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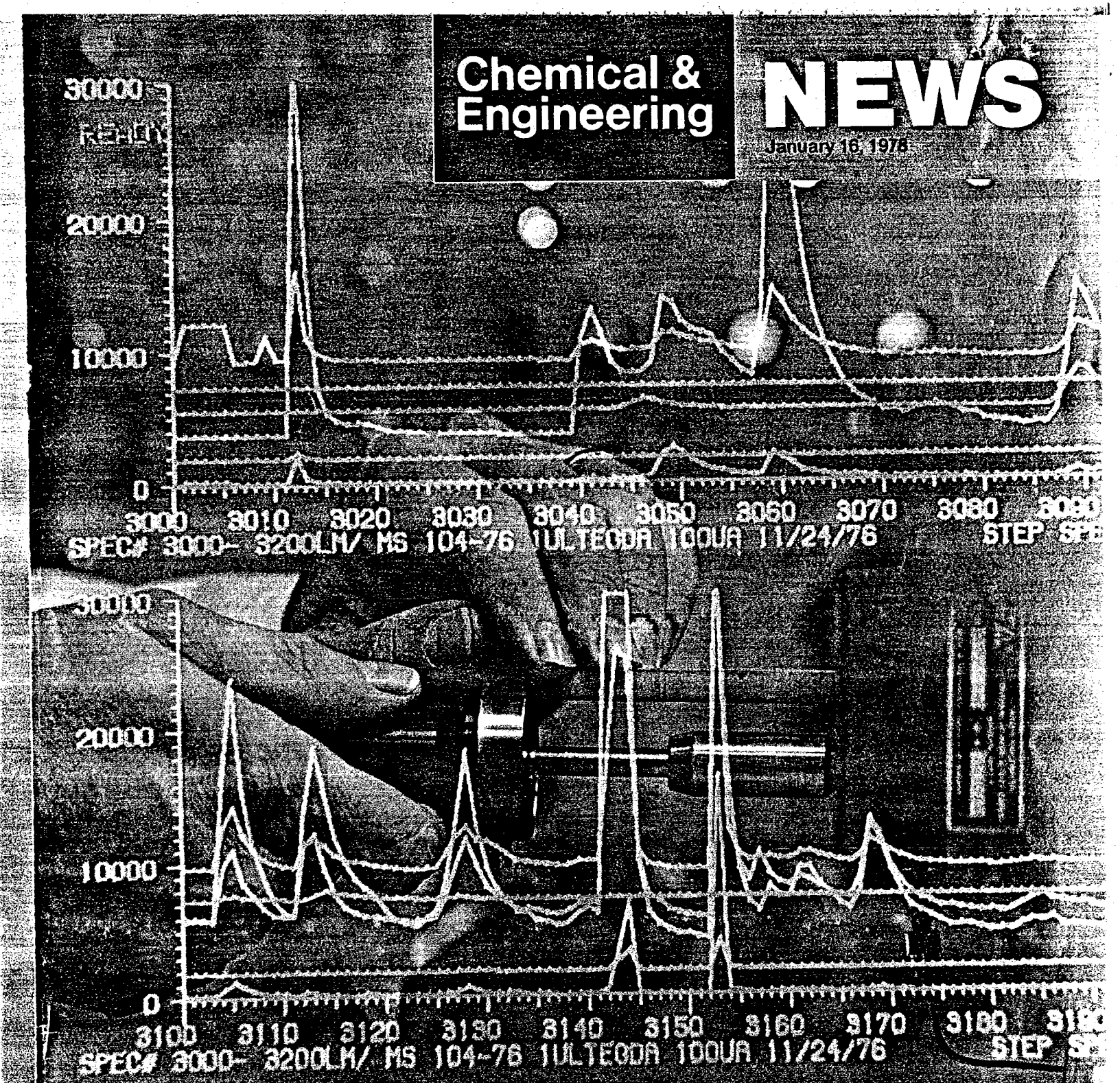

Chemical companies' R&D funding

C&EN's annua

Chemicals and cancer

"Chemicals" and "cancer" are two words that most chemists hate to see juxtaposed. They believe, with justification, that the public at large interprets chemicals in this case as industrial chemicals only and so gets the impression that the chemical industry is responsible directly for most of the cancer problems in this country. Of course, this is far from being the case. As chemists point out constantly, everything is chemical, whether man-made or natural. Also, they stress that most cancers are related to overall environmental factors and to the way we live—for instance, to smoking and the food we eat, and not to exposure to industrial chemicals.

However, the fact remains that a few industrial chemicals have been shown to cause cancer in humans. And a growing number are suspected of doing so. Hence, the issue of the relationship between cancer and man-made chemicals is a serious and increasing one for chemical makers as well as for both the research community as it seeks ways to detect carcinogens reliably and for a host of government agencies as they strive for well-founded protocols to contain or eliminate cancer hazards.

In this special presentation, C&EN offers two views of the issue of chemicals and cancer—one from government, one from industry. They were given at different times and at different forums, hence they are not meant to rebut each other. Indeed, there is a fair amount of agreement between them. But they do represent somewhat different perceptions of what needs to be done.

Barbara Hackman Franklin has been a commissioner for the Consumer Product Safety Commission since 1973. She is serving a seven-year term. She calls for greater government involvement in the cancer issue, believing that the current efforts of government, industry, and others are "akin to 30 different acts being performed simultaneously at a three-ring circus that lacks a ringmaster." She apparently sees President Carter as filling the ringmaster role by "providing the leadership for a strong, sustained, and coordinated national commitment to bring the hazards down to size and to help reduce the confusion and uncertainty over cancer and chemicals."

John F. Schmutz is assistant general counsel for Du Pont. He calls for setting acceptable exposure levels for chemicals. For each chemical this would be the level at which it would be reasonable to predict that no one would be likely to get cancer or another chronic illness. He thinks that the legislative basis for such an approach has been set by passage of the Toxic Substances Control Act and that success now depends on the development of balanced regulations.

Commissioner Franklin is a 1962 graduate of Pennsylvania State University. In 1964 she became one of the first women to receive a master's degree from Harvard Business School. She moved to Washington, D.C., in 1971, working for two years on the White House staff where she was charged with launching a program to recruit women to fill policy-making positions in the federal government. She earlier had worked for Singer Co. and for First National City Bank in New York City.

Schmutz joined Du Pont in 1955 in the firm's Washington, D.C., law office. He assumed his present position as assistant general counsel in 1975. He graduated from Cornell University in 1955 with a chemical engineering degree. He earned a J.D. degree from Georgetown University law school in 1958.

The Franklin presentation was given last month in Los Angeles at a meeting of the Town Hall of California. Schmutz presented his views late last year at the National Symposium on Chronic Hazards.

Cancer control: a bigger role for government

Barbara Hackman Franklin, Consumer Product Safety Commission

The little-understood, thorny dilemma of chemicals and cancer may have a devastating impact on millions of people. It is a problem increasingly central to businesses. My contention is that we must find more rational, responsible ways to deal with the issues in pretty short order.

In a real-life twist to what was science fiction, some substances have surfaced as potential hazards not only to the environment but to human life as well. The rallying cry is cancer, the six-letter word that probably summons more dread and fear in the minds of the American people than any other disease. And with good reason. In the U.S., cancer is the second leading cause of death. Among all developed nations, it ranks number two. This year in the U.S. alone, some 900,000 new cases will be diagnosed.

Looking ahead, the situation may be no better. Indeed, it may worsen, because of the long incubation period of the disease and its inclination to strike middle-aged and older Americans, our fastest growing population. Expectations are that we must deal with high incidence rates for years to come, even if cures (such as those developed for many victims of Hodgkin's disease and childhood leukemia) were announced today. Eventually, according to the American Cancer Society, one in every four of us will develop cancer, and about two thirds of those who get it are likely to die.

With this as background, it is understandable why, as a nation, we must make the best possible efforts to get at the root causes and cures and to insist on better diagnosis, treatment, and rehabilitation. Three successive Presidents and Congress have recognized the importance of this work. They have boosted, for example, the budget of the National Cancer Institute, the "Pentagon" of the effort, from $180 million in 1970 to $815 million this year.

It is an expensive proposition. The program is big. But the stakes are high, too. And like so many areas of public health and safety that seem to cost a lot and rely heavily on research, controversy mounts in direct proportion to the rate at which conclusive answers and miraculous cures seem outside our grasp.

One controversy is whether the strategy aimed more at cures than at prevention is lopsided, in view of accumulating evidence

that most cancers—perhaps as many as 60 to 90% of them—are environmental in origin. 60 to 90%? It's an astonishing figure, based on the best estimates available.

What are environmental factors? They include smoking, alcohol consumption, diet, exposure to radiation—and a range of chemicals and other substances. What does this mean? It means that more and more, the concern is over potentially dangerous substances in the air we breathe, the food we eat, the products we use and the manufacturing processes we depend upon. And, more and more, a target of the concern is chemicals.

Cranberry scare was the first of many

It was the 1959 cranberry scare that first aroused the public consciousness about environmental hazards. Others followed. Congressional hearings over passage of the new Toxic Substances Control Act sparked some of the current debate. But for most Americans, it was the proposed ban on saccharin earlier this year that brought the message home. With President Carter's recent signing of legislation to delay the ban pending the outcome of further testing, I believe we should expect even more public attention.

Developments along this line are changing the thrust of the battle against cancer. The developments are sending scientists scurrying back to their labs and lawyers back to law libraries. They are provoking Congressional hearings and regulatory proposals in the *Federal Register* at a rapid clip, and are filling the nation's newspaper columns and air waves with what cynics call the "cancer of the week" syndrome.

Across the board, chemicals and cancer are escalating into a major issue headed toward a full-blown crisis. Public confusion and the pressures on government and business "to do something" are running at about 75 decibels. Will this situation result in a government snafu? Frankly, it is too soon to tell. But it is not too early to make another prediction.

As a nation, we must come to grips with all of the issues and seek solutions that industry can live with, government can live with, and most importantly the American people can live with. If we don't, we may well have a bureaucratic snafu. But we will have far more on our hands than that. We will be courting a crisis, even a calamity whose consequences stretch far beyond the banks of the Potomac and into virtually every home, community, and workplace.

Why do I say this? Because what is at stake is the very real possibility that we stand on the threshold of reducing the ominous threat of cancer. At the same time, we face the possibility that havoc is at hand for the $100 billion a year chemical industry and for countless other industries that use chemical compounds in a variety of ways—with distinct benefits to consumers.

The hard, cold reality is that even this represents only the tip of the iceberg. Beneath the surface are technical, political, and ethical questions that are highly complex and intricate.

At our agency [Consumer Product Safety Commission], the point has been boldly underscored time and time again throughout our first four years. With a staff of 890 and a $40 million budget to deal with far more than chronic hazards, the commission already has addressed fluorocarbons, lead in paint, vinyl chloride, asbestos, acrylonitrile, benzene, and Tris.

Sleepwear problems still not resolved

It is our struggle over children's sleepwear that particularly illustrates the difficulties. Some years ago, the federal government ordered that children's sleepwear be made flame retardant to protect children from serious burn injuries. So it was, with the result that the severity of childhood burns has been reduced. But concern suddenly arose with charges that Tris, one of the chemicals that industry used to make children's sleepwear meet the federal regulations, was carcinogenic. After presentation of substantial evidence (including linking the results of long-range animal tests to human experience) and after serious economic, social, and legal considerations were weighed, the commission banned Tris last April.

Today, the debate rages on. Inside the courtrooms and outside, there are those who maintain too much was done by the government and those who complain of too little. Some object to the procedures followed. Others find fault with the substance of the ban; still others, with its implementation.

Judges still are wrestling with questions like these: In proceeding under one section of the law in order to protect consumers with a minimum of delay, did the commission violate the due process rights of producers? How far back in the distribution chain can the economic effects of the ban be spread? On Capitol Hill, companies involved in production of children's sleepwear are seeking indemnity for financial losses suffered when Tris was banned. Bills are pending in the House and Senate.

There's more.

Close on the heels of Tris came allegations that Fyrol, one of the substitutes some companies used in the wake of Tris, also might be carcinogenic. One major retailer voluntarily removed Fyrol-treated garments from the store shelves. After a public hearing, study by our staff, and review of conflicting test results, the commission determined that we lacked sufficient evidence to ban Fyrol or to require labeling. All the furor is taking its toll, and to the extent the public is perplexed or annoyed, it certainly is understandable.

The curtain has yet to come down on the safety of flame-retardant chemicals. As a result, it is neither possible nor desirable to write the final reviews. At this point, however, it is clear that the drama, if not a smash hit, is well on its way to a long-playing run. So it goes, with Tris and many, many other chemical hazards at the commission and other agencies.

In fact, federal involvement with chemicals and cancer cuts across many agencies. Eight have principal regulatory and/or research responsibility in this area, to the tune of about a billion dollars, according to my rough estimates.

President Carter has asked the Council on Environmental Quality to review the activities of the various agencies and to make recommendations how they can be done better. Our commission, the Food & Drug Administration, the Environmental Protection Agency, and the Occupational Safety & Health Administration also have agreed to take a hard look at the way we regulate chemicals and how we can work together more closely. But as Lyndon Johnson said, "The hardest part of government is not trying to do the right thing; the hardest part is knowing what the right thing is."

For all the agencies, the $64,000 question is what does constitute adequate public protection? There are other questions. Should there be consistency on the ways agencies move from research results to regulation? Or will this always boil down to a case-by-case situation within the framework of each agency's laws? How do we reduce delay in the regulatory process yet assure a solid basis for regulation, meaningful public participation, and adequate due process? And another question. Do federal agencies scrap cost/benefit thinking altogether, as some suggest?

Simply banning a substance may be the one quick way out now—but it certainly is not an adequate or acceptable answer over the long term. For example, do the benefits of saccharin for people who are diabetics outweigh the risks of cancer? And what about the substitutes for saccharin such as xylitol? Are they equally or more dangerous? Finally, what about the impacts of a ban on businesses and their employees?

My point is that banning a specific substance may indeed be the proper approach. But other factors must be weighed—before decisions are made so that we don't dreadfully shortchange the public health and safety or cause unnecessary economic upheaval.

Then there's the battle of the tests. As a nation, we're short on tests and testing protocols that are reliable, fast, and cheap. Animal tests to determine carcinogenicity can cost up to a quarter of a million dollars each and can take years. Meanwhile, the public health and safety is in limbo, government agencies really cannot do much, and industry's ability to market new, beneficial chemicals can be hamstrung.

Some short-term testing is being used but no one in or out of government is certain just yet how conclusive it is as a basis for regulation. As a result, each agency has or is formulating its own testing guidelines and criteria. So is industry. The consequences can be chaotic.

As companies try to evaluate new chemicals on the theory that safety should be tested in the lab and not in the environment, they find no uniform position—in the scientific, federal, or business communities–on what tests should be conducted and how the results should be interpreted. It can be especially bewildering if two or more agencies are focusing on the same chemical—or, as in the case of Fyrol, the same test is used but conflicting results emerge. Another issue is threshold levels of exposure—in other words, points below which carcinogenic compounds may have no adverse effects on human health.

If there were scientific certainty or even consensus on what these levels are—or even if they exist—decision making for regulators and business people would be easier. But such is not the case, and the mere suggestion of it sends many of my scientific friends up the wall. One result is that the approach of each agency differs, depending on the specific substance and the provisions of the particular law which apply.

The proposed ban on saccharin, for example, was in accordance with a specific provision of FDA's law, the Delaney clause, which triggers an automatic ban. The laws administered by the Consumer Product Safety Commission, on the other hand, do not contain a Delaney-type provision. At our agency, regulation must follow a decision of a majority of the commissioners that a substance presents an "unreasonable risk" of injury, illness, or death.

Effective course of action needed

Where do we go from here? I only wish I could plot an effective course of action which would make sense for industry, government, and most of all, for consumers—those who must feel increasingly confused or cynical. And frankly, I'm hard pressed to blame them.

At the moment, products whose benefits consumers have enjoyed, sometimes for years, are headlined as hazards that may be garrotes around their throats. At the same time, they are besieged with conflicting news reports that there is absolutely no cause for concern. Is nothing safe any more, they ask? Are we victims of overdramatization by the media? Regulatory overkill or underkill? Industrial conspiracies? Is this the necessary price we pay for living in a highly industrialized society?

I say to you emphatically that neither I nor any other single individual, agency, company, or public interest group has conclusive answers to all of these questions. The issues are much too complex and interdependent and their impact too extensive to expect that the answers are the sole prerogative of any one person, organization, or profession. But the questions are good ones, and they underscore the urgency and seriousness of the challenge of chemicals and cancer before us all. Fundamentally, this strikes at the heart of my major concern.

It is that we in government seem to be talking too much to ourselves and too little with industry and consumers, whose knowledge and concerns may differ—or may be the same. The point is that we're not sure. Industry, too, is cruising along on its own course—without full consideration of the attitudes and information of others. It's akin to 30 different acts being performed simultaneously at a three-ring circus which lacks a ringmaster.

Eventually—or sooner I hope—we all must recognize that the heady problems with chemicals and cancer are truly shared ones and that it serves the broad public interest to face them squarely. So it goes with the solutions, if they are to be sound, equitable, and lasting. They, too, must reflect information and involvement from many sources and in the final analysis, consensus and compromise—abhorrent though these words may seem to some.

This is why, in many public forums, I have called for wide, open, and frank discussion of the causes and control of cancer. It is essential that all segments of the public be more adequately informed and actively concerned and involved. Not just when cancer strikes a family member or friend. Not just in reaction to a specific regulatory proposal. And not just when writing a check to support cancer research and related activities, as important as all of these are.

President Carter must spearhead effort

The concern must go much deeper, and the public consciousness and understanding must be raised proportionately.

This is why I repeatedly urged President Carter to provide the leadership for a strong, sustained, and coordinated national commitment to bring the hazards down to size and to help reduce the confusion and uncertainty over cancer and chemicals. With vigorous support from the White House, I believe we can achieve it—and head off the possibility of a government snafu.

The first major step needed was the one the President took—to ask an interagency group to conduct a study and make recommendations. But much more must be done. The next step urgently needed is serious discussion with the scientific, academic, and medical communities; business community; the public and the federal agencies themselves—beginning now. Together, we must explore the issues and suggest sound strategies to deal with them.

This is why I will continue to urge formulation of a national policy on carcinogens with the weight of the White House behind it.

Again, government must take the lead responsibility but the policy must reflect the diverse concerns of the public. A policy, developed in concert with the public, should articulate—so that everybody will know—the posture and program of the federal government in this area and the guiding principles behind it.

At a minimum, I believe a policy must address issues including these: information needed to regulate cancer-causing chemicals, the tests that should be used, how the results should be interpreted, and factors other than public health that should be taken into account.

The policy must recognize the need for flexibility so that developing scientific knowledge can be applied and so that the individual agencies can perform the jobs that the President and Congress expect. Perhaps most of all, such a policy must spell out the magnitude of the problem, the need for adequate consumer protection and for timely, intelligent, and informed action to achieve it. I am, in essence, urging support for *more* governmental involvement.

Historically, business has resisted the concept of government intrusion—and not without sound reason. But with chemicals and cancer, this is not the response called for. With this issue and the chaos and high stakes that surround it, more federal involvement is inevitable and should be welcomed, if it is rational and responsive.

For business, the immediate challenge—and I believe, the opportunity—is to make a serious commitment to working with government. We need actions that serve the public interest and are good business—before the chaos runs its course and before decisions are made when there are no longer good alternatives.

Is there room for voluntary initiatives? Of course. Government regulation is never the complete answer. That was the name of the game when Congress passed the Consumer Product Safety Act and created our agency and even more recently, when EPA's Toxic Substances Control Act was enacted. The spirit of both, as I see it, is that it is in the public interest and industry's own economic self-interest to take any precautionary steps needed before products are marketed, not afterwards.

With certain chemical hazards, however, the crux of the issue is precisely what these "precautionary steps" are. This is why, at this point, more governmental leadership is needed. Serious discussions—triggered by the highest level of our government—could bring perspective, direction, and visibility to the need to control cancer. A national policy would establish the framework, lay the ground rules, and coalesce the diverse concerns of many federal agencies, industry, and the public.

Not all the scientific evidence to confirm or refute our worst fears is in. But it seems to me that we know enough to know the odds are against complacency or reluctance to work together.

Can we reduce the uncertainty and broad array of issues to a common denominator from which total unanimity will emerge? Maybe not. The risks are such that we must try. □

Chronic health hazards: a national challenge

John F. Schmutz, Du Pont

Chronic health hazards are of concern to me, my company, industry, and the nation. Twenty-five years ago, two or three chemicals were known to cause cancer in man. Today, the Occupational Safety & Health Administration regulates 17 as potential carcinogens, and the National Institute for Occupational Safety & Health has a list of 2415 suspected materials. We must move up aggressively to deal with the issue—and we are.

We are now in the same status with regard to chronic hazards as we were with respect to air and water pollution control five to 10 years ago. Key laws have been enacted, and we are in the process of developing policies and the bases for regulations necessary to carry out the statutory authority. From a policy viewpoint, I feel we can draw from our prior experiences with the environment in charting a course which focuses our effort, conserves our resources, and makes positive progress toward a clean and healthful environment.

Today, I would like to:

- Provide a perspective to chronic health hazards.
- Discuss the critical issues, particularly acceptable risk.
- Provide a suggestion as to how we might deal with those issues.

Because it is so personal to each of us, the question of chronic illness, particularly cancer, is one that is difficult to view in perspective. The deep concern for those stricken leads us to react emotionally rather than rationally. To manage chronic health hazards effectively, they must be looked at by a reasoned approach, based on available facts. Let me give you a list of five which help me frame the chronic health hazards issue with respect to chemicals.

First, chemicals are not necessarily "good" or "bad," "man-made" or not. Almost everything in nature involves chemicals. To change from man-made materials to naturally based products does not avoid chemicals. Food is as much an organic chemical as a plastic sheet or a solvent.

Second, chemical carcinogens and other chemical chronic health hazards are not necessarily man-made. Asbestos, which helped initiate the focus on chronic health hazards, is a chemical and a naturally occurring carcinogen. Peanuts and grains frequently contain traces of aflatoxin, a potent carcinogen formed by a common mold. Charcoal-broiled steaks contain benzopyrene, a carcinogen.

Third, many chemicals essential for health in small quantities are highly toxic in larger quantities. We would die without zinc, manganese, copper, molybdenum, selenium, chromium, fluorine, silicon, nickel, tin, vanadium, potassium, and many others that also have severe acute and chronic toxicity in larger amounts. For example, nickel and selenium in some forms are carcinogens.

Fourth, the incidence of cancer is not rapidly increasing. If the effects of cigarette smoking are excluded and statistics are age adjusted, cancer incidence and cancer deaths per unit of population have remained about constant over the past 25 years.

Fifth, the statement that 80 to 90% of cancers are environmentally caused does not mean that 80 to 90% of cancers are caused by industry. Environment in this sense includes not only the air we breathe and water we drink, but our diet and all elements of our life style, at home and elsewhere, on and off the job. "Environment" does not equal industry. The major causes of environmental cancer are smoking and diet. Reliable experts estimate that 5% or less of cancer is industrially related. That number includes known hazards such as asbestos, β-naphthylamine, and others now well under control.

Industrial chemicals part of problem

In summary, health hazards are a national problem resulting from a variety of causes of which industrial chemicals are only a part. Let me hasten to add that because of the human suffering involved, industrial chronic health hazards are a major concern to industry. However, industrial hazards are far from being the principal cause of chronic illnesses.

Why then the focus on industry? This brings me to my second topic—the need to define the issues. Cancer is an immediate, readily identifiable, and emotional issue in all our lives. All of us have had relatives who have died from it. Also, tragic events in the past several years have focused on several instances where cancer or other serious chronic illnesses have been caused by industry-related chemicals. This has led to a tendency to assume that if an industrial chemical is present in the environment, it is harmful. Emotionally, we are prone to consider a man-made chemical found in the environment as more serious

than a naturally occurring chemical found there in the same or larger quantities.

Enormous strides in the detection of chemicals in our environment also have helped focus attention on the many chemicals to which workers have been exposed over long periods. During the past five years, our techniques for detecting chemicals have increased greatly. In water, for example, accuracy of detection has progressed from parts per million to parts per billion—from drops per 100 gal to drops per *100 thousand* gal.

The rapid evolution in toxicology and epidemiology in pinpointing hazards over the past 20 years also has made it difficult to segregate the events of today from the events of many years ago. Cancer and other chronic illnesses diagnosed today often have resulted from exposure of many years ago when hazards were unknown and practices were far different.

Judging the work practices of 20 years ago by the increased knowledge and more informed standards of today often is not constructive. Let me note one of Du Pont's experiences in this regard.

More than 20 years ago, Du Pont established a system to collect morbidity and mortality data. Its purpose was to provide one check among many on the exposure of our workers to chronic health hazards. In the past several years, the cancer registry part of this epidemiology program has been examined in depth by government. It was one of the few available to examine. In voluntarily submitting data from it, we ourselves have pointed out deficiencies in our registry—deficiencies not unique to our system. Yet, focus from some sources on shortcomings has unfortunately masked the fact that it is a unique and pioneering effort and a contribution to the health of our employees. There is an emotional conditioning to focus on the negative, rather than the positive.

I think there also is some element of frustration caused by the very nature of chronic hazards. In most things, we are able to see improvement in response to our positive actions. Fish are returning to the water. People can swim again in waters previously polluted. There is reduced smog and air pollution. But with chronic hazards exposures of many years ago may cause illnesses today and possibly will for years to come. The results of today's control are not yet apparent.

That frustration increases the pressure to "do something" and feeds the desire to mandate uniform technology-forcing control at "absolutely" safe levels. I submit, however, that *that* approach will not solve the problem of chronic hazards nor is it in the national interest.

Because of the foregoing, there is a critical need to attempt to bring objectivity to the issue of chronic health hazards and to focus upon what I believe to be the critical issue, an acceptable level of risk.

Zero risk or zero exposure is neither technically possible, nor, given its consequences, desirable. For example, it would not be possible to reduce the exposure to a gaseous chemical to zero in a plant or in products made from that material. Industrial exposure could be reduced to a level above zero at which cancer would not be expected. There may be no hazard from minute quantities of residual monomer in a polymer, but, technically, the quantity of monomer could not be zero.

The delicious aroma of your Thanksgiving turkey is in part caused by acrolein, a highly toxic chemical. That delectable picnic-grilled meat contains benzopyrene, a carcinogen. Are we going to stop all turkeys for Thanksgiving or outdoor grills? Are we going to ban peanuts? Those would be the consequences of zero risk.

In speaking of an acceptable risk, I am not talking about those situations in which it is known that the level and duration of exposure would be likely to cause some people to contract a chronic illness. What I am talking about is accepting a level of risk at which it is unlikely that anyone will become chronically ill but at which one *cannot* prove whether *or not* there is 100% safety. It means living with reasonable assurance of safety and acceptable uncertainty.

Congress has accepted that uncertainty. The House report of the Toxic Substances Control Act states: "The committee has limited the administrator to taking action only on unreasonable risks because to do otherwise assumes that a risk-free society is attainable, an assumption that the committee does not make."

Note that many years ago the concept of acceptable risk was adopted in handling radiation. The risk of x-rays is generally accepted. The nuclear power industry is regulated on that premise.

The concepts of zero exposure and zero risk ignore another point—the many positive benefits of chemical products. They ignore the fact that those products have become essential to our health and safety as well as our comfort and convenience. They ignore the many jobs made possible by chemicals. They ignore the many socially beneficial results obtained with taxes generated by the manufacture of products made from them.

Acceptable levels of risk must be set

How is an acceptable level of risk set? I would start with the fact that the effect of carcinogens and other chronic health hazards is related to dose and period of exposure. Considering level and duration of exposure, those conditions should be found under which no effect is observed. Then a substantial margin of safety should be applied by further reducing the level and duration of exposure. Let me add, however, that a necessary element of this approach is full disclosure of all known significant hazards to all those accepting the risk.

It follows from the concept of acceptable risk, that use of a rigid guideline of control to the lowest level feasible is inappropriate, except as an interim measure. With a potent carcinogen, for which a no-effect level has not been established, lowest level feasible may present an unacceptable risk if it is continued over a prolonged period. In such case, use of the carcinogen should be discontinued if a no-effect level cannot be established. In other cases, control to the lowest level feasible may unnecessarily waste jobs as well as capital, energy, and other resources.

Duration of exposure, as well as level, is important. Control to a level while further data are gathered may provide reasonable assurance of safety and acceptable uncertainty. Prolonged exposure at that level may be unacceptable.

I can well sympathize with the regulators' frustration at extended proceedings and the delay involved in a product-by-product approach. I agree that factors such as oncogenicity vs. carcinogenicity and screening tests are subject to policy deci-

sions. I agree with many aspects of recent proposals for regulation of chronic hazards in the workplace. But, ultimately, hazards must be evaluated on a product-by-product basis. Furthermore, controls mandated—that is, whether administrative controls, engineering controls, or personal protective equipment are to be used—should vary from case to case. In water pollution, the promulgation of effluent guidelines has confirmed the administrative feasibility of the case-by-case approach. The National Permit Discharge Elimination System permits to tens of thousands of individual plants confirm it.

Just as product-by-product evaluation of risk is essential if there is to be socially effective regulation, so, too, is the setting of priorities for efforts. The nation does not have the laboratories or the toxicologists to test the chronic effects of all chemicals immediately, nor would such effort be desirable. I endorse the efforts of the advisory committee, established under the Toxic Substances Control Act to help set priorities. Selectivity also should be applied to all aspects of the regulation of chronic hazards. For example, broad production of detailed data can only obscure the critical issues and delay meaningful analysis by the government.

Let me describe a case history to illustrate the complexity of the carcinogen issue from an industrial viewpoint. One of our promising new products, Kevlar aramid fiber, is made using hexamethyl phosphoramide (HMPA) as a polymer solvent in an early step. That chemical is and has been used widely as a solvent in laboratories for many years. No human cancer has been attributed to it.

From our earliest use, because of acute hazards, we had treated HMPA as a no-contact chemical and controlled it to very low levels. Based on early toxicological screens, rat inhalation tests also were begun, but before we could run the tests, we had to develop special techniques to handle the low exposure levels. Then, eight months into the rat tests, cancer emerged at levels as low as 400 ppb and after 13 months, at 50 ppb.

Although our cancer registry showed no evidence of cancer-related problems with employees, one first step was to quickly and systematically disclose our finding to employees and government agencies to which our findings would be helpful. Since the chemical was widely used in research, we also sought disclosure in major publications.

Concurrently, as the test data developed, we lowered the permissible airborne exposure limit to 25 ppb then to 5 and, within one year, to 0.5 ppb. Initially, we had no method to detect such small quantities, the equivalent of about one drop per 10 million gal. Therefore, our research and engineering people had to devise a test method. In the plant, a combination of engineering controls and personal protection was used, the latter because of the freedom of manipulation required of employees for some of the fiber operations.

Simultaneously, new animal tests were initiated to substantiate a no-effect level.

Although the search for an alternate was begun immediately, at least 100 man-years of research will be necessary to re-engineer the process even after a suitable candidate is found.

I have attempted to give you a perspective on chronic hazards from an industry viewpoint and an example of how one company has dealt with one new discovery. How should such hazards be regulated?

Basis for sound regulation has been provided

The condition precedent to sound regulation is an adequate and balanced legislative base. With the passage of the Toxic Substances Control Act, which was generally supported by industry, that base has been provided. We can all thank Congressman [Bob] Eckhardt for his efforts that made that legislation possible. Now success of its implementation will depend critically on balanced regulation.

An Interagency Regulatory Liaison Group, representing the Consumer Product Safety Commission, the Environmental Protection Agency, the Food & Drug Administration, and OSHA, has been formed to coordinate approaches to such issues as testing, risk assessment, regulation, and enforcement. Another group called the Toxic Substances Control Act Group, chaired by J. B. Speth, has been formed to develop policies and coordinate the federal regulatory approach to toxic chemicals. I believe that these groups can do much to help keep that regulation within the bounds of Congressional intent by assuring a stable, coordinated approach. I support and encourage them in their work.

To the regulators, I suggest five guidelines in drafting chronic hazards regulations.

First, I suggest a review of data within federal agencies to determine where additional data acquisition or development may be necessary. Where gaps exist, EPA can selectively require submission of information from the private sector and develop testing requirements. Appropriate selection criteria would include the magnitude and routes of exposure, the extent of existing data, and chemical properties. This approach would focus on those chemicals that may present unreasonable risks and permit meaningful utilization of existing testing resources to evaluate priority needs.

Demands for reporting of substantial data on all chemicals as currently proposed by EPA for TSCA inventory reporting would be counterproductive and serve merely to slow down review of major high-risk areas of concern. Similarly, recommendations for testing by categories of chemical substances threaten priority needs by requiring extensive and unnecessary pre-emption of limited testing resources.

Second, there should be full disclosure of all significant hazards to all those who may need to act on that information, including employees, customers, the government, and others. Existing authority under TSCA provides an adequate statutory basis to require industry to notify the government of pertinent health and safety data.

Third, workplace concentrations of suspected animal or human carcinogens should be promptly but temporarily limited to the lowest feasible level considering length of exposure, the physical form of the material, its concentration, and existing toxicological data. The level of control should take into consideration existing data and apply a safety factor. For example, in some cases the acceptable airborne concentration might be one tenth of the observed no-effect concentration in a suitable animal study.

The level and duration of control, not the means thereof, should be of primary concern. The means of control should be a practical combination of engineering controls to the extent technically and economically feasible augmented by administrative controls and personal protective equipment as necessary.

Fourth, an acceptable risk level should be defined as quickly as possible. Acceptable risk should be based on a suitable reduction from the observed no-effect level in animals, epidemiology studies, or their equivalent. Functionally, the acceptable risk level would be a level at which it would be reasonable to predict that *no one* would be likely to get cancer or another chronic illness from the chemical. In making this determination, it must be recognized that one could not prove, nor is it possible to ever prove, that some uniquely sensitive person could not get cancer.

Fifth and finally, there should be control to the acceptable exposure level. If extended testing is required to determine that level, we should continue control to the lowest level feasible. If an acceptable risk level cannot be determined and the product cannot be made and used safely, then the operation should be discontinued.

It will be a challenge for industry, labor, the government, and the public to work together objectively on chronic hazards. But the stakes are high and we must do it. Our mistakes and successes will not be measured for many years. In the interim—while we are hard at work finding and reducing the hazards—good judgment, objectivity, and an acceptance of the fact that life cannot be made risk-free must tide us over. □