All Hazards Are Not Equal

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ALL HAZARDS ARE NOT EQUAL

While there are no perfect indices to measure trends taking place in technology and innovation, the evidence presented by changes in some very important indicators strongly suggests that a slowdown has been occurring. In real terms (constant 1972 dollars), research and development spending in the United States has been on a plateau of slightly under thirty billion dollars a year since 1965. In the private sector, research and development, which rose at an annual rate of more than seven percent from 1953 to 1957, has been increasing at a more modest one percent a year since.

The employment of scientists and engineers in industry decreased by fifteen thousand in 1975 from 1,046,000 in 1968. Enrollments for advanced degrees in science and engineering have represented a steadily shrinking share of college enrollments since 1965. The U.S. Patent Office issued fewer patents to U.S. citizens in 1973 than in 1963, but issued more than double the number of patents to foreign nationals in 1973 than in 1963.

A key to future trends in innovative activity lies in the commitment to basic research, as opposed to overall research and development, which includes not only product development but also research dedicated to fulfilling regulatory requirements and minimizing liability exposure. Federal funding of basic research has declined since 1968 (in constant 1967 dollars) and industry funding began a modest rate of decline in 1971. In its forecast of research and development expenditures for 1977, Battelle Columbus Laboratories noted that the shift from basic to pragmatic research continues, particularly in industry where the change has been toward “defensive” research because of “growing governmental emphasis on environmental protection, occupational safety and health, and consumer safeguards.” To be sure, the overall slowdown in research and development outlays is the result of multiple causes, such as the shift in federal spending priorities from defense to social welfare programs.

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Government Regulation

What is the role of government regulation in the slowdown? First, let us state the obvious: government regulation often has yielded important benefits - less pollution, fewer product hazards, reduced job discrimination and other socially desirable objectives. These government programs were established in response to rising public expectations about business performance. But the worthiness of these social objectives should not make the specific methods being used in attempting to achieve them totally immune from criticism.

At first blush, government imposition of socially desirable requirements on business through the regulatory process appears to be an inexpensive way of achieving national objectives. The practice apparently costs the government little and represents no significant direct burden on the taxpayer. But the public does not escape paying the cost. Every time, for example, that the Environmental Protection Agency imposes a more costly (and perhaps less polluting) method of production on any firm, the cost of the company’s products to the consumer will rise. Similar effects flow from the other regulatory efforts, including those involving product safety, job health and equal employment opportunity.

These higher prices, we need to come to recognize, represent the “hidden tax” of regulation which is shifted from the government to the consumer. It is not inevitable that every regulatory activity increases inflationary pressures. In those instances where regulation generates social benefits (such as a healthier and thus more productive work force) in excess of the social costs it imposes, inflationary pressures should be reduced. But if the costs are ignored and the focus of public policy is only on the benefits, it is almost inevitable that the regulation will be pushed beyond the point where the benefits equal the costs and into the zone of “overregulation.” Overregulation, to an economist, is not an emotional term, but merely the shorthand for situations where the costs imposed by regulation exceed the benefits from the regulation.

At times the impact of regulation on the prices that consumers pay is direct and visible. For example, in the case of the passenger automobile, the federal government has required the producers to incorporate a wide variety of specified safety and environmental features. For the average new car sold in the U.S., those government-mandated requirements add a cost of approximately $666 (or more than seven billion dollars a year for all the new vehicles purchased). We are not justified, however, in jumping to either extreme conclusion — that there are no offsetting benefits or that the benefits are overwhelming. But surely, drivers and their passengers who always put on seat belts derive no benefit from the expensive and annoying buzzing contraptions mandated by the federal government.

Government regulation also pushes up prices indirectly, by increasing the overhead costs of producing goods and services. There are more than four thousand different types of federal forms which must be filled out, in addition to tax and banking forms. Business firms and individuals spend more than 143 million hours a year filling them out. Consider these examples: A small five-thousand watt radio station in New Hampshire spent more than $26 just to mail its application for renewal of its license to the Federal Communications Commission. That was before the last postal rate increase. An Oregon company, operating three small television stations, reported that its license renewal application weighed 45 pounds.

At the other end of the size spectrum, the Exxon Company is required to file more than four hundred reports each year to 45 federal agencies. The Standard Oil Company of Indiana maintains 636 miles of computer tape just to store the data that it must supply to the Department of Energy.

Economic Growth

Federal regulation also affects the prospects for economic growth and productivity by levying a claim on a rising share of new capital formation. This impact is most evident in the environmental and safety areas. According to the U.S. Council on Environmental Quality, private outlays for pollution control in the United States in 1976 were six and a half billion dollars higher than would have been the case in the absence of federal ecological requirements. Similarly, the McGraw-Hill Department of Economics estimates the cost to American industry of meeting the occupational health and safety regulations at $3.2 billion in 1976. These two programs alone account for about six percent of total capital spending in the private sector of the American economy.

Capital formation is also adversely affected by the uncertainty about the future of regulations governing the introduction of new processes and products. Take this example from the energy area: A task force of the President’s Energy Resources Council, in evaluating the requirement for environmental impact statements, claims that the major uncertainty was not whether a project would be allowed to proceed, but rather the length of time that it would be delayed pending the issuance of an environmental impact statement that would stand up in court. In assessing the overall impact of government regulatory activity on the establishment of a new energy industry, the task force concluded “… some of these requirements could easily hold up or permanently postpone any attempt to build and operate a synthetic fuels plant.”
In the occupational safety and health area, professional safety staffs are often diverted from their basic function of training workers in safer operating procedures to filling out forms, posting notices, and meeting other essentially bureaucratic requirements. And so, we find safety personnel answering such trivial questions as: How big is a hole? When is a roof a floor? How frequently must spittoons be cleaned? Of greater concern, no doubt, is the detail of the regulations. Occupational Safety and Health Administration (OSHA) directives, for example, contain very specific requirements for virtually every piece of equipment used in the production of steel. These requirements range from such major items as coke ovens all the way down to such minutiae as the ladders used in plants and the mandatory 42-inch height from the floor for portable fire extinguishers. The results measured by any improvement in safety are almost invariably disappointing. The number of workdays lost to injury and illness per one hundred workers in American industry rose from 53.1 in 1974 to 54.4 in 1975.

Innovation

The hidden cost of government regulation that potentially is perhaps the most costly of all is a reduced rate of introduction of new products and manufacturing processes. The longer it takes for a new product or production technique to be approved by a government agency - or the more costly the approval process - the less likely that the new product will be created. In any event, innovation will be delayed. The banning or forcing out of existing products likewise has a negative effect on the incentive to proceed with new products that may be rejected on similar grounds.

The saccharin case, while the best known, is not an isolated example of proposed product bans based on the zero risk approach to health and safety. In August 1975, the National Cancer Institute reported that the solvent trichlorethylene, known as TCE, might be a possible cause of cancer. TCE at the time was used in decaffeinated coffee. The government used a generous dose of the chemical on test animals - the equivalent of a human being drinking fifty million cups of decaffeinated coffee every day for an entire lifetime. But did the industry laugh at or ignore the government's report? Hardly. With the cyclamate episode still firmly in mind and a saccharin ban being seriously considered, one major producer quickly changed to another chemical.

Or, turning to the chemical industry - one of the largest technically oriented sectors of the American economy - more than twenty federal laws cover the regulation of chemicals, ranging from the Consumer Product Safety Act and the Federal Insecticide, Fungicide, and Rodenticide Act to the Clean Air, Clean Water, and Solid Waste Disposal Acts. A newcomer to the scene is the Toxic Substances Control Act (Tosca) of 1976. The concern within the industry is that Tosca will have a severe impact on the entire industry in the same way the 1962 Food and Drug Act Amendments affected the pharmaceutical manufacturers.

Sam Peltzman of the University of Chicago has estimated that the 1962 amendments to the Food and Drug Act are delaying the introduction of effective drugs by about four years, as well as leading to higher prices for drugs. Due in large part to the stringent drug approval regulations, the U.S. is no longer the leader in introducing new medicines. According to William Wardell of the University of Rochester School of Medicine, we were the thirtieth country to approve the anti-asthma drug meta-proterenol, the thirty-second to approve the anti-cancer drug adriamycin, the fifty-first to approve the anti-tuberculosis drug rifampin, and the sixty-fourth to approve the anti-bacterial drug tobramycin.

Henry Grabowski and John Vernon of Duke University report that the more stringent Food and Drug Administration regulation of pharmaceuticals over recent years has been a major cause of higher costs, time lags and rising risk in pharmaceutical innovation. They contend that increased regulation alone accounts for the doubling in the cost of developing and introducing a new chemical entity in the U.S. What's more, they conclude that innovation has become increasingly concentrated in the large, multi-national drug companies, apparently because these firms are better able to bear the additional costs and risks of innovation than smaller firms and, in addition, because they can shift resources on a worldwide basis.

The shift away from basic research toward evolutionary or applied research is already evident among chemical manufacturers. Chemical and Engineering News (October 3, 1977) noted that "DuPont, the U.S. chemical industry's leader in research and development spending, has, over the past few years, shown a notable retrenchment in its real-dollar research and development support. In the process, the company has shifted many of its research and development efforts from new venture research to work on established product lines . . . "

In addition, "defensive" research is competing with basic research for the research and development budget dollar. Monsanto found that thirteen percent of its research was spent on compliance and therefore reorganized its research and development efforts into two parallel organizations, one traditional and a new Environmental Policy Staff.
Pesticide manufacturers form a subgroup of the chemical industry that has already experienced the effects of direct regulation under the Federal Environmental Pesticide Control Act. Harold L. Straube, vice president of Stauffer Chemical and at one time president of the National Agricultural Chemicals Association, believes that "government meddling in terms of excessive regulation has skyrocketed the costs of doing business to a level we never thought possible... a climate is being developed in which research and development could grind to a halt." He noted that in 1967 the cost to discover and commercialize a new pesticide was three million four hundred thousand dollars and the average time lag was five years but the 1976 figures are eight million dollars and eight years.

Delaney Amendment

Surely the Delaney Amendment to the Food, Drug and Cosmetic Act is worthy of some attention as a prime example of the futility of a zero risk approach to health and safety regulation. That statute prohibits the use of any chemical substance (in any amount) as a food additive if that substance has been found, by "appropriate" tests, to induce cancer in human beings or laboratory animals. A major problem becoming increasingly evident is that scientific progress over the last twenty years has brought about a ten thousand to one million times improvement in the ability to measure "any amount."

The requirement to enforce the Delaney Amendment led the FDA to ban the use of acrylonitrile (AN) in beverage bottles effective January 1978. Since tests by Monsanto (the company with the largest investment in the AN bottle) indicated a migration of an average of ten parts per billion from the bottle to the beverage after six months at room temperature, AN must be considered to be a "food additive" from the FDA's point of view. Thus the only question is whether AN has been "appropriately" tested and adjudged a carcinogen. In banning the AN bottle, FDA commissioner Donald Kennedy said, "The record shows AN is a frank teratogen in the rat, a tumorigen and probable carcinogen in the rat, a possible carcinogen in man, and a mutagen in several test systems. Under these circumstances, it is inconceivable that the scientific community could recognize that any level of AN has been shown through scientific procedures to be safe."

The manufacturer must prove that there is a "safe" level of a "probable" carcinogen that may be consumed by human beings. Monsanto states that the lowest level of feeding that showed harm to animals requires, in human terms, that a child drink three thousand bottles of soda every day for life in order to duplicate the test conditions. The company further points out the impossibility of producing products with zero risk as carcinogens through the example of lettuce. Lettuce contains nickel, a metal which causes cancer and would therefore, if commercially produced, have to be banned under the Delaney Amendment. The fact that we do not drop face down in our salad bowls indicates that the human organism must have a tolerance for some level of nickel—how much is the serious but unanswered scientific question.

The inconsistency in federal policy, however, is awesome. Compare the counsel of perfection implicit in the Delaney Amendment's attitude toward food additives with the government's position on tobacco. The American Cancer Society recently has forecasted three hundred ninety thousand cancer deaths in the United States in 1978. Nearly one in four of these deaths will be from lung cancer, twenty percent of which is due to smoking. What is so incongruous is that the U.S. government subsidizes a proven carcinogen through its price support of tobacco administered by the Department of Agriculture.

Common Sense

What action might the optimist envision? First of all, a large measure of common sense is needed on the part of our elected officials and civil servants responsible for drafting and enforcing regulations. They must know that a totally risk-free environment is an impractical objective. Literally realized, it would put us back in the Stone Age, which was hardly a safe period for human existence.

Any realistic appraisal must acknowledge that important and positive benefits have resulted from many of the government's regulatory activities. It should also be realized that the American people have a right to expect business to respond to the public's desire for less pollution, fewer product hazards, and protection from unknown health hazards. But the worthiness of social objectives does not justify government closely regulating every facet of private behavior. Indeed, the experience with existing governmental efforts shows that further expansion of government involvement in the detail of business decision-making is likely to be self-defeating.

To be sure, the exercise of judgment in regulatory matters can involve striking a balance in some extremely difficult areas, literally affecting human life. As a former commissioner of food and drugs, Alexander Schmidt, has said, "In FDA decisions, as in all aspects of human endeavor, we must accept the probability of nonexistence of absolute..."
safety.” He goes on to raise some very difficult questions: Just where and when does one draw the line in weighing demonstrable benefit against theoretical risk? Who is to draw the line? Government or industry or the individual consumer? Schmidt criticized the anti-cancer clauses in existing food safety laws because, literally interpreted, they leave no room for scientific judgment, calling for zero risk from all new food ingredients.

There is a real need for scientists in industry and the universities to take part in the debates on regulation. William Baker of Bell Laboratories has suggested that industry and university researchers should work as equal partners in defining the appropriate regulatory systems. He says that such a partnership “would help overcome the often negative influence of special interest groups and of naive generalizations about science and engineering in setting regulatory policies.”

Restraint

A new attitude of restraint in imposing additional regulations on the private sector would lower the risk and the cost of research and development by business. We need to adopt sensible, operational notions of practical threshold levels and of toxicological insignificance. To put it bluntly, all hazards are not equal. Government policy needs to make such distinctions as between hidden and visible hazards, voluntary and involuntary hazards, easily avoidable and hard-to-avoid hazards, remote and commonplace hazards, and negligible and severe hazards.

Such a new attitude would have a salutary effect on the pace of technological innovation and scientific progress in the United States. The benefits would be widespread. They would include lower prices for American consumers, greater job opportunities for workers and ultimately an improved quality of life for the average citizen.