had publicly requested all available data on the toxic effects of VC. In March, 1973, the Manufacturing Chemists Association recommended to NIOSH a precautionary label for VC that made no reference to toxic or carcinogenic effects on animals or humans.

July reported to NIOSH NCI had data in 1973

Also in March, 1973, following complaints of an unpleasant taste, Schenley Distillers found 10-20 ppm levels of VC in their liquors sold in PVC bottles. On the basis of these findings, and still knowing nothing about the carcinogenicity data, FDA then banned the use of these liquor bottles. In December, 1973, the Society of Plastics Industry, the plastics industry trade association, provided the FDA with data on migration of VC from PVC containers to food, but made no reference to problems of carcinogenicity.

On January 22, 1974, B. F. Goodrich announced that since 1971 three PVC workers in their Louisville, Kentucky, plant had died of angiosarcoma of the liver. On that same day, the Manufacturing Chemists Association revealed the by now fifteen-month-old Italian data to NIOSH.

According to a recent special committee report of the American Association for Advancement of Science, the Manufacturing Chemists Association "appears to have deliberately deceived NIOSH regarding the true facts. . . . Because of the suppression of these data, tens of

thousands of workers were exposed without warning, for perhaps some two years, to toxic concentrations of vinyl chloride."[11]

Distortion by the Industry of Data on the Carcinogenicity of Vinyl Chloride

The first published case reports of angiosarcoma of the liver in VC/PVC workers generated an intensive epidemiological investigation of cancer mortality in the industry in several countries. A British Petroleum Corporation study, published in *Lancet* in 1975, concluded that the longer one worked in a VC plant, the less was the risk of getting cancer.[12] Closer examination by NIOSH, however, questioned the interpretation of the English data. Expected death rates in workers exposed to VC for fifteen or more years were artificially reduced, and rates in workers with lesser exposures were artificially inflated. Re-analysis of the data by NIOSH, using standard methods, showed a clear excess of mortality from all causes and all cancers, besides angiosarcoma of the liver (Table 5.3).

Exaggeration by the Industry of the Costs of Regulating Occupational Exposure to VC

As information on the carcinogenicity of VC began to surface, OSHA was prodded into action. On April 5, 1974, OSHA reduced permissible exposure levels from 500 ppm to a new emergency standard of 50 ppm. Under pressure from labor and independent scientists, who insisted that the new standard was still too high for safety, OSHA then proposed reducing this further to 1 ppm.[13] Even at that time, it had been shown that exposure of small numbers of rats to 5 ppm VC induced an increased incidence of cancer, and there was no evidence then (or now) of any safe exposure level for VC, or indeed to any other carcinogen.

Table 5.3 Comparison of Causes of Death in VC Workers Reported by British Petroleum (BP) and Recalculated by NIOSH

Cause of Death, Reported by BP and Recalculated by NIOSH	Standard Mortality Ratios* for Workers Exposed to VC for Varying Times		
	Years of Exposure		
	9 or less	10–14	15 or more
All causes			
BP	112	107	61
NIOSH	79	137	353
All cancers			
BP	123	58	73
NIOSH	86	76	428
Digestive system cancer			
BP	106	47	121
NIOSH	75	62	702
Lung cancer			
BP	129	101	62
NIOSH	90	133	366

Source: J. K. Wagoner, P. F. Infante, and R. Saracci, "Vinyl Chloride and Mortality," *Lancet* 2(1975): 194–195.

*Values greater than 100 indicate excessive deaths relative to expected population values.

Nevertheless, industry objected strongly to the 1 ppm proposal on the grounds that it was both unnecessary and beyond their compliance capability. To bolster these claims, contracts were given out by the Society of Plastics Industries to Arthur D. Little, Inc., of Cambridge, Massachusetts. Also, OSHA gave out a contract to Foster D. Snell, a division of Booz, Allen and Hamilton, for the purpose of estimating the economic impact of the new standard. The consulting firms predicted costs as high as $90 billion and losses up to 2.2 million jobs, persuasive arguments in the depressed economic climate of 1974.

However, these estimates were shown by the subsequent experience of the plastics industry to be gross exaggerations.[14] In spite of massive industry lobbying and pressures, OSHA stood firm on the new 1 ppm standard, which was passed on April 1, 1975.

Within one year, the VC/PVC manufacturing industry had successfully met the new standard, and without any major economic dislocation. B. F. Goodrich, one of the industry giants, redesigned its manufacturing technology to enclose VC manufacturing and handling processes and plug possible sources of leaks. Additionally, a "stripping" process was developed to reduce levels of the unreacted VC monomer in the PVC resin and to decrease VC loss in the process. The initial capital costs of the compliance technology were only $34 million. Contrary to the estimates of the industry consulting firms, B. F. Goodrich found that the new clean-up technology actually cut labor costs and could be profitably leased. (In spite of this, B. F. Goodrich increased the price of its PVC products in 1976, claiming higher production costs and blaming these on regulatory standards.) The experience of Union Carbide is similar. In late 1975, an official expressed surprise as to how unexpectedly easy it had been for his company to comply with the 1 ppm standard. However, earlier intercompany reports had documented the economic advantages of compliance through recovering and recycling VC which would have otherwise been discharged into the environment. Estimates of the economic impact of compliance had ignored the major costs to industry from losses of VC gas, with resulting air pollution of the plant and adjacent community. They had also ignored or discounted the major costs to society, both direct and indirect, from failure to regulate, with resulting VC-induced disease. Finally, these estimates did not reflect the emergence of a small and booming industry manufacturing the monitoring equipment now required to meet OSHA regulations.

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Cancer and Other Diseases Due to VC

Long before the 1974 reports of angiosarcoma in VC/PVC workers, VC was known to be toxic to experimental animals and to humans at relatively high concentrations. Studies on experimental animals in the early 1960s, by Dow Chemical Company and others, established that VC induced toxic effects in the liver and kidney at concentrations as low as 500 ppm, then the U.S. occupational standard.[15] At higher levels skin and bone abnormalities were also noted.

Acute toxic effects, such as headaches, disorientation, dizziness, drowsiness, and loss of consciousness had been noted in VC/PVC workers as long ago as 1949.[16] In the same year, the Russian scientific literature reported the occurrence of chronic gastritis, hepatitis, and skin lesions from VC exposure. In 1957 there appeared the first report of a new occupational disease among vinyl plastic workers called acroosteolysis, characterized by a thickening or clubbing of the fingers and toes, spasmodic contraction of the blood vessels, painful bone changes, and arthritis of the knuckles. Additional cases of acroosteolysis have since been noted from plastic plants all over the world. By 1966, it was recognized that liver damage, hepatitis and cirrhosis, was common among PVC workers and in some cases occurred after only one or two years of employment. Scattered cases of chronic lung disease have been noted since 1970 in workers inhaling PVC dust; any possible role of unreacted VC contained in or absorbed on the dust is not yet known. Also, a characteristic "meat-wrapper asthma" has been noted among supermarket and wholesale meat workers who, in packaging cuts of meat, use a "hot wire" or "cool rod" to cut and seal the sheet of PVC plastic film used.[17] In the cutting process, fumes are often given off, particularly by the hot wire. While the industry has ascribed the asthma to common irritants, such as hydrochloric acid, it is not known yet whether there are

long-term health hazards caused by unreacted VC liberated from the film.

Since 1974, more than forty deaths from angiosarcoma of the liver have been recorded in VC/PVC plants in the United States and elsewhere.* More ominously, four cases have been reported in PVC fabricating plants where VC exposure levels were under 10 ppm. Cancers at various other sites, including the brain, lung, and kidney, have also been found in VC/PVC workers; it should be noted that cancers were also induced at these sites in the animal tests. While the occupational exposure preceding the cancers has usually ranged from thirteen to twenty years, there have been four reports of liver angiosarcoma following less than six years of human exposure. The true incidence of VC cancers in exposed workers is still unknown, because of the long latency periods. However, the ever-increasing number of reported VC cancer cases in organs other than the liver indicates that they can no longer be considered a rarity.[18]

Despite the growing evidence of chronic human disease and the many thousands of workers at risk worldwide, the industry failed for more than twenty years to undertake any carcinogenicity tests in animals. Such tests could as easily have detected the carcinogenic effects of VC in the 1950s as they eventually did in the 1970s.

There are still elements of the academic community who minimize the risks of VC exposure. A recent brochure from the University of Louisville's Vinyl Chloride Project, a multimillion dollar NCI-funded program for the prevention and detection of VC-induced occupational cancer and other diseases, states:

> The low incidence of cancer development among people with prolonged exposure to vinyl chloride is a reflection of

*At least seven fatal cases of primary carcinoma of the liver, subsequently diagnosed as angiosarcoma, had been recognized in VC/PVC workers before 1970. Six of these cases occurred in the United States between 1961 and 1968, and the other in Sweden.

VC as a propellant in cosmetic products, including hair sprays. However, the FDA did not consider the matter serious enough to order a recall of VC-containing products so that the public could avoid further exposure. The Health Research Group eventually pried out from the FDA the brand names of hair sprays that used VC as a propellant, identifying Clairol as a top selling product. According to a recent survey by Consumer Product Safety Commission staff, no new consumer products containing VC have been manufactured since 1974, and no VC-containing products remain on the market in 1978.

The FDA also showed reluctance in moving against the use of PVC containers for food products, although it was aware that unreacted VC was leached out of the container walls by the foods or fluids inside. By 1974 the FDA knew that VC levels as high as 9 ppm had been found in vegetable oils sold in rigid PVC containers.[25] High levels were also found in other PVC-packaged products, including beverages and cosmetics. While the FDA banned the use of rigid PVC containers for food products and beverages, it did not recall them from the market. The FDA still allows the use of PVC film for wrapping foods.

Extensive research is now being done by industry with the object of reducing VC levels in PVC products, especially those intended for food packaging and medical applications.[26] However, as indicated in a recent trade journal article, the prospects of success seem slim:

> At present conventional devolatilizing techniques cannot be successfully offered to PVC. . . . It cannot be expected, however, that a completely monomer-free PVC resin will be a commercial reality in the near future.[27]

Summary

Vinyl chloride (VC) is a simple gaseous chemical which can be polymerized to form a wealth of plastic materials. Despite recognition for several decades of a wide range of

chronic toxic effects in animals and exposed workers, it was not until 1970 that the carcinogenicity of VC was first established experimentally. A consortium of European plastics manufacturers then funded further carcinogenicity testing of VC which confirmed and extended the earlier findings. These results, which were shared with the Manufacturing Chemists Association, remained unpublished for over eighteen months until the announcement by B. F. Goodrich in January, 1974, of the occurrence of three fatal cases of an extremely rare cancer, angiosarcoma of the liver, among its VC/PVC workers. On the same day, the Manufacturing Chemists Association revealed the results of the animal tests showing VC to be a potent carcinogen in rodents, inducing angiosarcoma of the liver and a wide range of cancers at other sites at exposures of 50 ppm and below.

In the absence of available information on the carcinogenicity of VC in animals, its effects in exposed workers were only first recognized because of the occurrence of the three rare angiosarcomas of the liver. Had VC only induced lung cancer, its carcinogenicity would in all probability have remained unrecognized or ascribed to smoking.

The present occupational standard of 1 ppm was promulgated by OSHA in spite of estimates by industry of grossly exaggerated costs and unemployment. While the standard affords some degree of protection to workers in VC/PVC plants, it does not protect the greater number of workers in PVC fabricating plants, nor does it prevent exposures to VC of the public-at-large, particularly those living in the vicinity of VC/PVC plants, with attendant risks of cancer and also possibly birth defects.

My own company is very conscientious and careful about the chemicals we use in the manufacturing process.

Ellington M. Beavers, Medical Director and Vice President, Rohm & Haas Company, 1974.