

## EVIDENCE OF AN ILLEGAL CONSPIRACY BY INDUSTRY

In the mid-1960s, as the chemical industry was struggling with how to respond to the general problem of pollution, it discovered a terrifying fact: vinyl chloride monomer (VCM), the basis for polyvinyl chloride (PVC), one of the most widely used plastics, was linked to acroosteolysis, a degenerative bone condition affecting workers in a number of its plants. In the early 1970s the Manufacturing Chemists' Association (MCA), the industry group representing close to 200 companies, received even more troubling news: secret animal studies performed for European chemical manufacturers showed cancers at surprisingly low levels of exposure to VCM as well.

Industry leaders became terrified. The industry was faced by the question of what would it mean if the public knew that vinyl chloride, the basis for Saran Wrap and hundreds of other consumer products such as hair-sprays, car upholstery, shower curtains, liquor bottles, floor coverings, and wiring, was linked to cancer? Would the public begin to view all plastics as threats to their health? To avoid public disclosure of industry-sponsored research indicating cancers caused by vinyl chloride monomer, the chemical industry planned and executed an elaborate scheme to deceive the government and mislead the public.

The MCA closed ranks to protect the image of its product as safe and to hide information about its health costs. As more data emerged from European investigators, confirming and even extending the findings of cancer, the Manufacturing Chemists' Association (now the Chemical Manufacturers Association) privately expressed extreme distress though it continued to show a calm and reassuring face to the government and the general public. The industry considered such deceit necessary in light of

the unlimited liability it could face from lawsuits that might be brought by millions of Americans who used vinyl chloride every day.

Plastics had emerged in the 1950s as a mainstay of the petrochemical industry. In 1953 the industry employed 200,000 people and boasted annual sales of over \$23 billion. It produced 3.5 billion pounds of plastics and resins per year.<sup>1</sup> Polyethylene, polypropylene, polystyrene, and polyvinyl chloride among others were all synthetic materials. Some, particularly polyvinyl chloride, were unusual in that they were created from chemical combinations that did not exist naturally. Chlorine-carbon molecules do not exist in nature, so their effect on the environment and on human health was completely untested. Of all the plastics, PVC is the most persistent in the environment. Because of its stable chemical properties, chlorine chemistry became a major part of the plastics industry, and polyvinyl chloride quickly assumed a major role in the post-World War II world.

Polyvinyl chloride was first manufactured in the United States in 1928 at the Union Carbide plant in Charleston, West Virginia; commercial production began in 1933.<sup>2</sup> Production skyrocketed during World War II, going from 1 million pounds per year to 120 million pounds per year; by 1952, production had grown to 320 million pounds.<sup>3</sup> In 1973 27 billion pounds of plastics were produced. Polyvinyl and vinyl chlorides accounted for 5.4 billion pounds, behind polyethylene with 8.4 billion pounds and more than polystyrene with 5 billion and polypropylene with 2.2 billion pounds.<sup>4</sup> With the addition of plasticizers that increased flexibility and durability, polyvinyl chloride was extremely adaptable to a variety of uses, especially in construction (40 percent of consumption); in wire and cable (10 percent); manufacture of pipe (25 percent); film and sheet for packaging and coated fabrics (15 percent); and flooring (10 percent).<sup>5</sup> Because of its low cost and great durability, it became a widely used substitute for woods, metals, glass, rubber, ceramics, and other plastics.<sup>6</sup> By the 1960s, VCM gas was also used as an aerosol propellant in beauty aids and cosmetics, drugs, pesticides, and a variety of other products.

There are four broad stages in the production of polyvinyl chloride plastics. First, salt (sodium chloride) is broken down through an electrolytic process to release chlorine as a greenish gas. Inherently unstable, chlorine alone does not naturally exist; about three-quarters of all chlorine is presently used in the chemical industry as a feedstock (i.e., component material) in the production of plastics, pesticides, solvents, and other products unknown in the natural world.<sup>7</sup> In the second stage, chlorine is

combined with a variety of hydrocarbons to produce vinyl chloride monomer. (In the late 1940s it was used as an anaesthetic, but it was ultimately discarded because of dangerous side effects).

In the third stage, the monomer is formed into a polyvinyl chloride resin. In the fourth stage, it is fabricated into finished products. Vinyl chloride monomer plants are often huge open-air complexes of metal and steel tubing connecting large and small tanks to one another, much like oil refineries. By and large they are located in southern and western states, especially Louisiana and Texas. PVC plants are somewhat more enclosed and are located in a variety of states, principally New Jersey, Ohio, and Massachusetts in addition to Louisiana and Texas.<sup>8</sup>

While relatively few workers are employed in the production of VCM and PVC, the consequent fabrication processes employ many more. In the mid-1970s only about 1,000 workers were employed by the vinyl chloride monomer industry and another 5,500 workers in the PVC industry. (In total, from 1939 through the mid-1970s, only about 30,000 were involved in VCM and PVC production.) But many more were engaged in the fabrication of finished consumer goods or construction materials. In the mid-1970s there were nearly 350,000 workers using PVC in the fabrication of the wide variety of finished products.<sup>9</sup>

Americans have always been ambivalent about plastics. On the one hand, plastics provided Americans with a wide variety of consumer products previously reserved for the upper middle class and wealthy. On the other hand, many Americans felt that plastics undermined the very quality of American life. Mass produced, affordable consumer goods with faux metal and wood-like finishes were offered to the new middle class at a fraction of the cost of the "real thing," yet they were still recognized as "mere imitations."<sup>10</sup> In the postwar decades, Japan was often identified by Americans as the source of cheap plastic toys "invading" the American consumer market. Yet at the same time the plastics industry was increasingly perceived as critical to America's own economic advancement. So it was that Dustin Hoffman, as a cynical 1960s college graduate in the film *The Graduate*, would sneer when a family friend told him that he had just one word for him: *plastics*.

#### THE HAZARDS OF VINYL CHLORIDE

For much of the twentieth century, Americans took solace in the notion that industry and science used refined methods to ensure that workers in dangerous trades were not exposed to harmful levels of toxins. Because Americans believed in the ability of technicians and scientists to under-

stand what constitutes danger and how to guarantee safety, they did not worry much about the chemical industry. They felt assured that there were levels below which danger from exposure to chemicals and other substances did not exist—and that the industry observed these strictures. This concept of a maximum safe concentration can be traced back to the nineteenth century when K. B. Lehmann, a German researcher, ordered his laboratory servant to spend an hour inhaling a variety of volatile fluids that he released into the atmosphere. Observing the reaction of the servant to this exposure, he determined levels "just tolerable for short-term exposure."<sup>11</sup> During the first three decades of the twentieth century, lists detailed "harmful concentrations of contaminants," and in 1927 the American Chemical Society identified limits for exposure for twenty-five noxious gases. In 1938 the American Conference of Governmental Industrial Hygienists (ACGIH) was founded as a voluntary agency of industrial hygienists who worked for government rather than industry. In 1941 it began to establish exposure limits for a wide variety of industrial toxins and to use the term *threshold limit value* (TLV) for the levels that it recommended. In 1940 Manfred Bowditch published for the Massachusetts Division of Industrial Hygiene a "code for safe concentrations of certain common toxic substances used in industry."<sup>12</sup>

From the 1930s on, the establishment of safety standards was a central concern of an industry worried about liability suits. But the question of standards was misleading. Most of the established standards were only vaguely dependent upon experimentation and epidemiological study. More often they resulted from bargains struck between industry leaders and public health officials.<sup>13</sup> By the 1960s the chemical industry had privately determined that whatever level of safety was represented by the official TLV for vinyl chloride monomer, it was not adequate to protect the workforce. The industry knew that TLVs were a benchmark of what was achievable, although not necessarily what was safe. Still, the industry continued to rely on standards for which there was often inadequate information and that today look arbitrary.

Through the 1950s and 1960s and even into the early 1970s, vinyl chloride was said to present "no very serious problem in general handling aside from the risk of fire and explosion" but vinyl chloride monomer (VCM) was known to pose a potential danger when workers were exposed to extremely high quantities. It caused faintness, disorientation, drowsiness, and other acute, but passing, effects. In 1954 the MCA set an upper limit of safety at 500 ppm (parts per million), a figure that would stand for two decades.<sup>14</sup> Prior to the establishment of OSHA, most standards from

chemical exposure were arrived at in the same loose and often arbitrary manner that vinyl chloride standards were set. As Henry Smyth of Union Carbide stated in an internal memo, the 500 ppm TLV for vinyl chloride was "based largely on single guinea pig inhalation studies by the Bureau of Mines" during the Great Depression.<sup>15</sup>

The producers of vinyl chloride had a sense that vinyl chloride could possibly cause chronic conditions for the workers even before it was linked to any specific disease in the mid-1960s. In May 1959, Dow Chemical's Verald K. Rowe, who would later become that company's director of toxicological affairs in health and environmental research, worried about the fact that there was "no good toxicological data . . . of the chronic toxicity of vinyl chloride."<sup>16</sup> A graduate with a master's degree in biochemistry from the State University of Iowa in 1937, Rowe joined the biochemical research laboratory directly upon leaving the university.<sup>17</sup> In a correspondence with William E. McCormick, manager of the department of industrial hygiene and toxicology at B. F. Goodrich, he admitted privately that the 500 ppm TLV "cannot be relied upon to [sic] strongly when considering chronic exposures." He had "been investigating vinyl chloride a bit and [found] it to be somewhat more toxic when given by repeated daily inhalations." It was "too early yet to tell what vapor concentrations will be without adverse effect." Although he did not inform anyone outside the industry, he expected that the current TLV would produce "appreciable injury" to full-time workers.<sup>18</sup>

This study indicated that "vinyl chloride monomer is more toxic than has been believed"<sup>19</sup> and that repeated exposures at 200 ppm resulted in micropathological changes in the livers of rabbits. As a result of these experiments, in 1961 Dow recommended a 50 ppm TLV, but the American Conference of Governmental Industrial Hygienists failed to change the TLV for more than a decade.<sup>20</sup> The inaction of the ACGIH in revising the TLV and the refusal of the chemical industry to take notice, despite hints of toxicity problems in the plastics industry, provide an insight into the way industry would handle problems in the future. Sometimes the industry would make a crass attempt to control and even suppress information by misleading the government about what it knew about VCM's carcinogenicity. Sometimes the industry would take action within the factory to hide from workers the dangers they were exposed to. Often the industry saw itself at war with regulatory agencies or environmental and labor groups and established a pattern of hiding information about vinyl chloride's dangers.

#### BRACKETING THE TROUBLE AREA

When the industry learned in the mid-1960s about vinyl chloride workers who suffered from acroosteolysis (AOL), a previously undefined condition, it developed a strategy regarding health issues that it would use over the coming decade. While privately seeking to understand the source of the problem and by funding research that would provide the information it needed to devise a response, the industry released only the information that would reassure people as to the essentially benign nature of the finished products. The industry would also work to forestall any regulatory action.

The industry learned that a few workers who entered the polymerizer vats, where polyvinyl chloride was synthesized from vinyl chloride monomer, in the Louisville, Kentucky, plant of B. F. Goodrich, were developing hand and systemic health problems. The problem was discovered in 1964 by Dr. John Creech, a physician who had grown up in the mountains of Harlan County, Kentucky. In addition to his private practice (surgical oncology) in Louisville, Creech conducted physical exams of the Goodrich workforce. One day a worker came to Creech in the dispensary "complaining about his tender fingers and asked me 'what's going on . . . with my fingers?'" Creech noticed that the skin on the man's fingers, as well as elsewhere on his body, was thickened. Creech asked him "if he knew of anyone else over at the plant [who] was having this type of problem." He learned that another worker couldn't even open up his lunchbox because his fingers were so tender. Subsequent x-rays and examinations showed that the two workers had similar conditions.

Over the next six weeks Creech accumulated a few more cases and reported his observations to the plant management. "If four people doing the same type of work in the same room, the same department," Dr. Creech recalled thirty-five years later, "they come down with a bizarre situation like this, it doesn't take a rocket scientist to link it to industry—to their workplace."<sup>21</sup> It may not have taken a rocket scientist, but it may have taken a physician like Creech, who was not dependent on the chemical industry, to discover this syndrome, which was called acroosteolysis. The syndrome involved "skin lesions, absorption of bone of the terminal joints of the hands, and circulatory changes."<sup>22</sup>

Shortly thereafter, Goodrich officials asked Robert Kehoe, now nearing retirement as director of the Kettering Laboratory, to commence an investigation for the company.<sup>23</sup> After studying some cases, Kehoe concluded

that this was an "entirely new" occupational disease.<sup>24</sup> Meanwhile, Rex Wilson, head of Goodrich's medical department, asked the physician of another Goodrich plant "to determine as quietly as possible whether similar disabilities" existed at his plant. It was clear that he did not want the employees to know the reason for any examinations. He told the doctor, "I would appreciate your proceeding with this problem as rapidly as possible, but doing it *incidentally* to other examinations of our personnel. We do not wish to have this discussed *at all* and I request that you maintain this information in confidence."<sup>25</sup>

Monsanto sought to gather information about the extent of the disease in one of its plants without telling the workers the cause of the company's concern. The workers were to be x-rayed, but a Monsanto official wrote, "I am sure Dr. Nessell can prepare these people with an adequate story so that no problem will exist. Depending upon what happens following this x-raying, we will have to see what our next step is."<sup>26</sup> Noting that it was not just polymerization workers who were coming down with the disease, Goodrich and Monsanto worried that this issue could become public, to the detriment of the industry.

In an attempt to forestall any disclosures, a curtain of secrecy was lowered around the diseases appearing in polymerization plants around the country and the world. In January 1966, Harry Warner, corporate vice president of B. F. Goodrich, learned of a physician with the Solvay et Cie Chemical Company in Brussels, Belgium, who had reported seeing at least two workers who exhibited the same bone destruction that was seen in the Goodrich cases and who was planning to publish a report about them.<sup>27</sup> "Goodrich was concerned enough about the response to such a published article that Mr. Warner attempted to have one of [Goodrich's] representatives, who was in Europe, stop by and try to discourage or to influence the wording of such an article to be sure that it didn't condemn PVC in general." The attempt was unsuccessful, but Goodrich made plans to send a team to Brussels in another effort to "discourage or edit the publication." Monsanto, which had its European headquarters in Brussels, offered to "cooperate with Goodrich" in this effort.<sup>28</sup>

At the same time that they sought to hide information from the public and the workforce, Goodrich warned other companies to be on the lookout for workers suffering from similar symptoms. In June Goodrich presented its findings to representatives of six major U.S. and European companies at a private meeting.<sup>29</sup> At the conclusion of this meeting, the MCA was asked to organize a larger meeting of all the plastics companies to decide on a common course of action regarding the medical and public relations dan-

gers that lay ahead. Goodrich revealed to the companies that "1% of all PVC plant personnel were found to be affected" with AOL and that not all of these were in manufacturing jobs. Fully 6 percent of those working in the vats were affected.<sup>30</sup>

The growing plastics industry was terrified about the effect any public disclosure of a problem with an essential ingredient would have on its market. At the meeting a representative from Airco noted what was obvious to all—that "any action at the plant must be properly handled to avoid labor relations and publicity problems."<sup>31</sup> The problem went beyond labor relations and union issues, however, and B. F. Goodrich hoped that other companies would "use discretion in making the problem public," because of the need "to avoid exposes like *Silent Spring* and *Unsafe at Any Speed*," which had publicized the worst kind of nightmare faced by major industrial executives in the mid-1960s.<sup>32</sup> Goodrich noted that the condition "may be a systemic disease" and, if so, Goodrich "worried about possible long term effect on body tissue, especially if it proves to be systemic."<sup>33</sup>

Union Carbide's Robert "Nick" Wheeler emphasized the need for secrecy in light of the "definite health problem related to polyvinyl chloride manufacture."<sup>34</sup> Wheeler, who graduated from Virginia Polytechnic Institute in 1943 with a degree in chemical engineering, had been employed by Union Carbide since then in the development and manufacture of synthetic polymers. In the 1960s, he was the area superintendent at the Union Carbide Company's South Charleston, West Virginia, plant and production manager for vinyl resins.<sup>35</sup>

While the PVC manufacturers were concerned about the potential dangers from VCM exposure to the workforce, they were more concerned about the negative publicity. In the words of Wheeler's follow-up memo relating to a meeting of the MCA's Occupational Health Committee, "the need for bracketing the trouble area was believed essential. Unfavorable publicity with regard to exposure of finished products to the human anatomy could be very damaging to the industry."<sup>36</sup> If plastic products, particularly those that wrapped or came in contact with food, were implicated, the industry would find itself besieged not just by workers and their unions, but also by the general public and federal authorities.

Even though there had been no study on the danger of this consumer product, the technical director of the MCA, Dr. Frank H. Carman, had already prepared a short press release, agreed to by all at the meeting, to be disseminated in the event that word leaked out about any problem. The statement "stressed that [the] condition probably is an occupational disease and there is no indication of any hazard whatever to [the] general

public."<sup>37</sup> The participants at the meeting also agreed to fund an epidemiological study of PVC workers to be conducted by epidemiologists at the University of Michigan's Institute for Industrial Health. This study would "hopefully be expected to . . . confirm that the condition is purely an occupational disease and in no way affects the general public using PVC products."<sup>38</sup> Underlying the study was the assumption that in eight months' time, the investigators would "have identified the offending agent or agents" that was poisoning workers in PVC manufacturing plants.<sup>39</sup>

Meanwhile, at the end of the summer of 1967, almost three years after vinyl chloride-related disease had been noticed in the Goodrich plant, researchers from B. F. Goodrich published in the *Journal of the American Medical Association* a report of thirty-one cases of acroosteolysis among vinyl chloride workers.<sup>40</sup> According to John Creech, the draft of the article that he first saw specifically identified the monomer as the cause, a piece of information that vanished by the final version.<sup>41</sup> The study, the first public acknowledgment of a hazard from working with vinyl chloride, reported that less than 3 percent of these workers presented symptoms of AOL.<sup>42</sup> Even so, Goodrich Chemical's president, Anton Vittone, instructed his managers that the article "was and is intended for medical people" and should "only be circulated to your key people." Vittone saw the article as a fail-safe, in the event "the general press becomes aware of this problem."<sup>43</sup>

In the late 1960s, however, the media were not in the habit of following up on revelations made in medical journals, as they are today. A year and a half later, in February 1969, the results of the University of Michigan study were presented confidentially to the MCA's Medical Advisory Committee. The report acknowledged that AOL involved connective tissue as well as bony structures and that an assumption that AOL was a localized problem involving just fingers was incorrect. It had been assumed that only when workers could smell vinyl chloride was there a possibility of overexposure. But the report indicated that the "odor threshold" of vinyl chloride was about 4,000 ppm, not 400 ppm as previously believed, and well above the threshold limit value of 500 ppm. More importantly, the document noted that it should not be assumed that vinyl chloride workers were safe from disease even at the 500 ppm TLV. The study suggested that "sufficient ventilation should be provided to reduce the vinyl chloride concentration [to] below 50 ppm."<sup>44</sup>

The members of the MCA's Occupational Health Committee were particularly troubled by this recommendation. To propose reducing exposure to 50 ppm implied that vinyl chloride was the direct cause of disease. The members, by a vote of seven to three, refused to accept the report as writ-

ten and unanimously voted to accept the report only if it were changed to avoid any implication that the 50 ppm was "a threshold level for general safety when exposed to VCM."<sup>45</sup> The MCA's PVC resin producers agreed that the wording must be changed to read thus: "Inasmuch as the etiologic agent of the disease is unknown, a level of vinyl chloride below 50 ppm should be used as an index of adequate ventilation."<sup>46</sup> Their object was that there should be no implication that exposure to vinyl chloride monomer at such low levels could cause disease.

The industry's viewpoint was reflected in the final version of the report when, in 1971, the University of Michigan researchers published their findings in the *Archives of Environmental Health*. Even the whiff of a suggestion that the 500 ppm standard was inadequate had disappeared; nor did the published report recommend that the 500 ppm TLV for vinyl chloride exposure be reduced. In fact, it paraphrased the MCA's assertion that the etiologic agent responsible for the workers' symptoms was unknown: "Although this study provided no evidence to suggest that vinyl chloride per se is the etiological agent, the measurement of vinyl chloride concentrations may serve as a useful index to the adequacy of reactor ventilation."<sup>47</sup> The University of Michigan researchers made no reference to the information provided to industry representatives two years earlier about the odor threshold. This meant that workers who smelled vinyl in the air were exposed to levels far above, not slightly below, the TLV. The report, masquerading as objective science, was in fact nothing more than an obfuscation of the real truth that served industry's purposes.

As late as 1969, fully five years after the first cases of AOL were identified in Goodrich's Louisville PVC plant, the industry still sought to promote the view that there was no causative relationship between vinyl chloride and systemic disease. Goodrich executives also decided "not to accept any proposals for additional research into the causes of acroosteolysis at this time."<sup>48</sup> In effect, they were saying that they did not want to know more than what they already knew. Instead, the MCA agreed to establish a case registry to be run by researchers at the University of Michigan, who by now had well proven their willingness to play ball with the industry.

Although the MCA had agreed to establish the registry, the industry soon lost interest. Bertram Dinman, the University of Michigan researcher who had collected the data, believed that the maintenance of the registry was essential for future researchers and the industry to understand the extent of the problem. In May 1971, Dinman advised the MCA's Occupational Health Committee that the "submission of case registry data has

been slow."<sup>49</sup> Two months later, Dinman wrote to one of the member company physicians that the AOL registry was in serious trouble. Unless it continued, he warned, "we will never be able to determine the extent of the problem and reply to contentions that the problem is under control."<sup>50</sup> The MCA confirmed that the registry was "perilously close to collapse in consequence of the failure of most of the PVC producers to submit requested case data."<sup>51</sup> The registry limped along for the next two years and then was abandoned.<sup>52</sup>

#### SECRET AGREEMENTS: THE EVOLUTION OF THE CANCER DEBATE

The reactions of the industry to the link between vinyl chloride and acroosteolysis were a mere preview to how the industry would react when faced with a much larger and uncontainable problem—the link between vinyl chloride and cancer. When cancer became an issue, the industry took more extreme and potentially explosive actions to cover up the danger. The industry moved from denial and obfuscation to outright deception. Motivated by money and power rather than health, the industry was largely successful in hiding its information about cancer from the government and in deflecting national attention away from the potential hazards of thousands of mostly untested new chemicals and of vinyl chloride in particular. In the years to come the nation would learn the serious pitfalls that result when regulation of an industry is left in the hands of that industry.

The fear that vinyl chloride or other chemicals would cause cancer among consumers had haunted the chemical industry. In November 1967 the MCA's Food, Drug, and Cosmetic Chemicals Committee suggested spending \$20,000 to develop "a position paper on carcinogenesis in an attempt to refute the Delaney Clause philosophy," which prohibited the use of a suspected carcinogen in any food product. They acknowledged that such an effort "will be difficult, maybe impossible," but the possibility that the principle of no acceptable risk would extend "into other legislative areas, such as atmospheric pollution" made such an effort important. Specifically, the MCA sought to "retain the services of a group of experts on carcinogenesis" who would support their position that there were safe levels of carcinogenic chemicals to which the public could be exposed.<sup>53</sup>

The so-called Delaney clause was a piece of federal legislation that had been passed less than a decade earlier, in 1958, as part of the Food Additives Amendment to the Food, Drug, and Cosmetic Act of 1938 (itself a revision of the Pure Food and Drug Act of 1906). For virtually half a century the

federal government had been grappling with the problem of how to protect the public from potential harm caused by adulterations to foods and cosmetics. Beginning in 1906 "poisonous or deleterious substances" were banned as ingredients in foods if government could show affirmatively that such substances were harmful under conditions of normal use. The burden of proof for proving danger rested with the government and its relatively limited laboratories and scientific establishments. In 1938 the Food, Drug, and Cosmetic Act modified the act modestly, essentially allowing poisonous substances into products if they were deemed essential to their production and within the "tolerance promulgated as safe by the Secretary [of Agriculture]."<sup>54</sup> This language made the process of proving additives dangerous much more difficult. Legislative attempts were made to revise the act to develop more absolute criteria for determining whether additives could be banned.

Between 1950 and 1953 Representative James Delaney, a New York Democrat, held hearings about the adulteration of the food supply, which led to three significant pieces of legislation: the Pesticides Amendment of 1954, the Color Additive Amendment of 1960, and the Food Additives Amendment of 1958, which included the Delaney clause. The clause was of special concern to the chemical industry during the 1960s and early 1970s because it banned from foods any additive that caused cancer in animals.<sup>55</sup> While the structure for evaluating all chemicals proved to be difficult to administer, the Delaney clause proved to be the most enduring and effective legacy of this midcentury attempt to implement a federal policy for food safety. It lasted virtually untouched until 1996, when Congress passed the Food Quality Protection Act, which eliminated it.<sup>56</sup>

Businesses involved with pesticides, preservatives, food colorings, and the like were most concerned by the Delaney clause. Throughout the 1960s, the trade literature was filled with attacks on the clause by chemical manufacturers who objected to the "no tolerance" principle upon which it was based. While other potentially toxic substances were deemed "safe" when present in small quantities below an established threshold, the Delaney clause banned *all* cancer-inducing chemicals, no matter how small, as food additives.<sup>57</sup>

In the late 1960s a growing number of environmentalists and public health advocates used the law to ban even small quantities of substances once thought harmless, like the artificial sweetener cyclamate. Cyclamates were discovered to induce cancer in rodents when given in massive amounts; because cyclamates were widely used as a sugar supplement in soft drinks and diet foods, the industry responded quickly. In light of a

rapidly changing technology that was capable of detecting substances in extremely miniscule amounts, the industry felt called upon to argue that even though miniscule amounts could be detected it did not mean that these amounts would harm people. According to industry members, the Delaney clause was fundamentally misguided: carcinogens, they argued, were no different from other toxic materials, which had threshold levels below which no danger to humans existed. Following the logic of the Delaney clause, the industry argued, many obviously benign substances, such as common table salt, could be considered carcinogens if administered in massive amounts or under special circumstances.<sup>58</sup> One well-worn argument in the early 1970s was that even hard-boiled eggs, when fed to mice in sufficient quantities, produced cancers and would therefore have to be banned for human consumption. This argument finally lost steam when it was pointed out that those eggs might very well have been tainted with cancer-causing agents such as DES or DDT.<sup>59</sup>

This debate evolved within the context of the popular recognition that chronic illness, and especially cancer, was replacing infectious and acute diseases as the major killers of Americans. In 1971 President Nixon began a War on Cancer that, he promised, would find a cure for the disease in less than a decade. Americans were told that the infusion of money into research would enable the country to win the war on cancer just as money would win the War on Poverty, the war in Vietnam, and the space race against the Soviet Union. It was assumed that the model used to conquer polio, smallpox, and even measles and other infectious diseases would work again. Medical researchers in universities, government, and industry were to be given the money and time to find a virus, a germ, or another agent that "caused" cancer; it was expected that a means to a cure would emerge from the nation's laboratories.

Many environmentalists and public health activists were not convinced. They proposed a fundamentally different approach, focused not on the search for a cure but on prevention as the first line of defense. Since evidence was accumulating that foreign substances such as nicotine, food additives, pesticides, or pollution caused cancer, environmentalists surmised that the culprit was the chemicals produced by industrial and human institutions. While it was a precept of industrial hygiene that safe levels of toxins like lead or arsenic could be established, it was becoming clear to many industrial hygienists that it was impossible to establish threshold levels for carcinogens. Unlike traditional industrial toxins, which caused a variety of conditions, carcinogens "triggered" a biological process that was virtually impossible to stop. It was theoretically possible for a

single exposure to a carcinogen to begin the process. Given this, no exposure could be deemed safe. Nor did removing the person from exposure to the carcinogen do anything to stop the growth of tumors. Thus, reducing exposure to "no detectable limit" became the goal of environmentalists, many occupational health advocates, and many industrial hygienists.

The industry had recently learned that an Italian researcher, Dr. Pierluigi Viola from the Regina Elena Institute for Cancer Research in Rome, had presented a paper on the carcinogenic effects of vinyl chloride exposure in animals at the 1970 International Cancer Congress in Houston. Viola reported that rats exposed to 30,000 ppm of vinyl chloride monomer gas developed tumors of the skin, lungs, and bones.<sup>60</sup> In May 1971, the same month that Viola published his findings in the journal *Cancer Research*,<sup>61</sup> he was invited to Washington by the MCA's Occupational Health Committee to present a summary of his work. While executives were upset by his findings, they hoped that his results would be deemed not applicable to other animals or to humans who were exposed to far lower levels of vinyl chloride. As a result of the meeting, the MCA began to develop a research protocol aimed at evaluating the carcinogenicity of vinyl chloride and to consider conducting an epidemiological study.<sup>62</sup> They hoped that because the cancers showed up in the rat's zymbal gland, an ear gland that does not exist in humans,<sup>63</sup> the cancer might not show up in humans. The industry decided not to revise the Material Chemical Safety Data Sheet, the document used by producers to establish safe practices in their plants.<sup>64</sup>

A few months later the MCA learned that "further studies [by Viola] on the toxicity of vinyl chloride have confirmed the carcinogenicity of this monomer" even though it "has not been confirmed in the human body." Viola suggested, on the basis of his research, that a safer TLV would be 100 ppm, for he found that the "danger of a toxic action of the monomer on nervous apparatus, bones and liver is negligible if vinyl chloride concentrations are no more than 100 ppm."<sup>65</sup> Viola also reported to the MCA that he had found tumors in 10 to 15 percent of rats at 5,000 ppm.<sup>66</sup> He suggested that animal studies of vinyl chloride's carcinogenic properties be conducted at low concentrations, down to 50 ppm.<sup>67</sup> Union Carbide's Robert Wheeler understood that "publishing of Doctor Viola's work in the U.S. could lead to serious problems with regard to the vinyl chloride monomer and resin industry." Wheeler was concerned about this link to cancer because "the Delaney amendment bans the use of any material in food that can cause cancer" and, more broadly, that "the present political climate in the U.S. is such that a campaign by Mr. R[alph] Nader and

others could force an industrial upheaval via new laws or strict interpretation of pollution and occupational health laws."<sup>68</sup>

Viola's finding of tumors at 5,000 ppm and his recommendation that a 100 ppm threshold would probably avoid future problems were tough enough for the industry to swallow. But the reports of research done in 1972 by another Italian researcher represented a potential catastrophe. PVC was now central to the economic viability of a number of critical American chemical companies. Between 1966 and 1971, PVC production in the United States doubled, from 1.2 billion to 2.4 billion pounds; in the case of B. F. Goodrich, for example, the chemical division was replacing rubber as the most profitable sector, and PVC accounted for half of the chemical division's sales.<sup>69</sup>

Late in 1972 the American chemical industry received a series of reports from European vinyl manufacturers who had, in the wake of Viola's reports, hired Cesare Maltoni, director of the Bologna Centre for the Prevention and Detection of Tumors and Oncological Research, to investigate whether Viola's findings had any merit. During the summer of 1972, the Europeans began receiving preliminary results of Maltoni's confidential work, which indicated that cancers were appearing in rats exposed to lower levels of vinyl chloride than in Viola's studies and in sites other than their zymbal gland. Almost immediately, the European producers began to enlist their American counterparts in secrecy agreements aimed at preventing any public discussion of this work.<sup>70</sup>

According to the Americans, the European chemical companies were especially insistent on the need for a secrecy agreement. "Apparently, Dr. Viola's presentation at Houston about 2 years ago was made without Solvay's permission," reported Allied Chemical's William A. Knapp to his superiors.<sup>71</sup> The secrecy agreement demanded that "the members of our task group as listed on the attached sheet, are the *only* ones entitled to receive information about the European project. In turn, they should feel honor bound to make sure such information remains within their own companies unless and until formal permission has been granted for its release."<sup>72</sup> Dow felt "honor-bound to make sure that information received from the European producers remains within our own company until formal permission has been granted for its release." To accomplish this, Dow instructed that no one "discuss the European work" even within the company unless such persons "have a need to know." Even then, such discussion should be cleared in advance.<sup>73</sup>

While it is common practice for researchers to jealously guard their findings until they are published, in cases where human lives are at stake,

most researchers accept that they have an obligation to share knowledge about potential harm. Further, the insistence on confidentiality was not coming from the scientific researcher, but from the vinyl manufacturers. The secrecy was not entered into at the beginning of the experiments, but only when it became apparent that vinyl chloride monomer was carcinogenic at half the accepted TLV. Secrecy, in this case, was not to protect product information, patent secrets, or even innovative experimental procedures. Rather, its sole aim was to avoid a public relations and legal nightmare.

In October 1972 Dr. Walter Harris, representing the MCA, visited Maltoni in Bologna and concluded that the MCA's plans to study high dosage exposure were irrelevant since Maltoni was already finding carcinogenicity at lower levels of exposure.<sup>74</sup> Maltoni's results were revealed to American producers of PVC and VCM at a confidential meeting at MCA headquarters in Washington on November 14, 1972. Members were requested not to take notes; in fact, a European representative, D. M. Elliott of the British vinyl manufacturer Imperial Chemical Industries (ICI), "insisted that the work tables be swept clear of paper for note taking before he would discuss anything regarding the European group's efforts. Such was done."<sup>75</sup> The most disturbing fact that Elliott presented was that Maltoni had discovered "the occurrence of primary cancers in both liver and kidneys with one positive at 250 parts per million," half the long-held 500 ppm threshold value that ostensibly protected workers from AOL and other toxic effects of vinyl chloride.<sup>76</sup> In January 1973, company representatives were given a chart that showed that angiosarcomas of the liver were reported at exposures as low as 250 ppm. Maltoni was finding cancers in a variety of sites and at very low dosages. The MCA did not doubt the accuracy of this data.<sup>77</sup>

By the early 1970s it was becoming more difficult for the industry to keep information about carcinogens secret within the industry. Previously, what happened in the workplace remained largely a private matter concerning the employer, the employee, and, perhaps, a union. Only when a problem escaped the private sphere of the factory and ended up as an issue in a liability lawsuit or on the front page of a newspaper did an occupational health issue become a source of potential harm to a company's well-being.

Growing environmental awareness among consumers in the late 1960s and early 1970s resulted in new liability issues. Because of workers' compensation, it was extremely difficult for workers to sue employers who had exposed them to dangerous chemicals. Workers' compensation had been enacted in the early twentieth century as a means of compensating workers

for injuries incurred on the job—and, later, for work-related health effects. But it also was a means of protecting industries from lawsuits brought by injured or diseased workers. Workers were assured a small sum of money, but in return they gave up the right to sue their employer. Industry was not protected, however, from *consumers*, who could, under product liability laws, sue manufacturers for defective products. The need to protect industry from suits by *users* of vinyl chloride products was foremost in the minds of executives as they considered the implications of Maltoni's, Viola's, and even their own research. What was the potential exposure for their industry from possible suits by consumers? Which products were worth continuing to produce and which were too risky? Which products could be abandoned without financial loss to the growing plastics industry?

The minutes of a December 1971 MCA "planning group" reveal that this ad hoc body developed a set of "principles" for its research in which the search for truth was secondary to protecting the industry: First, there was "the need to be able to reassure the public that polyvinyl chloride entails no risk to the user." Second, workers needed to be reassured "that management was concerned for, and diligent in seeking, the information necessary to protect their health." Third, research had to serve the purpose of developing "data useful in defense of the industry against invalid claims for injury for alleged occupational or community exposure."<sup>78</sup>

In the aftermath of Maltoni's research discoveries, the industry had to do something about its potential liability if its products were proven dangerous. The industry's actions with regard to aerosol propellants are an interesting case in point. Vinyl chloride monomer was used not only to create polyvinyl chloride plastics but also as an aerosol propellant in a variety of consumer products. Vinyl chloride was first used as an aerosol propellant in Japan in 1958.<sup>79</sup> By 1959, the Dow Chemical Company was considering using VCM as a propellant in hairsprays, insecticides, room deodorants, and spray paints. Dow expected that its market for vinyl chloride monomer in aerosols to be about 10 million pounds annually and did not believe that the current TLV of 500 ppm would be problematic for them.<sup>80</sup>

Ten years later, however, it was becoming clear that 500 ppm could pose a danger. B. F. Goodrich, after the experience with acroosteolysis, acknowledged privately that "the people in the cosmetics trade have been concerned about the possible toxicity" of vinyl chloride propellants. Measures of vinyl chloride in the air of hair salons had indicated that the "average concentration of VCl monomer is 250 ppm by volume." While this was bad enough in light of earlier recommendations by Dow that the TLV be

lowered to 50 ppm, Goodrich worried that "in some cases where the duration of spraying is long (3 minutes) the concentration may be as high as 1400 ppm." The implication was frightening. Both beauticians and their customers may be "exposed to concentration of VCl monomer equal to or greater than the level in our [polyvinyl chloride plants]."<sup>81</sup>

Nonetheless, vinyl chloride was used as an aerosol propellant until sometime in 1974. Only after learning of Maltoni's findings did the MCA's research coordinators argue that "serious consideration should be given to withdrawal from this [aerosol] market since value of the product was limited and potential for liability great."<sup>82</sup> One participant at the meeting stated the issue succinctly: "If vinyl chloride proves to be hazardous to health, a producing company's liability to its employees is limited by various workmen's compensation laws. A company selling vinyl chloride as an aerosol propellant, however, has essentially unlimited liability to the entire U.S. population."<sup>83</sup>

Awareness of evidence of the dangers of chemicals to the broader public was becoming more widespread, as reflected by actions on the part of the government. In May 1973, the Food and Drug Administration suspended approval of the use of PVC bottles for packaging whiskey and wine. Because of the Delaney clause, the FDA, which had previously not regulated the use of vinyl chloride in food packaging, was forced to address the issue posed by the Viola studies and their indication of carcinogenic and other health effects.<sup>84</sup>

In January 1973 the FDA learned that the Treasury Department's Bureau of Alcohol, Tobacco and Firearms, which had been testing liquor bottles since November 1968, had found that plastic bottles were leaching vinyl chloride monomer, creating an unpleasant taste in alcohol products. The FDA's more sophisticated tests confirmed that "vinyl chloride monomer migrates to alcohol in PVC bottles used to package distilled spirits and wine."<sup>85</sup> In the end, the FDA established a much more stringent safety standard for consumer food products than existed for the safety of workers in the factory or among community residents subjected to environmental pollution. The FDA's regulation placed the burden of proof on the industry to show that food additives were noncarcinogenic. In the case of the workplace and in the case of toxins released into the ground, air, and water, the industry was held to no such standard. Workers and neighborhood residents still had to prove a substance dangerous. The FDA ultimately banned the use of vinyl chloride for liquor bottles because it knew "of no studies which establish a safe level of consumption when this monomer is leached from containers into alcoholic foods."<sup>86</sup>

The chemical industry's commitment to objective science and public access to information was tested in January 1973 when NIOSH published in the *Federal Register* a "Request for Information" on the potential hazards of vinyl chloride. NIOSH was preparing a document on the appropriate and safe exposure levels to vinyl chloride and sought information about potential health hazards from all quarters, including scientists, corporations, and public health officials.<sup>87</sup> This request for information put tremendous pressure on the MCA members as they sought to develop a common position concerning the health risks of vinyl chloride. NIOSH was a relatively new government agency. Its mandate to establish "criteria documents" that would guarantee a safe work environment meant that safety and health standards, previously a private matter for individual companies and their trade association, were now in the public sphere.

The industry faced a serious dilemma over NIOSH's request for information. In order to maintain its influence with the agencies that regulated it, the industry would need to comply with the request but would be providing information that would lead NIOSH to recommend standards that were anathema to industry. In this context, Dow's vice president, George J. Williams, believed that the information should be revealed to the government because "it would be extremely damaging to the chemical industry reputation if someone should discover that we have this information and have not disclosed it to the Government."<sup>88</sup> The MCA, as an organization, even acknowledged in a detailed letter to all its management contacts that it had a "moral obligation not to withhold from the Government significant information having occupational and environmental relevance," specifically Maltoni's new findings. It also recognized that by taking the initiative in sharing information the MCA could forestall the scandal that would result if the information eventually became public.<sup>89</sup>

But the MCA also recognized that the confidentiality agreement it had recently made with the Europeans inhibited any free interchange of scientific findings with government. This posed a moral and political dilemma. Would the American industry be willing to fulfill what it considered to be its moral obligation by revealing Maltoni's findings to the United States government even if it meant violating the trust between the American chemical companies and their European brethren?<sup>90</sup> Or would it keep vital information secret and thus prevent public health authorities from having the information they needed to pursue a rational public policy?<sup>91</sup>

In the spring of 1973 the MCA's members agreed on a plan that would both maintain their secrecy agreement with the Europeans and give the

appearance of responding to NIOSH's request for information. Rather than waiting for NIOSH to contact the organization, the MCA set up a meeting with Dr. Marcus M. Key, NIOSH's administrator, whose role was to provide OSHA with state-of-the-art scientific information that could be used to establish regulations to ensure safe and healthy working conditions.<sup>92</sup>

In May 1973 the MCA began to plan for its meeting with Key and the NIOSH staff, scheduled for July. The pressure on the MCA was enormous because at that moment OSHA was announcing emergency standards for fourteen other potential carcinogens, and the industry had sued to forestall its implementation.<sup>93</sup> From the first, its Task Group on Vinyl Chloride Research and the Vinyl Chloride Research Coordinators were aware that "a significant element for consideration . . . was the development of an alternate presentation in the event that the release of European data cannot be negotiated with reasonable dispatch."<sup>94</sup>

The MCA's lawyers briefed the members "on their responsibilities and obligations under the confidentiality agreements." The lawyers' "admonishments" were that the American companies "should not volunteer reference to the European project or substantive data derived therefrom," but if asked a direct question, they should answer it.<sup>95</sup> Given that the European experiments were not known to NIOSH, there was little danger that a question could be formed that required such an answer. The MCA Research Group also decided that the companies would not volunteer information regarding "potential hazards" that involved consumer safety since NIOSH was "concerned with employee health matters" alone.<sup>96</sup> It appears that all references to consumer safety issues, particularly aerosol propellants, were removed "at the insistence of UCC [Union Carbide] and Allied [Chemical]" because it was not "a worker-exposure problem except for beauticians and can-fillers."<sup>97</sup> As Robert Wheeler of Union Carbide explained: "Hazard to UCC's interests exists if vinyl chloride is declared to be a carcinogen or if vinyl chloride monomer is detected by FDA in foods exposed to vinyl chloride polymers as film, coatings, or gasketing."<sup>98</sup>

Perhaps most troubling to the MCA representatives was the realization that their letter "to Company Contacts," which acknowledged "a moral obligation" to inform NIOSH about Maltoni's studies, was a legal minefield. They feared the letter could be interpreted to indicate that the industry was planning to mislead the government. According to Wheeler, the memo "could be construed as evidence of an illegal conspiracy by industry if the information were not made public or at least made available to the government."<sup>99</sup>

The industry also planned not to tell NIOSH about its own information indicating that the threshold limit should be reduced well below the 500 ppm recommended in the Chemical Safety Data Sheet and even below the 200 ppm level recommended by the American Conference of Governmental Industrial Hygienists. The MCA decided to remove references to Dow's recommendation that the TLV be reduced to 50 ppm for fear that the government would reduce the TLV even further.<sup>100</sup>

The policy to keep quiet about Maltoni's studies influenced the plastics companies' public statements as well as their private preparations for the NIOSH meeting. As these preparations were in progress, *Modern Plastics*, the industry magazine, published an article about the potential problems that industry could face from NIOSH's program to develop new criteria for testing the dangers posed to workers by various chemicals. In a long review of potential problems for the chemical industry, the article noted that vinyl chloride monomer had come under new scrutiny as a result of "recent animal studies conducted in Italy (at an elevated exposure level of 30,000 ppm)" that had led the MCA to study VCM's "potential hazards." Nowhere in the article is there a reference to Maltoni's discoveries of angiosarcomas in animals at 250 ppm.<sup>101</sup>

Throughout the early summer of 1973, the Americans continued to meet among themselves and with the Europeans to plan the presentation to NIOSH, scheduled for July 17. On June 15, 1973, the Europeans met and "agreed that the MCA would be given permission to reveal to NIOSH data arising from the Bologna study." Three weeks later, however, Montedison, the Italian producer of vinyl chloride, let its European counterparts know that this was unacceptable. Dr. David P. Duffield of Imperial Chemical Industries came to the United States to inform the American producers that the Europeans had decided to keep the information secret.<sup>102</sup> The moral qualms afflicting some of the American vinyl producers evaporated.

The Europeans and Americans decided on a much more pragmatic plan for protecting the industry. They would "comply" with NIOSH's request for information but do so in a way that was less than thorough and diverted attention from the seriousness of what the industry knew. If pressed by the NIOSH people, they should "acknowledge Maltoni's data" but point out that "Maltoni had done his work only with rats, whereas [future research by] the MCA . . . calls for mice and hamsters as well." The American chemical industry planned to provide NIOSH only with information about what they were finding in their own animal and epidemiological studies "in very general terms without leaving any written information."<sup>103</sup> The goal of the meeting was to make sure that the agency would

"take no precipitous action now." Furthermore, "We should recommend no shift in priority" and at the meeting "our people [should] get off the topic of animal work as quickly as possible."<sup>104</sup>

The July 17 meeting took place at 1 p.m. at the NIOSH offices in Rockville, Maryland. Five industry representatives met across the table from five government scientists. Dr. Verald K. Rowe of Dow, Dr. William E. Rinehart of Ethyl, Robert N. Wheeler of Union Carbide, and George E. Best of the MCA represented the U.S. industry. Dr. David P. Duffield of ICI represented the Europeans (Dr. Tiziano Garlanda of Montedison was unable to attend). Dr. Marcus M. Key, the director of NIOSH, and members of his staff—Dr. Keith Jacobson, Richard B. James, Dr. Donald Lassiter, and Dr. Frank Mitchell—represented the U.S. government. The meeting was polite, collegial, and seemingly open. The American and European vinyl producers presented an apparently complete and forthright description of the industry and any potential problems. In fact, only the industry knew how skewed, deceptive, and distorted the presentation was.

Rowe made the formal presentation, speaking from pencilled notes. He began by emphasizing the size and scope of the vinyl chloride industry and described the industry's efforts to address the health concerns about acroosteolysis and cancer. Duffield described the "exhaustive" studies of vinyl chloride and polyvinyl chloride workers at ICI's European plants that revealed no "indication of hazard." He also described Viola's published research that had identified cancers in the rat's zymbal gland—a gland that does not exist in humans—and in the lung; he reassured NIOSH that "none of the observed lung tumors were primary tumors." He also referred to other ongoing research that confirmed Viola's studies while pointing out that "the program is still in progress and no firm conclusions [were] yet drawn."

No mention was specifically made of Maltoni, and no mention was made of kidney or liver cancers. According to the MCA, when NIOSH's Lassiter asked about the lowest concentration at which tumors had been observed, Duffield answered that nothing had been found below 250 ppm.<sup>105</sup> According to the notes taken by NIOSH's Richard James, however, although the industry told of Viola finding cancers at 30,000 ppm, there was no mention of tumors at 250 ppm.<sup>106</sup>

Of special note was a question raised by Jacobson of NIOSH. Jacobson had received a phone call asking him why it seemed so hard "to purchase vinyl chloride for use as an aerosol propellant." Avoiding any indication that concerns about liability from its use in consumer products like hair sprays had led to its removal, Rowe of Dow and Rinehart of the Ethyl

Corporation simply stated they were "no longer selling it for this purpose." They implied that the use of VCM in aerosol cans was not very important because it had "been used in this way only in relatively small quantities in paint and lacquer spray cans" and that it was likely to be "discontinued altogether by the end of the year."<sup>107</sup>

In truth, vinyl chloride was used much more widely. At least 3.5 million cans of aerosol products, including drugs, pesticides, and cosmetics "containing VC [were] in the possession of manufacturers, distributors, and consumers" in January 1974.<sup>108</sup> Although the manufacturers did not admit it to NIOSH, they understood that the potential liability problem was truly immense. True to their earlier plan, the companies left little other than previously published or reported materials: a single sheet summary of the vinyl industry, the single-sheet American Conference of Governmental Industrial Hygienists TLV report, the MCA's Chemical Safety Data Sheet for vinyl chloride (an eighteen-page booklet), the condensed protocols for the MCA's animal and epidemiological studies, and the MCA's news releases on these studies.<sup>109</sup>

At the close of the meeting, Rowe went to a separate office and spoke with NIOSH's Key. According to Wheeler, "this private discussion of the carcinogen problem was worth the whole effort."<sup>110</sup> NIOSH asked "to be kept fully apprised of the on-going work both the U.S. and the European industries have in progress," believing that they had been brought up to date on the status of knowledge up to that point.<sup>111</sup>

At the end of the day, the MCA and its various companies were ecstatic about the meeting and reported that "the chances of precipitous action by NIOSH on vinyl chloride were materially lessened."<sup>112</sup> The word that spread to member companies whose representatives had not attended the meeting was that "no problems were encountered" and that the "presentation was well received and appreciated."<sup>113</sup> Leaving the government with the impression that the companies were on top of the issue and that research up to that point had not indicated any serious problem with cancers among workers, the industry had accomplished its most difficult objective. It had appeared forthcoming and responsible to NIOSH officials without violating the agreement of secrecy with its European counterparts regarding the Maltoni studies.

The industry had avoided the issue of environmental danger in consumer products, remained silent on the primary liver and kidney cancers observed in the European experiments, and not mentioned the industry's own concern that the 200 ppm threshold value for vinyl chloride exposure was not adequate, while raising questions about the significance and even

the integrity of Viola's work and reassuring NIOSH that there was no indication of danger to workers. In short, the industry's trade association had succeeded in preventing NIOSH from learning about the dangers to workers and consumers from vinyl chloride.

Almost immediately after the meeting, however, the industry's position that vinyl chloride was safe began to erode. Newspapers in Europe, and later in the United States, spoke of a very different reality. An article published in an Italian newspaper quoted Dr. A. Caputo, one of Viola's collaborators in the original cancer studies, as saying that vinyl chloride was responsible for the recent concerns among 40,000 workers in European vinyl chloride plants. Caputo said that dozens of workers had already died as a result of exposure and that it was potentially a huge environmental as well as occupational hazard. Responding to the view that "only" 40,000 workers were at a small risk of developing disease, Caputo had replied that "the menace applies to everybody... and [is] particularly hazardous in containers for foodstuffs... in filters for artificial kidneys, in cardiac valves."<sup>114</sup>

The MCA translated the article and circulated it to its Task Force on Vinyl Chloride as a way to alert the industry to the fact that information about the dangers of vinyl was leaking out. In late November, *Chemical Week*, the trade journal, reported on meat wrappers who had developed respiratory problems as a result of breathing fumes created by the heating of PVC film. Recalling the earlier ban on PVC bottles, the weekly told its readers that the Environmental Protection Agency had also been concerned that "a substantial increase in the use of PVC in packaging would be harmful to the environment."<sup>115</sup>

Around this time the MCA, recognizing that the issues of occupational and environmental cancers were not going away and that it was only a matter of time before events might occur which could threaten the industry's careful management of the problem, wrote to its member companies that a greater level of coordination of the entire industry, both American and European, was necessary.<sup>116</sup>

#### PLASTIC COFFIN

In January 1974 the nation learned that vinyl chloride monomer had been implicated in the deaths of four workers. A rare cancer, angiosarcoma of the liver, had struck down the workers at the B. F. Goodrich plant in Louisville, Kentucky. Throughout the nation newspapers reported that polyvinyl chloride, a seemingly benign and inexpensive replacement for wood, metal, and even wax paper in the homes and workplaces of millions

of Americans, was now a possible deadly threat. Joe Klein, writing on the discovery of angiosarcoma in *Rolling Stone*, called the PVC plant a "Plastic Coffin."<sup>117</sup>

Dr. John Creech, who was still doing exams at the plant where he first identified acroosteolysis, had reported his concern over employee liver problems to Dr. Maurice Johnson, Goodrich's director of environmental health.<sup>118</sup> (Johnson, a graduate of the University of Minnesota medical school, had been involved in occupational medicine since 1954 and had only recently joined B. F. Goodrich, in 1972.)<sup>119</sup> After reviewing plant records, Creech discovered that four workers had died from angiosarcoma of the liver, among the rarest of cancers, a disease previously associated with heavy metal poisoning and arsenic. Usually accounting for fewer than two dozen deaths in the United States in any given year, the occurrence of four deaths from angiosarcoma of the liver in a population of a few hundred workers at one plastics plant was truly alarming.

These deaths were especially worrisome because this rare cancer was "identical to that seen in the European rat feeding studies" conducted by Maltoni, something that the industry had failed to let NIOSH, or even Creech, know about. Creech and Johnson met with Dr. Irving Tabershaw of Tabershaw Cooper Associates, who was then in the midst of an epidemiological study of vinyl workers for the MCA.<sup>120</sup> The information that Creech had revealed was terrifying to Goodrich's management.

On a Sunday afternoon, top executives met in Akron, Ohio, in what was described as "absolutely [a] crisis." All day lawyers, management, and physicians discussed the vast implications of the medical findings, including the company's liability. Finally, at 7 PM, top executives of Goodrich decided that the only thing to do was to let the information out immediately.<sup>121</sup> According to a private memo by another company's official, "At the insistence of Dr. Creech, [they] decided to reveal the information [about the angiosarcoma deaths] to the authorities and the industry."<sup>122</sup> On January 22, Goodrich informed NIOSH of the deaths, and NIOSH then informed OSHA.<sup>123</sup>

In all, Creech and his associates documented eleven cases of hepatic disease, including seven cases of angiosarcoma of the liver identified among workers at the plant, with the earliest diagnosis dating to almost ten years earlier, in April 1964.<sup>124</sup> Four of the workers died between 1968 and 1973, the very period when the decision to mislead the government was taking shape.<sup>125</sup> All the victims had been "pot cleaners" in their careers at Goodrich. Pot cleaners climbed into tanks no more than six feet across

and ten feet high "to chip polymer residue off the inside surfaces. Their only source of fresh air was a 2-foot opening at the very top of the deep tanks."<sup>126</sup>

The industry responded to the crisis by preparing "a low key statement for the press," to be released if pressed, and drafting a letter to Marcus Key of NIOSH "reaffirming industry support and cooperation as offered in the meeting with NIOSH last summer."<sup>127</sup> Initially, Goodrich reported that its practices at the Louisville plant were unexceptional and that the air in the plant and, hence, the exposures to vinyl chloride were "generally 15-20 ppm with excursions above 50 ppm," well below the existing TLV.<sup>128</sup> Later this estimate would change dramatically.

But within three weeks, the vinyl chloride producers gathered in Cleveland under the auspices of the Vinyl Chloride Safety Association to assess the problems facing the industry.<sup>129</sup> According to Goodrich officials, other chemical companies were not pleased with the company's decision to reveal the information to NIOSH. One official recalled that "Goodrich was not a hero in the chemical industry" and was "given a fair amount of harassment."<sup>130</sup> The companies discussed means to limit the amount of VCM workers were exposed to and to more closely monitor VCM levels in the air of its plants.<sup>131</sup> Only after the issue had become national news did the industry act to protect workers by reducing their exposure to vinyl chloride monomer. It would not be until months later that the hint of scandal and cover-up would be raised, and not until almost thirty years for the true dimensions of its history to emerge.

For most in the industry, the crisis at Goodrich's Louisville plant represented a major challenge to the hegemony of industry over the science of vinyl chloride toxicology. No longer would discussions about the dangers of plastics be contained among a small group of government and industry officials. Although most Americans believed that the crisis was about cancer in the workplace and not outside, environmental and labor groups knew differently. They took seriously the headlines about a link between vinyl chloride and cancer and vigorously pressured new governmental organizations like the EPA and agencies concerned with consumer protection to address the danger.

It would soon be suspected that VCM posed a threat to consumers. Even after polyvinyl chloride, a stable material, is produced, vinyl chloride gas is trapped within the finished product. The gas can escape, creating potential hazards to the consumer. Further, when it was burned, PVC produced dangerous fumes.<sup>132</sup> It was also feared that communities neighboring the

plants were in danger. Cancer, birth defects, and other conditions were documented among populations living near chemical plants where vinyl feedstock was being leaked and spewed into the water, air, and soil. The crisis that loomed for the chemical industry was this: If such a seemingly benign product as plastic could prove so dangerous and far-reaching, then what of the thousands of new chemicals that were introduced every year?

## DAMN LIARS

The cancer deaths of four workers at the Louisville, Kentucky, B. F. Goodrich plant demonstrated to the Occupational Safety and Health Administration (OSHA) that its current standard for vinyl chloride was clearly inadequate. In 1970, OSHA had been given the mandate to "set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure . . . for the period of his working life."<sup>1</sup> After the deaths at the Goodrich vinyl plant were reported, OSHA immediately called a hearing to elicit testimony about what emergency standard should be established. Some in industry feared, and many in labor hoped, that OSHA would interpret its mandate to mean creating a no-exposure level for employees.

The stakes were enormous. Ten companies with fourteen plants and more than fifteen hundred workers produced vinyl chloride monomer. Another twenty-three companies with thirty-seven plants and more than five thousand production workers used that monomer to create polyvinyl chloride. Finally, it was "difficult to estimate the number of workers employed in converting, molding, and fabricating the polymers into finished products" although "it is in the order of tens of thousands working in thousands of plants throughout the country."<sup>2</sup>

In an atmosphere of crisis, scientists, industry, and labor representatives gathered in mid-February 1974 for a standing-room-only OSHA hearing in Washington to discuss what was emerging as the major occupational health crisis of the early 1970s.<sup>3</sup> They all came prepared for battle. Dr. Irving Selikoff, "white-haired, gracious," and incredibly energetic, was a leading occupational physician and director of the Environmental Sciences Laboratory at New York's Mount Sinai School of Medicine. In the words

of *Fortune* magazine, he was "a crusader and reformer" who seemed "personally as well as professionally close to nearly everyone who matters in government occupational medicine."<sup>4</sup>

Selikoff, whose work on asbestos-related disease had gained him international renown in the late 1960s as an advocate for labor, posed a difficult question to the OSHA hearing: Why was it only now that the dangers of vinyl chloride were beginning to be recognized? Vinyl chloride-related disease was "not a new problem," Selikoff began. "There has been evidence of a potentially serious disease among workers engaged in vinyl chloride-polyvinyl chloride manufacture for 25 years."<sup>5</sup> Why was it, he asked, that the issue had "been incompletely appreciated and inadequately approached" by scientists and government?<sup>6</sup> For Selikoff, although definitive proof of cancer-producing effects were not yet established, controls over vinyl chloride should have been established earlier. "We have had ample warning that cells, tissues, and organs could be badly damaged during VC-PVC production. Despite this, our approach to the problem... seems to have been somewhat leisurely."<sup>7</sup> Had industry and the state acted earlier this conference would not have been necessary.<sup>8</sup>

Now that cancer had appeared, he had a number of recommendations. First, there was no question that "vinyl chloride-polyvinyl chloride exposure should be added to the list of carcinogens promulgated by the Department [of Labor]," since "no threshold is known that would serve to prevent cancer among exposed workmen."<sup>9</sup> Second, it was necessary to "rapidly study whether health effects will be associated with end-product or consumer use."<sup>10</sup> Finally, he stressed the broader implications of the vinyl crisis. The substance was emblematic of "'invisible pollution,' associated with... [the] 'new industrial revolution, based on the chemical-process industry.'" Workers were paying for the rapid expansion of this industry, and their sacrifice was "becoming visible in terms of disease and death." Those who worked with new chemicals had "every right to expect that scientists, industry, and governmental agencies would protect them against known or suspect hazards. This we failed to do." Selikoff concluded, "Our task here today is to address this and insure that it go no further. No effort should be spared and no control considered too rigorous."<sup>11</sup>

Tony Mazzocchi, legislative director of the Oil, Chemical and Atomic Workers Union (OCAW), emboldened by the new influence labor appeared to have with the creation of OSHA and by his sense that labor could dramatically influence scientific decision making for the first time, challenged the very idea that safe doses could be established for carcinogens. He reminded the audience of the principle embodied in the Delaney

clause, saying it was "impossible... to establish any absolutely safe level of exposure to a carcinogen for man."<sup>12</sup> He demanded that OSHA set a no-detectable-limit standard for vinyl chloride. "Today, somewhere in the United States a worker is being exposed to vinyl chloride that will someday cause him cancer and a slow, painful death."<sup>13</sup>

The presence of recognized experts and professionals speaking on behalf of labor was extraordinary. Scientific meetings were generally dominated by industry scientists, whose arguments prevailed. Now, it appeared, the tables had turned. Dr. Thomas Mancuso, a professor in the Department of Occupational Health at the University of Pittsburgh, spoke on behalf of the Industrial Union Department of the AFL-CIO. He described a pattern of denial on the part of industry when a hazard was uncovered in the workplace. "Invariably, whenever a new occupational cancer is discovered, it is played down for fear of alarming the workers and the general public... Nevertheless, from past experience, what happens is that as further work is undertaken and information obtained, the problem gets broader and broader with more implications." Mancuso argued that neither OSHA nor industry should wait for danger to appear before taking a course of action, especially given the extraordinary and rapid growth of the chemical industry. "The chance recognition of an occupational cancer by a unique combination of circumstances, clearly demonstrates what is not known about the carcinogenic potential of thousands of industrial chemicals that have been in use for decades." The case of vinyl chloride "focuses attention on the total absence of a national concerted study of occupational cancer in this country."<sup>14</sup>

#### THIS COMPLEX PANDORA'S BOX

Mancuso raised the specter of broader environmental disaster. "The serious national question that is raised and not resolved, because it is either too shocking to contemplate or because the agencies responsible for the protection of the public are reluctant to open this complex Pandora's box, is, in essence, that a national study directed at the industrial environment might uncover a whole series, a succession of occupational cancers, which in turn would implicate in the distribution of these chemicals a larger and larger portion of the population exposed to the risk of cancer." He also raised the question of chemicals interacting with one another. There was not sufficient knowledge since the "real carcinogenic potential of these chemicals acting alone or in combination with each other has never been established."<sup>15</sup>

The industry, as might be expected, vigorously disagreed with this version of the history of the problem of vinyl chloride, as well as with the proposed OSHA emergency standard. The industry's representatives argued that the vinyl producers had acted responsibly. Albert C. Clark, vice president and technical director of the Manufacturing Chemists' Association (MCA), and Dr. Kenneth E. Johnson, the association's assistant technical director, suggested that the MCA "as a regular and continuing service to its members, has long had active programs in occupational health and safety." They portrayed their response to the acroosteolysis (AOL) problems encountered in the 1960s as a sign of corporate responsibility. When cancer was suspected, the industry invited the Italian scientist who conducted the research, Dr. P. L. Viola, to the United States to give them ideas on how to design a research protocol to answer outstanding questions regarding the carcinogenic properties of vinyl chloride.<sup>16</sup>

These industry representatives failed to mention that the goal of their research was not to gather information in order to protect workers but to "reassure the public," to "assure the employees . . . that management was . . . diligent . . . to protect their health," and "to develop data useful in defense of the industry."<sup>17</sup> They maintained that the industry had been seeking to test Viola's conclusions using "vinyl chloride of a source and quality characteristic of a U.S. industrial product," honorably trying "to determine, if possible, whether a no-response level exists."<sup>18</sup> In contrast to Selikoff's and Mazzocchi's position, the industry clung to the notion that any substance could be used safely if exposure levels were low enough.

Given that industry documents remained secret, there was no way to understand that the industry had acted to hide from the government information about vinyl as a carcinogen. As a result, the companies could still pass themselves off as working openly and cooperatively with the government. It would take decades for researchers and lawyers to shed light on industry documents and to learn of the cover-ups, denials, and lies. Until then, the industry could maintain that its desire to protect the workforce had led the MCA to initiate contact with NIOSH and to be completely forthcoming in providing information. The MCA officials pledged that its member companies would reduce exposures to the lowest possible levels. The hint of MCA's less honorable intentions was that it opposed OSHA's proposal to issue an emergency temporary standard. Even after the Louisville revelations, the MCA suggested that OSHA should take its time and begin a regular rule-making process, which could take years.<sup>19</sup>

Dow's representative, V. K. Rowe, countered Mancuso's alarmist position by calmly maintaining that industry had cleaned up its act and that

the vinyl problem was an isolated incident, not representative of the workplace practices in the entire industry. Like representatives of industry today, who claim that the past is irrelevant,<sup>20</sup> Dow argued that "rule-making should not be based on conditions that existed in the past, but should be based on conditions as they exist now." Because of the "widespread voluntary actions by industry, . . . we believe a temporary emergency standard would result in polarization rather than constructive definition of areas of concern and constructive problem solving."<sup>21</sup>

Management, having argued earlier that companies had never exposed workers to dangerous amounts of vinyl, now reversed course, arguing that the deaths from angiosarcoma of the liver resulted from "very high exposures years ago when . . . firms were 'much more cavalier' toward vinyl chloride's hazards."<sup>22</sup> Industry members assured the government that the angiosarcomas that had been found at Goodrich were a product of past, not current, practices.

Shortly after the hearing, Robert Wheeler of Union Carbide notified NIOSH that the company had discovered a case of angiosarcoma of the liver in a worker in its plant in South Charleston, West Virginia. Dr. David Duffield, of Imperial Chemical Industries (ICI), a British vinyl manufacturer, reported as well on the death of one of ICI's employees in December 1972, and Dr. William E. Rinehart of Ethyl reported that a worker had died on December 28, 1973, in Ethyl's Louisville bottle manufacturing plant.<sup>23</sup> Pressure began to mount on the industry within two weeks of the OSHA hearing after the MCA's Technical Task Group on Vinyl Chloride Research learned that 50 ppm would not necessarily protect the worker. As a result, the MCA's Work Practices Task Force decided not to recommend a threshold level for VCM.<sup>24</sup>

Very little information exists about the reactions within the industry to the gathering storm concerning exposure levels. But the records of Pittsburgh Plate Glass (PPG), a major producer of vinyl chloride, indicate that its medical director, Lee B. Grant, objected strongly to PPG's statement to OSHA in support of the MCA position that work practices be established under Section 6(b) of the OSHA Act: He pointed out that in OSHA's three-year history not one health standard had been issued under the regular process for "the procedure is very time-consuming." Instead, Grant argued, OSHA should use Section 6(c) of the OSHA Act, which permitted the issuance of emergency standards when there was "a grave danger to persons from a newly recognized hazard." He worried, "The delay as 6(b) requires in developing a standard, in my opinion, is unwarranted when considering the significant degree of the hazard for human carcinogenesis

potentially represented by permitting a continuation of exposure of persons to the present OSHA Standard for Vinyl Chloride Monomer of 500 ppm." He supported the use of the mechanism that "permits the emergency standard to become effective the day of publication in the *Federal Register*."<sup>25</sup>

NIOSH officials, still believing that the MCA was being candid with them, invited the trade association to provide industry experts as consultants in establishing new work practice guidelines, a request that the MCA quickly and gladly embraced. From a list of candidates provided by the MCA, NIOSH named Zeb Bell of PPG, Maurice Johnson of Goodrich, Mayo Smith of Air Products, and Robert Wheeler of Union Carbide to its panel of consultants.<sup>26</sup>

Before meeting with NIOSH, the MCA's Sub-Task Group on Work Practices held its own meetings to formulate a common industry position. Bell, the manager of environmental control and industrial health for PPG, privately expressed concern that the industry was not taking seriously enough the link between vinyl chloride and cancer. He admitted that "there [was] little doubt that VCM [was] a 'cancer suspect agent'"<sup>27</sup> and worried about industry's resistance to being forthright about the seriousness of the vinyl chloride cancer problem. He felt that the MCA's draft of what it hoped OSHA would adopt as its work practice standard for vinyl chloride workers reflected the industry's attempt to minimize the danger. The term *cancer suspect agent* had first appeared in the *Federal Register* when OSHA issued work practices for the first fourteen carcinogens in January 1974. According to Bell, "the industry did not like it" and proposed instead to call it a "hazardous chemical agent," even though Bell believed the prior term was more accurate.<sup>28</sup> Nonetheless, in a public statement to *Chemical Week*, Bell proclaimed that industry was a responsible corporate citizen. Bell claimed, "We were complacent before January, but we insist on strict compliance with work rules now."<sup>29</sup>

In March, shortly after the industry made assurances that the sloppy practices and high exposure levels that had been responsible for the angiosarcoma deaths were now corrected, a meeting of high-level vinyl chloride industry managers learned some surprising news. Richard Fleming of Air Products revealed that the industry was actually doing better than it had suspected in terms of keeping exposure levels at its plants relatively low. It was quite common for most companies, he told the executives, to keep VCM time-weighted average levels below 50 ppm. Rather than taking pride in this fact or congratulating themselves, the company representatives at the meeting found the news quite worrisome. Fleming

warned that the "current low levels could jeopardize [the industry's] case [before NIOSH and OSHA] if not presented properly." He reasoned that if NIOSH and OSHA understood that the exposure level "[had] always been this low"—when angiosarcomas appeared at their plants—then it would mean that reducing the TLV to 50 ppm was inadequate and the TLV would have to be lowered even further.<sup>30</sup> A day later, on March 22, Goodyear announced in another press release that two more workers had died from liver angiosarcomas.<sup>31</sup>

#### THE EVOLUTION OF A NEW SCIENCE

The vinyl chloride crisis was raising complex problems about how to determine the potential dangers of the thousands of new chemicals that were being produced in factories and introduced into the environment through air and water emissions and consumer products. As Italian cancer researcher Cesare Maltoni, whose work on vinyl chloride finally appeared in print in the early spring of 1974, put it: "In the past 10 years, the number and amount of oncogenic agents produced and scattered in the working environment have increased and continue to increase in a distressing way. . . . As a result of this situation, an increase in occupational tumors and of environmental agents in a broad sense is recorded."

Maltoni argued that although the recording of workers' diseases and deaths provided information, it was an insufficient way to address the problem and that the industry needed to find a way to predict what chemicals and levels of exposure would cause cancer. Retrospective epidemiological studies, which identified toxins long after they had harmed individuals, were a case of too little information too late. "Epidemiological proof should be avoided. For all new agents produced and used, systematic experimental tests should rather be carried out to predict their possible oncogenic potential." He acknowledged that a lack of standards and other methodological problems had caused skepticism about how animal data could "be extrapolated to man." But Maltoni believed that his results showing the carcinogenic effects of vinyl chloride in animals represented "the first time that an oncogenic hazard . . . [had been] predicted with absolute accuracy by means of an experimental test."<sup>32</sup> In other words, animal experiments could help predict which substances would be dangerous.

Industry found this position untenable and maintained that evidence of human disease, not animal studies, should be used for regulatory purposes. Industry spokespeople had maintained until the human deaths "no special

significance could be attached to the types of tumors observed by Maltoni.<sup>33</sup> Public health practitioners, labor leaders, academics, and government administrators disagreed. The American Association for the Advancement of Science had established the Committee on Scientific Freedom and Responsibility and had already identified the reliance on epidemiology as a major concern in the study of carcinogens.

John T. Edsall, a professor at Harvard University and a member of the committee, worried that industry was seeking refuge rather than information when it ignored animal studies and waited for evidence of death and disease among workers. "The extremely ominous findings in the animal studies did not trigger any major alarm" among industry officials, Edsall observed, "until cases of cancer in factory workers exposed to vinyl chloride began to be reported." What he did not know was that the animal studies *had* caused alarm, so much alarm, in fact, that the industry had hidden the results from the government so NIOSH would not move to regulate the industry. He believed that the lesson of the vinyl chloride crisis was that "new reagents introduced into industry on a large scale should be regarded as dangerous until proved safe."<sup>34</sup>

The dilemma for the government however was that it might take years, even decades, to prove a substance dangerous and it might not be possible to ever prove to the scientific community that a substance was completely safe. Nevertheless, the government had to develop guidelines that would protect the public and not paralyze industry.

Joseph Wagoner of NIOSH was more direct in his assessment of the relative values of animal bioassays and epidemiology. He maintained that animal studies "and in vitro studies should be the 'front line' of the attack on job-related cancer." He noted that vinyl chloride was not the only case in which human cancers had been accurately predicted, and he outlined the numerous times in which animal evidence had alerted the scientific community to a problem that was ultimately confirmed by epidemiological research. Epidemiology, while "a powerful qualitative tool," was "weak or inadequate" in identifying carcinogenic risks. By studying death from cancer and "not induction of cancer," epidemiology could only underestimate risk. Because it was "post hoc in nature," it could only record, not address, the "failure of government, industry, and society to . . . control chemical carcinogens introduced decades ago." Animal and microbial tests, in short, could be a more powerful and usable tool in assessing carcinogenesis and mutagenesis.

Louis Beliczky, director of health and safety of the United Rubber Workers, supported the use of animal studies, asking "will it take human

deaths" to establish a substance's toxicity? "The only sane policy," he argued, "is to be conservative, to err on the safe side."<sup>35</sup>

While objecting to the government's use of animal studies, the industry privately considered animal studies a perfectly appropriate source of data. Before the issue of regulation arose, the industry had been properly sobered by the animal studies of Maltoni and Viola, which pointed to the carcinogenic properties of vinyl chloride. This was why they were so anxious that NIOSH not learn of them. Yet in the months following the exposé of the angiosarcoma deaths at Goodrich and other companies, the industry's position regarding the usefulness of these animal studies went through a metamorphosis. It was more a change in tactics than a change in attitude. Industry was now interested in delaying government regulation. By arguing that animal studies were inadequate for assessing the effect of their product on humans and demanding more long-term observational data, they could buy time. By maintaining that only epidemiological studies could accurately gauge the true danger of chemicals to humans, the industry could continue to claim that their products were safe until these laborious studies were done.

The industry maintained that there had been no "quantitative data that provides a basis for extrapolation of animal carcinogenesis to man."<sup>36</sup> Unlike Selikoff, who traced the vinyl chloride issue to 1940 studies among Soviet workers, or Mancuso, who saw vinyl chloride as a broad-based environmental issue, B. F. Goodrich officials argued that animal studies had proved of little value and that there was no reason to suspect that vinyl was a carcinogen. (Goodrich was arguing this after the MCA knew of Maltoni's studies and had accepted the implications for humans in them.) They held that only Viola's paper had previously reported on a relationship between cancer and vinyl chloride and that the cancer identified was not located in the liver.<sup>37</sup>

Robert Wheeler of Union Carbide also argued, "Data from animal toxicology studies cannot be directly applied to forecast human experience since laboratory animals, such as mice, tend to develop angiosarcomas spontaneously, they metabolize vinyl chloride differently, their lifetimes are shorter, and their rate of metabolism is higher. For these reasons, safe-exposure limits for workers must be based on human data and experience."<sup>38</sup> Paul Kotin of Johns Manville Corporation even argued that "some cancers will heal if the victim is removed from exposure." He said, "There are very few chemicals that produce malignant tumors exclusively. In some cases a heavy dose may produce a malignant tumor and a light dose a benign tumor."<sup>39</sup>

Public health experts and even industry placed such importance on Maltoni's findings of cancer in animals because finding cancers in such studies was statistically quite improbable. Carcinogens were known, even in the 1970s, to affect a very small percentage of any given population. For instance, if a substance affected only one out of two hundred animals, in a study of one hundred animals there would be a 60 percent chance that not even one cancer would appear. Even if two studies of such magnitude were conducted, there was a 30 percent chance that no animal would be affected. Such a "serious limitation on the validity of animal tests" made it economically unfeasible to conduct animal studies large enough to provide results that could reliably prove danger.<sup>40</sup> Thus, as scientists understood, most animal studies dramatically understated the potential harm that could result from exposure to a particular substance. That Maltoni found multiple cancers in multiple sites at low exposures at one-half of the human TLV was very alarming.

On April 4, 1974, OSHA issued an emergency temporary standard setting a permissible exposure limit (PEL) of 50 ppm of vinyl chloride rather than NIOSH's recommended level of 1 ppm.<sup>41</sup> The MCA's Sub Committee on Work Practices was greatly relieved by OSHA's action. Because this standard was already the usual practice within plants, it imposed no new economic hardships on industry. The MCA Work Practices group stuck to its position that anything below a 50 ppm "working level concentration" would be "uneconomic and all but impossible to meet" and that anything below this would be "simply a requirement for liquidation of a major industry." But they did not tell OSHA that the 50 ppm level did not satisfy Maltoni, who did "not wish to be quoted that 50 ppm is safe for man."<sup>42</sup>

The industry sought to maintain a common position. In early May the director of packaging service of the Society of the Plastics Industry wrote to PVC producers about the data they were gathering to present to OSHA about a permanent standard for VCM. "We must show that significant numbers of people are involved and that these people have been exposed long enough for the disease to become evident," the letter began. OSHA would certainly want to know what levels of exposure workers were already experiencing, and the industry data "must at least derive the implication that TWA [time weighted average] exposure levels were at least 50 ppm and possibly higher."<sup>43</sup>

If the industry could not show that the levels had previously been higher, OSHA might conclude that its proposed standard of 50 ppm was not low enough to protect workers. Indeed, the industry had already changed its claim that the plants in which the workers died had low expo-

sure levels, now arguing that they worked in plants where exposures were high. Union Carbide's Robert Wheeler said that in the past "exposures at the affected plants were ten times" the current level. He concluded, "a maximum exposure level of 50 ppm TWA" was the proper standard.<sup>44</sup>

Shortly after OSHA issued its emergency standard, Industrial Bio-Test Labs, the company conducting the industry's animal tests, phoned the MCA with more troubling news. Preliminary results suggested that mice exposed to 50 ppm VCM were developing angiosarcoma. The MCA immediately forwarded that information to NIOSH, OSHA, and the EPA.<sup>45</sup> The MCA's Vinyl Chloride Research Coordinators met with representatives of the government to discuss the ominous implications of this finding. Shell Oil Company's representative, Howard L. Kusnetz, reported, "The consensus of the group was that despite these minor discrepancies, the tumors were real and they confirmed Maltoni's findings." One OSHA person, Donald Lassiter, "felt that the results reported would support the NIOSH recommendation of 1 ppm."<sup>46</sup>

A split emerged between the MCA and its constituent vinyl chloride manufacturers as the intense scrutiny of the plastics manufacturers threatened the public's perception of the entire chemical industry. The MCA leadership, as representatives of the broader industry, sought to insulate itself from the furor by withdrawing from all but the most technical aspects of hazard identification. When the vinyl industry asked the MCA to convene a meeting of the vinyl chloride and polyvinyl chloride producers "for the purpose of exchanging information and coordinating efforts to establish a safety standard," the MCA Executive Committee shocked the manufacturers by denying their request. The MCA claimed that such a meeting "would involve a standard-making activity concerning a single product which is potentially sensitive from an antitrust viewpoint." Such an activity, the MCA claimed, would be "beyond the approved purpose of the vinyl chloride research project MCA is administering," which they asserted was limited to animal and epidemiological research.<sup>47</sup>

The MCA, long the public face of the plastics industry, now sought ways to lessen its exposure. A. C. Clark of the MCA's staff was dispatched to the MCA's Technical Task Force for Vinyl Chloride Research to clarify for its members the new face that the MCA wanted to show. The MCA, he stated, would "not concern itself or become involved in non-technical or non-scientific items such as profit, return on investment, feasibility or lack thereof, or other industry problems that cannot be solved by scientific or technical studies." Nor would the MCA become "involved in any controversy or litigation whether of industry benefit or not."<sup>48</sup>

Meanwhile the public image of the plastics manufacturers continued to take a beating. The MCA staff learned that "Jane Brodie [Brody] of the New York Times" called about results of a meeting and that "CBS was preparing a one hour special on vinyl chloride" that would include film of Goodyear's plant in Niagara Falls, New York, and an interview with industry's nemesis, Dr. Irving Selikoff.<sup>49</sup>

Robert Wheeler of Union Carbide expressed his own and other vinyl producers' frustrations with the MCA's actions. "At the week's end, my own reaction as well as many other PVC industry representatives was first to question the value of being an MCA member and, second, to question whose side MCA was on besides its own."<sup>50</sup> It was felt that the MCA was not focused enough on the plastics industry to be a reliable spokesman for vinyl manufacturers. What was needed was another body whose interests were synonymous with plastics to lobby legal challenges against OSHA, NIOSH, the EPA, and the FDA. Such lobbying could forestall what the industry feared would be crippling regulations.

On April 16, shortly following the disastrous meeting with the MCA, "the VCM/PVC Industry Management Committee held an Ad Hoc meeting in Washington DC . . . and decided to form a permanent action group within the Society of the Plastics Industry where Bylaws of the SPI are compatible with present industry needs."<sup>51</sup> In the end, the MCA and the Society of the Plastics Industry succeeded in dividing their work and reinforcing each other's positions. "A considerable overlap of committee members has made this a very workable relationship."<sup>52</sup> The plastics manufacturers would "form a single, unified group to deal with all of the phases; actions to be taken with OSHA, NIOSH, EPA, FDA, and other agencies will be on a groups [*sic*] basis rather than each producer acting as an independent agent."<sup>53</sup>

Because the Society of the Plastics Industry, unlike the MCA, was an association of the plastics producers alone, it was not forced to address the multiple agendas of the entire chemical industry. It represented 1,400 member companies that accounted for 75 percent of the plastics industry sales in the United States. The Society's Vinyl Chloride and Polyvinyl Chloride Resin Producers Committee represented "more than 90 percent of the U.S. capacity for the production of vinyl chloride monomer and polyvinyl chloride resins."<sup>54</sup>

The SPI group expected that within days the MCA would publicly announce its findings that angiosarcomas were appearing in animals with exposure to VCM of only 50 ppm. They fully believed that this would result in OSHA's adopting NIOSH's 1 ppm standard and that "none [of

their members] could operate if the NIOSH Work Standard were imposed on the industry."<sup>55</sup>

The vinyl industry was faced with a dilemma. On the one hand, it maintained that a threshold limit could be developed that would both protect workers while allowing the industry to maintain production. On the other hand, evidence indicated that there was no known safe level of exposure. Every time a new level of exposure was tested on animals, cancers appeared. The MCA, still responsible for gathering the scientific data, reported to industry representatives in early May some more discouraging news. "[M]ice in the 50 ppm exposure group were experiencing malignant tumors, including angiosarcomas of the liver, [and thus] industry was left without any exposure level of vinyl chloride that it could identify as a one at which there was no direct evidence of adverse effects. . . . [A] new series of experiments [should] be undertaken in an effort to show a no-effects level in a sensitive, rapidly-reacting species, i.e. mice."<sup>56</sup>

In mid-May OSHA published in the *Federal Register* its long-awaited "Comprehensive Proposal on Vinyl Chloride" and called for comment and criticism. The proposal included a "no detectable level" of 1 ppm permissible exposure limit for VCM. Two sets of public hearings were held in the summer, and enormous controversy arose as industry, labor, public health practitioners, and the academic community weighed in with advice. Simultaneously, a conference on the "Toxicity of Vinyl Chloride-Polyvinyl Chloride" at the New York Academy of Sciences learned that both Maltoni and the MCA had discovered angiosarcomas in animals at 50 ppm.<sup>57</sup>

Just as the OSHA proposal was announced, the industry held a meeting at which members decided, as they generally did when faced with a threat, that whatever their different success in reducing exposures, they would maintain a common front against OSHA and other agencies in the escalating battle over vinyl chloride. While most of the companies could live with an exposure limit well below the emergency standard, one company warned "against a company accepting a low VCM level that the majority could not live with." Furthermore, what was possible for the companies was not necessarily what they considered desirable. Goodrich had proposed an exposure level one-tenth the emergency standard. But this caused "serious consternation among many of the members and warnings against such low levels within the short time period."<sup>58</sup>

As scientific and popular consensus about the dangers from vinyl grew, the industry developed a sophisticated public relations campaign aimed at shaping regulatory decisions. The MCA staff feared that the vinyl chloride revelations were threatening the whole chemical industry, not just the

vinyl producers. A staff report made to the association's board of directors stated: "A recent story by a leading newspaper in the Nation's Capital discussed the health dangers which have been associated with the manufacture of vinyl chloride and went on to criticize the inaction of Congress in failing to pass a toxic substances control law." If, as this article suggested, the growing attention to the vinyl deaths might result in increased regulation by Congress, the industry had better take charge. Recognizing that the public's concern about toxic substances would not go away, the MCA staff suggested that it might be beneficial to pass toxic control legislation in the present Congress, rather than to await a new session in which public opinion could force an even more stringent law.<sup>59</sup>

The carcinogenicity of vinyl chloride, seen as a problem solely for workers before the B. F. Goodrich angiosarcoma deaths, was now the subject of a heated national debate about carcinogens; the efficacy and role of animal biological studies in understanding and regulating chronic illnesses; the definition and identification of carcinogens; and the roles of OSHA, NIOSH, the EPA, the FDA, the Consumer Product Safety Commission, management, and labor in controlling industrially produced carcinogens. Aerosols, meat wrappings, PVC tubing, spills, tank car accidents, and plastic liquor bottles all came under suspicion for posing a long-term threat.

Within weeks of the crisis at Louisville in January 1974, Sidney Wolfe's Health Research Group, a consumer advocacy organization, called for a ban on the use of vinyl chloride as a propellant in spray cans and for a regulation requiring the publicizing of the brand names of products using vinyl chloride as an aerosol (a year earlier various VCM producers had quietly stopped selling VCM for aerosols but had done nothing to warn consumers of the danger). Shortly after Wolfe's action in late February, the FDA and the EPA asked for the recall of "over 100 hair sprays, insecticides, footsprays and deodorants, and other products which were determined to contain vinyl chloride as a propellant."<sup>60</sup>

In April, Clairol pulled 100,000 cans of hair spray from store shelves.<sup>61</sup> The EPA issued an "Emergency Suspension Order Concerning Registrations" under the Federal Insecticide, Fungicide, and Rodenticide Act for "all pesticide spray products" containing vinyl chloride "for uses in the home, food handling establishments, hospitals or in enclosed areas." A notice of intent to cancel registrations was published in the *Federal Register* in part because tests showed that "a 30 second release of the aerosol could result in a concentration as high as 400 ppm in the air" and that "a detectable

concentration of vinyl chloride could still persist for several hours after spraying."<sup>62</sup> During the summer of 1974 the FDA, EPA, and the Consumer Products Safety Commission initiated or took final action to ban vinyl chloride's use in bottles and certain other consumer items.<sup>63</sup>

At a private session organized by the National Cancer Institute with representatives from ten federal agencies, including OSHA, NIOSH, the FDA, the CDC, the EPA, National Institutes of Health, and the Armed Forces Institute of Pathology, Nancy Beach, the coordinator of the EPA's efforts concerning vinyl chloride, told the group that estimates showed a 6 percent loss of vinyl chloride monomer during the production of PVC. She commented, "It sounds small, but if one considers that the annual production of PVC in the U.S. is well over 5 billion pounds a 6% loss figure is on the order of 250 million pounds, which is somehow getting out of the workplace." Preliminary studies by the EPA indicated this was a significant problem, especially for those living near a plant.<sup>64</sup> In monitoring environmental pollution around vinyl chloride plants the EPA had found that although the average exposure was less than 1 ppm, outside one plant there were readings of 33 ppm and even of 3.4 ppm three miles away from another plant. Russell Train, the administrator of the agency, acknowledged that "there is no scientific evidence to indicate that these emissions pose an imminent hazard to people living near these plants." He thought it "prudent" that "reasonable steps should be promptly taken to reduce vinyl chloride emissions to the lowest practical level."<sup>65</sup>

While the discovery of various kinds of industrial pollution had led the EPA to begin pressing for passage of a Toxic Substances Control Act (TSCA), the publicity and seriousness of the vinyl crisis would become the impetus for more assertive efforts to get TSCA passed, with a view toward regulating more chemicals than vinyl chloride. One report noted that "many of the considerations and uncertainties that have punctuated the vinyl chloride/polyvinyl chloride deliberations undoubtedly characterize a far broader swath of concerns over high volume industrial chemicals in general, and plastics in particular." TSCA "would provide a mechanism for addressing those products using vinyl chloride not now subject to regulation under other laws."<sup>66</sup>

In December 1974, the FDA "received from the [PVC] industry research findings showing that vinyl chloride residues had also migrated from bottles and packages into vinegar, apple cider, vegetable oil, mineral oil and packages used to wrap meats."<sup>67</sup> It would take another two years for TSCA to be passed. TSCA gave the EPA the authority to test chemicals for toxic-

ity before they were introduced into the market and the right to test the toxicity of those already being used.<sup>68</sup>

The vinyl chloride crisis substantially blurred the line between occupational and environmental dangers. No longer could the field of occupational medicine be segregated from the emerging field of environmental health. In the coming years, with the disasters at Love Canal, Times Beach, and even Bhopal, what had been a side issue in the extraordinary battle over occupational exposures to vinyl chloride would become a national preoccupation. The SPI Producers Group knew that industry was in for bigger trouble and set out to hire the firm of Ruckelshaus, Beveridge, and Fairbanks as "counsel on EPA matters."<sup>69</sup> Because William Ruckelshaus had been the past administrator of the EPA, the very agency the chemical companies were seeking to influence, getting his firm on board would provide the industry with legitimacy as well as important contacts.<sup>70</sup>

As all this was unfolding, the industry was faced with the immediate problem of what to do about OSHA's call for a permanent standard of "no detectable limit" and the impending hearings planned to begin on June 25, 1974. The industry contracted with Hill & Knowlton, a major public relations firm, to refocus public and congressional attention and to reshape the national debate about the effect of plastics on American society. Shortly before the OSHA hearings, the SPI's Vinyl Chloride Public Relations Committee received a report from Hill & Knowlton outlining the dangers that awaited the industry at the hearings and proposing a public relations campaign that would focus on four points: the "important role" that vinyl played in American industry, the number of jobs that could be lost if the industry were to shut down, the unfeasibility of meeting the strict standards that had been recommended by OSHA and NIOSH, and the fact that "it has not been demonstrated that a health hazard exists at the levels recommended by SPI." This formulation shifted the burden onto government to prove danger and away from industry to prove safety. This was important to do, the industry noted, because "it has not been scientifically demonstrated that the SPI recommended levels are truly safe."<sup>71</sup>

The authors of the public relations campaign were acting with full consciousness of the nightmare that the asbestos industry had lived through over the past few months. In late October 1973, the *New Yorker* magazine had published the first of a series of sensational articles by Paul Brodeur that were seen as an indictment not only of the asbestos industry but also of American industry in general. The articles, according to a publication of the United Rubber Workers, detailed "how the medical-industrial com-

plex hides the facts [about occupational disease], prevents real action and makes the key decisions in OSHA and NIOSH."<sup>72</sup> During the controversy about asbestos, which had proven disastrous to Johns Manville and other asbestos companies, the industry had been completely outmaneuvered by Irving Selikoff and his union allies, who were now at the center of the vinyl debate.

Control of public perceptions of the vinyl crisis was no easy task for industry. Even within the vinyl chloride producers' inner circle anxiety about the health risks of VCM had mounted. Lee Grant, the medical director at PPG who had earlier called upon the industry to support an emergency standard, now objected to the companies' position that "significant exposure levels be permitted without the use of respiratory protection."<sup>73</sup> He believed that although from an engineering standpoint it might make sense to slowly reduce exposure levels, doing so was inadequate "from a health standpoint." He believed that employees should not be exposed to concentrations above 1 ppm TWA and that "respiratory protection should be recommended until such time as the air concentrations of VCM are so reduced," which he thought could be accomplished in short order. Dow Chemical, he pointed out, had already accomplished this.<sup>74</sup> Grant, however, never told the government or the public about his misgivings.

Far more damaging than Grant's internal dissent was public criticism of the chemical community by its own members. In mid-July 1974, *Chemical & Engineering News* reported that the American Chemical Society (ACS), a professional organization representing chemists in a variety of industry and academic settings, "entered the vinyl chloride dispute... coming out, in essence, in support of the Government's proposed 'no detectable level' permanent standard for worker exposure to the chemical." Testifying at the OSHA hearings, Howard H. Fawcett, chair of the ACS Committee on Chemical Safety, and Dr. Stephen T. Quigley, head of the Society's Department of Chemistry and Public Affairs, argued that such a level was attainable.<sup>75</sup>

The ACS's action brought an immediate response from Union Carbide's A. B. Steele, who wrote to the ACS's executive director that the director and members of the ACS had overstepped their professional mandate. He complained that their testimony before OSHA represented the point of view of a limited group of committeemen and was not the consensus of the organization. He also maintained that it was unclear whether "even continuous exposure to vinyl chloride monomer in high concentrations over a period of time will necessarily result in any deleterious effects in

humans."<sup>76</sup> Steele made his statement despite all that was known within the industry about the dangers of vinyl chloride.

In the midst of this dissension the industry was faced with a much bigger potential threat. Government officials came forward with information that they had been deceived by the industry. NIOSH Director Marcus Key reported that he had personally been misled by the MCA at the critical July 1973 meeting set up by industry to appear compliant with NIOSH's request for information. The MCA had led him to believe that the only information it possessed regarding cancer was that derived from the Viola studies, which indicated that tumors had been induced only "at very high levels of vinyl chloride" and primarily affected the Zymbal gland, which does not exist in humans. "At this meeting," Key asserted, "there was no mention of angiosarcoma of the liver in humans or animals, no reference to production of liver tumors in animals by another Italian investigator, and no reference to Professor Cesare Maltoni by name."<sup>77</sup>

The industry leadership knew that Key's statement could mean that the industry would lose any influence it had in the controversy over the angiosarcoma deaths. The statement implicitly accused the MCA of having conspired a year earlier to deny critical information regarding vinyl's toxicity to NIOSH, the federal agency responsible for establishing safe work practices. Although members of the vinyl industry wanted to refute and argue with Key about the meeting, they feared such a debate would bring attention to the issue. They decided to avoid a fight and hope it would just go away. A. W. Barnes of British producer ICI told other industry representatives that he did not want "any more public commotion over this."<sup>78</sup>

But NIOSH officials were unwilling to let the matter drop, for with the Watergate scandals and the impeachment hearings of President Richard Nixon playing out in the background, the public was more than ready to see corruption and scandal at every level of government. According to J. William Lloyd, NIOSH's director of occupational health surveillance and biometrics, there was a pervasive "questioning [of] the integrity of our public officials and scientists who are deeply dedicated to protecting the health of the worker." Lloyd believed that industry took advantage of the public's heightened skepticism about government to attempt to deflect attention from themselves by circulating rumors that government officials had kept secrets.

In an angry letter to Barnes of ICI, Lloyd accused the chemical industry of misstating the facts regarding the meeting with NIOSH on July 17, 1973. He was particularly irked that the British chemical trade association maintained in a press release that "American industry and government

(NIOSH) were told" of Maltoni's work. He argued that "as best as I could determine no representative of NIOSH was ever made aware of these findings prior to January 22, 1974, and even on that date, they were transmitted with the stipulation that they be kept confidential." He believed that the British chemical industry release had been "intentionally misleading since it was at variance with the facts as I knew them." Further, he believed that the MCA was also trying to avoid responsibility by releasing a "chronology of events that also inferred that NIOSH had been given the same information." He was, "to say the least, very upset," and when asked by a British television interviewer his "reaction to the [British] statement that NIOSH had been informed," he responded, "I would characterize those making such statements as 'damn liars.'"<sup>79</sup>

Because of continuing pressure from Key and Lloyd, Barnes finally responded privately to Lloyd with a long, convoluted argument. He acknowledged that the industry had not revealed the critical information from the Maltoni studies, but he insisted it had acted in good faith. He asserted that the British had gone to the NIOSH meeting fully intending to reveal any information they had about Maltoni's studies, but since NIOSH had not asked about the studies, the British assumed that NIOSH was not interested. Barnes maintained that David Duffield, the European representative at the meeting, "was a guest at a formal meeting between NIOSH and MCA and, as such, it would have been improper to force the meeting into detailed discussions which it appeared not to want."<sup>80</sup>

Barnes rejected Lloyd's assertion that anybody had knowingly misled the U.S. government and insisted it was all a big misunderstanding. Barnes asserted that the Europeans had "attempted to get the right actions taken throughout Europe and the USA as soon as the possible significance of Maltoni's findings were appreciated,"<sup>81</sup> although he offered no explanation of what the Europeans had done to accomplish this. Whatever his intent in sending this response to Lloyd, Barnes's letter was an admission that the vinyl industry had failed to mention at the meeting with NIOSH what it knew from Maltoni's studies—that primary angiosarcomas and other tumors had been caused by vinyl chloride.

While NIOSH officials were fuming over the MCA's deceptions, in the summer and fall of 1974 industry, labor, and public interest groups were battling over OSHA's proposed "no detectable limit" standard.<sup>82</sup> The industry made two arguments: first, that the epidemiological and scientific evidence regarding the dangers posed by vinyl chloride was ambiguous and that sacrificing a crucial industry by imposing untenable and unreachable standards would be irresponsible; and second, that the costs of initiat-

ing unnecessary workplace reforms would be so economically unfeasible that it could wreak havoc with the national economy.

The general counsel of the Society of the Plastics Industry, Jerome Heckman, told the OSHA hearing that "much of the scientific data obtained by researchers to date is quite inconclusive" and that "misplaced reliance on mere suspicions rather than proven data, or precipitous and emotional reaction to such incomplete information . . . could lead to major economic consequences." Heckman relied heavily on a recent decision of the United States Court of Appeals for the District of Columbia, *Industrial Union Department, AFL-CIO, vs. Hodgson*, which declared that the secretary of labor and OSHA were "required to consider feasibility of proposed standards" during their deliberations.<sup>83</sup> Interpreting this to mean not just technical or engineering feasibility, but also feasibility in terms of the costs of meeting these standards, the industry argued that greater emphasis on the economics of change should be critical to any OSHA decision.

Hooker Chemical and Plastics Corporation, which would soon become infamous for the Love Canal disaster in Niagara Falls, New York, also voiced its concerns. Its representative, Raymond J. Abramowitz, stated flatly that "it is the firm opinion of technical experts in our engineering and production departments that we could not continue to operate our plants and contemporaneously meet the proposed OSHA standard of 'no detectable level' of vinyl chloride." To do so would result in the loss of fifty thousand jobs, including both Hooker employees and those using their PVC to produce finished products, he maintained.<sup>84</sup> In sum, the industry believed that it was unfair to impose a "no detectable" limit because there had been no evidence of angiosarcomas at levels of exposure below 50 ppm.<sup>85</sup> For the industry a reasonable compromise would have been to establish a standard somewhere between the industry's and labor's position, "say 25 ppm."<sup>86</sup>

The industry's companies were counting on the likelihood that, despite their reckless deceit, they would still be seen as responsible partners in the decision-making process and that the delay in reporting Maltoni's findings would be viewed as an isolated episode born of the special circumstances of a covenant between the European and American manufacturers. They maintained that the industry had conducted responsible research that the government could rely on for making policy.

But confidence in the industry would be further eroded in the coming years when it was revealed that the industry's own animal studies had been so corrupted as to make them virtually useless. In 1977, the MCA learned that Industrial Bio-Test, the laboratory that had tested the toxicity of vinyl chloride on animals, was being investigated. The EPA and the FDA

had swept through IBT's laboratories, finding conditions so horrendous and confused that no data coming from that lab could be considered reliable. *Chemical Week* described how "the stench of the IBT animal room, known as 'the Swamp,' was so noxious that government inspectors armed themselves with gas masks before entering it." Reporting logs were so unreliable and the control over lab conditions so deplorable that the owners were brought up on criminal charges of fraud and deception.<sup>87</sup>

The MCA's own investigators learned in 1979 that IBT's research on vinyl chloride's effect on rats, mice, and hamsters was so flawed that "the study by IBT is scientifically unacceptable."<sup>88</sup> IBT had "failed to save most tissues as specified in the protocol," had "failed to conduct histopathologic examinations of many of the tissues that were saved," and had failed "to examine sufficient organs from sacrificed animals." Specifically, "90 per cent of the brains of those animals surviving to the most critical period were never examined."<sup>89</sup> The MCA's consultant on the matter concluded that "the study was conducted in an extremely sloppy fashion," such that "foul play by IBT" was a definite possibility.<sup>90</sup>

Four years later *Chemical Week* would report that the serious problems with IBT's methods had not been a result of happenstance but that over the years IBT had "systematically falsified test data collected on scores of drugs and chemicals." One observer the journal quoted called IBT's practices the "'most massive scientific fraud' in American history."<sup>91</sup> How could the government continue to rely on private labs and industry research as part of its system for the development of standards, given this fact? The data that the industry had relied upon which claimed that vinyl chloride did not pose a danger were without scientific legitimacy.

But all this was as yet unknown in 1974 as the industry assured OSHA that its research could be relied on for information about potential problems. Only labor and consumer advocacy groups directly challenged this point of view. A broad coalition of unions, including the United Rubber Workers, the Oil, Chemical and Atomic Workers, and United Steelworkers (the three unions representing the vast majority of the VCM and PVC workers), joined the Industrial Union Department of the AFL-CIO and the International Association of Machinists and Aerospace Workers to argue for the "no-detectable" standard. Rubber Workers union President Peter Bommarito challenged the industry's argument that the country depended upon plastics for its progress. "This country survived for nearly 200 years without polyvinyl chloride and we can survive in the future without it," he began. "If PVC can not be made and used safely, then the proposed standard must be replaced by [a] . . . phase out [of] vinyl chloride production."<sup>92</sup>

Rudy Kaelin, the president of the Rubber Workers local of the Goodrich plant in Kentucky where the first cases of angiosarcoma of the liver had been discovered, said that the workers "knew for a long time that something was wrong, but did not know what, nor who to turn to." As recently as November of the previous year, when the MCA and its member companies already knew of the angiosarcomas in Maltoni's rats, the union had requested medical screenings, particularly of liver function, but had been refused by Goodrich. "We have argued for better ventilation for years with very little results."<sup>93</sup> The president of an OCAW local, Vern Jenson, confirmed Kaelin's opinion that the industry rarely provided workers with information about the chemicals they worked with. The workers believed that they were working with a "totally innocuous" substance. At the least, he said, "someone in our industry should have been sensitive and aware to what experimental findings were going on elsewhere in the world, and that we should have been informed in some manner that we were incurring some degree of hazard."<sup>94</sup>

The OCAW's Tony Mazzocchi went even further in his accusations, arguing that industry's economic arguments were a smokescreen meant to delay the implementation of a "no detectable" standard and minimize the costs of renovation and reform within the industry. "The tactic they have used is to . . . forecast economic disaster and widespread unemployment. It is our hope that OSHA will not succumb to these pressures." When one of the commissioners asked Mazzocchi whether the industry was trying to "con" OSHA, he replied that it was fine "if you wish to use the word *con*."<sup>95</sup> Other union spokespeople observed that "only the perverse or the exceptionally naïve or ignorant think the determination of consensus should simply be one of . . . accepting a given percentage of death and disease at a given so-called feasible limit of exposure."<sup>96</sup>

Other parties also weighed in on what seemed to be a labor-management confrontation over the interpretation of the OSHAct and its mandate. Andrea Hricko and Bertram Cottine, staff assistants in Sidney Wolfe's Health Research Group, made an eloquent argument for a different conception of caution than the one provided by the business community. Waiting for epidemiological proof before improving work conditions or reducing exposure to suspected carcinogens was neither practical from the scientific standpoint nor moral. "Unfortunately, [epidemiological proof] is always retrospective in nature and can only be accumulated after the harmful effects have already manifested themselves." Hricko argued that all new chemicals introduced into the human environment—whether in the workplace or through the distribution of consumer products—should

be tested for their harmful effects before being put into wide use. "Had adequate animal studies to determine carcinogenic effects been conducted when vinyl chloride was first introduced as a chemical, and timely regulatory action taken on the basis of those animal studies, the subsequent human toll of disease could have been prevented."<sup>97</sup>

Cottine amplified Hricko's indictment of the industry's callous cost-benefit analysis, pointing out that the industry wanted to talk only about the economic costs of protecting workers and not about the social costs. By attending only to its own "short ranged financial considerations," the industry conveniently neglected the "cost of disease and death." "The pain and suffering as well as the cost to the exposed worker and his family and the social costs of insurance, hospitalization, treatment and welfare payments cannot be ignored in assessing the economics of an inadequate standard."<sup>98</sup>

Others argued that while the focus of public attention was presently on workers' exposure to vinyl chloride, experience with asbestos showed that "the hazard might not stop at the factory gate but that it might invade workers' homes and the neighborhoods about vinyl chloride, polyvinyl chloride facilities."<sup>99</sup> Hricko added that aerosol propellants were a danger "in the home as well as the occupational setting."<sup>100</sup>

Other union representatives asked OSHA to ensure the safety of workers in the meatpacking industry, where vinyl products were used to wrap meat. When the vinyl wrapping was heated in the packaging process, workers were exposed to vinyl chloride fumes, creating a condition known in the industry as "meat wrappers asthma."<sup>101</sup>

In late August, Irving Selikoff, the elder statesman of occupational medicine, told the Senate's Committee on Commerce Subcommittee on the Dangers of Vinyl Chloride of the growing uneasiness of the occupational and environmental health community with the rapid and uncontrolled growth of the plastics industry. "I believe it fair to say that in the past 20 years we have all been sort of looking out of the corners of our eyes at the petrochemical industry, and particularly the plastics industry," he began. This industry has been "growing rapidly about us and permeating every aspect of our lives." Undoubtedly, "the valuable products and their benefits were obvious." But, he said, "uneasiness existed because we knew very little concerning their biological potential, which remained largely untested and unstudied." The angiosarcoma deaths were a telling indictment of society's consumerism. "We now know that this uneasiness was justified and the lack of study . . . [was] a mistake. The discovery that one of the chemicals central to much of our plastics industry, a simple chemical,

assumed to be benign, was not simple, in biological terms, and surely not benign."<sup>102</sup>

#### THE DEVELOPMENT OF THE PRECAUTIONARY PRINCIPLE

Dr. Irving Selikoff and industry representatives alike recognized that the battle over vinyl chloride was not about the dangers and carcinogenic effects of one substance. Rather, it was what the prestigious business periodical *Fortune* called "the tip of an enormous regulatory iceberg."<sup>103</sup> Coming shortly after the formation of the EPA, NIOSH, OSHA, and the Consumer Product Safety Commission, the storm over vinyl chloride forced regulators, industry, consumer groups, and labor to confront "all the indirect costs of running a modern economy."

Sheldon W. Samuels, the health director of the Industrial Union Department of the AFL-CIO, argued that labor saw the battle as an attempt to put an end to industry's "free ride on social costs." *Fortune* magazine, on the other hand, suggested that it was as important to prevent the death of an industry as it was to prevent workers' deaths: "If government allows workers to be exposed to the gas, some of them may die. If it eliminates all exposure a valuable industry may disappear."<sup>104</sup> Vinyl chloride presented a situation where "medical and economic considerations collide[d] head-on."<sup>105</sup>

Yet it was the language of science, rather than politics or economics, that dominated the debate about the causes of cancer, the means of prevention, and the responsibilities of the government. Consumers, labor, and public health advocates argued that there was no level at which exposure to carcinogens could be presumed effective in preventing cancers. "Advocates of the 'no-detectable level' argued for the so-called 'one-hit' theory of cancer causation," wrote Paul Weaver in *Fortune*, describing the position that there was "no such thing as a risk-free exposure to a carcinogen." The industry, on the other hand, argued that "cancers appear when the immune system breaks down." A healthy immune system had to be weakened before a cancer could develop. Industry held that "what a carcinogen does is to weaken the immune system" and that the "weakening process requires a certain level of dose." According to this interpretation, it was possible that there was "a risk-free level of exposure."<sup>106</sup>

This debate over whether there were safe levels of exposure to vinyl chloride forced the new regulatory agencies to formulate the principles

that would guide government's role in economic, scientific, and political decisions. The argument that played out over vinyl chloride is played out today over all toxic substances.

The vinyl chloride issue brought to the fore the question first raised during the tetraethyl lead controversy a half century before: Should industry be asked to prove that a substance was safe before introducing it into the environment, or should society be forced to prove it dangerous before banning it? Since the tetraethyl lead crisis, industry had largely prevailed in this debate, but vinyl chloride represented a whole new class of chemical products of enormous importance to the chemical industry and, perhaps, society.

Writing in the *Wall Street Journal* in October 1974, Barry Kramer described the stakes. If the labor and consumer advocates' view prevailed, Kramer observed, "industry will no longer be able to assume blithely that untested chemicals . . . are safe simply because they've never demonstrated any overt harm. Like vinyl chloride, which took years to take its toll on worker health, many chemicals thought to be harmless may be equally insidious."<sup>107</sup> The prestigious British medical journal *The Lancet* was optimistic. "Whatever happens the vinyl chloride episode will have provided a salutary lesson," *The Lancet* wrote. "It will not be quite so easy in the future as it has been in the past for any chemical manufacturer to assume, until proved otherwise, that a chemical to which workers are exposed is carcinogenically safe."<sup>108</sup> Kramer quantified the seriousness of the problem, noting that there were twenty-five thousand industrial chemicals already in use and that more than five hundred chemicals were added every year, and virtually none of them had been adequately tested or followed.<sup>109</sup>

On October 4, 1974, OSHA published its "Standard for Exposure to Vinyl Chloride."<sup>110</sup> The *Federal Register* reported that the record in this proceeding was "one of the most exhaustive ever relied upon by OSHA." It had documented that three animal species—rats, mice, and hamsters—developed cancers after exposure to vinyl chloride and that "more tumors occur at higher exposure levels." The finding of cancer in animals met the criteria of the 1970 Surgeon General's Ad Hoc Committee on the Evaluation of Low Levels of Environmental Chemical Carcinogens, which held that "the finding of cancer in two or more animal species may be extrapolated to indicate a carcinogenic hazard to humans." The thirteen documented deaths among vinyl chloride workers from angiosarcoma of the liver, in addition to "evidence of tumor induction in a variety of other organs including lung, kidney, brain and skin as well as non-malignant

alterations, such as fibrosis and connective tissue deterioration indicates additional oncogenic and toxicologic properties of vinyl chloride."<sup>111</sup>

OSHA concluded that there was "little dispute that VC is carcinogenic to man. . . . However, the precise level of exposure that poses a hazard and the question of whether a 'safe' exposure level exists cannot be definitively answered on the record. Nor is it clear to what extent exposures can be feasibly reduced. We cannot wait until indisputable answers to these questions are available, because lives of employees are at stake. . . . These judgments have required a balancing process, in which the overriding consideration has been the protection of employees, even those who may have regular exposure to VC throughout their working lives." OSHA concluded that the permissible exposure limit (PEL) had to be reduced to 1 ppm TWA, which OSHA believed could be reached through engineering controls. OSHA acknowledged industry's worry that this standard would put an especially heavy burden on manufacturers who used PVC to produce plastic products but argued that this standard should apply to every company because "at least some employees in the fabricating industry are exposed in excess of the permissible control limits."<sup>112</sup>

Although it was viewed at the time as a victory for labor, journalist Michael S. Brown argues that OSHA's decision to abandon the "no detectable level" for a 1 ppm standard meant that economic feasibility became "a major consideration in the determination" of other health standards.<sup>113</sup> Since the vinyl standard was set, OSHA has been plagued by the threat of lawsuits from industry groups demanding close attention to economic feasibility, which has resulted in lack of action on numerous substances.<sup>114</sup> (Even the revision of the silicosis standard which was proposed in the mid-1970s has yet to be issued, despite the fact that it has been clear for eighty years that silica dust causes silicosis and despite former Secretary of Labor Robert Reich's urging that silicosis be eliminated as a problem. Witness also that OSHA's abandonment of the recent ergonomic standard in the first months of the Bush administration, despite years of research, planning, and effort, was based on the fact that implementation of the standard would cost too much. Economic feasibility was a readily accepted factor in the consideration of danger.)

OSHA assumed that industry had the technology to enable it to implement the vinyl chloride standard immediately. The industry, however, claimed it would need to immediately reorganize its production and introduce new filtering, cleansing, and protective equipment. New plants would have to be built to replace older plants that could not easily be adapted to new processes.<sup>115</sup> Within a week of the publication of the new standard, the

Society of the Plastics Industries (SPI) met and decided to file a petition challenging the permanent standard in the U.S. Court of Appeals.<sup>116</sup>

It may be that the sense of crisis within the industry was heightened by two unrelated but parallel events. In 1973 the Arab oil embargo had substantially raised prices for crude oil, leading to a substantial rise in production costs for all vinyl chloride products. In addition, a recession in 1974-75 hit the construction industry hard, causing a severe slump in the plastics industry and particularly the producers of PVC. David Doniger writes that this was a particularly difficult time for the industry because business analysts had not predicted the slump and had, in fact, forecast virtually uninterrupted growth for the industry. Coming after an unparalleled boom in PVC consumption in the 1960s and early 1970s, the slump, combined with the challenge posed by OSHA and NIOSH, may have contributed to the intensity with which the industry resisted the government's attempt at regulation.<sup>117</sup> In December 1974, the various legal challenges to OSHA's vinyl chloride standard were consolidated in the Second Circuit.

Despite its public challenge to OSHA, there was little dispute within the plastics industry that vinyl chloride was a real hazard.<sup>118</sup> Joseph Fath, vice president of Tenneco Chemicals and acting chair of the SPI's Vinyl Chloride Monomer and Polyvinyl Chloride Producers Group, put it succinctly when he noted in an internal memo that regarding "vinyl chloride and human health[,] probably not much can be said to mitigate the fact that the two are incompatible." Fath, who had graduated from Cornell University with a B.A. in chemistry in 1944 and had since the mid-1950s been directly involved in the research and development of polyvinyl chloride, argued that the SPI had to develop a new public relations approach that addressed "itself precisely to the separation of the finished consumer good from its chemically derived raw material." He proposed "a program dealing primarily with the merits, benefits, assets and rightful place of PVC products in a modern industrial society. I believe we can easily demonstrate how PVC has benefited all of us in the supply of economical consumer goods, has aided our defense industries in preserving our political system, our communications industry in enabling us to conduct the business of our modern society and has played a key role in assuring us through the plastics industry in particular and the chemical industry in general, of a continued increase in our standard of living."<sup>119</sup>

This effort to convince the public that there was a world of difference between the dangers associated with VCM and the finished products made from polyvinyl chloride called for an intensive public relations campaign. In order to accomplish these objectives, relationships with the press had to

be fostered, even by assisting "reporters, feature writers, etc. [in] preparing stories on vinyl chloride." The SPI's Public Affairs Committee also recommended developing strong ties with a "small body of informed, interested and effective Senators and Congressmen who can and will be ready to become an active support group for the VCM-PVC industry."<sup>120</sup> On December 6, the SPI and the Producers Group approved this proposal, emphasizing the objective of "the differentiation between vinyl chloride and polyvinyl chloride."<sup>121</sup>

The machinations of the industry as it tried to delay and limit the implementation of the OSHA standard through litigation came to a screeching halt in late January 1975 when the U.S. Court of Appeals for the Second Circuit issued its decision regarding the SPI's challenge to the OSHA standard. In a scathing review of the industry's history, Justice Tom Clark, retired from the U.S. Supreme Court, noted the long policy of delay, feigned ignorance, and irresponsibility of the chemical manufacturers. He rejected all the fundamentals of the industry's position, pointing out that while the "fatal character of VCM did not emerge until early in 1974 when the three workers in Goodrich's PVC plant at Louisville were reported, strong warning signals had appeared long before." Clark wrote, "We need not outline in detail the morbid 'Vinyl Chloride Chronology,' . . . in order to illustrate the mounting evidence of VCM's carcinogenicity. Indeed, the record shows what can only be described as a course of continued procrastination on the part of the industry to protect the lives of its employees." Despite years of warnings and research, including studies dating as far back as 1949 and continuing through the acroosteolysis studies by the University of Michigan, "nothing was done." Despite Viola's early studies "the industry did nothing." Months and years went by, but "it was not until February of 1973 that a protocol was agreed upon and a research contract for animal exposure studies signed. Meanwhile, startling results from European experiments were . . . kept confidential."<sup>122</sup>

Justice Clark identified the important regulatory principles that were being worked out around the vinyl chloride crisis. The "ultimate facts" regarding the proper standard for protecting workers were "in dispute" and "on the frontiers of scientific knowledge." Although the "factual finger" points to the need for a low permissible exposure limit, no science could definitively establish it. But "under the command of OSHA, it remains the duty of the Secretary to act to protect the workingman, and to act even in circumstances where existing methodology or research is defi-

cient." Hence, "the Secretary [of Labor], in extrapolating the MCA study's finding from mouse to man, has chosen to reduce the permissible level to the lowest detectable one. We find no error in this respect."<sup>123</sup>

Despite Clark's unambiguous ruling, the SPI Vinyl Chloride Monomer and Polyvinyl Chloride Producers Group decided to proceed with a petition for a writ of certiorari at the U.S. Supreme Court. A stay was denied on March 31, 1975, however, and the 1 ppm standard went into effect on April 1, 1975.<sup>124</sup>

Despite all the objections by the industry, its claims of technical and economic impossibility, its legal challenges and maneuvering to stop the imposition of the standard, companies quickly and efficiently adapted to the new standard. "They offered dire warnings of plant closings, job losses, price increases and massive economic dislocation," the *New York Times* reported. But the predictions may have been nothing more than the industry crying wolf. "One year later," the *Times* noted, "not one of the doomsday predictions has proven accurate." Prices had not increased, supplies of vinyl chloride were plentiful and the industry was actually expanding, not contracting.<sup>125</sup> Engineering controls developed by Goodrich were fully adequate to reduce exposure, the *Times* reported. The initial costs for development, while expensive, could easily be introduced into new plants and retrofitted to older plants as well.<sup>126</sup> A December 2000 analysis of the costs of providing workers with a safe environment confirmed this: in the mid-1970s, OSHA estimated that it would cost industry \$1 billion to comply with the standard while industry estimated it would cost up to \$90 billion. The actual costs, however, in this huge and growing industry were a modest \$278 million.<sup>127</sup>

In 1974-75 researchers documented that the dangers of vinyl chloride monomer were more far reaching than first thought. Findings indicated that vinyl chloride may be mutagenic, as well as carcinogenic.<sup>128</sup> Peter Infante, a young researcher with the Ohio Department of Health, found that women living in three Ohio communities with polyvinyl chloride plants "gave birth to a significantly greater number of children with malformations during the period 1970-1973" than expected.<sup>129</sup> In 1976, a story in the *Wall Street Journal* reported on a CDC study that indicated that vinyl chloride "apparently also causes a higher incidence than normal of miscarriages among workers' wives" as a result of "damage [to] the sperm cells of the worker-husbands." The *Journal* revealed that although the study had been presented several months earlier at a scientific meeting in Czechoslovakia, it had not been released in the United States "until

Ralph Nader's Health Research Group demanded a copy from the U.S. government under the Freedom of Information Act.<sup>130</sup>

The response of most companies to the possible teratogenic impact of vinyl chloride was to prohibit women of childbearing years from working in the areas of the plant where workers were exposed to chlorinated organics, lead, or mercury. H. B. Lovejoy, a company physician at a Pittsburgh Paint and Glass plant in Lake Charles, Louisiana, reported that he was "surprised and disturbed" to learn at the Health and Toxicology Committee meeting of the Chlorine Institute, a group of companies that used chlorine chemistry, that PPG was alone in "permitting women of child bearing ability" to work in those areas of the plant. Despite his conviction that PPG protected its workers from undue exposure to VCM, lead, and mercury, "the possibility of unexpected exposure remains" and that PPG should follow the example of the other companies "until such time as the courts or EEO [Equal Employment Opportunity Commission] say we must" permit them to work.<sup>131</sup>

In 1980, the trade press reported on more studies indicating the mutagenic effects of vinyl chloride monomer. Although *Chemical & Engineering News* quoted an evaluation by a Columbia University statistician that "the question of whether vinyl chloride is a reproductive hazard has not yet been answered,"<sup>132</sup> evidence mounted in the 1980s confirming various aspects of Peter Infante's observation about the deleterious effects of vinyl chloride among community residents. Joseph Wagoner, formerly of NIOSH but then working as an independent consulting epidemiologist, published a broad review of the "toxicity of vinyl chloride" in 1983. Citing a number of studies of individuals close to polyvinyl chloride plants who developed angiosarcomas of the liver, he concluded that "these study findings are supportive of the role of indirect modes of vinyl chloride exposure in the etiology of liver angiosarcoma."<sup>133</sup>

With the decision of the U.S. Court of Appeals in January 1975, the business community feared that its longtime domination of the industrial hygiene arena had suffered a great change. Vinyl chloride had come to symbolize "the manner in which the initiative passed out of the hands of industry," seized by what *Fortune* magazine would describe as "a loose but not uncoordinated network of regulatory agencies, government research institutes, academic medical teams, labor unions, and other groups united by a common commitment to eradicate environmental causes of disease." This network, which *Fortune* disparagingly dubbed the "regulatory-medical complex," had evolved as a result of the social movements

of the 1960s and the new regulatory agencies that had arisen in their wake.<sup>134</sup>

Industry and OSHA each learned important lessons from the vinyl crisis about the process of regulating toxic substances. Industry learned that it needed to follow OSHA's activities ever so closely, combating the agency at every turn. OSHA's lesson was the rather dispiriting recognition that an industry could be expected to fight standards tooth and nail, to question the validity of all unfavorable scientific evidence, to mount massive public relations campaigns, and to sue OSHA whenever necessary. After 1980, rather than becoming more determined to maintain control, an intimidated OSHA tried to avoid conflict by moving slowly, usually at a snail's pace. OSHA's hope was that by careful review and compromise it might forestall industry's opposition and/or prevent the kind of exhausting process the industry had dragged OSHA through concerning the vinyl chloride standard. In the end, however, OSHA virtually retreated from its original mission of establishing a safe and healthful workplace.

OSHA's reputation as an activist agency stems almost completely from its activities in regard to a few substances and the brief period when Dr. Eula Bingham was at its head. Right after its establishment, OSHA produced standards for asbestos and thirteen carcinogens. During Dr. Eula Bingham's tenure as assistant secretary for OSHA during the Carter administration in the late 1970s, the agency added standards for acrylonitrile (another ingredient in many plastics), arsenic, cotton dust, lead, and benzene, the benzene standard ultimately suspended by the Supreme Court. But this was a tiny fraction of the number of standards recommended to OSHA by its sister agency, NIOSH.<sup>135</sup>

The gutting of OSHA was accomplished in part by industry's victory on the benzene standard. In the first decade of its existence, OSHA had set the lowest possible level of exposure for a chemical if it had qualitative evidence that the chemical had the potential to cause cancer. But the Supreme Court overturned the OSHA standard for benzene in *Industrial Union Department vs. American Petroleum Institute* (July 2, 1980) on the grounds that OSHA had not provided quantitative evidence that there would be a "significant risk of material health impairment" if the old standard of 10 ppm were not reduced to the agency's proposed 1 ppm. As a result OSHA and other government agencies were forced "to develop quantitative information on risks to human health before setting a standard." In the words of Justice Thurgood Marshall in his dissent in the benzene case, this placed "the burden of medical uncertainty squarely on the shoulders of the American worker."<sup>136</sup>

By 1981 NIOSH had recommended over two hundred fifty standards but OSHA had acted on only twenty-one of them.<sup>137</sup> The Reagan years saw a virtual cessation in OSHA's standard-setting and regulatory activities, as a hostile administration and a newly emboldened industrial community threatened suits and noncompliance. This pattern of inactivity based upon the fear of litigation from industry and the lack of support from Congress and the executive branch was reversed briefly during the early years of the Clinton administration. But even then OSHA focused most of its energies on preparing one major standard—for ergonomics—that Clinton approved just before he left office. Within weeks of George W. Bush's assuming residence in the White House, Congress abolished the only significant standard OSHA had established in over a decade.

#### EPIDEMIOLOGY OF VINYL CHLORIDE

When it became clear in 1973 that vinyl chloride was an animal carcinogen, the MCA contracted with Tabershaw-Cooper Associates to conduct epidemiological studies of the industry's workforce. While over the years there had been many problems with collecting data from member companies and other methodological problems, as early as 1974 bad news began to emerge from these studies. Tabershaw-Cooper submitted what it called its "Final Report," dated April 15, 1974, to the MCA, but the report ended up in the files of the MCA renamed "draft." On every page the words "Final Report" were crossed out and replaced by "draft."

The first results indicated "a measurable excess of digestive cancers, especially liver, respiratory cancers and other unspecified cancers in which brain cancer predominated."<sup>138</sup> The revised "Final Report," which was dated May 3, was substantially less pointed than the first. Despite the findings reported earlier, the report emphasized that the increased mortality and cancer rates among vinyl chloride workers were not statistically significant<sup>139</sup> and even below the national average for males in the appropriate age group. The "Final Report" told the industry that "overall mortality [of workers in the vinyl industry] was approximately 75 percent of what would be expected in a comparable population of U.S. males." Further, "no cause of death showed a statistically significant excess over what would be expected in a comparable U.S. male population."<sup>140</sup>

The *MCA News*, the trade association's newsletter, trumpeted the lack of statistical significance in a page-one headline: "Study Shows Death Rate Average for VC Workers." Its lead paragraph told readers, "The findings of

a survey contracted by MCA show that vinyl chloride workers, in the aggregate, experience death rates from all causes that compare favorably with other U.S. male industrial workers." What was a warning and a matter of concern in the first "Final Report" had become a favorable finding a month later. The newsletter also reported that there appeared to be a dose-related increase in cancer rates at other sites than the liver, such as urinary organs and the brain.<sup>141</sup>

Epidemiologists from NIOSH who studied the report questioned its rosy conclusions. "The greatest limitation in this study," one epidemiologist observed, "is that some of the deficiencies [such as the omission of some workers with the longest exposure to VCM] tend to increase the number of expected deaths, and to decrease the number of observed deaths." This epidemiologist concluded that even "the information that they have provided is certainly not information that can reassure us on the question of carcinogenicity of vinyl chloride."<sup>142</sup>

In August, Tabershaw-Cooper Associates reported its results in the *Journal of Occupational Medicine*. The study, which looked at 8,384 men who had worked with vinyl chloride for at least one year, "demonstrated that cancers of the digestive system (primarily angiosarcoma), respiratory system, brain, and cancers of unknown site, as well as lymphomas, occurred more often than expected in those members of the study population with the greatest estimated exposure." While the article proclaimed that "this [was] the first epidemiological study which suggests that in humans vinyl chloride may also be associated with cancer of multiple sites," the authors tried to soften the blow by reiterating claims from previous reports that "the overall mortality of the study population was approximately 75% of what would be expected in a comparable population of U.S. males" and that "no cause of death showed a statistically significant excess over what would be expected in a comparable U.S. male population."<sup>143</sup>

Dr. Joseph Wagoner, director of field studies and clinical investigations for NIOSH and the Centers for Disease Control, was damning in his analysis of the Tabershaw-Cooper methodology. Although 75 percent of those exposed to vinyl chloride for twenty years or longer could not be found,<sup>144</sup> Wagoner had identified 930 white male vinyl chloride workers who had begun their careers between 1950 and 1973. He told the U.S. Senate Committee on Commerce's Sub-Committee on the Environment that there was a "57 percent increase in deaths due to cancer, beyond what would have been expected" among vinyl chloride workers, a difference

that was "highly significant." Further, he called into question the epidemiological data of the MCA-sponsored study conducted by Tabershaw-Cooper.<sup>145</sup> "The overall mortality risk is at variance with an earlier reported industry wide study of vinyl chloride employees which showed a deficit in total mortality," he maintained. Wagoner attributed Tabershaw-Cooper's findings to a possible flaw in its research design: the study included a "disproportionate number of recently hired employees," who presumably diluted the measurement of harm.<sup>146</sup> In his study, Wagoner's delimiting criterion was that the workers "had to be engaged in the polymerization for 15 or more years, since we knew indeed that we were looking for the latent effects or the effects of a carcinogen which would appear many years after a person was initially employed."<sup>147</sup> He had corrected for this by excluding from his analysis the "first five or 10 years after a person comes into employment."<sup>148</sup>

While the industry sought to focus attention on its success in attacking the problem of angiosarcoma of the liver among its workers, its own epidemiological studies confirmed the research of others, finding cancers at other sites on the body in workers exposed to vinyl chloride. The MCA's initial epidemiological study by Tabershaw-Cooper Associates had found an excess of brain cancer deaths among vinyl chloride workers, and a supplementary study commissioned by the MCA found similar results.<sup>149</sup> A retrospective cohort study published a year later, in 1976, by researchers at NIOSH found "an excessive number of deaths due to cancer . . . [of] the liver, lung, and the lymphatic and central nervous system."<sup>150</sup> In early 1979 an employee at Union Carbide's plant in Texas City, Texas, filed a complaint with OSHA based on his observation that too many of the plant's workers were developing brain tumors. Newspapers picked up the story, reporting that this plant had "an unusually high number of workers [who] . . . died of a type of brain tumor that has been linked to the cancer-causing agent, vinyl chloride."<sup>151</sup>

In an internal memo, Robert Wheeler of Union Carbide confided to a fellow Union Carbide physician that the company "appears to have an excess incidence of brain tumors at Texas City and at South Charleston [West Virginia]," but he doubted that it was due to vinyl chloride. Union Carbide was not as frank with its own employees, writing that it did "not yet have sufficient data to answer" the question of whether there was a "higher than normal incidence of brain tumors."<sup>152</sup> It appeared that of the 454 workers for whom there were death certificates on file, 110 had died of a variety of cancers, of which 11 were probably primary brain tumors.<sup>153</sup>

Officials of other companies acknowledged privately the legitimacy of the workers' fears.<sup>154</sup> Conoco's F. C. Dehn wrote privately that "several epidemiological studies . . . have shown higher incidences of brain cancer when VCM is exposed. . . . There have been warnings of this type based on some animal studies, too."<sup>155</sup> PPG responded in much the same way it had when acroosteolysis was a problem: the company sought ways to survey workers without raising their consciousness about the cancer hazard. A suggestion that workers be sent a letter to their homes was rejected because it "would be overly inflammatory," especially in light of the "start of [labor] negotiations which will be very much concerned in part with safety and health."<sup>156</sup>

A two-day conference at the National Institutes of Health in the early spring of 1980 brought together thirty-five scientists who were involved in vinyl chloride research. Maltoni's continuing work on animals corroborated the fears of those who suspected that vinyl chloride was a multipotent carcinogen. Peter Infante summarized epidemiological studies that "taken together . . . indicate an even greater incidence of brain cancers than liver cancers among workers exposed to vinyl chloride."<sup>157</sup>

In late 1980, the MCA's VCM Research Coordinators Task Group discussed a possible update of the Tabershaw-Cooper epidemiological study in order to "gain information to help in future law suits."<sup>158</sup> This update, done by Environmental Health Associates (EHA) for the MCA, found that "vinyl chloride workers experienced significant mortality excesses in angiosarcomas (15 deaths), cancer of the liver and biliary tract . . . and cancer of the brain and other central nervous system [parts]."<sup>159</sup> By 1987, review articles accepted the possibility that brain cancers, even among children, could be associated with vinyl chloride exposure.<sup>160</sup> Even industry representatives recognized the connection. In a private memo to Conoco's legal department, W. D. Broddle, the company's director of toxicology, wrote that vinyl chloride had "some tendency to cause cancer of the brain, lung, breast and digestive tract."<sup>161</sup>

In 1991, Otto Wong, the chief researcher in the EHA study, went public with his findings, publishing an article based upon his research. He reasserted the "significant mortality excesses" in angiosarcomas, cancers of the liver and biliary tract, and cancer of the brain and other parts of the central nervous system.<sup>162</sup> The industry reacted strongly to what it perceived as Wong's violation of trust, since it had funded his research. A Goodrich manager complained to the Vinyl Institute that Wong had failed to send a draft of his paper to the MCA "for review prior to publication"

and had thereby "violated their contract." He hoped that "the authors will be agreeable to add some clarifying comments in a letter to the editor."<sup>163</sup>

In a conference call among members of the MCA's Vinyl Chloride Panel, the MCA discussed how to respond. It appears that members did reach Wong, for in one of the most curious cases of "self-correction" Wong wrote a letter to the journal's editor, Philip Landrigan, retracting some of his most devastating findings and concluding that his own interpretation of the data rejected a connection between the excess brain cancer deaths and vinyl chloride exposure.<sup>164</sup> Landrigan had no idea at the time of the intense pressure that Wong was under to retract his findings. After all, Wong's "methodology was very standard," noted Landrigan in an interview with Bill Moyers. "The findings were very believable, and the retraction was really quite unexpected." Reflecting on this incident and on industry-sponsored lead research, Landrigan observed that most people "don't understand that science can be bought and paid for."<sup>165</sup>

By 1991 management had lost credibility among workers in the vinyl industry. Workers were no longer willing to accept the industry's assurances that it could be relied upon to protect their health, let alone that the industry should be the final arbiter of what was to be deemed safe in the workplace. Despite all the evidence to the contrary, the industry maintained a public stance that vinyl posed no risk, either to the workforce or to the broader community. Workers worried that the workplace was getting more and more dangerous and that the materials they worked with, vinyl chloride monomer and ethylene dichloride, were responsible for "high rates of employee deaths due to cancer."<sup>166</sup>

Workers at the Vista plant in Lake Charles, Louisiana, called the presentations by management and medical staff explaining the deaths of five employees from cancer "a snow job, bull shit." Questions from the workers were not only left unanswered but the workers also were told "to shut up and not make trouble." The workers pleaded with the company to pay attention. "We like our jobs. We like Vista; it's a good company and it pays well, but we don't want to die. We think our jobs are killing us. No one listens." In the end the workers came to feel that management just didn't care; they didn't see the workers as people. "We're just a social security number. If we die, they'll just get some other sucker to take our place. They're afraid of the liability but we just want some answers."<sup>167</sup>

It seems that even four years later the Vista workers were still not being heard. One company official wrote, "Study after study has confirmed there

is no evidence that vinyl affects human health—not for workers in the industry, not for people living near vinyl-related manufacturing facilities, not for those who use the hundreds of vinyl consumer and industrial products."<sup>168</sup> The skepticism of the workforce was just one indication of the battering that had taken its toll on the chemical industry.<sup>169</sup>

But even as the industry came under increasing scrutiny in the early 1970s, it did manage to develop a variety of tactics to undercut OSHA and the EPA. The industry argued over what constituted good science, shifted the debate from health to economic costs, challenged all statements considered damaging to industry, and lied about what was known about the cancer-causing potential of vinyl chloride. These arguments about adverse effects of regulation on industry were all the more salient in the mid- to late 1970s, when the country entered a period of economic stagnation, high inflation, and energy shortages. At this point business began to recruit academics for scholarly justifications for its positions. Data from think tanks and academic institutes funded by industry were used to counter the champions of greater regulation. In the 1970s, for "every horror story about corporate irresponsibility that had circulated at the beginning of the decade, by its end there was a matching horror story about the shortcomings of government regulation."<sup>170</sup> Even the most principled and vigorous government officials were stymied. While Eula Bingham's tenure as assistant secretary of OSHA was a brief moment of regulatory activism, the vinyl crisis and the broader business onslaught instilled a long-lasting culture of fear within OSHA.

The industry had come a long way over the past decade, developing sophisticated means to influence government policies. But industry leaders still longed for the earlier era when they had much greater power. As the MCA's Government Relations Committee pointed out, in the not-so-distant past the business community was "listened to with considerable attention by those members of Congress that wore either a Republican or Southern Democrat label." But now, "business is not as influential in Washington as we would like" nor was it able to protect the varied interests of "private enterprise . . . in this country."

How did this situation come to pass? asked the committee. First and foremost the country had been fundamentally shaken and democratized by the civil rights movement, which brought the nation's attention to the plight of the powerless and to the unequal distribution of power in the corridors of Congress. In the late 1950s, Southern Democrats who controlled the chairmanships of important committees could easily promote or divert

legislation of interest to the industry, recalled Don Goodall, the committee chairman. "But that day went out with the one-man, one-vote drive that took place more than a decade ago, and for a variety of other reasons."<sup>171</sup> By the late 1960s and early 1970s, in addition to the gains brought by the civil rights movement, labor was better organized. Television informed the public about environmental and industrial issues in ways not previously available. In addition, "the wide exposure TV gives to candidates tends to open up the selection process," leading to greater discussion of political issues. Finally, the committee pointed out, public interest groups used the media to gain the public's attention to a degree never attained before. These changes left business grappling with how to regain the initiative in setting policy.<sup>172</sup>

Toward this end, business began to look for the next generation of chief executive officers in their legal and public relations departments—executives who spoke the language of lobbyists and politicians and who were prepared to shape the regulatory climate. One survey of CEOs revealed that the amount of time they devoted to "public issues" had doubled between 1976 and 1978. Irving Shapiro, chosen as CEO of DuPont in 1974 because of his skills in government relations, was the first head of DuPont with no background in engineering, science, or finance. He was the epitome of the "modern business leader," with "one foot in the boardroom and the other in Washington."<sup>173</sup>

In fact, the CEOs of the two hundred largest U.S. corporations got together in 1972 to form the Business Roundtable, which, according to *Fortune*, "was the biggest and baddest lobbying group in Washington." Called the "Green Berets of business influence," the Roundtable "helped defeat a slew of pro-labor laws" and government regulatory actions in the 1970s.<sup>174</sup> In view of the new political environment, it was difficult for environmental, consumer, and labor advocates to fashion an effective opposition to industry's closed ranks. Each new federal action became the focus of intense, acrimonious, and divisive discourse as conservative and business groups framed every issue as a battle over America's future. Advocacy groups were faced by a wall of intense resistance and were forced to decide between competing strategies of political reform. Should they be content with occasional small victories in legislative arenas, particularly in light of the rolling back of earlier legislation and regulation? Or should consumer groups set their sights on grand goals of the sort that bear fruit only over time?

Future battles over regulation of the chemical industry would come from newer, less institutionally predictable community groups that could

not as easily be manipulated by industry's lobbyists, lawyers, and political action committee money. In the 1980s and 1990s the struggle would be waged between the chemical industry and the drastically refigured and politically empowered constituencies of the labor and civil rights movements, environmentalists, and a core of professionals who came of age in the activist 1960s and were trained in the post-NIOSH, post-OSHA era.