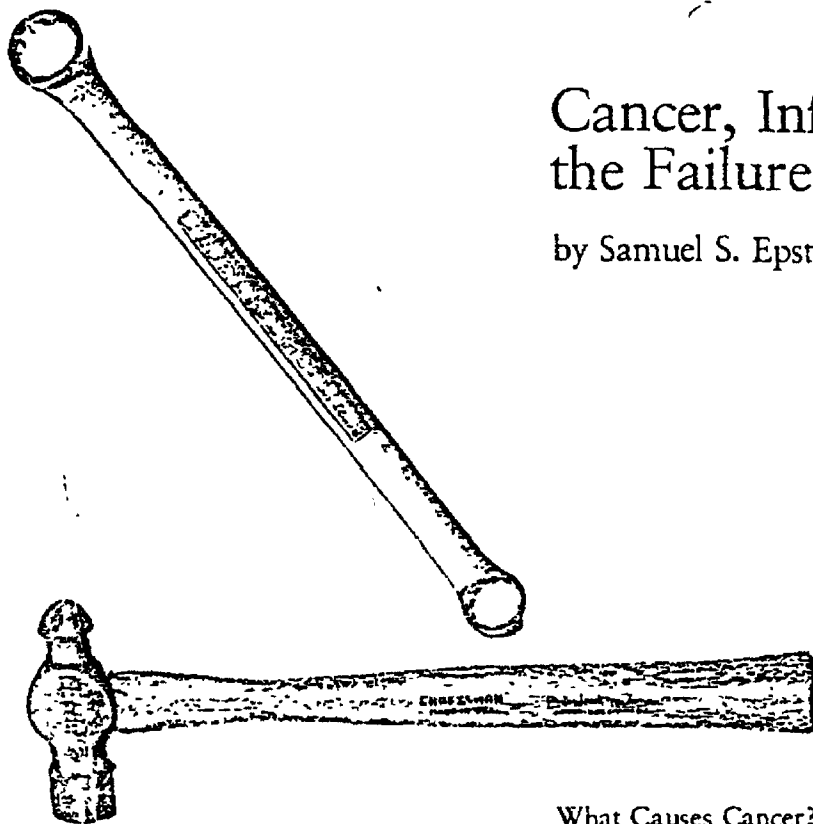




Cancer, Inflation, and the Failure to Regulate

by Samuel S. Epstein

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What Causes Cancer?

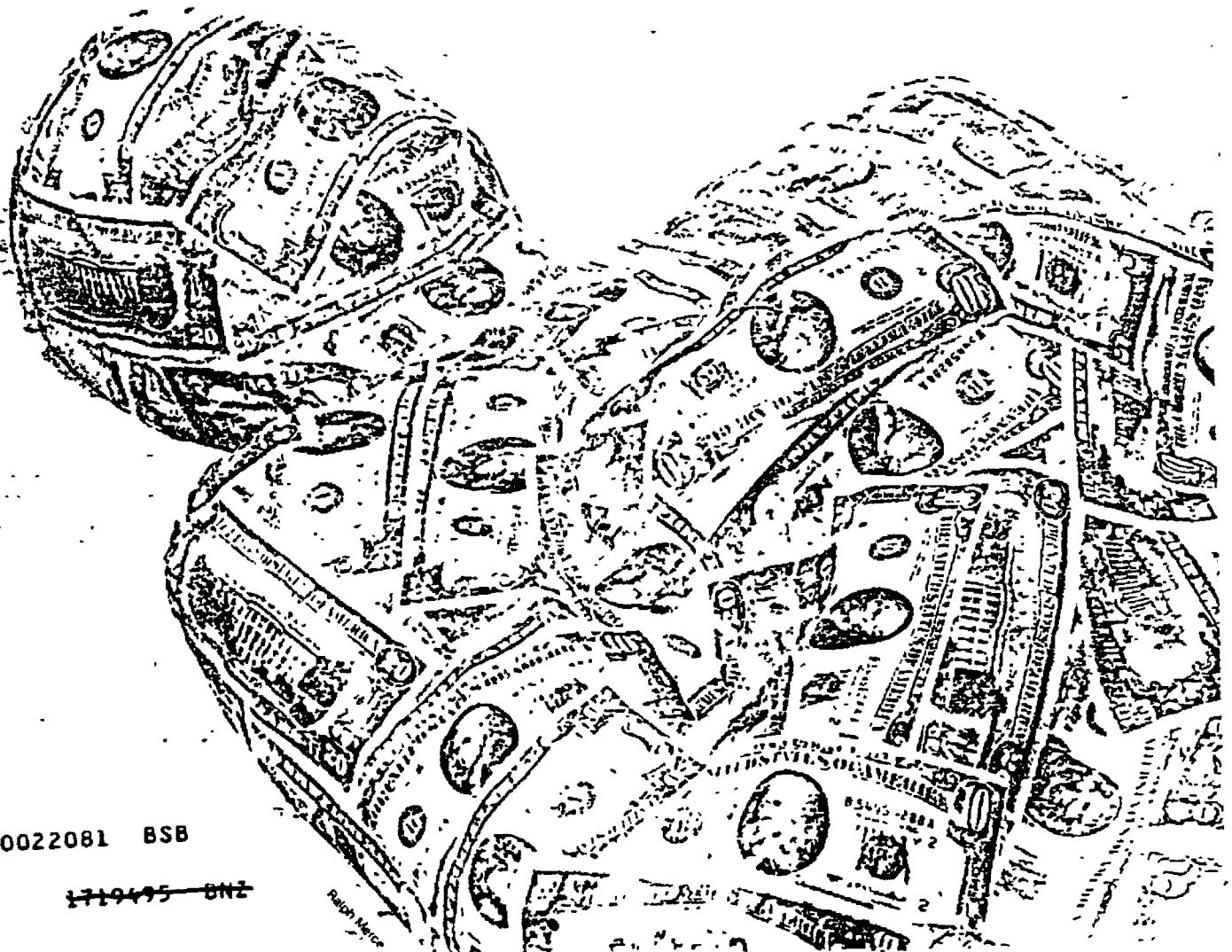
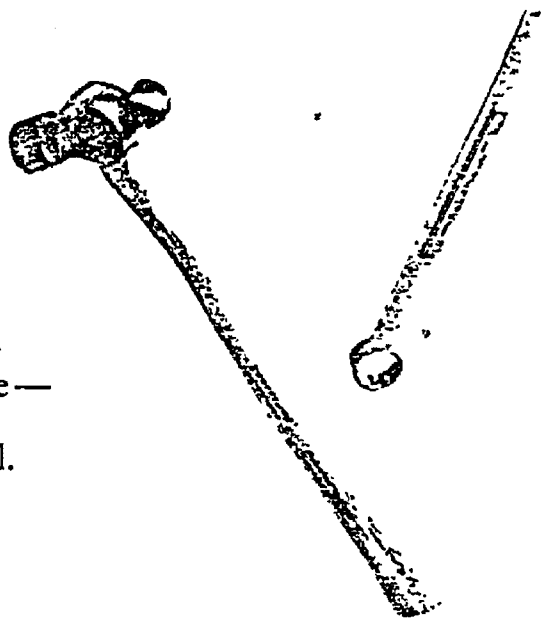
Over the past few decades, there has been a steady accumulation of scientific data on occupational and environmental carcinogens. There has also been a parallel increase in our ability to test for carcinogenic effects of chemicals in animals and to recognize such effects in humans. Not only is the level of this information generally adequate, but there are ample laws — in spite of their occasional inconsistencies and ambiguities — to translate such information into regulatory action. Yet this has rarely been done.

The problem is thus not one of inadequate information or limited authority, but rather one that derives from economic and political constraints. The combination of powerful and well-focused pressures from industry, together with an indifferent scientific community, public confusion, and a relatively weak public-interest movement, has created a major political imbalance. This has been further exacerbated by the "anti-inflation" policies of the Carter administration which fail to recognize that the true costs of failure to regulate are excessive and inflationary.

Cancer strikes one in every four Americans and kills one in five. It is not a disease of degeneration or aging. There is little or no evidence that viruses play a significant role. Similarly, migration studies have shown that genetic factors are unlikely to be important determinants of human susceptibility. Cancer affects all ages and is largely an expression of past exposures to carcinogens in air, water, food, drugs, consumer products, and the workplace.

Our overall ability to treat and cure cancer — once it has been manifested — has not materially improved over the past few decades. With the exception of prostate cancer and certain relatively rare cancers such as Hodgkin's disease and acute leukemia in children, the odds of a cure for the major cancer killers — those of the lung, breast, and colon, for example, — are not much better now than they were 20 years ago (*see table, p. 44*). This is true despite the billions of research dollars spent on a cure for cancer, despite the high priorities for cancer research created by the 1971 National Cancer Act (which have been and continue to be directed toward curing rather than preventing cancer), and despite the optimistic assurances of the American Cancer Society (even though based on the same National Cancer Institute (N.C.I.) data such as in the table).

If industrial chemicals remain underregulated, they will yield costs — quite apart from suffering and loss of life — that far outweigh the immediate, supposedly inflationary costs of control.



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Cancer is now the only major fatal disease whose incidence is on the rise. Standardized cancer death rates (i.e., adjusted for age and based on the total U.S. population) show an overall and progressive increase of about 11 per cent from 1933 to 1970. This increase has been even more striking over the last decade (see table, p. 48), and cannot be accounted for by smoking or increased longevity. At today's death rates, the probability of a person born today getting cancer by the age of 85 is 27 per cent (in contrast to about 20 per cent for a person born in 1950).

In addition to the documented increase in overall cancer death rates in this century, evidence for the environmental causes of the disease is provided by a constellation of other scientific findings:

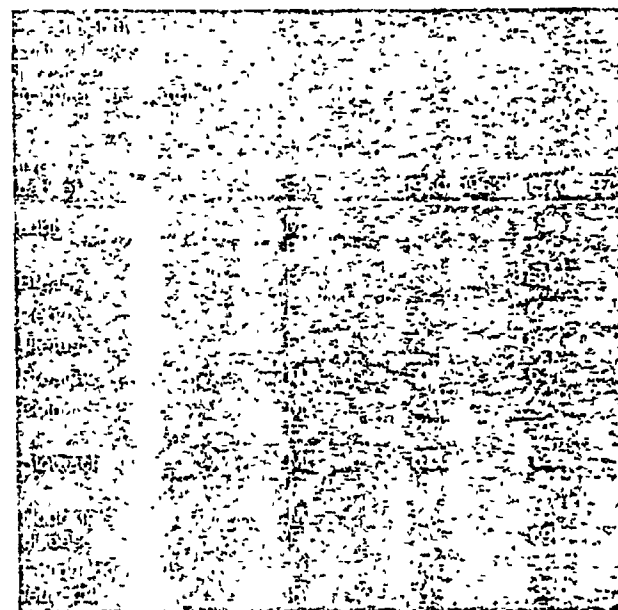
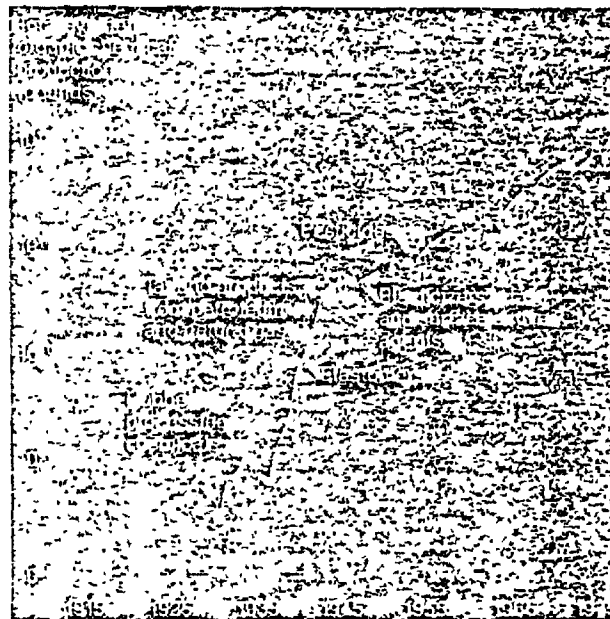
- The striking increase in cancer death rates for certain "high-risk" population sub-groups: such as workers in asbestos or petrochemical industries, premenopausal women who have been subjected to repeated mammography, and postmenopausal women who have been administered estrogen "replacement therapy" for prolonged periods.

- The major international geographical variations (in some instances by as much as 2,000 per cent) in specific organ cancer rates which have largely disappeared over the course of one or two generations following population migration from high to low cancer areas.

- The clustering of excess overall cancer rates and organ-specific cancer rates in men and women living in heavily industrialized U.S. counties (see table, p. 47), particularly those with a high concentration of petrochemical and certain mining and processing industries.

- The experimental demonstration of the carcinogenic effects of a wide range of chemicals, particularly synthetic organics.

Since the advent of the petrochemical era in the 1930s, a vast array of new synthetic organic chemicals has been introduced into commerce — and into the environment — generally without prior testing for carcinogenic and other chronic toxic effects. By 1976, total U.S. production of synthetic organic chemicals had reached 300 billion pounds per year, up from about 1 billion pounds in 1940 (see figure above). And about 700 new chemicals are presently being introduced into commerce each year. But it must be appreciated that the "cancer problem" thus created can readily be solved. The property of carcinogenicity is in fact relatively rare, and can be practically and economically detected by animal tests that are highly predictive of human effects. Of the



Above.

Production of synthetic organic chemicals in the U.S. has grown dramatically during this century. In 1940, for example, one billion pounds were produced; by 1976, total production reached 300 billion pounds. (Arrows indicate when usage of specific product types became officially "significant.") (Source: U.S. International Trade Commission)

Below

These data — obtained in 1979 from the National Cancer Institute's Surveillance Epidemiology and End Results (SEER) Program — suggest that our overall ability to cure cancer has not materially improved over the past decade.

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Conservative estimates
of the total
national cost of cancer
for 1979
are in the region of \$30 billion.

myriad of synthetic chemicals in commerce, less than 1,000 have been shown to be carcinogenic in animals, and these mostly belong to special sub-classes — such as chlorinated olefins, alkyl halides, and aromatic amines — widely used by industry.

There is substantial evidence incriminating industrial chemicals as major causes of cancer. Consider, for example, "Estimates of the Fraction of Cancer in the United States Related to Occupational Factors," a draft report issued by the U.S. Department of Health, Education and Welfare (H.E.W.) in September, 1978. (The final report is in the process of being submitted to the *Journal of the National Cancer Institute*.) Prepared by ten leading experts from the National Cancer Institute, the National Institute of Environmental Health Sciences, the National Institute for Occupational Safety and Health (N.I.O.S.H.), and the International Agency for Research on Cancer, the report conservatively estimates (with documented exposure and epidemiological evidence) that up to 38 per cent of total cancer mortality over the next three decades will be associated with asbestos and five other "high-exposure" carcinogens (arsenic, benzene, chromium, nickel oxides, and petroleum fractions).

The report is in striking contrast to industry "guesstimates" that occupational exposures cause less than 5 per cent of all cancers. Not only are such industry allegations undocumented in relation to exposure data — which industry still insists are confidential — but they also reflect simplistic assumptions that single causes (including questionable carcinogenic factors such as high-fat diets) are responsible for most cancers. The causes of cancer are generally multiple, with more than one factor contributing to risk (as illustrated, for example, by synergistic interactions between smoking and asbestos exposure in the induction of lung cancer among workers).

The findings of the H.E.W. report, alarming as they are, still represent a serious *underestimate* of the impact of occupational carcinogens: they exclude the effects of radiation and about twelve other epidemiologically confirmed occupational carcinogens; the effects of occupational carcinogens on the general community, due to their discharge or escape from industrial plants into the outside air, water, and land, are not considered; the effects of more recently introduced industrial chemicals have not been gauged through current cancer rates; the majority of epidemiological studies so far undertaken in the workplace, and on which the estimates

are based, have been in larger industries which are likely to be less hazardous than the more numerous small plants (manufacturing, handling, or processing carcinogenic chemicals under even more poorly controlled conditions); and the duration of follow-up in most epidemiological studies on carcinogenic exposures in industry has been for periods less than the necessary lifetime observation period, and are therefore likely to minimize the degree of risk. These exclusions from the H.E.W. estimates are likely to outweigh possible overestimates of exposure due to alleged industry-wide improvements in work practices.

The Costs of Cancer

Total direct costs of treatment for an individual cancer patient were estimated by H.E.W. in 1971 to range from \$5,000 to \$30,000. Indirect costs, such as loss of earnings from premature disability, are often much greater. Total national costs from cancer, both direct and indirect, were estimated by H.E.W. in 1971 to be about \$15 billion annually, and estimates for 1979 are in the region of \$30 billion.

In addition to these *recognized* costs of cancer, there are a variety of other costs — often referred to as "externalized" costs — that have generally been ignored or denigrated. Consider workers' compensation. Payments to workers who have contracted occupationally related cancer result not only in externalization of industry's costs but also seriously mask the full extent of the national costs of the disease. And the efficiency and equitability of these procedures leave much to be desired. For instance, state compensation systems have abjectly failed to deal with occupational health problems, particularly for diseases with long latency periods (such as cancer). Impossibly heavy burdens are placed on workers, or their heirs, to unequivocally demonstrate causal relationships between their cancers and prior occupational exposure to carcinogenic agents. Furthermore, state compensation systems make no provisions for identification and medical examination of former workers (retired or active elsewhere) who were previously exposed to carcinogens but who are not yet clinically ill.

Workers' compensation laws, which vary from state to state only in their degree of inequity, are based on an implied trade-off in which workers surrender their rights to sue their employer in exchange for the guarantee of adequate compensation in a

nonadversarial process. The courts have almost consistently upheld the legality of the denial of right to sue, but have generally failed to maintain the right to an uncontested adequate compensation.

Results of recent surveys by the Department of Labor highlight the problem:

- The average length of time from onset of disability to the first disability payment is one year for a disease claim (compared to two months for an injury case).

- Sixty per cent of disease cases that are eventually compensated are contested (compared to ten per cent of injury awards).

- The probability of litigation approaches ninety per cent for serious diseases such as cancer.

- Fifty-five per cent of disease claims are settled by compromise and release agreements (compared with sixteen per cent of injury cases).

- The total average compensation payment for permanent occupational disease is less than \$10,000 (compared with \$23,400 for similar injury cases).

- Compensation for death caused by occupational disease averages about \$3,500 (compared to \$57,500 for an injury case).

- Foreign countries settle proportionately more disease claims than does the United States. (In the case of Sweden, the disparity is about twelve-fold.) The claims-determination process in most other countries is in the hands of a disinterested party, in contrast to the U.S. procedure.

An important recent development in attempts to reform the inequities of current compensation systems, which would help to internalize some of the costs of occupational cancer, has been the introduction of S.3060 by the Senate Human Resources Subcommittee on Labor. This bill is designed to provide comprehensive reform of compensation programs, and to mandate uniform national guidelines, while allowing a reasonable degree of autonomy at the state level. Regrettably, S.3060 has not been reported out of committee, and its chances for passage are slim (even though earlier versions of this bill were introduced beginning in 1972).

Consider also occupational surveillance costs. N.I.O.S.H. has recently estimated that for the relatively small number of regulated carcinogens alone, the associated cost of worker surveillance is in the region of \$8.5 billion.

Another category of externalized costs derive from medical malpractice suits against company doctors who fail to inform workers of medical findings that might otherwise have motivated them

to limit further exposure. For example, there are ten lawsuits (totaling over \$50 million) against Kent Wise, former physician for a Johns-Manville plant in Pittsburgh, Calif., on the grounds that he deliberately withheld information from workers on X-ray evidence of asbestos-induced lung disease. In the future, such professional malpractice lawsuits — for failure to protect workers and to inform them of occupational hazards — will almost certainly be filed against company-employed engineers, chemists, industrial hygienists, and executives.

The "spillover effect," and potential community cancer suits, represent a major but as yet unexplored additional set of externalized costs. Toxic and carcinogenic chemicals from inside a petrochemical plant, for example, are discharged or escape to the outside community, so that the occupational disease hazards are "shared" with local residents. It is also awesome to note that an entire calculus of other externalized costs — the dimensions of which have been barely considered — reflects the consideration that many carcinogenic chemicals possess other toxic effects, notably teratogenic (causing birth defects) and mutagenic.

Industry's Responses: A Poor Track Record

"Industry," a heterogeneous array of interests and objectives, has generally presented a common front of intransigence in response to proposed regulation of toxic and carcinogenic chemicals. Accumulation of information on chemical hazards in the workplace has not been paralleled by development of technological means to control them. Indeed, industry insists that attempts at regulation are stifling technological innovation.

In support of the status quo, industry appears to have evolved a complex set of strategies. Their essence is to downplay risks due to a particular product or process, to overstate the social benefits and uniqueness of the product or process, and to exaggerate the costs and difficulty of regulation. These strategies are sometimes presented frankly as industry positions, but they usually come from industry front organizations and quasi-professional associations (such as the Nutrition Foundation, the American Council on Science and Health, and the Council on Agricultural Science and Technology), or from well-selected academic consultants who usually give no hint of their often close and pre-existing relationship with the client industry. The elements of these strategies, with some examples, include:

heavily industrialized states such as New Jersey, experience excess overall and organ-specific cancer rates (Data displayed here are for white females, age-adjusted, and expressed as annual mortality rate per 100,000 population for the 1950-1969 period) (Source: Mason and McKay)



Minimizing risks. The Quebec Asbestos Mining Association maintains that asbestos-caused disease is a reflection of past working conditions that have improved so much that the industry is now safe. A frequent position of trade associations and industry front organizations in general is that there is no risk in exposure to "relatively low" levels of carcinogenic chemicals.

Blaming the victim. The American Industrial Health Council, an offshoot of the Manufacturing Chemists' Association (M.C.A.), ascribes cancer among workers to smoking, poor diet, alcohol, sunlight, and individual hypersusceptibility rather than to exposure to carcinogens in the workplace.

Diversionary tactics. Industries insist on degrees of scientific precision and legal definition that cannot possibly be met in toxicological or epidemiological studies, often coupling this with rejection of carcinogenicity test data in animals and demands for long-term human studies over the next few decades. Naturally, regulatory action should be deferred until the results of such studies are in.

Influencing policy. Powerful, well-focused, and well-financed industry lobbyists, and the national Chamber of Commerce network, represent a national force that has often been galvanized to subvert the enactment of protective legislation and the promulgation and implementation of standards.

Exhausting the agencies. Once an agency has decided to regulate, or has been obliged to regulate in response to pressure from labor or public interest groups, industry generally resorts to legal action, insisting on a protracted case-by-case reexamination of fundamental principles of toxicology and car-

cinogenesis, while at the same time claiming trade secrecy on related questions of exposure and alternative noncarcinogenic products and processes.

Central to the complex of industry strategies has been *control of the data* — their generation, interpretation, and availability — which form the basis for regulation. Such data extend beyond health and safety to product efficacy and to manufacturing, marketing, and compliance costs as well. Detailed analyses of the track record of industry, with reference to a wide range of case studies in the workplace, consumer products, and the general environment, provide ample documentation for the overall thesis that information provided by industry, or by individuals and institutions with direct or indirect industry connections, should be suspect until proven otherwise. Data are commonly destroyed, manipulated, or suppressed.

Examples of suppression include:

- The policy of the Chemical Manufacturers' Association (formerly the M.C.A.) to deny workers the right to know what chemicals they are exposed to in trade-name products;
- The assertions of the asbestos industry that the hazards of asbestos products were largely unknown before the 1960s, when as recently revealed (particularly by the 1978 "Asbestos Pentagon Papers"), such information was known to industry executives and scientists in the 1930s;
- The early failure of the Dow Chemical Company to reveal to the Occupational Safety and Health Administration (O.S.H.A.) and the Environmental Protection Agency (E.P.A.) results of tests showing chromosome damage in workers who were exposed

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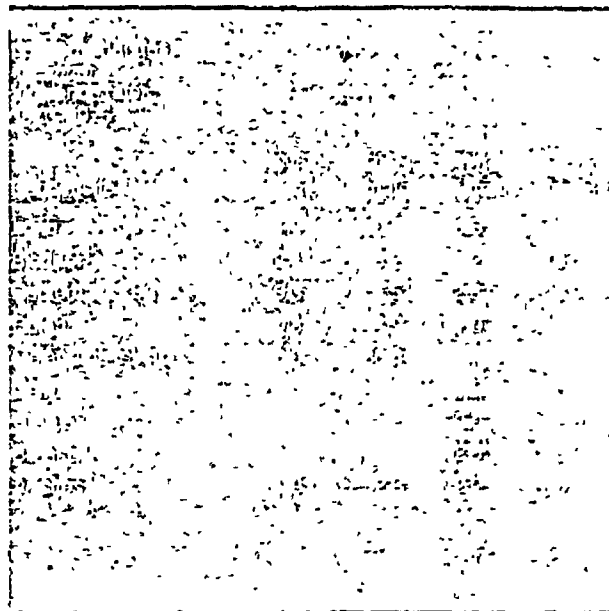
to levels of benzene under 10 ppm. Simultaneously, the company was fighting against regulations designed to limit such exposures and was insisting on their harmlessness;

□ The action of the Pharmaceutical Manufacturers Association and American College of Obstetricians and Gynecologists in filing suit against the Food and Drug Administration's September, 1976, decision to label estrogens with warnings of the risk of uterine cancer.

Examples of manipulation include the alteration of records and reporting of nonexistent slides by Hazleton Laboratories in the course of toxicological tests on the sweetener Aspartame and the drug Aldactone; and the economic analysis, commissioned by the Society of the Plastics Industry, on the impact of meeting a less-than-one ppm vinyl chloride standard in the workplace, which predicted massive costs that subsequent experience proved to be exaggerated by many orders of magnitude.

Examples of destruction include both the *routine* — Dow and Du Pont admitted in 1973 that workers' records were destroyed after ten years, even while both companies had claimed in-house epidemiological evidence of the long-term safety of three occupational carcinogens (ethyleneimine, 1-naphthylamine, and MOCA) that O.S.H.A. was attempting to regulate; and the *dramatic* — immediately prior to a federal investigation in April, 1977, Industrial Biotech Laboratories destroyed its records on thousands of industrial chemicals, drugs, food additives, and pesticides (many of which had been developed under contract to the Chemical Industry Institute of Toxicology, a proclaimed source of reliable data for the major chemical companies).

But industry is now evolving a new set of strategies — as before, to counter and limit the regulation of toxic and carcinogenic chemicals — which represent a radical departure from previous policies. Industry is now shifting emphasis from denial of risks to an admission that these risks do exist but must be accepted as part of a trade-off for alleged societal economic benefits. This shift in emphasis derives from the depressed economic climate and other considerations, including: a continuing series of damaging disclosures on the extreme unreliability and self-serving nature of much industry safety data; the evolution of independent scientists whose concerns about public health have encouraged successful challenges of a wide range of industry's contentions in toxicology and epidemiology; and some outstanding new administrative appointments to



Since 1933, and especially over the last decade, there have been progressive increases in cancer incidence rates for all ages throughout the U.S. (Source: NCI, Third National Cancer Survey, 1969-1971, and S.E.R. Program)

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Cancer is
now the only major
fatal disease
whose incidence is
on the rise.

federal regulatory and research agencies. Faced with these conditions, industry is now shifting its prime focus from the scientific debate in regulatory agencies to the economic debate in Congress, the courts, and the Council on Wage and Price Stability.

Ever sensitive to changing national moods, industry's demands for deregulation have recently become more clamorous and linked to Proposition 13-style tax reform, inflation, alleged free-spending by runaway regulatory agencies, and the growing big-government intrusion into free enterprise. Full-page advertisements in leading national newspapers complain that "the spiraling costs of regulation" (both for administration and compliance) are inflationary and innovation-stifling. The industry position is buttressed by articles and letters in leading journals and newspapers from prominent academic spokesmen and industry front organizations, and by restrictions on health and environmental regulations originating from the White House itself. Apart from the self-serving nature of industry demands for deregulation, these reflect the myopia of traditional economists preoccupied with the G.N.P. and the immediate costs of compliance rather than with the heavier and largely externalized delayed costs of failure to regulate.

Industry demands for deregulation in pollution and preventive health areas are in interesting contrast with its insistence on continued economic regulation to protect monopolistic practices. In spite of all the praise lavished by industry and its public relations machinery on the concept of free competition in a deregulated market, industry fights vigorously to foster economically protective regulation ("corporate socialism") whenever its interests are threatened.

To Regulate or Not to Regulate

In March, 1978, President Carter issued an executive order on regulatory reform which included the requirement that regulatory agencies develop economic impact analyses (i.e., to estimate the effects on business) of all major proposed standards. The order was warmly received by the business community and was promptly endorsed by the U.S. Chamber of Commerce, among others. Since then, the administration has imposed increasing restrictions on health and environmental regulations, particularly through its agent, the Regulatory Analysis Review Group of the Council on Wage and Price Stability (C.O.W.P.S.).

C.O.W.P.S. issued a report in October, 1978, for example, sharply critical of O.S.H.A.'s "generic" cancer policy (which would require automatic but flexible rule-making procedures for all proven carcinogens instead of developing rules on a tedious and protracted chemical-by-chemical basis). C.O.W.P.S. cited the economic impact analysis prepared for the American Industrial Health Council by Booz, Allen, & Hamilton — admitted by C.O.W.P.S. to be "seriously flawed" — as its authority for stating that the total costs of the proposed regulation would be inflationary. The C.O.W.P.S. report was roughly coincident with President Carter's announcement of his new anti-inflation program, asserting that inflation is the nation's number one problem and that prompt remedial action, including across-the-board austerity measures, must be undertaken. C.O.W.P.S. was also critical of the O.S.H.A. benefits analysis which, not surprising in a generic approach, failed to address the cost-benefit question on a carcinogen-by-carcinogen basis. This criticism was buttressed by reference to the October, 1978 decision of the Fifth Circuit Court which overturned O.S.H.A.'s proposed benzene standard largely on grounds of economic infeasibility and cost-benefit considerations. The case is now pending before the Supreme Court.

Cost-benefit analyses (upon which the administration's approach heavily depends) do not adequately reflect the delayed costs of deregulation, or of failure to regulate, in terms of disease, death, and environmental degradation. Some uncertainties inherent in quantitative risk assessment from animal test data are illustrated by the 10-million-fold range in current estimates of the carcinogenic hazards of saccharin (*see table, p. 51*). Quantitative risk assessment is a premature science fostered by pressures to express public health hazards in economically simplistic terms. And complicating, difficult-to-measure factors, such as synergisms and multiple exposures, only magnify the uncertainties. The recognized annual costs of cancer (in the region of \$30 billion) reflect medical bills and income loss — minimal but hardly adequate value estimates for pain, suffering, and loss of life — quite apart from a wide range of externalized costs.

Furthermore, cost-benefit analyses raise important questions of equity. Those few who profit from the manufacture or processing of the carcinogen and who resist bearing the immediate costs of compliance (despite the fact that many of these costs are generally "redistributed" through tax write-offs and

Federal research efforts emphasize
cure instead of prevention.
And for an environmentally induced
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price pass-throughs) are not the many who suffer the long-delayed but serious consequences of failure to regulate. It would seem reasonable to require that the interests of a worker exposed to hazardous conditions and of a consumer exposed to hazardous consumer products (both generally involuntarily and unknowingly) should receive substantially more protection than is now afforded by the regulatory process.

The costs of regulation are incorrectly evaluated, often failing to incorporate the economic advantages of regulation-stimulated innovations such as alternate technologies and product or process substitutions. (A good example was the substitution of toluene for benzene in the early 1960s, an action that virtually eliminated occupational leukemia in the photogravure and shoe-making industries in northern Italy.) Compliance may also encourage substantial economies by recovering and recycling valuable chemicals, otherwise lost as air and water pollutants, and may create whole new pollution-control industries that provide goods and services and, of course, jobs.

An important consideration for "economic impact" is that in most cases the regulated industry — not the regulatory agency — has a virtual monopoly on data needed to assess costs of compliance. And it is no great surprise that industry estimates of the costs of regulation are often highly exaggerated.

The clear need for detailed independent scrutiny of industrial compliance estimates and economic impact assessments (and of analyses by C.O.W.P.S. based on industry claims) is afforded by the vinyl chloride (VC) example. The plastics industry strongly objected to the 1974 O.S.H.A. proposal for a less-than-one ppm occupational standard for VC on the grounds that it was beyond their compliance capability and too expensive besides. To bolster these claims, the Society of the Plastics Industry hired Arthur D. Little, Inc., and O.S.H.A. hired Foster D. Snell, Inc., to estimate the economic impacts of the new standard. The consulting firms predicted costs as high as \$90 billion and the loss of up to 2.2 million jobs. These estimates were grossly exaggerated and also failed to reflect the high costs of VC-induced cancer and other diseases in workers as well as excess miscarriages in women living in proximity to VC plants. In spite of massive industry lobbying and pressures, O.S.H.A. stood firm on the new 1 ppm standard, which it put into effect on April 1, 1975.

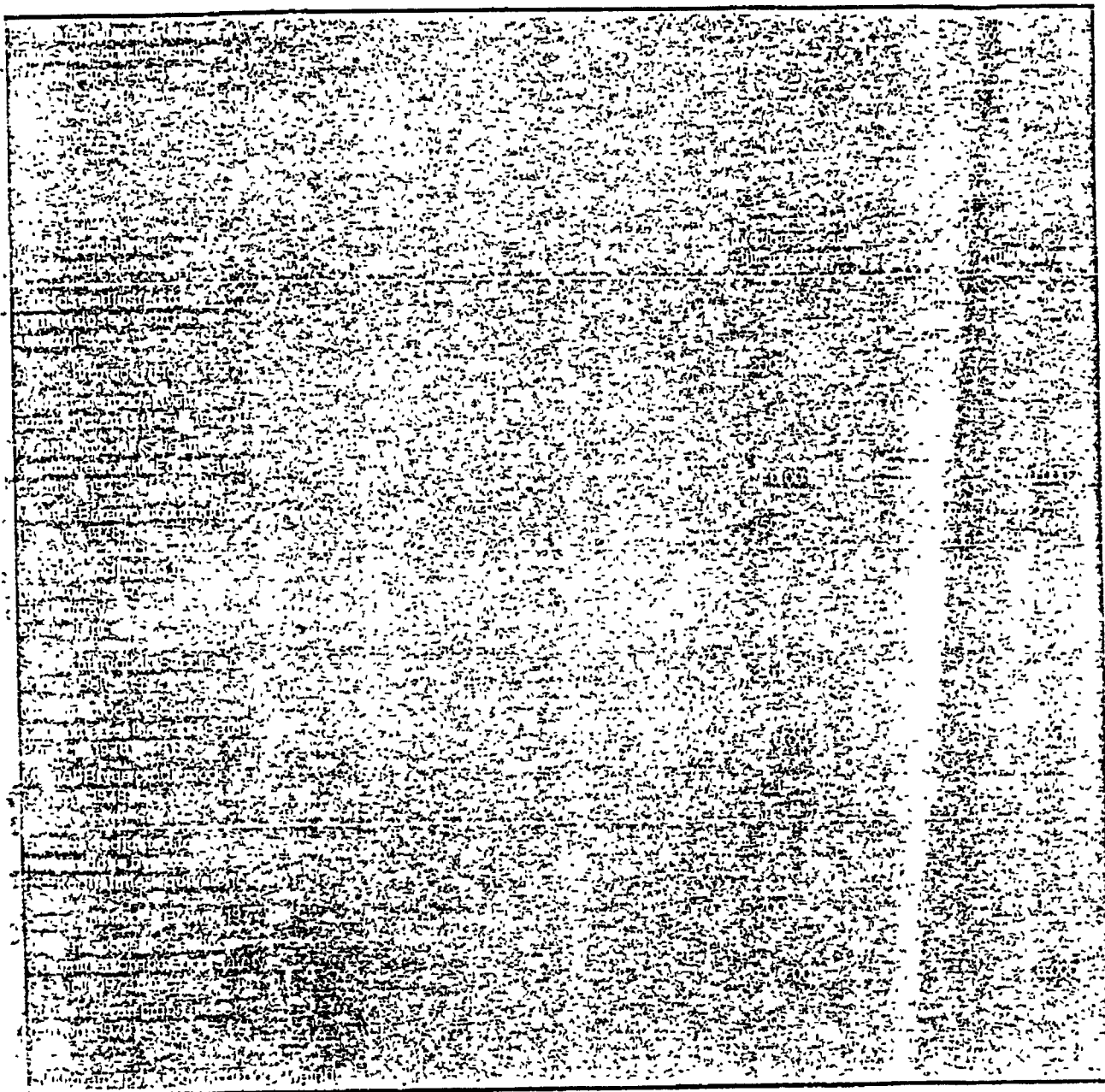
The above estimates, in light of subsequent exper-

ience in the plastics industry, proved to be incorrect by several orders of magnitude. Within one year, the new standard was met without any major economic dislocation. B.F. Goodrich, one of the industry giants, redesigned its manufacturing technology to enclose VC manufacturing and handling processes and to plug possible sources of leaks. Additionally, a "stripping" process was developed to reduce levels of the unreacted VC monomer in the polyvinyl chloride (PVC) resin and to decrease VC loss in the process (thus reducing both worker exposure and contamination of the surrounding community). The initial capital costs of compliance were about \$34 million. Contrary to the estimates of the consulting firms, B.F. Goodrich found that the new clean-up technology actually cut labor costs and could be profitably leased. (In spite of this, B.F. Goodrich increased the price of its PVC products in 1976, claiming higher production costs and blaming them on regulatory standards.) The experience of Union Carbide was similar. Late in 1975, a company official acknowledged how unexpectedly easy it had been to comply with the 1 ppm standard. Currently, the VC/PVC industry is enjoying an unprecedented boom.

Compliance costs are generally estimated on the implicit and self-serving assumption that a particular product has societal efficacy and utility, even in the absence of supporting evidence or in the presence of contrary evidence. Such assumptions cannot be substantiated for a wide range of carcinogenic products. Saccharin's efficacy in the treatment of diabetes and obesity, for example, has never been documented in the scientific literature, and its main use, ironically, is by healthy adolescents. Aldrin and Dieldrin have produced widespread environmental and human contamination, but their manufacturer (Shell Chemical Co.) was unable to produce evidence of efficacy in the 1973 E.P.A. cancellation hearings. The major target insect population, it turns out, is resistant to these pesticides.

The costs of carcinogenicity tests are often cited by industry as a heavy and unjustified compliance expense, particularly on the grounds that too many new chemicals are being introduced into commerce each year to be handled by conventional animal testing and that the cost of such testing would be prohibitive. In fact, the number of these new chemicals is under 700 annually. There is every reason to believe that current facilities could be expanded to cope with this number of chemicals, and without excessive strain. There are large potential facilities at

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Estimating risk is by no means an objective, universally agreed-upon procedure, as the divergence of these data — derived by a variety of methods — can attest (Source: Committee for a Study on Saccharin and Food Safety Policy (National Academy of Sciences))

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The absence of a
national public health constituency
at a grass-roots level
is probably the single most important
impediment to cancer prevention.

the national laboratories, such as at Oak Ridge, Tenn. and Argonne, Ill., in addition to a large facility at the National Center for Toxicological Research in Arkansas. In addition, the bioassay program (under the new leadership of the National Toxicological Program) is planning to substantially increase its testing program to handle larger numbers of chemicals.

With regard to expense, the annual cost of testing one chemical for carcinogenicity (in groups of 50 mice and rats, of each sex, at two dose levels) is about \$200,000. Properly conducted carcinogenicity tests also provide information on a wide range of other chronic toxic effects, including testicular damage (leading to sterility), central nervous system damage (leading to paralysis or behavioral changes), and damage to the liver (leading to cirrhosis). The \$140-million cost for testing 700 chemicals would be unlikely to result in substantial increases in production and retail product costs. Such testing costs are about 0.2 per cent of the 1976 \$72-billion gross sales of the chemical industry. The immediate costs of testing should be further contrasted with the far greater delayed costs of failure to test and regulate.

Federal efforts are substantial but misplaced — they emphasize cure instead of prevention. And for an environmentally induced disease such as cancer, this is irrational. Health care leads the nation's inflationary spiral, having soared from \$30 billion in total national expenditures in 1960 to \$185 billion by 1978. In the last five years, the total has grown by 15 per cent annually. In 1978, health care costs were roughly 9 per cent of the G.N.P. and \$55 billion more than the defense budget. But as former H.E.W. Secretary Joseph Califano has pointed out, fully 96 per cent of the \$48 billion federal expenditures on health care in 1978 were directed to treatment — leaving only 4 per cent for disease prevention programs.

Few would doubt the need to fight inflation, to avoid needless regulation, and to implement only those rules that yield some net benefit to society at large. But the administration's initiatives raise important constitutional and legal issues, particularly as they appear to represent direct executive usurpation of legislative authority.

However, such initiatives are likely to forestall intemperate Congressional antiregulatory sentiments, such as those embodied in the September, 1979 amendment introduced by Senator Dale Bumpers (D-Ark.). Attached to a routine judicial improvements bill, this amendment would switch the burden

of proof to agencies who would then be obligated to show "preponderance of evidence" before they could regulate. If enacted, therefore, it would effectively produce regulatory paralysis and declare open season for assault by toxic agents.

Ironically, past Republican administrations have achieved more effective environmental regulation with weak agency heads than has been or is likely to be achieved by the present Democratic and liberal administration aided by strong and progressive agency leadership. Determinants of this paradox include emerging fiscal conservatism, increasing pressures by the administration and industry for deregulation in the name of anti-inflation, the public and Congressional perception of major uncertainties in the scientific base of environmental decision making and risk assessment, and the false issue of freedom of choice being pitted against regulation. In addition, there is concurrently a strong decline in the environmental and anticancer forces in Congress with the recent retirement of Congressmen James Delaney (D-N.Y.), John E. Moss (D-Calif.), and Paul Rogers (D-Fla.), and with the emergence of the new fiscal conservatives. The future role of labor has been made uncertain by recent wage limitations imposed by President Carter, and it is unclear whether organized labor will make wage or environmental controls its main priority. The likelihood of success of the deregulation trend seems enhanced by the absence of an effective national environmental and anticancer constituency.

The Single Greatest Impediment

It is difficult to mobilize a national constituency against carcinogenic products and processes when these hazards cannot easily be quantified and when the penalties of failure to regulate them will be manifest only in 20 years or so. It is simple, however, for an industry to mobilize immediate pressures against the regulation of its activities.

Despite increased funding of federal agencies, priorities on cancer prevention are still low. For instance, only about 10 per cent of the National Cancer Institute (N.C.I.) budget, approaching \$1 billion, is spent on research activities that can be reasonably defined in terms of cancer prevention. Additionally, there is no requirement for N.C.I. Cancer Centers to involve themselves in actual cancer prevention — such as carcinogenesis testing, surveillance of high-risk populations, and establishment of tumor registries geared to occupational

and environmental carcinogenic exposures.

The American Cancer Society has been an important element in the distortion of N.C.I. priorities toward cancer treatment rather than prevention, and the society has misled the public into the reassuring viewpoint that there have been major advances in the treatment of cancer. The society has fought against or withheld critically needed support from both legislative (for example, the Clean Air Act, the Safe Drinking Water Act, and the Toxic Substances Control Act) and regulatory (of saccharin, red dye number 2, hair dyes, Tris, DES in cattle feed, and Aldrin/Dieldrin, for example) actions designed to control carcinogens. While the traditional explanation for the society's position on cancer prevention lies in an amalgam of conservatism and ignorance, questions have recently been raised in the press about the possible influence of the wide range of industries in which society directors have direct or indirect financial interests. In any case, it seems unlikely that the society will play an effective role in cancer prevention unless its public image and fundraising ability are threatened.

The absence of a national public health constituency at a grass-roots level is probably the single most important impediment to serious attempts at cancer prevention. The efforts of public interest groups and organized labor, both of which have been responsible for instigating most regulatory actions against carcinogens over the last decade, are unlikely to prevail in the future unless their spheres of influence can be extended. Important and key additional constituencies that do not yet appear to have been mobilized include senior citizens, on whom the impact of unregulated carcinogens is heaviest in terms of cancer incidence and their ability to meet crippling medical costs, and the church, whose historic mission of social equity needs to be introduced into the debate on disease prevention versus cost.

The costs of current failure to regulate toxic agents will be a crippling inflationary legacy to future generations, and industry will sow a grim harvest of burgeoning cancer carnage unless it develops long-term policies more consistent with public health and welfare.

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