

CHEMICALS ON TRIAL: THE CASE FOR BETTER CONTROL

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A modern Rip Van Winkle awakening today after a 10-year sleep would, I am sure, be surprised by the growth of the environmental awareness in the United States. A decade ago, such concerns as air and water pollution, land use, and the preservation of wilderness areas worried a comparative few of us - and even those few were frequently regarded as cranks.

Today, by contrast, environmental concern is widespread, as evidenced, for example, by front-page reporting of plans for oil drilling on the Outer Continental Shelf, or for strip mining coal in the Northern Great Plains. Ten years ago we would have been concerned only with the energy that such developments would make available. Now, we are also concerned that such development proceed in a manner that minimizes the risk of damage to the environment. Our new attitudes about environmental matters present a remarkable case study in rapid social change. Yet, it is ironic that we should have made progress in some environmental matters so quickly and be so slow in other areas that directly affect human health. I refer of course to the regulation and control of hazardous chemicals.

In 1971, the Council on Environmental Quality (CEQ) issued a report on toxic substances. The report pointed out that about 2 million chemical compounds are known, and that thousands of new chemicals are discovered each year. Most new chemical compounds are laboratory curiosities that will never be produced commercially. However, several hundred of them do go into commercial production each year. Although most of these substances are not toxic, the sheer number of them, the increasing diversity of their use, and the environmental problems already encountered in connection with some warn us that we are dealing with a major problem. The report further concluded that the environmental impact of most substances is not well understood. Of those compounds studied, testing has largely been confined to acute effects - those which show up quickly and are easily perceived; but our knowledge of chronic, long-term effects is inadequate. We know that cancer, genetic alteration, and various sorts of mental, physical, and physiological change can be chemically induced. In general, however, we find it difficult to pinpoint the chemicals which cause such effects.

On the basis of this study, CEQ concluded that there was an urgent need for a program to screen toxic substances before they went into commercial use. The report conceded that our understanding of environmental threats, our skill at testing substances for adverse effects, and our ability to monitor and predict these effects were not fully adequate. Nevertheless, it concluded that our knowledge in these areas was sufficiently developed to justify immediate action. No longer did we have

to maintain a purely reactive posture with respect to toxic substances to limit ourselves to attempting to repair the damage after it has been done. Nor should we, the report stated, "continue to allow the entire population or the entire environment to be used as a laboratory."

The council recommended new legal authority in February, 1971, on the basis of the Council's recommendations, the President submitted to Congress a proposed Toxic Substances Control Act.

It is now February, 1975, four years since the initial submission of that proposed legislation. Each year since 1971, the CEQ Annual Report has cited new instances of health crises caused by chemicals such as PCB's, mercury, haloethers, and vinyl chloride. Each year since 1971 versions of the Toxic Substances Control Act have been debated in Congress, but none of them has been voted into law.

I repeat that in connection with the commercial production, distribution and use of chemical compounds, we are dealing with a major problem. More accurately, we are *failing* to deal with it. This important legislation was badly needed four years ago; we need it even more today. I want to urge you, therefore, as individuals and as members of a new but "influential society" to join me in urging passage of legislation which will meet the goals of the Toxic Substances Control Act. Such legislation has formidable opposition, principally, but not entirely, on economic grounds. Understanding those objections and their validity, or lack of it, requires some basic understanding of the proposed bill.

What should a Toxic Substances Control Act do? It should meet three major needs. First, it should provide for reporting to the government of chemical production and intended use. Second, it should permit the government to require testing of chemicals so an assessment of their potential for human and environmental risk can be made. Third, it should give the Administrator of the EPA the authority to regulate the production, distribution, and use of all chemical substances not currently regulated under other authorities.

In addition, the legislation should take a new approach to two aspects of the regulatory process. The first of these is *responsibility for safety and health testing* for commercially produced chemicals. Under present regulatory patterns, this responsibility is assumed entirely by government. Over the years the FDA, the NCI, the NIEHS, and the EPA have spent millions of tax dollars annually to test commercially produced chemicals. The thrust of proposed Toxic Substances Control legislation, however, is to require industry to test both new and existing compounds at its own expense.

I strongly support this latter approach. Testing to assure the safety of a chemical for the workers who will be involved in its

production, for the public who uses or consumes the chemical, and for the environment itself, is a proper developmental cost. We can no longer afford in fact, we could never afford to allow the production each year of thousands of chemicals whose consequences are vaguely understood or totally unknown.

The second issue arising from past efforts to regulate chemicals involves *information access*. In some cases, individuals and organizations that have information pertinent to the regulatory process withhold it. Sometimes data are held back in the name of protecting trade secrets; this is a legitimate concern, and proposed Toxic Substances Control legislation is written to safeguard such secrets. In other cases, regulatory agencies have been hampered by the suppression of health data--or by the submission of data which, by accident or design, tell a misleading story.

You are all aware of one, far-reaching example of this in the arsenic field. Inorganic arsenic, a by-product of smelting, is processed by only one plant in the United States. This plant ships the processed arsenic to companies in more than 40 major industries for subsequent use. We now know, thanks to disclosures in 1974 by Allied Chemical and Dow Chemical, that workers who had handled inorganic arsenic have been contracting lung and lymph cancers at dramatically higher rates than workers who were not exposed--from 3 times as high to 60 times as high. We also know (now that we have started digging back in the files) that reports suggesting a link between arsenic and cancer date back to the turn of the century.

Arsenic levels in industrial plants are regulated by Federal standards; why did we not know (until the Allied and Dow studies told us) that these standards were much too high?

Federal standards for arsenic exposure in industrial sites are based on a single study, performed in 1963 by an employee of the one and only arsenic processor in this country. In essence, that study compared cancer rates between two groups of workers in the plant: one group regularly exposed to arsenic, and another group that supposedly was not. The study found no significant difference in cancer rates between the two groups and concluded, therefore, that regular exposure to arsenic did not result in any excessive incidence of cancer.

In 1969, however, Drs. Frederick Lee and Joseph Fraumeni of the NCI pointed out an astonishing gap in this study--investigators had not compared the plant workers with people who worked outside the plant, that is, with those who definitely were not exposed, day in and day out, to inorganic arsenic. In their own study, Drs. Lee and Fraumeni found that lung cancer rates for smelter workers, whether supposedly "exposed" to arsenic or not, were three times higher than rates for the general

population.

As a result of this and subsequent studies, the government will propose a dramatic reduction in Federal exposure standards for inorganic arsenic. On the basis of the original study, those standards were set at 500 $\mu\text{g}/\text{cu m}$ of air. In 1973, NIOSH, research arm of OSHA, recommended that exposure levels be cut to 50 $\mu\text{g}-1/10$ the old standard- and now, largely as a result of the Dow and Allied studies, OSHA will propose a new standard of 4 μg .

All of the returns are not in on arsenic studies, so no comment on the causes of the awareness of what appears to be bias in the original can be made. However, a proposed reduction from 500 μg to 4 μg is comment enough. This history of arsenic exposure standards supports the argument that Federal regulatory agencies cannot be restricted to filtered information.

The final issue that arises in connection with proposed Toxic Substances Control legislation is perhaps the most important; that is *burden of proof* in the decision making process. Where does that burden lie? Before a chemical is approved or rejected for mass production, should the government be required to prove that the compound presents an unacceptable risk to public health, or should the manufacturer or processor be required to demonstrate that it does not? I believe that the proposed Toxic Substances Control legislation is correct in placing the burden of proof on the manufacturer.

Just last month, as you know, the United States Court of Appeals for the District of Columbia, in a three-judge decision, overturned an EPA regulation governing the content of lead in gasoline. Last year, the Eighth United States Circuit Court of Appeals in St. Louis issued a stay of a District Court ruling which, in effect, would have shut down the Reserve Mining Company. The implication in both cases was that the government bears the burden of demonstrating a definitive link between chemical use and a health hazard.

In my view, these decisions constitute precedents which are not only major, but dangerous. The reason is that these rulings, with their perspective on burden of proof, fail to address a critical phenomenon--delayed health effects.

In the Reserve Mining Case, the Justice Department asserted the following:

1. Reserve Mining opened its plant and began dumping into Lake Superior eighteen years ago.

2. The corporation was processing 100,000 tons of taconite (low-grade iron ore) daily, and dumping 67,000 tons of taconite waste in Lake Superior.
3. Asbestos fibers averaging less than 2μ in length were found in concentrations ranging up to 100 million/liter in the drinking water of Duluth and nearby communities.
4. These fibers were directly traceable to the taconite dumping.
5. Over the last 18 years, approximately 200,000 people have ingested considerable amounts of asbestos fibers in their drinking water.
6. In addition, levels of asbestos in the air near the plant range from about 100,000 to 10 million fibers/cu m. Besides drinking asbestos fibers, therefore, the residents of the community have been inhaling them.
7. Asbestos, finally, is a known carcinogen.

These assertions were all demonstrable. What the Federal Government, 3 states, 5 environmental organizations, and 3 cities (all plaintiffs in the suit) could not demonstrate, however, is that anybody had actually contracted cancer from the asbestos.

Of course, they could not. With asbestos-induced cancer, the average period from first exposure to initial symptoms is 20 to 40 years. Reserve Mining has not been in business long enough for any one to prove that its waste is hazardous to human life.

But in 5 to 10 years, we should start accumulating enough evidence to know for sure. It may be that the exposure to asbestos in the area will not induce cancer and the Reserve Mining Company and the Eighth U.S. Circuit Court of Appeals will be vindicated in their gamble that this is the case. If those levels are proven high enough, however, it will be 20 years too late for those who contract cancer to do anything about it.

Reversing the burden of proof would, I realize, invert a cherished legal principle, one that has been a fixture in Anglo-Saxon jurisprudence for over a thousand years--the accused is innocent until proven guilty. In connection with health hazards whose effects do not show up for years, however, it is questionable whether we should apply the presumption of innocence to chemicals.

Reversing the burden of proof would, in some cases, result in major economic loss. This would be especially true in situations where this

approach were applied after the fact. The Reserve Mining case is an example in which about 3,200 employees would have lost their jobs until Reserve devised an alternate means for disposing of its waste. Certainly, all of us whose professional actions and personal concerns involve occupational health must maintain a prudent concern for the economic impact of our decisions.

However, our present inability to demand proof of safety with many new chemicals, and our recognition of the prospect of economic loss, create a circular process. Today we cannot prohibit production of a new chemical because its health hazards are not yet proven. By the time the health hazard is proven, however, production of the chemical may involve the investment of millions of dollars and the employment of thousands of people. So, when and if the chemical becomes a proven health hazard, it is very expensive to prohibit. More important, by that time many citizens may be suffering from cancer or other long-term effects which, had the chemical been tested, might never have occurred.

Those opposed to the Toxic Substances Control Act have put forward a number of objections to the concepts in the proposed legislation. Their primary argument is that the process of regulation would be time consuming and would keep promising new chemicals out of use for many years, thereby stultifying the process of research and development.

There is, undoubtedly, some validity to this argument. It will take a certain amount of time to properly test a number of chemicals, particularly those similar in structure to other chemicals that have proven toxic, of those that are entirely new. But, this is a necessary price to pay. The only alternative is to permit the continued use of our environment as a testing ground, and of ourselves as guinea pigs (a form of Russian roulette unacceptable to ourselves and to our children).

Chemicals are on trial in the United States. We cannot afford to hold them innocent until they are proven guilty.

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