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OSHA AND ENVIRONMENTAL HEALTH

INTRODUCTION

The 1970s produced an onslaught of environmental laws aimed at eliminating or controlling contaminants believed to harm human health as well as other life forms on earth. More than 25 major statutes were enacted. Concomitantly, in the last decade, the federal government began to pay great attention to cancer, the second leading cause of death in the United States, which inadvertently had been linked to environmental causes. The man who established the relationship between the dread disease and the environment was Dr. John Higginson, director of the World Health Organization's International Agency for Research on Cancer. His widely-publicized findings, which estimated that 80-90 percent of all cancers are due to environmental factors, were seriously misinterpreted - for Higginson used the word "environment" to mean all external factors which affect a person (including such personal habits as cigarette smoking, poor nutrition, and excessive alcohol consumption).

However, given the tremendous apprehension caused by cancer and its profound uncertainties, it is no surprise that the disease has attracted the attention of the federal government. Cancer is a terrible disease and a pressing problem, debilitating and often irreversible. It starts in a single cell and, unless checked early, slowly spreads until it brings a painful, prolonged death. One in four people contracts it and only one in three survives. In 1980, over 400,000 people are expected to die - about 1100 a day or one every minute and a half.

In the 1971 State of the Union message, then-President Nixon first declared war on cancer. That same year, Congress passed the National Cancer Act whose appropriation of a few hundred million dollars has soared to over $1 billion for the National Cancer Institute - the largest expenditure ever aimed at curing a disease.

With a cure elusive, President Carter has shifted the government focus to protection of public health through prevention of the disease. In his environmental message to Congress in May 1977, he asserted, "Rather than coping with hazardous substances after they have escaped into our environment, our primary objective must be to prevent them from entering the environment at all!" The same year, the Occupational Safety and Health Administration (OSHA) transmitted for review and comment a draft of a proposed cancer policy to deal with exposure of workers to possible carcinogens.

OSHA recently issued its far-reaching and controversial final cancer policy. Seeking to identify, classify and regulate cancer-causing substances that could pose chronic health hazards to workers, the agency has chosen to rely heavily on animal tests for assessing carcinogenicity in humans and has failed to use risk assessment to determine the level of exposure to workers in the workplace. These two questions were the central issues debated each time suspected carcinogens were proposed for regulation. Guidelines will be such now that according to Eula Bingham, assistant Secretary of Labor for OSHA, "we won't have to reinvent the wheel every time we attempt to regulate a potential carcinogen."

Essentially, the OSHA regulations set a comprehensive national cancer policy. The magnitude of the cancer policy is much greater than the effects it has in the workplace for it will affect the air, the water, food, drugs, and consumer products, as well as hinting at a direction in which the federal government is going to accommodate environmental health concerns. Four other Federal regulatory agencies which comprise the rest of the Interagency Regulatory Liaison Group (IRLG) set up by President Carter to coordinate regulatory activity most likely will adopt the scientific principles set forth in the OSHA policy, thus making it a government-wide method of regulating carcinogens. Under their respective statutes, OSHA has authority to regulate hazardous substances in the workplace; the Environmental Protection Agency (EPA) can regulate contaminants of the air, water and land; the Consumer Product Safety Commission (CPSC) can regulate products in the marketplace; and the Food and Drug Administration (FDA) along with the Agriculture Department's Food Safety and Quality Services (USDA-FSQS) have had long-standing authority to protect food and drugs.

Moreover, the spirit and thrust of the numerous environmental laws of the 1970s are being extended from a concern for prevention of environmental hazards to the area of compensation or after-the-fact considerations.

The approach of the Carter Administration in seeking to prevent cancer will be the prime focus of this paper. A follow-up report will look exclusively at "superfund" legislation as it deals with compensation as well as clean-up issues relating to cancer-causing substances and other environmental health hazards.

OSHA'S CANCER POLICY PROVISIONS

Announced January 16, 1980, the Occupational Safety and Health Administration's final cancer policy fills nearly 300 pages in the January 22 Federal Register. It differs in some significant respects from the initial proposal of October 1977 as a result of extensive public participation at hearings whose transcript exceeds a quarter of a million pages. The rules are set to go into effect April 22, if they survive the legal challenges against them.

The main changes were two concessions to industry. Emergency temporary standards will not automatically be issued for Category I Potential Carcinogens as was originally proposed. Instead, they can only be set when deemed appropriate. Secondly, recognizing that methods for determining carcinogencity are not yet conclusive, OSHA now permits greater flexibility by allowing petitions to the agency based on "substantial new evidence or issues" and by calling for review of past actions or even the entire cancer policy every three years in light of any significant scientific and technical advances.

More specifically, the provisions define a potential occupational carcinogen as

> ...any substance or combination or mixture of substances which cause an increased incidence of benign and/or malignant neoplasms (tumors) or a substantial decrease in the latency period between exposure and onset of neoplasms in humans or in one or more experimental mammalian species (all warm-blooded quadrupeds) as a result of any oral, respiratory or dermal exposure, or any other exposure which results in the induction of tumors at a site other than the site of administration.

Based on a scientific review of available data, the agency will publish in the Federal Register, at least annually, a "candidate list" of suspected carcinogenic substances.

From such lists, the substances may be classified as Category I Potential Carcinogens if the evidence is relatively conclusive, that is carcinongenic in humans or in a single mammalian species in a long-term bioassay (laboratory determination) where the results are in concordance with other scientifically evaluated evidence. Concordant evidence includes positive results from testing in the same or other species, positive results in short-term tests (on bacteria, yeast or other cell structures), and evidence derived from tumors or injection or implantation sites. A permissible exposure limit for Category I substances will be set "as low as feasible" through engineering and/or work practice controls and will follow guidelines for other protective measures contained in model standards. The proposal will contain provisions

for monitoring, regulating areas, methods of compliance, respiratory protection, protective clothing and equipment, medical surveillance, employee information and training, signs and labels, recordkeeping, and observation of monitoring of employees. Lastly and very importantly, if OSHA decides that there is a safe substitute, then the carcinogen will be banned from the workplace.

Category II Potential Carcinogens will be classifed as such if on scientific evaluation the substance meets the criteria for a Category I determination but the evidence is only "suggestive," or based on positive results in a long-term bioassay in a single mammalian test species. Also, the regulatory standards are less stringent for these substances than for the Category I carcinogens.

Category I and II substances will arise out of two "priority lists" to be published at least every six months. Each priority list made up from the candidate list will consist of approximately ten substances for each of the two categories. Some factors that will be considered in selecting the substances on the priority lists include: the estimated number of workers exposed, the estimated levels of human exposure, the levels of exposure that have been reported to cause increased incidence of cancer in humans or animals or both, and the extent to which regulatory action would reduce not only cancer risk but other health hazards as well.

Lastly, to aid in the identification, classification and regulation of any potential occupational carcinogen, OSHA may request at any time that the heads of the three federal health research institutes [National Institute for Occupational Safety and Health (NIOSH), the National Cancer Institute (NCI), and/or the National Institute of Environmental Health Sciences (NIEHS)] convene a scientific review panel.

LEGAL ACTION

Within days after the issuance of the cancer policy, both industry and labor mounted challenges in the courts. Generally, the review of an OSHA standard is heard in a court where the earliest petition has been filed. The American Petroleum Institute was the first group to challenge in petition to the Fifth Circuit Court of Appeals in New Orleans on January 9, 1980. It questions the validity of the scientific methods OSHA uses in determining carcinogens in the workplace. The AFL-CIO filed on January 16 in the District of Columbia Circuit challenging OSHA's removal of the automatic emergency temporary standard provision from the final policy. The American Industrial Health Council followed with a petition in Texas on January 18 charging that the OSHA policy "for the sake of administrative convenience, ignores scientific developments, the tremendous difference in the physical and toxicological characteristics of chemical substances, and the differences in the workplace."

The court decision to have the greatest effect on the future regulatory activities in the occupational, or in general the environmental, health area will be the ruling in the landmark benzene case before the Supreme Court. Expected this year, it squarely addresses the controversial and fundamental question of how much an agency must weigh costs of regulation against its potential benefits. A U.S. Court of Appeals ruled in October 1978 that OSHA cannot legally regulate occupational health hazards without first using cost-benefit analyses "to determine whether the benefits expected from the standard bear a reasonable relationship to the one-half billion dollar price tag." Although many agencies have resisted cost-benefit analyses for health and safety rules on grounds that benefits, such as how many lives may be saved, are often immeasurable, a decision upholding the appellate court ruling would force OSHA and other agencies to measure costs and benefits before issuing regulations like the cancer policy.

No doubt influencing the Supreme Court on the benzene (a petrochemical used in plastics, resins and motor fuels that allegedly induces leukemia) case will be the federal appeals court decision of October 1979 endorsing OSHA's cotton dust standard. The court rejected cost-benefit analyses and supported costly engineering controls of cotton dust in the workplace. OSHA estimates that compliance would require capital expenditures of $550 million but industry figures the cost at about $2 billion. About 600,000 workers are exposed to cotton dust which purportedly results in chronic respiratory problems.

Other legal challenges in recent years involving risk-benefit analysis as it strives to achieve workplace safety wherever it is feasible, not just where it is cheapest, deal with arsenic (emitted into the air from copper, lead and zinc smelters, glass-making plants and certain pesticide producers, and charged with causing lung cancer), vinyl chloride (in many plastic plants and purportedly a cause of liver cancer), acrylonitrile (a substance used to manufacture synthetic fibers and plastic materials that may be carcinogenic), and others such as asbestos, coke-oven emissions, lead, kepone, DDT, and Red Dye #2.

SCIENCE

Alongside the economic questions of cost-benefit analysis, upon which many of the legal actions turn, are scientific uncertainties in the national cancer policy. OSHA believes that as a policy matter, it must accept and use the best information available and not wait for conclusive human results.

The difficult questions surrounding OSHA's decisions are:

1) Should the agency have placed less weight on positive studies, whether human or animal, when negative human epidemiological data provide refuting evidence? With

the final policy, negative human tests would not supersede positive animal results.

2) Should OSHA not have assumed that there is no threshold level below which exposure to carcinogens entails no risk? The cancer policy assumes no consistent relationship between dose and response that would call for threshold levels at low doses.

3) Should risk assessment relating to the potency of a suspected carcinogen have been used only to establish priority lists and not have been considered in determining exposure levels?

4) Should government scientists alone have been used to identify and classify carcinogens or should an independent scientific panel have determined the carcinogenicity of substances - at which point regulatory agencies could then have applied appropriate action?

5) Did the decision for a candidate list with its subsequent priority lists deny due process in ostensibly "blacklisting" substances? Inclusion or exclusion of a substance on either candidate or priority lists "shall not be subject to judicial review nor be the basis of any legal action."

In the agency's desire to answer them, it ignored important scientific and economic arguments in order to facilitate regulation of potential health hazards. Contrary to newspaper headlines and the sensationalized stories that follow, cancer is not an epidemic and it demands no severe answers with their major consequences. The proportion of cancer cases brought on by occupational or industrial carcinogens is not very high. In fact, Higginson estimated that they cause only about five percent of cancer deaths. No matter how small the percentage is, it still represents human suffering that can and must be addressed. The questions are to what degree and at what cost.

Should tens of billions of dollars be spent by industry on compliance costs with conceivably minimal reduction of cancer incidence and mortality; or should more attention be given to lifestyle factors (such as cigarette smoking, alcohol consumption and dietary practices) which have shown more conclusively to increase cancer risk (these factors contribute to approximately 40 percent of cancer deaths); or should more of a concerted effort be given to cancer research and its quest for a cure?

OTHER ENVIRONMENTAL HEALTH CONCERNS

Aside from the many thousands of substances susceptible to regulation as carcinogens by the federal regulatory agencies guided by the national cancer policy, the federal government is

being pressed to consider more than just preventive measures. Groups calling themselves victims are going to court seeking compensation for apparent environment-related health illnesses and to Congress for changes in federal court rules to make it easier to collect damages.

The most organized are the Vietnam veterans who claim a potent herbicide, Agent Orange, caused cancer as well as other illnesses in them and the children since born of them, and the Nevada residents who claim nuclear tests have increased the incidence of their contracting cancer and other health disorders. In Vietnam, the U.S. Army used Agent Orange, a dioxin which has been the subject of controversy for a decade, to defoliate the dense jungles that provided cover for the enemy. Banned domestically in 1970, it has been back on and off the market ever since as one study would show its harmful effects and another would negate it.

The numbers that could conceivably seek compensation due to radioactive fallout make the 750 veterans in litigation seem insignificant. Radiation which passes through a cell may cause damage that a cell may repair. It may also cause irreparable damage that is reproduced in new cells as the injured one divides, resulting in hazardous health effects. Scientist believed low dosage of radiation caused no harm so many military personnel were exposed to test areas shortly after the nuclear devices exploded. But studies have found a surprising increase in leukemia among the people in the vicinity of the test sites and the children born during the test years.

Three Mile Island is becoming another big question with respect to radioactive fallout. Some indications are that children born near the nuclear plant since the time of the accident have an unusually high incidence of serious thyroid problems. U.S. military personnel stationed in Japan may have suffered effects from atomic bombing in World War II. Uranium miners exposed to radon gas have an extraordinarily high incidence of lung cancer. Are these groups more environmental health victims?

Congress reacted in the late 1960s with a compensation program for coal miners afflicted with "black lung," a disease caused by prolonged exposure to coal dust. The government paid approximately $1 billion before shifting the responsibility to industry. A couple of other programs in the late 1970s also compensated victims who developed environmentally-related diseases.

Neither Congress nor industry wishes to continue compensating the unknown number of victims for environmental illnesses caused by multiple factors and developed over a long latency period. Science does not show adequate causation which the law demands and the economics of compensation and/or compliance costs could be as debilitating to industry as cancer is to its victims.

CONCLUSION

Current public fear of environmental health hazards may cause an analogous government overreaction in the 1980s to the barrage of environmental laws in the 1970s. To protest and restore environmental quality the federal government responded with the simplest and quickest form of control - regulation. Promulgating regulations and enacting laws, it addressed the problems and noticeably improved the quality of the environment. At the same time, the plethora of uniform standards commensurate with the fervor with which they responded were so strict and inflexible that many older industrial plants could not achieve abatement levels. As a result, they closed; unemployment rose; tax bases were lost; and other negative economic impacts were felt.

Similarly, the generic national cancer policy rejects cost-benefit analysis. Given the present pressures of the economy, would it not be wiser at least to use the guidelines of cost sensitive analysis? It is misdirected for converging on a very low percentage of cancer cases. More judiciously, a national cancer policy should focus on the single simple largest cause of cancer - personal habits.

The compensation issue expands the breath of environmental law. Because contaminants pervaded the environment, they presumably caused various illnesses. With the increased number of legal claims and subsequent proposals in Congress, the federal government will have to make some final arrangement and it is hoped with the deliberateness lacking in the emotional reactions of the past.

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