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## Council on Public Affairs



**Diamond Shamrock**

June 26, 1978

To Diamond Shamrock Management:

The accompanying article, "OSHA's Ill-Conceived Crusade Against Cancer", from FORTUNE's July 3, 1978 issue, represents an objective interpretation of the current controversy over regulation of carcinogens in the workplace.

This is an issue which effects Diamond Shamrock, its customers, suppliers, and each of us as employees and consumers. I encourage you to read the article, become better informed on this important matter and share your observations and conclusions with others.

R. P. Batchelor, Jr.  
Chairman  
Council on Public Affairs

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by TOM ALEXANDER

Of all government agencies, the seven-year-old Occupational Safety and Health Administration has displayed the most talent for driving businessmen up the wall. Recently, however, in response to a crescendo of protest from industry and Congress, the agency announced that it was recalling some 1,100 costly and ineffectual safety regulations. Henceforth, OSHA said, it would pay more attention to workers' health than to workers' safety.

But industry's celebration of a reformed OSHA is not exactly getting out of hand. Gloom returned the minute industry got a look at some of the health measures OSHA had in mind. The one that has aroused the strongest opposition is the agency's far-reaching proposal for identifying and regulating cancer-causing substances in the workplace. Currently, this proposed standard is the subject of public hearings, which promise to be some of the lengthiest of their kind ever held. More than 160 parties—companies, trade associations, unions, "public-interest" groups, and government agencies—have asked to testify. Says Monte Throdahl, a vice president of Monsanto: "For the chemical industry, it's the most important regulatory issue that has ever come down the pike."

Declaring itself fed up with trying to regulate carcinogenic substances one at a time, OSHA has proposed to lump all the thousands of chemicals that industry makes and uses into three broad categories. What would distinguish substances in one category from those in another would simply be the strength of the evidence that the substances can cause cancer. Category I substances would be "confirmed" carcinogens, defined as those that have been shown to promote any kind of tumor in human beings, or in two species of laboratory animals, or in a single species if the experiment has been duplicated. Category II, "suspected" carcinogens, would be substances for which evidence of carcinogenicity was reported but less reliable—for example, the results of a single, unduplicated animal test. Category III would include all other toxic substances found in the workplace for which evidence



Under OSHA's carcinogen rules, some workers would wear protective clothing.

## OSHA'S ILL-CONCEIVED CRUSADE AGAINST CANCER

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Last year the agency won applause by  
junking hundreds of nit-picking safety standards.  
Now it is threatening business with some  
ruinous new rules on carcinogens.

of carcinogenicity was meager or absent.

According to OSHA's proposal, once a substance is assigned to a category, a more or less standard set of regulations would follow. Category I substances would first fall under an "emergency temporary standard," which would require companies to reduce exposures to minimal levels, warn workers, give them physicals, and begin monitoring their exposure.

After six months, full permanent standards would go into effect. Occupational exposure would be prohibited altogether if a "suitable" substitute could be found. If not, all companies, large and small, would have to reduce exposures to the "lowest feasible" level, primarily through engineering controls—e.g., better seals, vapor-recovery devices, ventilating fans, and machinery-enclosing capsules. On top of that, all companies must also provide protective clothing, changing rooms, showers, laundries, and lunchrooms ventilated with filtered air. They must post signs carrying such warnings as "Danger. Benzene. Cancer Hazard." They must also monitor carcinogens present in the plant, and workers' health, and keep records of both for forty years.

For Category II substances—suspected carcinogens—the requirements would be much the same, except that OSHA might prescribe a permissible level of exposure somewhat higher than "lowest feasible." Category III substances—those for which evidence of carcinogenicity was meager—would simply be regulated as their other toxic properties might call for.

#### **A speedup that may backfire**

The aim of the new policies is to speed up regulatory decision-making. In its seven years of existence, OSHA complains, it has managed to curb only nineteen cancer-causing substances; Secretary of Labor Ray Marshall has compared the process with putting out a forest fire one tree at a time. But while there's much to be said for the idea of a generic standard for carcinogens—and while government unquestionably has a legitimate role to play in protecting workers from dangers that are hard

to identify and expensive to control—OSHA's proposal promises to create more controversy and delay than ever.

In the past, most of the controversy has revolved around the parlor question of what is and isn't a carcinogen. OSHA has had to prove its case against each substance in the face of the fact that scientists' understanding of cancer is at about the same level as knowledge of infectious disease was before the discovery of germs. To simplify the identification process, OSHA's proposal states that henceforth reliable evidence of carcinogenicity from animal experiments will supersede any amount of contradictory evidence from human exposure. OSHA contends that the difficulties of gathering reliable human data, plus the fact that five to forty years may elapse between the time a person is exposed to a carcinogen and the appearance of cancer, limit the value of human epidemiology.

The trouble is that animal experimentation is not all that easy or reliable either. No animal responds to chemicals precisely the way human beings do: there are animals that are not susceptible to some human carcinogens, and people don't appear to be affected by many substances, such as eggs and lactose, that can produce tumors in animals. Moreover, the number of animals that can realistically be tested is generally far smaller than the number of people at risk, so identifying a weak carcinogen that might affect a few human beings out of thousands can be a tricky exercise. To speed experiments and minimize statistical ambiguity, experimenters usually administer unrealistically large doses of the substances being tested, which introduces a fresh kind of uncertainty into the result.

Generally speaking, scientists in industry tend to believe that there is a "threshold" or safe dose below which carcinogenic effects are negligible. Government scientists tend to discount such thresholds. And in recent years another viewpoint has been emerging somewhere in between. It holds, in effect, that the development of cancer is a multistage process involving more than one cause, and that the body musters de-

fenses and repair mechanisms to cope more or less successfully with small doses of carcinogens.

With science either mute or speaking in discordant voices, the differences between industry and OSHA boil down to the political questions of how, in the face of uncertainty and ignorance, government should balance economic and other factors against risks to health. Unfortunately, of all the hazards to which the public is exposed, none seems to call forth government's natural proclivities toward overreaction so much as cancer. Politicians discern little but political risk in appearing to compromise on such an emotional issue. Regulators, charged with moving against a danger that is at once clear and present yet deeply enigmatic, seek refuge from legal challenges in automatic laws that substitute flat prohibition for careful judgment.

#### **Traces in almost everything**

Until recently, politicians were accustomed to speak of things as being either "safe" or "unsafe" and to pass stringent laws requiring "zero discharge" of pollutants or "zero risk" from carcinogens. These instincts produced such measures as the Delaney clause, an amendment to the Food, Drug, and Cosmetic Act that forbids the use in foodstuffs of any substance that has been shown to cause cancer in man or beast. Taken literally, the clause could lead to more sickness than it prevents. Not only are some vital nutrients, such as vitamin D or selenium, and long-established food preservatives, such as sodium nitrite, probable carcinogens by OSHA's standards, but the growing sensitivity of laboratory instruments enables scientists to find traces of almost anything you can name in almost anything you can eat.

In recent years, the lack of realism in the concept of zero risk has become apparent to most politically responsive bodies. Officials in successive administrations have begun to see that environmental regulations divert resources from capital investment, thereby tending to exacerbate inflation. Lately, even Congress has been including clauses in environmental stat-

utes requiring regulators to weigh costs against risks. The most far-reaching legislation in the field of cancer, for example, is the Toxic Substances Control Act, which is administered by the Environmental Protection Agency. While it requires companies to test new chemicals for carcinogenicity, it also insists that regulators take the costs of compliance and the social benefits of the chemicals into account in setting standards.

### **An uncompromising purism**

Unhappily, OSHA seems to be spurning this trend toward moderation. To judge from the long preamble to its new carcinogen rule, the agency continues to approach the dilemmas of regulation with the uncompromising purism of a militant "public-interest" group.

For instance, the preamble juxtaposes facts in such a way as to suggest not only that there is an epidemic of cancer abroad in the land, but that much of it is attributable to occupational exposure to industrial carcinogens. The reality of the matter is otherwise, as OSHA itself partly acknowledges. While it is true that the overall incidence of cancer has been slowly rising for many years, most of the increase is due to the fact that the average age of the population is climbing. (Human susceptibility to cancer increases with age.) When the age factor is removed the largest single contributor to the increase in cancer is cigarette smoking, which some estimate to be implicated in about 40 percent of all male cancer deaths.

In recent years, there has been an increase in bladder, skin, and lung cancers that appears to be attributable in some way to industrial activity. Most of these cases are concentrated in regions with a lot of chemical plants (see map, opposite). Nevertheless, the contribution that occupational exposure makes to the total seems comparatively small: the National Cancer Institute estimates the figure at less than 5 percent of the total, while the International Agency for Research on Cancer says it is between 1 and 3 percent.

Absent from OSHA's preamble is much

indication that the agency gives a hoot for how much its standards would cost or for the benefits of substances it might effectively be banning. It gives no hint as to whether, in picking a "suitable" substitute or a "feasible" exposure level, any weight would be given to economic considerations as well as technological ones.

These omissions do not seem accidental. In a press conference held when the proposals were issued, Secretary of Labor Ray Marshall stated that OSHA intended to consider costs only when alternative methods of achieving lowest-feasible levels were available. In that case, the agency might permit industry to use the less expensive approach. "What we will not do," he said, "is to get ourselves in a position of trying to put a value on human life, or trying to equate the cost of a human being, or the cost of injuries or diseases at the margin." Whatever that may mean, it is cited by OSHA officials as prohibiting consideration of costs, benefits, and acceptable risks.

Perhaps it is understandable that public officials are reluctant to be caught in the act of pricing human lives. Nevertheless, in exercising judgment about everything from how often to collect garbage to how many traffic signs to install, officials have in effect been doing just that for hundreds of years. One principle that has emerged amounts almost to a law of nature: the cost of reducing risks tends to go up as the remaining risk gets smaller. Trying to remove the last 1 percent of a pollutant, for instance, may cost more than removing the other 99 percent. Since resources are always limited, a rational society would never pursue the chimera of "zero risk," because there will always be better ways of spending money—whether to save lives in other ways, or for other purposes.

Officials in other regulatory agencies—and even many industry leaders—concur that a generic approach to carcinogens is needed. But a number of them argue that a classification and regulation scheme based simply upon whether a substance has caused tumors in animals will make OSHA's task harder rather than easier. For

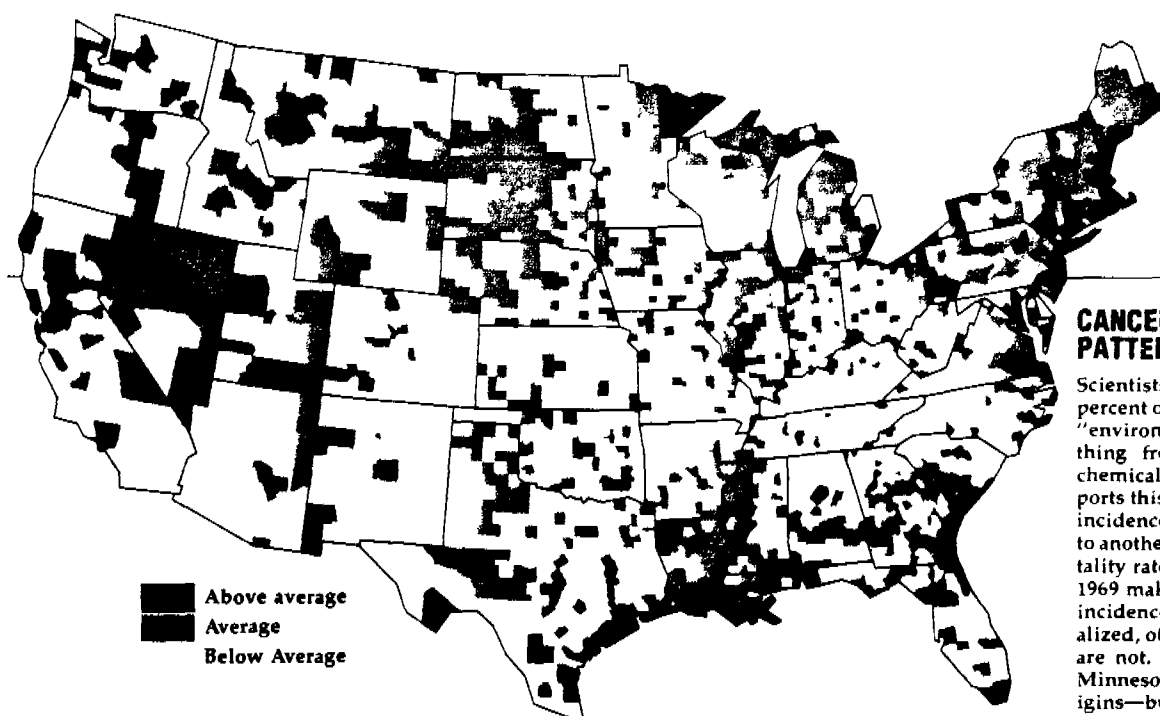
one thing, carcinogens vary enormously in strength and in the number of people who are exposed to them. Logically, the ones that are more potent and more widespread should be given higher priority and regulated more stringently than others. OSHA's broad-brush, categorical approach makes that difficult.

### **"OSHA's meat axe"**

While OSHA suggests that only a small number of substances would fall into Category I, other experts aren't so sure. One EPA official points out that of the 70,000-odd chemicals now in routine use, only about 1,000—generally the most suspicious ones—have received much testing for carcinogenicity. Of that number, about 20 percent give some grounds for concern. Therefore, this official argues, through its unwillingness to draw distinctions, OSHA might find itself saddled with the insuperable task of regulating thousands of substances.

Going further, Francis Roe—a specialist in experimental pathology, cancer research, and toxicology who is a consultant to the chemical industry—contends: "Any experienced experimental pathologist, given adequate resources, could show that any agent is 'carcinogenic' if the criteria for carcinogenicity are as loose as OSHA proposes they should be." So, industry has nightmare visions of thousands upon thousands of substances falling under what an EPA official describes as "OSHA's meat axe" and billions of dollars being spent to control substances that aren't very dangerous or are no threat at all.

OSHA's faith in animal experiments will not only lead to the misidentification of some innocent substances as human carcinogens, it also is likely to cause some real carcinogens to be overlooked. Two human carcinogens that OSHA already regulates—arsenic and benzene—have so far shown no clear tendency to cause cancer in animals. Moreover, a growing body of evidence indicates that many, perhaps most, human tumors have more than one environmental cause: most of the asbestos workers who have contracted lung cancer,



## CANCER'S MYSTERIOUS PATTERN

Scientists think that from 60 to 90 percent of human cancer is caused by "environmental" factors, i.e., everything from sunlight to industrial chemicals. A bit of evidence that supports this view is the variation in the incidence of cancer from one region to another, as this map of cancer mortality rates among men from 1950 to 1969 makes clear. While some high-incidence areas are heavily industrialized, others, like upper Minnesota, are not. Scientists hypothesize that Minnesota's rate may have ethnic origins—but nobody really knows.

for example, were also smokers. There is no way animal experiments can test all the thousands of possible combinations of substances that humans encounter in daily life. Thus, in the search for human carcinogens, epidemiological evidence, reflecting many years of exposure to many substances by millions of persons, is far too valuable a resource to be downgraded in the way OSHA seems to have in mind.

### Taking cleaners to the cleaners

Apparently the only serious attempt to analyze the economic implications of the carcinogen proposals is a 612-page "preliminary" study prepared for the chemical industry by the Foster D. Snell division of Booz, Allen & Hamilton. The Snell researchers selected seven substances from a list of 2,415 suspected carcinogens compiled by the National Institute of Occupational Safety and Health. They then estimated the cost of reducing exposures to various levels for different industries.

One of the substances selected, for example, was tetrachloroethylene, widely used as, among other things, a dry-cleaning and metal-cleaning solvent. Because of its nonflammability and ability to clean natural and synthetic textiles without color bleeding or shrinkage, tetrachloroethylene is the favored solvent in about 75 percent of all dry-cleaning establishments. Some 2.8 million workers are exposed to

tetrachloroethylene vapors in some 155,000 plants in the U.S. The Snell study estimated that the cost of regulating tetrachloroethylene as a Category I substance would be around \$1 billion per year, with small dry-cleaning companies paying more than a quarter of the total. Most of these would probably have to install machinery that could handle other solvents.

The Snell study estimated that the average annual cost of regulating the seven substances would be \$240 million apiece if they were all in Category II, and \$470 million apiece if they were in Category I. As for the overall cost of complying with OSHA's standard, Snell came up with figures ranging from \$6 billion to \$36 billion, depending upon the level of control judged to be "feasible" and upon whether the number of substances controlled was thirty-eight or 2,415. Capital requirements would amount to between 17 and 166 percent of total 1976 capital expenditures of all manufacturing industries.

The Snell study pointed out that the regulations would probably increase industry concentration, since many companies would go out of business. Productive capacity and productivity would probably decline, the trade balance would likely deteriorate, and about a point would be added to the annual rate of inflation.

Some argue that these conclusions, and the worries they prompt, are absurd, that

no matter what goes down on OSHA's books, the agency really has no intention of abandoning common sense. Industry's response is that whatever OSHA's hidden intentions are may not make much difference. Once regulations are promulgated, any organization could haul the agency into court and force it to abide by the letter of its own laws.

Not surprisingly, OSHA's standard has provoked the many industries that make and use chemicals as they have seldom been provoked before. Within weeks after publication of the rule last October, the chemical industry mustered all the vigor that private enterprise once devoted to invention and production and set up an ad hoc pressure group of the sort that has been proliferating in the Regulated Society. Named the American Industrial Health Council, the organization includes some ninety member companies and sixty trade associations and has enlisted top-flight law, public-relations, and economic-research firms, as well as a number of academic scientists.

As the businessmen see it, much more is at stake than regulation of the workplace. For some time now, all the government agencies regulating health affairs have been trying to devise a common federal policy for dealing with carcinogens. Industry representatives have been pacing nervously outside those closed bureaucratic

## "What we can reasonably demand is that no worker have a risk appreciably greater than other workers."

doors, wondering just what the Carter Administration's policymakers, heavily weighted with environmental activists, Naderites, and others with a studied disinterest in economic consequences, would come up with. So when OSHA's announcement appeared, businessmen took it to be a harbinger of government-wide policies to come—and a reversion to the kind of regulatory extremism that many thought had at last started to go out of fashion.

In addition to making a ruckus, the businessmen have developed a useful set of counterproposals on how carcinogens could be identified, classified, and regulated on a generic basis. A.I.H.C., for example, supports OSHA's concept of categories based on evidence of carcinogenicity, but insists that further distinctions should be made according to how much hazard the substances actually pose—some carcinogens are thousands of times more potent than others—and how many people are exposed to them. This would entail using all the available evidence, including human epidemiology, rather than the results of animal experiments alone.

Once a chemical is identified as a "confirmed" or "suspected" carcinogen, for example, the A.I.H.C. would have OSHA further decide whether it constitutes a "grave danger," before imposing emergency temporary standards. This resembles the approach that will be followed by the EPA in enforcing the Toxic Substances Control Act, which also requires EPA to balance costs against risks when considering whether and how to regulate a carcinogen in the environment at large.

### Some reasonable alternatives

To evaluate the evidence and make the classifications for all government agencies, A.I.H.C. advocates creation of an independent panel of scientific experts selected by the National Academy of Sciences. A.I.H.C. hopes that the panel's existence would isolate delicate scientific judgments from the rough and tumble of political pressure and the temptation to bend scientific testimony for regulatory expedience—a temptation that OSHA, together with other agencies,

has already shown signs of succumbing to.

A number of experts, in government and out, regard A.I.H.C.'s alternatives as more enlightened than OSHA's. "They're the most reasonable suggestions I've ever seen from industry," comments Glenn Schweitzer, who until last year was head of EPA's Office of Toxic Substances.

Even if these proposals were adopted, however, problems would remain. Despite the recall of all those ridiculous safety standards, OSHA still displays tendencies to manipulate public anxieties. Part of the explanation may be that the agency, feeling itself in danger of expiring of terminal silliness, wants to reestablish both its clout and the legitimacy of its mission. Also contributing to OSHA's tendency toward extremism is the fact that it is located inside the Department of Labor, a position with conflict-of-interest potentialities not unlike those that afflicted the old Atomic Energy Commission when it regulated nuclear safety, or the Department of Agriculture when it regulated pesticides. Either OSHA should be made more broadly accountable by removing it from Labor, or else some standard should be devised by which to gauge whether the agency is commandeering a disproportionate share of society's resources to alleviate hazards facing particular groups of workers.

One promising approach to such a standard is provided by the evolving new discipline of "risk assessment," which a number of analysts have been attempting to apply not only to the carcinogen problem but to other hazards, such as those created by nuclear-power production. Practitioners of risk assessment attempt to measure what degree of risk society already accepts in various fields; they use their findings as guidelines for allocating resources to improve health and safety.

One pioneer of this approach is Richard Wilson of Harvard's Energy and Environmental Policy Center, who concurs with OSHA's contention that, in the absence of reliable data about "safe" levels of carcinogenic exposure, it is only prudent to assume such levels don't exist. Nevertheless, Wilson argues, that is no reason to disre-

gard obvious differences in carcinogenic potency and actual hazard. Neither does it justify seeking to reduce risks from carcinogens to levels far below those that society tolerates from other hazards. He points out, for example, that an estimated 20,000 persons die each year east of the Mississippi as a result of breathing polluted air. This works out to a risk of dying as a consequence of living for a year in the East to about 1.5 in 10,000. That, in turn, is somewhat higher than the risks of frequent air travel or of household accidents.

In the past, workers in the vinyl chloride and asbestos industries were apparently exposed to much higher risks than these. But by now, regulation of these plants has probably reduced the risks to levels about comparable to those from air pollution and air travel. Many other occupations, by contrast, still carry much higher risks. Accidents and black-lung disease in coal mining, for instance, kill about 100 workers per 10,000 man-years. The hazards to railroad workers kill about thirteen every 10,000 man-years, and agricultural work kills about seven every 10,000 man-years.

### A bureaucratic temptation

"What we must reasonably demand," says Wilson, "is that no worker, by virtue of his job, should have a risk appreciably larger than other workers unless this is made abundantly clear and, in extreme cases, there is some compensation, financial or otherwise."

It is always tempting for bureaucrats charged with responsibility for guarding the public health and safety simply to impose bans or to demand heavy outlays from others. What they might keep in mind, however, is that risk cannot be eliminated from life; that resources are always limited; and that some of the most reliable and venerable data in the world demonstrate a relationship between a nation's health and its per capita G.N.P. In the process of trying to reduce hazards to very low levels, OSHA's regulators might wind up inflicting grave damage not only on the health of the economy, but ultimately on the health of the citizenry as well. ■

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