

- Lefkowitz, *Proc. Natl. Acad. Sci. U.S.A.* **74**, 1204 (1977).
34. J. J. Muscato, J. Nidel, J. B. Weinberg, *Blood* **54** (Suppl.), 89a (1979).
  35. C. Koo and R. Snyderman, *Clin. Res.* **28**, 373a (1980).
  36. J. E. Nidel, I. Kahane, P. Cuatrecasas, *Science* **205**, 1412 (1979).
  37. J. Nidel, J. David, P. Cuatrecasas, *J. Biol. Chem.* **255**, 7063 (1980).
  38. E. J. Goetzl, B. W. Foster, D. W. Goldman, *Fed. Proc. Fed. Am. Soc. Exp. Biol.* **40**, 365 (1981); E. J. Goetzl, *Clin. Res.*, **29**, 528A (1981).
  39. D. E. Chenoweth and T. E. Hugli, *Proc. Natl. Acad. Sci. U.S.A.* **75**, 3943 (1978).
  40. I. Spilberg and J. Mehta, *J. Clin. Invest.* **63**, 85 (1979).
  41. M. P. Fletcher and J. I. Gallin, *J. Immunol.* **124**, 1585 (1980).
  42. C. S. Liao and R. J. Freer, *Biochem. Biophys. Res. Commun.* **93**, 566 (1980).
  43. A. Tomonaga and R. Snyderman, unpublished observation.
  44. M. C. Pike, N. M. Kredich, R. Snyderman, *Proc. Natl. Acad. Sci. U.S.A.* **76**, 2922 (1979); R. Snyderman, M. C. Pike, N. M. Kredich, *Mol. Immunol.* **17**, 209 (1980).
  45. F. Hirata et al., *Proc. Natl. Acad. Sci. U.S.A.* **76**, 2640 (1979); F. Hirata and J. Axelrod, *Science* **209**, 1082 (1980).
  46. M. C. Pike and R. Snyderman, *Clin. Res.* **29**, 374a (1981).
  47. S. J. Sullivan and S. H. Zigmond, *J. Cell Biol.* **85**, 703 (1980).
  48. R. Snyderman and M. C. Pike, *Science* **209**, 493 (1980).
  49. H. S. Koren, S. J. Anderson, J. W. Larrick, *Nature (London)* **279**, 328 (1979).
  50. M. C. Pike, D. G. Fischer, H. S. Koren, R. Snyderman, *J. Exp. Med.* **152**, 31 (1980).
  51. J. Nidel, I. Kahane, L. Lachman, P. Cuatrecasas, *Proc. Natl. Acad. Sci. U.S.A.* **77**, 1000 (1980).
  52. E. K. Gallin and J. I. Gallin, *J. Cell Biol.* **75**, 277 (1977).
  53. E. L. Becker, P. H. Naccache, H. J. Showell, R. I. Sha'afi, in *Peptides: Structure and Biological Function*, E. Gross and J. Meinhofer, Eds. (Pierce Chemical Co., Rockford, Ill., 1979), p. 743; J. Nidel, *Fed. Proc. Fed. Am. Soc. Exp. Biol.* **39**, 1049 (1980); M. M. Boucek and R. Snyderman, *Science* **193**, 905 (1976).
  54. J. H. Hargwig and T. P. Stossel, *J. Cell Biol.* **71**, 295 (1976); O. I. Stendahl and T. P. Stossel, *Biochem. Biophys. Res. Commun.* **92**, 675 (1980).
  55. E. Schiffmann, R. F. O'Dea, P. K. Chiang, K. Venkatasubramanian, B. Corcoran, F. Hirata, J. Axelrod, in *Modulation of Protein Function*, D. E. Atkinson and F. C. Fox, Eds. (Academic Press, New York, 1979), p. 299; R. Snyderman and M. C. Pike, in *ibid.*, p. 285.
  56. M. C. Pike, N. M. Kredich, R. Snyderman, *Proc. Natl. Acad. Sci. U.S.A.* **75**, 3928 (1978).
  57. R. O'Dea, O. H. Viveros, J. Axelrod, S. Aswanikumar, E. Schiffmann, B. A. Corcoran, *Nature (London)* **272**, 462 (1978).
  58. E. Schiffman, personal communication; M. C. Pike and R. Snyderman, unpublished data.
  59. D. A. Kennerly, T. J. Sullivan, P. Sylwester, C. W. Parker, *J. Exp. Med.* **150**, 1039 (1979); S. Rittenhouse-Simmons, *J. Clin. Invest.* **63**, 580 (1979); R. L. Bell, D. A. Kennerly, N. Stanford, P. W. Majerus, *Proc. Natl. Acad. Sci. U.S.A.* **76**, 3238 (1979).
  60. F. A. Kuehl, Jr., and R. W. Egan, *Science* **210**, 978 (1980); B. Samuelsson, in *Proceedings of the Fourth International Symposium on the Biochemistry of the Acute Allergic Reaction*, in press; E. J. Goetzl, *Med. Clin. N. Am.*, in press.
  61. E. J. Goetzl, P. F. Weller, F. F. Sun, *J. Immunol.* **124**, 926 (1980); E. J. Goetzl, *Immunology* **40**, 709 (1980); J. T. O'Flaherty, H. J. Showell, E. L. Becker, P. A. Ward, *Prostaglandins* **17**, 915 (1979); H. J. Showell, P. H. Naccache, R. I. Sha'afi, E. L. Becker, *Life Sci.* **27**, 421 (1980); D. A. Bass, J. T. O'Flaherty, P. Szejda, L. R. DeChatelet, C. E. McCall, *Proc. Natl. Acad. Sci. U.S.A.* **77**, 5125 (1980); P. H. Naccache, P. Borgeat, E. J. Goetzl, R. I. Sha'afi, *J. Clin. Invest.* **67**, 1584 (1981).
  62. D. W. Goldman and E. J. Goetzl, *Fed. Proc. Fed. Am. Soc. Exp. Biol.* **40**, 1004 (1981).
  63. J. E. Smolen, H. M. Korchak, G. Weissmann, *J. Clin. Invest.* **65**, 1977 (1980); L. Simchowicz, L. C. Fischbein, I. Spilberg, J. P. Atkinson, *J. Immunol.* **124**, 1482 (1980); E. J. Goetzl, H. R. Hill, R. R. Gorman, *Prostaglandins* **19**, 71 (1980).
  64. J. Fehr and H. S. Jacob, *J. Exp. Med.* **146**, 641 (1977); J. T. O'Flaherty, P. R. Craddock, H. S. Jacob, *Blood* **48**, 987 (1977); P. R. Craddock, D. E. Hammerschmidt, J. G. White, H. S. Jacob, *ibid.*, p. 961; J. T. O'Flaherty, D. L. Kreutzer, P. A. Ward, *J. Immunol.* **119**, 232 (1977); A. R. E. Anwar and A. B. Kay, *Nature (London)* **269**, 522 (1977); A. I. Tauber and B. M. Babior, *Photochem. Photobiol.* **28**, 701 (1978).
  65. We thank C. Daniels for help in the preparation of Fig. 1. This work was supported in part by National Institute of Dental Research grant 5 RO1 DE 03738 and by National Institutes of Health grant HL 19777.

## Regulation of Technological Activities: A New Approach

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Success in satisfying the requirements and aspirations of the American citizenry depends greatly on the wise employment of advancing science and technology. The potential gains from proper use of these tools include reduced costs of production, the discovery of new resources and invention of substitutes for those in shrinking supply, and the design of new products whose manufacture would create needed jobs. Unfortunately, there is a deterrent to our full realization of the fruits of technology. It is that technological activities produce negatives along with positives. Build any machine or set up any process and, along

with the benefits, detrimental consequences also may result. Appreciation of possible disbenefits is now so widespread that government regulation of technological activities is a permanent policy, even if in practice it is an ambiguous one, difficult to implement.

Critics of present technological regulation abound. They complain that the regulation often does not provide needed, minimum protection; over-regulation is frequent; Congress has created bad regulatory legislation; the courts are called upon to do what they cannot and should not be asked to do; agencies sometimes have conflicts of interest; regulators often make inadequate investigations and stall to play it safe; value judgments are confused with economic or scientific factors; an unintegrated hodgepodge of disconnected decisions

dominates; balanced decisions, with the risks and benefits of all alternatives compared, are rarely made. Whether these criticisms are justified is itself a value judgment, my own being that all have considerable validity.

In this article I will discuss the nation's present pattern of regulating technology-based activities, arguing that it is overly beset with shortcomings. I will propose a new approach which I believe merits consideration for two reasons: (i) it satisfies some of the criteria fundamental to any more satisfactory system, and (ii) it constitutes beginning theoretical support for the belief that superior systems are inventable.

### Difficulty of Technological Regulation

Before considering the shortcomings of present regulatory policy, it is essential to recognize the inherent difficulty of technological regulation. To begin with, defining accurately what hazards are tolerable is essentially impossible. The unwanted ills conceivably present are too numerous and not always quantifiable. Even if for every activity we could measure every possible menace, we would not learn thereby what threshold level of impairment is acceptable. What we define as tolerable must depend on how much we are willing to risk losing. What degree of lowering of our life expectan-

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cies or vigor or joy of natural surroundings are we willing to countenance? Since people differ in value judgments even if they agree on the facts, how can we specify the limit of harm? Should we merely insist that the disbenefit be negligible, how shall we define negligible?

tection Agency (EPA) has completed examination of only a token part of the 50,000 chemicals for which testing is required by the Toxic Substances Control Act. Uranium mining has claimed the lives of miners because of radon gas-induced lung cancer.

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**Summary.** Efforts to regulate technological activities have led to confusing and inconsistent government actions, delays in realizing the benefits from scientific advances, huge financial burdens, and doubtful protection. In the absence of a clear decision-making authority on technological issues, appeal from regulations is frequently sought in the courts. A new approach to regulation is proposed in which the tasks of investigating a technological activity and of making decisions are separated. The former would be carried out by an investigatory agency charged with and enabled to determine the negative aspects of the technological activity, the latter by politically appointed decision boards. The boards would consider the negative evidence presented by the investigatory agency and balance it against the benefits of the proposed activity.

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Just as identifying detriments is a beginning to sound regulation, so is a listing of rewards. How much of a gain should we insist on before we are willing to accept a given risk? Industry's dollar costs of meeting regulations are eventually paid by all of us, and most such costs can be estimated. But we cannot readily put economic worths on improvements in health or prevention of accidents. No marketplace sets a price for an extra year of life or a month's supply of breathable air. Knowing that the decision-making required of us involves listing the pluses and minuses for each alternative, the lists perpetually incomplete, the items often unmeasured, we sit in the ridiculous position of pitting one alternative against another. How are we to balance the gains against the risks with limited knowledge of each and no clear weighing scale? Despite this quandary, we have created regulatory agencies to limit hazards.

Has regulation protected us from serious harm? Tens of thousands of chemicals are being manufactured and a thousand new ones are added every year. Billions of pounds of some are produced annually. Analyses have suggested that more of these substances might be hazardous than we have recognized. Before ethylene dichloride was found to be a strong carcinogen, 100 billion pounds of it was produced. Vinyl chloride reached a rate of 5 billion pounds a year before tests showed it to cause cancer. A 1975 report of the National Academy of Sciences stated that 1 billion pounds of toxic matter was being introduced yearly for pest control and that the government's knowledge of the potential harm was superficial. The Environmental Pro-

In principle, most cancer of environmental origin should be preventable. One tough problem in identifying environmental carcinogens is that it may take 25 years before the influences are felt. This is true not only of many industrial chemicals but of low levels of radiation, radium, coal mine environments, asbestos, and others. Another problem is in instituting practical controls even when we have positively identified hazards—for example, smoking (lung cancer), fat in the diet (colon and breast cancer), and charcoal-broiled steaks (containing charred protein, a mutagen).

Clearly, the investigatory task of identifying and measuring hazards is an enormous one. Regulation is unsatisfactory partly because we have not faced up to the science and technology part of the task. Usually the technical experts and laboratory facilities required are more than the agencies are in a position to assemble. Inadequate budgets and inspection powers often limit the making of studies leading to good regulations and the policing needed to ensure adherence to them. Restricted in investigatory capability, but anxious to protect against hazards, agencies sometimes hold back on approvals. Delays may curb harmful effects of new developments but also may deny us benefits. Regulation frequently involves voluminous, costly documentation on minor issues and long negotiations, the required industrial bureaucracy matching the government's.

Meanwhile, regulatory action sometimes appears to have results exactly opposite to those intended. For instance, the current clean air offset requirement mandates that "old pollution" has to be cut down before superior plants can be

built in the same area. Since it is not always practical to make an old plant pollute less, this rule means that up-to-date, efficient, low-pollution plants are discriminated against in an established region and will not be created there, while old plants that pollute heavily are allowed to remain. This discourages investment in new technologies that underlie cleaner plants.

Two decades ago it took 5 years and \$1 million to work an average new drug through the regulatory mill. Today the typical cost is nearer \$20 million and the time is approaching 10 years. In this period the rate of new drug introductions by U.S. firms has fallen by 50 percent. Should we be thankful that we are paying the added price in time and money to prevent hasty introductions of bad drugs? Or are we allowing needless suffering and deaths that new good drugs might prevent? We do not know, because no group has the function of answering these questions. During the 1970's, U.S. drug companies increased their annual R & D budgets in foreign countries from under \$50 million to over \$250 million. Trials with volunteers are permitted by other countries, who view differently the balance between the dangers of new drugs and the values they might provide. If pharmaceutical R & D moves abroad, then foreign countries, not we, will be penalized by the hazards, but they will be the early beneficiaries of the health benefits and financial returns. Perhaps it has worked out that our pattern has afforded us great protection and cost us little in missed gains. If so, that would be largely accidental, because no group is clearly charged with comparing these broad alternatives.

### Conflicting Roles of Regulatory Agencies

Can a regulatory agency be an adequate investigator of negatives if it is simultaneously an arranger of a flow of positives? For instance, is the Nuclear Regulatory Commission (NRC) in business partly to see that the nation obtains nuclear energy, or does it exist solely to protect us against the negatives of the nuclear approach? If both, does it not have a conflict of interest? Moreover, is it reasonable to assume that the NRC can balance nuclear reactor hazards against energy needs unless it is assigned the duty and given the means to determine how much energy the nation requires and is expert on alternatives such as coal and solar, on the politically acceptable level of oil imports, and on the

potential of more conservation effort? The NRC often has counseled the suppliers and utilities and can claim never to have had to turn down a request for a license. When it also takes upon itself the role of safety expert and the public's protector, the perplexity is natural. Immediately after the Three Mile Island event other utilities operating similar reactors considered closing down temporarily. The NRC was looked to for a decision about a shutdown. Here the mission of the NRC as a protector was understandably perceived by some to be in conflict with its also being a party to providing uninterrupted electric power.

There is an opposite side to this conflict of interest coin. Those wishing to get on with technological activities are frequently frustrated by the negating activities and indecisiveness of government agencies. Sometimes the critics of an agency are politically powerful, and the ultimate effect of their criticism is to cause the agency to depart from its mission of protection and seek to appear to be using a more even approach. In so doing, it compromises its role as a protector. Consider, for example, the political difficulties of the Occupational Safety and Health Administration (OSHA). It was not created either to promote industrial development or to slow it. Industry is disturbed by the costs of meeting OSHA's standards and the large staffs needed to deal with OSHA. The criticism has become so great that OSHA is now on the defensive. It may have to create for itself an image of balanced decision-making or face lower funding and restricted jurisdiction. This handicaps OSHA in fulfilling its mission of worker protection. At the same time, its actions will hardly be viewed by industry as contributing to expansion. Thus, all concerned—workers, industry, and government—will continue to be unhappy with OSHA.

#### **Trade-offs Between Benefits and Harms**

Decision-making on technological operations can hardly be sound unless it includes examining alternatives. Also, the decisions, once made, must be enforced. There is no such thing as zero risk, so to seek it can only generate an expensive bureaucracy with no chance of succeeding. Comparing imperfect options and balancing risks and gains, both in arriving at rules and policing adherence to them, is key. Severity in regulation is not necessarily an error on the safe side, because it can also have a

negative impact on productivity and employment. It can hurt our ability to compete in the world market, lower return on investment, raise prices, discourage new investment, and decrease average incomes. People who are made poorer suffer from health problems just as surely as do those who are not protected from health hazards.

Starting with the Pure Food and Drug Act of 1906, we have added laws governing therapeutic drugs, cosmetics, medical devices, occupational environments, pesticides, children's sleepwear, automotive safety, nuclear emissions, and pollutants in water and the atmosphere.

This article is part of a series on topics common to science, technology, and law commissioned by the National Conference of Lawyers and Scientists, a joint venture of AAAS and the American Bar Association. The articles are intended to increase communication and cooperation among lawyers and scientists; some of the articles will also be published in law journals. Preparation of the series was supported under a grant from the National Science Foundation. Other articles in the series will be published in forthcoming issues of *Science*.

All this regulatory effort is narrowly focused and disconnected. Effects of specific regulations on other government programs and overall national economic, physical, and social health would enter the deliberations if responsibility for comparing alternatives broadly accompanied government regulation. In some instances agency policies include finding evidence of positive benefits before allowing a new product on the market. However, usually the legislation setting up regulating agencies is silent on defining trade-offs. Congress has actually sometimes forbidden balanced decisions by the agencies and required unbalanced ones. The Clean Air Act specifically precludes the deliberate weighing of benefits against harms. The so-called Delaney Amendment to the Food and Drug Act tells the Food and Drug Administration that it must not consider the cost impact when making regulations.

The trade-off between improving the environment and increasing the energy supply is typical. The economy's being slowed by too low an energy supply is bad; allowing more pollution and accidents is also bad. With no one in charge of balancing positives and negatives, the government has taken several unrelated and conflicting actions. If coal use is expanded, then energy shortages may be eased, but environmental impairment and safety hazards will increase. The government first set a low ceiling price on natural gas, discouraging further ex-

ploration and simultaneously increasing demand. In an unrelated act, it then imposed drastic controls on coal. To cut air pollution, it mandated changeovers to oil and gas for utilities using coal. A little later, reacting to actions by the oil-exporting nations, it required greater use of coal. The government introduced strong air pollution restrictions on automobiles without considering the impending oil shortage. The EPA's isolated auto emission rules raised the demand for unleaded gasoline and lowered MPG (miles per gallon) performance. Less gasoline is produced from a barrel of crude in making unleaded fuel, so more refinery ca-

capacity was needed. At the same time, new restrictions were placed on refineries. While one agency thus pushed the demand for oil upward, another discouraged the expansion of capacity. Government policy in energy has preached conservation, encouraged dissipation (by keeping conventional fuel prices low), made development of new domestic energy sources through private investment less attractive, then started government-funded programs to pursue new energy alternatives.

The automobile pollution problem is a good example of the need to consider the inevitable impact of a ruling or inaction on the rest of the economy. The automotive industry employs more people, constitutes a higher fraction of our gross national product, uses more materials, consumes more energy, and influences our way of life more than any other industry. Regulations affecting the design of a car have an enormous effect not only on air pollution and accidents but also on unemployment, the national economy, and our international competitiveness. Government controls have much to do with the price of cars. The price influences the rate at which the public shifts from older (lower MPG, more polluting, less safe) cars to more desirable ones. Government actions dominate manufacturers' decisions as to where to put available funds—to meet regulations, enhance productivity, or improve the product. Yet little evidence

exists to suggest that federal regulation of the industry has been based on weighing overall national gains and costs.

Seat belts, safety glass, collision-proof door latches, and the energy-absorbent steering column were the first mandatory safety requirements. The regulatory bureaucracy then invented 5-mile-per-hour bumpers, the airbag, and interlocking of seat belts with the ignition. The public vetoed the last two. The new bumpers perhaps reduced repair bills after some accidents, but they cost consumers \$1 billion for the adornment and required hundreds of millions of gallons of extra gasoline annually to handle the added weight. It is not evident that any safety benefit has been attained. To this day, we do not know whether auto standards are in the right range, everything considered.

A different kind of example is the Georges Bank project, off the coast of Massachusetts, where the Labrador Current and the Gulf Stream converge and stir up nutrients. The fish catch there over the next 20 years is believed to be worth \$3 billion to \$4 billion. Geologists estimate that during the same period \$10 billion of oil and gas can be obtained from the area. The government is about to sell petroleum leases amidst controversy over potential harm to the fishing. Many agencies are involved and the pattern for setting standards is confused. No one group has the responsibility to compare alternatives.

#### Delays due to Indecision

The eastern United States has a refinery capacity for less than a quarter of the oil it consumes. No new refinery has been built on the East Coast for more than 20 years, and petroleum products must be shipped from a distance, using energy and adding pollution from its dissipation. Those seeking to locate a new refinery on the East Coast have contested for many years with those striving to prevent it. Involved, in addition to those who would operate the facility, are numerous citizen groups, the Department of Energy, the Department of Interior, the National Oceanic and Atmospheric Administration, the Commerce Department, local government groups, the Army, the General Accounting Office of Congress, the EPA, the Coast Guard, and others. None has decision power.

To secure approval for a pipeline from California to Texas, the Sohio Company spent 5 years obtaining 700 separate permits from regulatory authorities. Then,

seeing no end of legal challenges, the company gave up. But perhaps we badly need the pipeline. Who knows, and who is to say?

Another example particularly shows how our decision-making affects us internationally. California competes with Japan for liquefied natural gas (LNG) from South Alaska, Indonesia, Chile, Malaysia, Australia, and other Pacific locations. Anticipating a decline in U.S. gas supplies, California gas companies commenced arrangements 10 years ago for LNG deliveries from sources offering two or three decades of supply, well before the Japanese made similar contracts. The gas started flowing to Japan in 1977. The earliest the United States can now receive this gas is 1983, the period having been used up to get approval on a terminal site for the tankers. Similarly, the Alaskan North Slope gas pipeline project was blessed by the Canadian Prime Minister, the U.S. Congress, and the President in 1977. Many more years will be needed to complete approvals. Perhaps this slowness gives us worthwhile protection. It would be easier to be convinced of that if the decision process appeared so thorough as to require the time for selection of the wisest alternative. It seems instead to be a hodgepodge of fragmented confrontations.

It is interesting to compare Canada and the United States on similar technological projects, Canadian tar sands and U.S. oil shale. Both are huge energy resources but need additional development. Two commercial plants are in operation in Canada, a cooperative effort by government and private industry. There is nothing comparable in the United States. Canada began passing environmental protection legislation years before similar U.S. action, so they are not ignoring the problem, but they seem able to match reasonable environmental protection with desired use of the resources. Permits required in the United States for a single project in oil shale number in the hundreds. One disapproval is enough to halt action. Again, if our procedure results in well-balanced decisions, it will be partly fortuitous.

The Department of Agriculture estimates that if pesticides were banned, crops would decline 30 percent and food prices would rise 75 percent. Millions of people around the world would go hungry because U.S. food would no longer be available to them. Unregulated use of pesticides is unthinkable, but the standards should be based not alone on the dangers of their use but also on the

disbenefit of their nonuse. A recently introduced herbicide is said to be environmentally superior to existing ones. It was the result of 20 years of research and approval effort. Should the regulatory process be accelerated, the gains expected to exceed the potential harm of premature approvals? To weigh probable benefits against risks is not now a required regulatory procedure.

#### Role of the Judiciary

Interested parties now commonly seek appeal from regulations through the courts. Litigation has become so frequent that regulations are often rendered academic, their application requiring the step of winning in court. The U.S. Court of Appeals recently struck down a regulation by OSHA on the handling of benzene. Regulations originating several decades ago limited the allowable molecular concentration of benzene in industrial establishments to 100 parts per million. This was later lowered to 10 parts per million. Then OSHA ruled that the concentration should be decreased to 1 part per million. Would adhering to these more severe standards save 100 lives, or even one life, annually? OSHA had not performed tests to answer such questions; it was going on the assumption that if holding benzene in the air to a low value is good, then reducing it to a lower value must be better. On the other hand, it was quickly ascertained that OSHA's new standard would lead to industry expenditures of more than \$500 million. Immediately a value issue arose: some certain and large economic penalties versus some possible, but perhaps totally absent, health benefits. OSHA assumed that industry spending to meet regulations is not to be a criterion when the agency seeks to protect human lives. But surely some price is prohibitive and some of the expected benefits must be measurable, the court decided, ruling that OSHA could not apply the more severe standards. (The case recently was heard by the Supreme Court, which backed up the decision of the Court of Appeals.)

The inadequacies of the regulation process, while making the role of the courts more important, has also caused their function to be less distinct. Industry often complains that the courts unduly delay and interfere with industrial development. Labor and environmentalists argue that the courts defer valid prosecutions by regulatory agencies and are too subservient to industry groups.

Accusations are common that judges, without adequate knowledge of the highly technical matters involved, misuse their injunctive power, available at the beck and call of environmentalists at times and of industry groups at other times.

While fundamental questions exist as to the appropriate role of the judiciary in technological regulation, the legislation produced by Congress is in any case a key factor in the frequency and substance of actions before the courts. Congress has set up a new agency almost every time a new harm has surfaced, the empowering legislation occasionally directing the agency to do something bordering on the impossible, such as essentially eliminating a risk. The laws governing the agencies do not tell them whether to tolerate a trivial hazard when the cost of removing it is enormous while banning it may deny us a great benefit. By creating many narrow agencies and ignoring the impacts of an agency's regulations on the rest of the nation's activities, Congress has almost neglected its constitutional role as overall policy-maker and has created a base for isolated, piecemeal, and inconsistent decisions.

No really effective legal foundation for control exists over most regulatory agencies. Each new empire is constructed to be independent of elected officials, those who must answer to the voters. Although Congress has committees to oversee the work of regulatory agencies, these committees seem not to spot over-regulation or under-regulation readily, or an agency's lack of motivation or responsibility to compare alternatives, if that is what Congress intended, or the fact that an agency is inadequately funded to obtain facts essential for sound regulation. It has been estimated that \$100 billion to \$200 billion per year is spent by industry to meet government regulations, an amount comparable with the nation's annual capital investment or the federal tax revenues from business. Thus Congress could be excused for spending roughly as much time studying regulatory costs, to make sure they are justified, as pondering taxes. With a budget in mind to meet regulations, Congress could apply its own value judgments to the comparison of costs with benefits.

Admittedly, some benefits result when regulatory matters get to the courts. In bringing unresolved matters there, industry, environmentalists, and numerous other government and private groups help bring to the surface a very critical issue in technological regulation: the sur-

vival of democratic institutions in a technological age. This is more important than the courts' curbing bureaucratic excesses or catching inadequacy of expertise. If Congress did its job properly, creating an adequate organization to handle technological regulation, the role of the courts would become less cloudy. The courts could then concentrate on being the guarantor of the rights of the individual in a technological democracy.

Present court activity in technological regulation does not have this focus. Reflecting the unsatisfactory state of court actions on technological activities, David Bazelon, Appellate Judge of the Washington, D.C., Circuit Court of Appeals, recently suggested (1) that in cases involving technological and scientific hazards the courts should restrict themselves to the role of watchdog over the expert. The courts should ensure, he wrote, that the experts have fully considered all the evidence, but should refrain from inserting themselves as the final arbiters of complex scientific questions. This may be what, in practice, the judge must do in certain cases, but it does not mean that the courts can shy away when experts testify. Any proposed technological activity must meet the test of justice and fairness to the individual, which every judge swears to uphold, or our concept of democracy will not survive. Society's interests, whether or not an issue is based on technological matters, may occasionally deserve to outweigh an individual's rights. But the presumption underlying the Bill of Rights and the Constitution is still the supremacy of the individual. Historically, it has been the courts' duty to uphold fundamental values on which the majority or the powerful may be seeking to trample. In administering justice, the court is the expert. No matter how we organize technological regulation, society will feel frustration with court decisions much more deeply if the courts fail to articulate and implement basic concepts of justice than if they fall short in ensuring that decisions are scientifically accurate.

This may be all the more evident once it is fully accepted that a decision concerning a technology-based issue is not merely a matter of risk assessment. If it were, we could turn it over to expert calculators. Broad problems arising out of scientific and technological advance are never matters of science and technology alone. Instead, like all other important issues, they are dominated by their social, ethical, and political dimensions (2). Jeremy Bentham, in the early days of the industrial revolution, enunciated a

political theory of social policy based on the idea that one could compare the number of people benefited with the number harmed to arrive at an appropriate decision. He hoped that legislation could be based on such a quantitative criterion. (Bentham believed his system would protect the working class since no policy affecting laborers adversely could prevail, the large number harmed exceeding the small number of company owners.) But now it is clear that a program might benefit a large number but cause the death of a few. Is this just according to our ethical and legal standards? In many technology-related issues to come before the courts, the decision may hinge on this point.

Take only one example, the nuclear energy option. It can be given some useful evaluation through cost-effectiveness analysis, but it also involves matters that cannot be judged in terms of numbers. The analysis is likely to disclose only what is good for the majority. What the nuclear route does to a minority may always have to be for the courts to ponder and is definitely not a matter for technical experts alone (3).

#### A Proposed New Approach

With the foregoing description of the problems of technological regulation in mind, let us consider a regulatory organization that may be superior to present approaches as to timeliness of action, the reaping of benefits from technological advance, protection against hazards, and the minimizing of court actions on items best handled through legislation.

One route to improvement lies in decisively separating two duties of the government in regulation of technology: (i) to investigate and make recommendations concerning negatives and (ii) to balance the good against the bad aspects of various alternatives and make decisions. The proposed approach starts with a competent organization to discover, study, assess, provide recommendations, and present cases regarding all hazards to safety, health, and the environment. To remove conflicts of interest, we would relieve this investigatory unit of any responsibility for considering positives and attempting balanced decisions. Decision-making would not be its business. When it comes to clean air and water, nuclear safety, toxic chemicals, occupational health and safety, purity in food or drugs, and the rest, the group should be equipped with the experts, tools, and budgets needed to track down

all the detriments of existing or proposed activities. The operations of the Federal Bureau of Investigation (FBI) are a useful guide. The FBI is an investigatory agency; it investigates crime and finds criminals. It does not try or sentence lawbreakers. It does not decide whether capital punishment is proper or whether jails should punish or rehabilitate. When it finds culprits it turns them and the evidence it has found over to another part of the government.

If we accept the value of a separate, unambiguous mission to investigate disbenefits, it is sensible to bring all such activities together in one agency. Every potential harm to humans and the environment requires for discovery and evaluation an array of measurement equipment, laboratory facilities, field offices, and expertise in chemistry, physics, biology, engineering, toxicology, statistics, and other disciplines. Efficiency and flexibility of organization would result if the experts were all in one strong unit. No need would exist for Congress continually to perceive a new danger and launch still another agency to handle it.

In all technological activities, some entity presumably always exists, such as a drug manufacturing firm or an electric utility, that wants to move forward with a product or a project. These groups and the proposed technological FBI may often be opposing parties, one interested in the advantages of some activity it wishes to engage in, the other ready to say what detriments the activity will bring. Perhaps these two interested parties will agree that the activity is safe or, conversely, should be held up until identified disbenefits can be diminished. If they do not agree, then a decision board is needed to settle the issue.

We see at this point that the FBI model for our proposed agency to handle technological negatives is inadequate, and that in some respects the Department of Justice, which includes the FBI, offers a more complete analogy. This is because the new agency would be expected to bring actions before the decision board. It would present its evidence of hazards and recommend action by the board to disapprove or mandate the modification of technological activities. In this analogy the agency would resemble the office of the U.S. Attorney, which decides whether to take a case to court and, if it does, then prosecutes it. The party carrying on the technological activity would be analogous to the defendant, and the decision board would be like the judge. (If this analogy is applied crudely to a present regulatory agency, it

would say that the agency acts as both the prosecutor and the judge.) It would be hoped that most often the investigatory agency and the technological operator would "settle out of court."

The decision board, unlike the investigatory agency, should have the role of comparing alternatives, balancing the good against the bad, and the duty to connect the case before it to other national interests. It should have the unquestioned responsibility for banning or approving the challenged technological operation. The pluses and minuses of the activity and the alternative for regulating it would be argued as thoroughly as possible in the board's hearings, after which the board would make its decision. While a single agency may be the best way to manage the discovery and evaluation of hazards and the presentation of recommended means to handle them, we should not try to solve all society-technology interactions with one decision board, because of the expected number of cases and the wide array of value judgments to be included.

The decision boards should be regarded as extensions of the Executive Branch—that is, of the President—a conclusion arrived at by focusing on the intended board's missions. We want the boards to (i) constitute a credible and effective representation of the electorate, (ii) integrate the members' values to form criteria for judging the options and use these value judgments for decision-making, and (iii) compare the alternatives, seeking to balance benefits and risks. The President should appoint the members with the consent of the Senate, naming citizens of outstanding competence and character, with staggered, substantial terms of office. This process will cause the boards to be inherently political, as they should be, responsive to the country's goals and priorities, thus fulfilling (i) and (ii). By the congressional legislation setting up each board, by other pertinent legislation affecting the issues the boards will ponder, and by the boards' operating competently, (iii) will be satisfied.

The President, Congress, or the new investigatory agency would be empowered to call on a decision board to handle a question. Other private or public groups or individuals could also request the board's consideration of an issue (4). Because the boards would be expected to ponder every case on a broad basis, they would be expected to overlap frequently, one board being assigned the decision responsibility but typically calling on another board for advice. The

legislation setting up the boards would provide the first approximation to defining their jurisdictions and would name the activities (such as a nuclear reactor installation) specifically requiring their approval. In case of doubt as to which board should handle a particular issue, the assignment should be made by the President.

As the boards go about their tasks of rendering decisions, the courts will sometimes be sought out by interested parties. If the legislation setting up the boards is competently written, their decisions will be interfered with by the judicial only when they overstep their charter or ignore other pertinent legislation or fail to be just and fair. For example, a board may make a decision it regards as superior to any alternative for the good of the nation, but may overlook an injustice to some citizens caused by that decision. The Constitution and the courts will always be with us, and decisions reached in any way may end up in the courts. But we can do better than to encourage the present trend of relying on litigation to settle most important issues.

The need for the decision boards and the investigatory agency described, or some superior approach, can be summarized by quoting the words of John G. Kemeny, president of Dartmouth College and chairman of the presidential commission on the accident at Three Mile Island (5). "Our decision-making process is breaking down. The problem is whether our current political process can handle the complex issues of modern society—highly technical questions of science and technology that also involve value judgments. . . . I am still a believer in democracy, but I think some changes will have to happen in the practice of it. We have to have a forum for effective discussion of highly technological issues, so that there is a clear consensus on what science and technology say about an issue. Then the political process can make the value judgment."

#### References and Notes

1. D. Bazelon, in *The Outlook for Nuclear Power* (National Academy of Engineering, Washington, D.C., 1980), p. 26.
2. C. Starr and C. Whipple, *Science* **208**, 1114 (1980); A. J. Large, *Wall Street Journal*, 11 June 1980, p. 22.
3. For example, in New Mexico, the source of 50 percent of U.S. reactor uranium, the mining may benefit the majority of Americans but be hazardous to the Navahos who live there (A. Ramo, *Los Angeles Times*, 1 June 1980, part 5, p. 5).
4. This article is focused on federal regulation, but state and local regulation is also important. The latter will be aided by improved federal policy, organization, and performance. To some extent, the lower levels can also emulate the improvement at the federal level.
5. J. G. Kemeny, *Newsweek*, 19 November 1979.