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REGULATORY STATUS OF POLYVINYL CHLORIDE, 1980

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Abstract - The regulatory history of Vinyl Chloride and Polyvinyl Chloride, particularly at the Occupational Safety and Health Administration, the Food and Drug Administration, and the Environmental Protection Agency, is reviewed in detail. It is evaluated in terms of perceptions of the soundness of governmental actions and also as an example of responsible industry achievement. Despite constant reevaluation by the involved agencies, the urgency that initially characterized their actions regarding vinyl chloride has been tempered by continuing improvements in monomer management and recently maturing concepts of risk assessment. The most valuable benefit to flow from the vinyl chloride experience may well be its influence in focusing attention on the need for more objective risk assessment as an accepted basis for all regulatory decision-making.

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Many have waxed eloquently on the vinyl chloride (VCM) and polyvinyl chloride (PVC) sagas. Depending on their disciplines, motivation and timing, some have given the problem the kind of treatment designed to conjure up the image of the industrial holocaust of this century; others have used the handling of it as a model for diagnosis and corrective achievement in the "era of environmentalism." In short, you can find support for theorizing that the vinyl chloride regulatory story is the Last Supper, or "Chock Full of Nuts."

As usual, the truth lies somewhere in between, and the telling of it might well test the powers of a Tacitus or Toynbee. I have no such powers. My qualifications to retell the story are the same as those given by Talleyrand who replied when asked what he contributed to the French Revolution: "I lived through it." To this famous Frenchman's succinct response I must add "so far."

It is never accurate to break history into parts since events overlap, chronologically and dynamically. Nevertheless, the practice is time honored; it is also the approach least likely to add confusion to this discussion. Hence, please bear with me while I divide my tale into three chapters of regulatory history--the Occupational Safety and Health Administration (OSHA), Food and Drug Administration (FDA), and Environmental Protection Agency (EPA) PVC and VCM stories (Note a). All three areas have a begin-

Note a: Since we have no shortage of regulatory coverage at this time in our history, I note in passing that other agencies have also played some role in the vinyl chloride exercise. For example, in early 1974, the Consumer Product Safety Commission, as well as FDA and EPA, banned the already-outmoded use of vinyl chloride as an aerosol propellant. As with CPSC, I will only footnote the fact that the Departments of Transportation (DOT) and Housing and Urban Development, as well as many state legislative and other bodies, have at one time or another played roles on the VCM regulatory scene. The actions were necessary on occasion (e.g., DOT warning requirements). On others, this is questionable. For the purposes of this paper, little or no further mention will be made of these related activities since I think it fair to say that all amounted to "fall-out" from the more essential situations covered here.

ning, more or less well-defined. None of them has an end as yet, but then this is America in the last half of the Twentieth Century. It is a time when agencies issue documents with self-contradicting designations like interim final regulations, or temporary permanent standard. Keeping doors open in this peculiar way means few regulatory issues ever appear to be laid to rest.

The first regulatory crisis directly impacting the PVC marketplace came as a result of an FDA proposal after the surprising finding by Schenley Distillers that VCM was leaching into alcoholic beverages from polyvinyl chloride liquor bottles. This 1973 revelation, however, concerned a limited market. It gained nowhere near the media and consumerist attention that came in 1974 when OSHA focused its attention on vinyl chloride after an alert industry physician called attention to his uncovering of an unsuspected occupational health problem.

Somewhat arbitrarily, then, let's reexamine the OSHA experience following the principle that what the media finds most worthy of its attention gets the public's attention and thus must always be dealt with first. Next, I will review the current status of things at FDA, where the impact of regulatory reaction and inaction is still being felt strongly. Finally, I will do my best to tell you about the prologue for the present state of affairs at the Environmental Protection Agency (EPA).

As with many raw materials used in the production of safe and useful finished products, VCM, the essential building block for PVC, had long been known to cause side effects experienced by workers exposed to high concentrations. At extremely high levels, it exhibits a narcotic effect. Knowing what we do today, it is ironic that the medical profession used VCM as an anesthetic, halting this practice when the gas was found to cause heart arrhythmia (Ref. 1). At the high levels, vinyl chloride also presents a flammability and explosion risk, readily handled through careful monitoring and use of control technology.

Through the 1960s, although exposure to moderate concentrations of vinyl chloride was thought to be innocuous, it was discovered that exposure occasionally led to acroosteolysis, a reversible disease characterized by a softening or flattening of the bones in the fingertips (Ref. 2). The disease occurred among heavily-exposed PVC reactor cleaners and could be eliminated by appropriate industrial hygiene measures.

Although a relationship between vinyl chloride and cancer was first documented in studies by Viola in 1970, his findings went virtually unnoticed. Neither government, industry nor labor saw a need to take action because the Viola tests with laboratory rats had been conducted at unrealistically high atmospheric dose levels. They actually bordered on the lower explosion limit of VCM (Ref. 3).

Heads did start turning, however, when in January, 1974, Dr. Maury Johnson of the B.F. Goodrich Company identified three cases of angiosarcoma, a rare type of liver cancer, among PVC employees who had worked as reactor cleaners (Ref. 4). Suspecting VCM as the responsible agent in these three deaths, the company made a public announcement to this effect which attracted wide attention in the press and immediately brought OSHA into the picture. An extensive search by industry through old medical records ultimately confirmed thirteen angiosarcoma deaths of workers exposed to VCM in four U.S. plants (Ref. 5).

These findings prompted those like Dr. Irving Selikoff of Mt. Sinai Hospital in New York; and later Health, Education and Welfare (HEW) Secretary Joseph Califano, as well as many OSHA and organized labor leaders to predict an epidemic of environmentally-caused cancer as a result of worker exposure to vinyl chloride. Their ominous predictions that PVC was a virtual time bomb, certain to leave a trail of fatalities in its wake, have since proven as hyperbolic as industry immediately protested when the rhetoric was flowing with great impact. Now, some six years after the first of these predictions, and almost three years after Secretary

Califano's apocalyptic 1978 pronouncements (Ref. 6), there is no evidence of any excessive number of cases of angiosarcoma among workers in the vinyl chloride industry. Part of the explanation may lie in changes in industry practices and standards but we feel strongly that the predictions were ungrounded, if not irresponsible, when they were made.

At the time of Goodrich's announcement, the standard for occupational exposure to vinyl chloride was already down to 500 parts per million (ppm) whereas in earlier years levels may have been as high as 4,000 ppm. The 500 ppm exposure ceiling had been adopted on the basis of recommendations from the American conference of Governmental Industrial Hygienists (ACGIH). In 1962, it had chosen that level as an appropriate standard after careful review of all then-existing data (Ref. 7).

OSHA's Emergency Temporary Standard, promulgated in response to information presented during the fact-finding hearings held in February of 1974, lowered the maximum VCM exposure limits to 50 ppm (Ref. 8). This ten-fold reduction was based primarily on studies conducted by Dr. Cesare Maltoni of Bologna, Italy, showing that rats exposed to vinyl chloride developed liver cancer at levels above 50 ppm. Shortly thereafter, however, additional animal data from Industrial Biotest Laboratories indicated that angiosarcomas could in fact be induced in laboratory animals at 50 ppm. As a result, OSHA proposed a permanent "non-detectable" standard for occupational exposure to vinyl chloride prescribing use of an analytical method capable of measuring concentrations at least as low as 1 ppm. The standard further provided that, until such time as engineering controls capable of meeting the standard became available, air line respirator equipment would have to be worn when vinyl chloride concentrations exceeded the "non-detectable" level (Ref. 9).

By approaching the vinyl chloride problem in this manner, OSHA was charged with threatening to close down the entire VCM and PVC industry. Since the "zero" exposure limitations were technologically beyond known compliance capabilities, this limitation could only have been achieved by the full-time use of air line respirators which, were it possible, would involve a different but perhaps equivalent risk of injury to workers. As was stated in one of the briefs filed in the case:

That the use of respiratory equipment can lead directly to severe injury is almost self-evident. This is particularly true where such equipment must be employed in complex industrial manufacturing establishments. As a representative of Tenneco pointed out during the course of the OSHA Hearing, workers burdened with bulky breathing equipment or trailing long hoses can find themselves in serious jeopardy in a vinyl chloride facility which, typically, is a "multi-story operation /with/ many catwalks or narrow passageways, stairwells, /and/ moving machinery." Tenneco's representative had reason for being particularly impressed with the hazards involved for he was aware that his company had had at least one employee fatality which occurred when a worker wearing breathing apparatus connected to a lengthy air hose fell from a ladder due to the cumbersome nature of the respiratory equipment. (Ref. 10).

The atmosphere during the required proceedings to bring about adoption of the permanent VCM standard was highly charged. It was made more so by the media coverage which tended to heighten extravagantly hostile exchanges between labor and industry leaders. Labor and self-appointed environmentalist representatives were convinced that industry had an "in" with the Agency. Industry was sure that the case was prejudged and was incensed when the TV cameras and lay press reporters stayed around at

the hearings only while labor leaders spoke their pieces. Accusations of collusion and cover-ups flew like feathers before a fan.

Any suspicions about possible collusion between industry and OSHA were no doubt dispelled on October 1, 1974, when the permanent regulation setting a standard for maximum permissible exposure of 1 ppm (time weighted average, TWA) was signed by then Assistant Secretary of Labor for Occupational Safety and Health, John Stender (Ref. 11). Just the night before, the Washington rumor mill had the magic level pegged at a likely 10 ppm, the lowest industry said it could live with.

The regulations finally promulgated by OSHA were, nevertheless, substantially different from those originally proposed. Firstly, OSHA changed from a "non-detectable" to a 1 ppm exposure level for vinyl chloride. This brought the standard into the realm of technological feasibility, albeit the technology would have to be forced; some plants would ultimately be closed; and industry would have to surprise itself on how low it could go. Secondly, a major immediate compliance difficulty was eliminated when OSHA agreed to allow the use of cartridge gas masks rather than the cumbersome air line respirators initially proposed. But for these seemingly minor yet critically significant changes, the industry might have had to shut down as its spokesmen had predicted. As it turned out, the VCM and PVC producers turned a potential nightmare into what Dr. Irving J. Selikoff, then a thorn in industry's side, now refers to as one of industry's greatest success stories.

Although our unsuccessful challenge of the final standard in the courts was anything but amusing at the time, in retrospect it had its ironic aspects so I thought I would tell you part of the story.

In the period leading up to the formal announcement of the VCM standard by OSHA, industry had no prior knowledge as to what permissible exposure level would be selected. In fact, as I mentioned earlier, the night before OSHA's press conference to announce its decision, the Agency was rumored to be planning to adopt the 10 ppm time weighted average level, apparently unsure about the need for the much more stringent 1 ppm standard that was ultimately set.

There simply was no way to know or foresee how the Agency would make up its mind, except that it seemed clear it was probably going to have to make its decision on political grounds, not on need or feasibility. Thus, our only sensible course was to prepare a Petition for Review and stand ready to engage in a "race to the courthouse steps." We knew we would have to go "forum shopping" and pick a court because, under the Occupational Safety and Health Act appeal procedures, the party who files the first notice of appeal gets the United States Circuit Court of its choice. (Where suits challenging the same regulation are filed in more than one United States Circuit Court, all suits must be transferred to the circuit in which the appeal "was first instituted.") Our aim, of course, was to try to get our case before one of the Courts of Appeals that might be expected to interest itself in the complexities of such a matter.

Applying these concepts and objectives to the VCM rule making, the strategy we decided upon was to file our appeal--actually a Petition for Review of the final standard--in New York City in the United States Court of Appeals for the Second Circuit. Why this court? Simply because, in a previous decision, its Chief Judge had indicated at least some willingness to scrutinize OSHA decisions with enough care to reverse an unreasonable one, i.e., one which called for the use of more precautionary measures than seemed necessary or feasible.

We succeeded in securing the Second Circuit as a forum, but our luck ran out there. In what I believe may have been an unprecedented occurrence, every one of the thirteen judges of the Second Circuit disqualified himself from hearing the case, presumably because all of them had some remote financial interest (stock or bond ownership, probably) in one of the multitude of companies in the proceeding. After every judge of the court declared himself unable to hear the case, in accordance with the federal and court rules, retired Supreme Court Justice Tom Clark was appointed to preside with two District Court Judges completing the usual three-man panel.

In my opinion, Justice Clark did not even consider some of the statutory or other important legal issues ruled on later in cases like this year's Supreme Court decision on benzene. He was emotionally unable to get past the conceded fact that thirteen workers had by then died from liver cancer caused by occupational exposure to vinyl chloride. The late Justice turned a deaf ear to industry's point that these fatalities were the result of long-ago high exposure levels, since significantly reduced; gave short shrift to the other positions so arduously advanced; and, in his opinion for the court, denied our Petition for Review of the standard. In so doing, the Second Circuit declared that OSHA was not to be fettered by the limitations of existing technology but was well within its authority to adopt technology-forcing standards (Ref. 12). This ruling shook and continues to haunt the industrial community. Even so, it was not enough to induce the Supreme Court to take the case (Ref. 13).

Basically, this is where we stand today except that the PVC industry is again under investigation by some in OSHA. On December 18, 1979, the Agency published a notice requesting the latest information on the health effects of vinyl chloride and adding a new inquiry into alleged possible effects of polyvinyl chloride dust (Ref. 14). A conference was held in connection with OSHA's request for information in March of this year. We consider it fair to say that no data not previously known to government and industry were presented at the sessions. We are, therefore, hopeful that the Agency's latest expressions of concern will be resolved without further regulatory action. This remains to be seen and no one in the industry is taking anything for granted.

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Turning to the FDA front, our story goes back to 1968 when the Department of Treasury's Bureau of Alcohol, Tobacco and Firearms (BATF) began an industry urged program to test the suitability of using PVC containers for alcoholic beverages by allowing selected sizes to be marketed on an experimental basis (Ref. 15). This temporary authority to package distilled spirits in polyvinyl chloride was extended annually through a series of BATF circulars. During this time industry worked closely with the Bureau looking towards obtaining permanent regulatory authority to allow appropriate use of PVC packaging.

The effort to remove the "experimental" tag met its most unexpected first challenge when, in 1971, the Treasury Department decided that allowing full-scale marketing of PVC liquor bottles would be a "major federal action significantly affecting the quality of the human environment," thus requiring preparation of an Environmental Impact Statement (EIS) in accordance with the National Environmental Policy Act of 1969, commonly referred to as "NEPA." Without belaboring the details, the final Environmental Impact Statement issued by BATF in 1973 was very favorable to PVC manufacturers. Based in large part on a study conducted by an independent consulting group (Baillie Associates), the Impact Statement concluded that PVC bottles are less energy intensive to produce than their glass counterparts. The EIS endorsed approval of PVC as a suitable container for use with distilled spirits (Ref. 16).

With this hurdle out of the way, the road seemed clear for PVC liquor bottles. A stamp of approval here would also result in an increase in PVC's share of many processed food packaging markets where clear containers with good water vapor barrier properties were needed. Any authorization from BATF was always contingent upon satisfying FDA criteria for food safety, however, and suddenly another much more significant, and wholly unexpected problem arose.

About the same time BATF was finalizing its environmental assessment of PVC liquor bottles, representatives of Schenley Distillers, Inc. were discovering that trace amounts of vinyl chloride were migrating from PVC bottles into distilled alcoholic beverages, such as vodka and gin. Most scientists were taken completely by surprise by this discovery because VCM is a gas at ten to fifteen degrees below zero degrees centigrade. Hence, it was reasonably assumed that finding monomer in any foodstuff, much less a liquid, was not very likely.

Nonetheless, FDA and others subsequently confirmed the Schenley findings. It then advised BATF that it would be issuing a proposed regulation which, if finalized, would prohibit the packaging of alcoholic beverages in PVC bottles (Ref. 17).

BATF's reaction was immediate--some have said precipitous. In deference to FDA, the Bureau terminated experimental use of PVC packaging for distilled spirits on May 11, 1973 (Ref. 18).

FDA's 1973 proposal would have precluded the use of PVC resin for packaging alcoholic beverages while permitting the continued use of other rigid and semirigid PVC articles. On the basis of data generated from the OSHA proceedings concerning the toxic effects of exposure to vinyl chloride, FDA broadened its proposal in 1975 and thereby indicated an intent to ban all rigid and semirigid PVC products, while allowing continued use of thin film and coatings or closure liners (Ref. 19).

The Agency has never finalized its 1975 proposal. I think it fair to say that the reason its proposal remains just that, and is unlikely to become law, is because the problem of migration of residual VCM which resulted in the BATF liquor bottle ban in 1973 has been resolved. Continuous refinements in production techniques have reduced the level of monomer in bottle walls by a factor of nearly one million.

As recently as October 15, 1979, an official FDA opinion sent to an inquirer noted that "PVC continues to be prior sanctioned for food-contact purposes providing that no vinyl chloride monomer migrates to the food" and indicates that, since the 1975 proposal was published, "manufacturers have improved their manufacturing techniques so that little or no vinyl chloride monomer remains in the polymer" (Ref. 20).

Moreover, FDA's scientists have recognized the reality and importance of the progress made by industry by noting in a much-discussed, though not yet completely revealed, memorandum dated July 27, 1979, that "the distinctions between plasticized and rigid PVC have become irrelevant based on new manufacturing techniques, and the uses should be treated similarly." This statement was printed in Food Chemical News which quoted it and attributed the statement to FDA's Division of Chemistry and Physics, a part of the Bureau of Foods (Ref. 21).

Despite all of these favorable signs for PVC, it seems to be most difficult to blow away the "little black cloud" hanging over it. This has to be more because of history than today's reality, and much more because of FDA's inaction than any adverse action it has taken.

Thus, for example, notwithstanding a recent unique Petition filed by The Society of the Plastics Industry, Inc. (SPI) urging "reapproval" by BATF of PVC liquor bottles, the Bureau is not expected to move until FDA provides it with a statement clearly indicating that PVC is now considered legally acceptable for this use. Anomalously, there really is no valid question of legality here since PVC remains "prior sanctioned" for all uses under the Food Additives Amendment and FDA has so indicated in recent correspondence. This, however, is not enough to satisfy BATF--it feels it needs something more specific to avoid "being burned by FDA's vagaries again" (Note b).

There is a relevant collateral point worthy of mention here since it could have a bearing on when and how PVC's currently satisfactory legal status at FDA might ultimately be emphasized or at least become more clearly understood. In the wake of the United States Court of Appeals for the

Note b: The fact that this is so is demonstrated by a BATF letter directed to the Bureau of Foods of the FDA by Mr. William T. Drake, Assistant Director of BATF on February 27, 1980. In this letter FDA has been requested to inform BATF about its position and undoubtedly will do so at some time in the future. Thus, it should be recognized that the language in quotation marks in this sentence constitutes a paraphrasing of informal remarks made by BATF officials to inquirers; there is no official document where this language is used.

District of Columbia Circuit's decision in Monsanto Co. v. Kennedy, more commonly referred to as the acrylonitrile (AN) beverage container case (Ref. 22), FDA is known to be working on changes in its policies on indirect additives. Hopefully, whatever new "game plan" is adopted will make it possible for Food and Drug to declare non-additive status for components of food-contact materials in so-called de minimis situations where the potential level of migration into food of a particular substance is so negligible as to present no public health or safety concerns.

If and when this is satisfactorily accomplished, we would certainly hope that FDA could publish a notice unequivocally withdrawing its 1975 PVC proposal. Such action, along with the type of letter we hope FDA will soon send BATF to allow it to permit renewed use of PVC liquor bottles, should certainly push the "little black cloud" off the horizon. Meanwhile, PVC's food-contact regulatory status remains satisfactory; it's only the public relations sky that's cloudy.

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Moving to our third and final chapter, regulatory action by EPA to control plant emissions of vinyl chloride monomer got under way in December of 1975. This is when the Agency published a proposal calling for drastic reductions in emissions from VCM and PVC manufacturing operations. Precisely why EPA felt the necessity to act remains unclear to me since ambient air monitoring had revealed no indication of any hazard. Nevertheless, probably because of the impetus provided by the widely publicized OSHA proceedings, and perhaps public concern about all air quality matters, in 1976 EPA promulgated what amounted to a 10 ppm national emissions standard for vinyl chloride.

This standard, adopted under Section 112 of the Clean Air Act, is still in effect today (Ref. 23). According to EPA's own cost estimates, to comply with it industry will have spent \$763 million by 1986. For some reason, though, this standard seems to be a favorite target for environmentalist and Agency reevaluation even though (1) there is still no evidence whatsoever that VCM ambient air emissions have given rise to any public health problem, and (2) it would appear that the Supreme Court's recent decision in the benzene case (Ref. 24) would make some evidence of health relevance a prerequisite to lowering a standard at great cost to industry. This observer is of the view that the benzene case is as applicable to EPA's Clean Air Act regulatory authority as it is to OSHA's standards-making although it is recognized that EPA counsel may not agree.

Arguing that the standard merely reflected industry's best available control technology, rather than the degree of control necessary to protect public health, the Environmental Defense Fund (EDF) brought suit in 1976 challenging the final rule (Ref. 25). After lengthy negotiations between EDF and EPA, from which industry was flatly excluded over its vigorous protests, EDF and EPA reached a "settlement agreement." In accordance with this compromise, EPA proposed amendments to cut the 10 ppm level by one-half, prohibit emission increases within the vicinity of existing plants due to expansion, and set an ultimate goal of "zero" for vinyl chloride emissions.

However, these emission reductions, proposed by EPA in June of 1977, have, for all practical purposes, been abandoned by the Agency. EDF relatively recently sought to reopen the original proceedings on the grounds that EPA had reneged on its promise to take final action on the proposed amendments by January 1, 1978. Strong oppositions were filed by EPA and SPI, both of which protested that the Agency should not decide on whether to amend the vinyl chloride standard until after reconsideration of EPA's overall policy for dealing with carcinogens. Heading these arguments, the court denied EDF's motion and refused to issue an order requiring compliance with the so-called settlement agreement.

Vinyl chloride is still a "flagship" issue and appears to be one of the major stimuli behind the Agency's general review of its carcinogen regulations. This being the case, VCM may well be one of the first substances to which EPA's cancer policy, once finalized, will be applied. Meanwhile, industry is still having some difficulty coming into full compliance with

the 1976 standard, the major problems being emergency relief valve and reactor opening discharges.

In addition to the limitation on VCM emissions, the discharge of PVC waste into navigable waters is controlled through EPA's permit procedures established pursuant to the Clean Water Act (Ref. 26).

In the recently-issued Solid Waste Regulations--perhaps the most all-encompassing environmental regulations issued to date--EPA has been reasonably responsive to industry comments. For example, it adopted SPI's recommendation that PVC sludge be excluded from the rule making (Ref. 27). This could be a temporary "plus," however, because the Agency has indicated that it intends to issue final regulations this fall which will classify and regulate, on a generic basis, the batch and solution residues from the production of all chlorinated polymers.

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The PVC story clearly illustrates the increasingly interdisciplinary nature of regulatory issues. The problems that arose triggered a chain reaction among a variety of federal agencies including the three I have discussed in depth and the Consumer Product Safety Commission. These four agencies and the Department of Agriculture have since acknowledged that they share common regulatory concerns by joining together in the Inter-Agency Regulatory Liaison Group (IRLG), instituted to achieve a uniform approach to identifying potential carcinogens and estimating their risks.

Complicating all attempts to develop appropriate regulatory responses to carcinogenic hazards are the phenomenal, daily breakthroughs in scientific testing. Technological advancements are now enabling us to detect substances at levels where the impact may remain unknown forever.

There is no question in my mind but that regulatory agencies will have to integrate some sort of risk assessment methodology into their decision-making processes to prevent immobilization of industry. It has become too difficult to overcome the bureaucratic fear that a decision made today might look like a grievous error tomorrow because a more sensitive test method turns up a trace of a substance shown to be a carcinogen, mutagen or teratogen at high levels. FDA has already taken steps in this direction by moving forward on its policy for dealing with low levels of putatively carcinogenic constituents in animal drug residues. The other agencies will have to play variations on this theme or bring an already seriously threatened chemical industry economy to its knees.

Notwithstanding the general quagmire in which current Agency attempts to regulate deleterious substances rest, the combined efforts of a responsible industry and concerned federal agencies appear to have eliminated the hazards associated with the manufacture and use of PVC. Industry deserves much credit for having identified and controlled the vinyl chloride monomer problem. Assuming the government also acts appropriately, using the common sense that sound risk assessment and related action dictate, it will some day have played its role in bringing this episode to an exemplary conclusion. If these principles are kept in the forefront as debate continues, they should pay off in the form of a stable market place for industry and a safer environment for everyone.

If the VCM/PVC experience proves to have helped bring about this result, the "success story" label will be as worthwhile as it has been hard won.

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