# THE IMPACT OF REGULATION ON INDUSTRIAL INNOVATION

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in cooperation with

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#### PREFACE

In August 1976 a National Research Council Committee on Technology, Trade and International Economic Issues examined a number of technological issues and their relationship to the potential entrepreneurial vitality of the U.S. economy. The committee concerned itself with:

• Technology and its effect on trade between the United States and other OECD countries (Western industrialized members of the Organization for Economic Cooperation and Development);

- The relationships between technological innovation and U.S. productivity and competitiveness in world trade; the effects of technology and trade upon U.S. levels of employment;
- The effects of technology transfer upon the development of the less-developed countries (LDC's) and the impact of this transfer upon U.S. trade with these nations;
- Trade and technology exports in relation to national security.

The committee report, "Technology, Trade, and the U.S. Economy,"\* concluded that the state of the nation's international competitive position in world trade is a reflection of the health of the domestic economy. If this is indeed the case, the committee concluded, then the improvement of our position in international trade depends primarily upon improvement of the domestic economy. The committee further concluded that one of the major factors contributing to our domestic economy was the status of the industrial innovation process. Considerable evidence was presented during the study to indicate that the innovation process in the U.S. is not as vigorous as it has been.

The committee recommended that further work should be undertaken to provide a more detailed examination of the U.S.

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<sup>\*</sup>National Research Council, 1978. *Technology, Trade and the U.S. Economy*. Report of a Workshop held at Woods Hole, Massachusetts, August 22-31, 1976. National Academy of Sciences, Washington, D.C.

In addition, four 45-minute background presentations were made to the workshop participants by authorities in the field. They were:

1.

- "A Historical Perspective of Regulations and Their Impact" — Professor Ithiel de Sola Pool, Professor of Political Science, Massachusetts Institute of Technology
- "Effects on Research and Development of Price-Entry Regulation" - Dr. Edward E. Zajac, Director, Economics Research Center, Bell Laboratories
- "The Impact of Health and Environmental Regulations on Innovation" – Mr. Glenn Schweitzer, Senior Research Fellow, Program on Science, Technology and Society, Cornell University
- 4. "Uncertainties and Costs of Regulations" Dr. William Schulze, Professor of Economics, University of Southern California.

Following these presentations, the panel participants from government agencies were invited to present informally their perceptions of the major issues as viewed by their respective agencies.

This monograph is a product of the workshop, but does not constitute a workshop proceedings. To author this report, Professors Henry G. Grabowski and John M. Vernon were commissioned by the committee. Successive drafts prepared by the authors were circulated to the committee for review and critique. The authors also met with the committee to discuss the criticisms and comments. Thus, this monograph expresses not only the authors' views, but also is generally reflective of the views of the committee.

It is important to recognize what this monograph is and what it is not. It is an examination of the impact of U.S. regulatory activities on technological innovation and it addresses the question of how these activities might be modified to lessen any negative effects of this kind without significant loss of benefits flowing from the regulation. It does not in any sense attempt to weigh the pros and cons of regulation, nor does it seek to render any value judgments whatsoever on possible benefits of regulation. It starts with the premise that we are committed to regulation and that it is sensible to do it as well as possible. One aspect of regulation that has been widely criticized and which has received too little attention in setting regulatory policy, action, and mechanisms is the effect of regulation on innovation. To examine this with the purpose of exploring ways to reduce possible negative effects on innovation, without loss of benefits, is not to attack regulation

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Innovation in new products and new processes of production is of great importance to the United States economy. It brings about higher standards of living, offsets the effects of inflation through productivity increases, and is an important positive element in the international competitiveness of the United States. Beginning with the work of Robert Solow (1957), many economists have made estimates of the contribution of technological progress to economic growth. These estimates are generally quite large, ranging from 30 to 70 percent, and provide quantitative measures of the significance of innovation.

Recently there has been increasing national concern about several developments relating to the decline in the rate of technological change in this country. Among the factors given prominent attention in this regard are a declining trend in research and development expenditures in relation to the gross national product, slower rates of productivity advances, absolute declines in real industrial expenditures on basic research, and a dearth of new ventures involving high technology firms. In addition, a number of research directors for major corporations have noted a significant shift in R&D funding from high risk, longer term, major advances to short term, marginal improvements in existing products and processes.

These developments in turn have triggered a reexamination of the role of government policies in influencing the country's rate of innovation. Government can have an impact on the innovative performance of the economy in several obvious ways, such as research grants, subsidies, and taxation policies. A less obvious impact of government on innovation is through its regulatory agencies.

Regulation can influence innovation in diverse ways, varying by industry and type of regulation. Some ways are direct, such as by increasing cost or simply forbidding a particular innovation. It should be noted that, while regulations may be imposed on an industry, in some instances regulation has been sought by industry. (See, for example, Paul MacAvoy's study (1965) on the railroads.) In addition, there is now a considerable literature providing many historical examples which show that, once established, the process of regulation may operate to benefit the interests of the regulated industry rather than the general public. (See Stigler, 1971, Posner, 1974, Peltzman, 1976, and the references cited therein.) Several cases illustrating these phenomena (such as the trucking industry) will be discussed in Chapter 4.

In the past fifteen years another kind of regulation has grown rapidly. This has not been concerned directly with economic factors such as industry profit rates and entry and exit, but, rather, with social objectives such as safety, health, and pollution control. This type of regulation has existed for selected industries since the turn of the century, for example, in the Food and Drug Act of 1906. In recent years, however, new agencies have been established, e.g., the Environmental Protection Agency, the Occupational Safety and Health Administration, and the Consumer Product Safety Commission. These have been given broad discretionary power to set safety and environmental standards for industrial firms and to undertake other policy actions to further these goals.

In analyzing the rationale for and expected benefits from government regulation, the typical starting point for economists is to consider the nature of the market failure which regulation is designed to correct. At this point, it is useful to review briefly the sources of market failure that have been used to justify regulation.

At one extreme is the case of "natural monopoly." This involves the situation in which average cost declines over the relevant range of market demand so that a single firm is the most cost-efficient market solution. Rather than let such a firm achieve monopoly prices and profits, regulation to permit only a "fair" rate of return is often advocated. This is the approach taken in most traditional public utility situations, such as local telephone service, and the distribution of electric power and natural gas.

Sometimes rate of return regulation and entry restrictions are advocated not to curb excessive monopoly power or overcome inadequate competition, but rather to prevent "destructive" competition. It is argued in this regard that competition by firms in highly capital-intensive industries with high fixed costs and immobile capital is prone to dynamic instability in which prices and output fluctuate widely, resulting in excessive costs to producers and

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## THE COSTS OF REGULATION AND THE MOVEMENT FOR REGULATORY REFORM

Clearly, there are many sound reasons to expect substantial benefits from government regulation. However, regulation obviously entails costs as well as benefits. The most direct and visible costs of regulation are the public expenditures to maintain the administrative activities of the regulatory agency. Frequently, these are quite small or even negligible compared to the value of economic activities under the regulatory agency's control. Because the agency has the power to significantly alter or constrain the decisions made by the regulated firm and its consumers, the overall costs to society resulting from regulation may far exceed the direct administrative costs of operating the regulatory agency.

While earlier advocates of regulation assumed implicitly that government regulation would provide net positive benefits to society, a number of recent studies have demonstrated persuasively that this need not necessarily be so. In particular, these studies (see Chapters 3 and 4 for examples) have pointed to a number of regulatory situations in which the costs to society far exceed the apparent benefits. In some of these cases, the rationale for regulation appears sound but regulatory procedures and processes have not been very successful in achieving the intended benefits. In other cases, because of dynamic changes over time in technology or economic factors, the original rationale for regulation no longer applies but the process continues on in an inefficient or imperfect manner. Finally, in other circumstances the application of regulation appears to have been poorly conceived or misguided from the outset of regulation (e.g., the trucking and CATV examples in Chapter 4).

By the mid 1970's, a considerable movement toward regulatory reform and deregulation had been initiated. A central aspect of this reform movement was federal regulation of transportation--ICC regulation of trucking and CAB regulation of airlines. The consensus of economists studying these industries is that, far from benefiting consumers and the public, the rate setting and entry restriction policies of the ICC and CAB had imposed significant net costs to consumers in the form of higher prices for air and surface transportation. One study of surface transportation (Moore, 1975) put the net annual cost of ICC regulation at between \$4 and \$9 billion. Moreover, no convincing market failure rationale for continued regulation of these industries has been demonstrated by the supporters of regulation in this industry. In light of these findings, economists have almost unanimously concluded performance through modification of regulatory policies and methods. In particular, we wish to examine what changes could be made to lessen the negative side effects on innovation without sacrificing the essential benefits from regulation. It is not the purpose of this report to weigh the pros and cons of regulation, or to analyze the benefits. It is our purpose to explore one generally overlooked cost, the effect on innovation, and to suggest ways in which this might be reduced. Mansfield (1977), in a recent study of returns on 17 representative innovations, estimated a median social rate of return of 56 percentmore than double the median private (pretax) rate of return of 25 percent for these innovations.

While investments in R&D and innovation have been characterized by above-average returns, they also are subject to much greater uncertainties and gestation periods than other industrial investment activities. The greater risks associated with investment in industrial innovation are reflected both in the high probability of failure for most R&D projects and in the large variance in rates of return on new product and process innovation. Mansfield found in his empirical study of industrial innovations, for example, that, for about 30 percent of the innovations, the private rate of return was so low that no firm, with the advantage of hindsight, would have invested in them.

Three types of uncertainties affect the success of an innovation: technical uncertainty, market uncertainty, and general business or economic uncertainty. Recent studies by economists indicate that all three types of uncertainties are important. For example, an intensive examination of R&D projects for three firms by Mansfield et al. (1971) indicated that about 40 percent of the R&D projects that were begun were never completed. Of those projects that were technically completed; 45 percent were not commercialized. Furthermore, of those projects that were commercialized, about 60 percent did not earn an economic profit. The probability that an R&D project would result in an economically successful product or process was only about .12 overall. Other studies suggest even lower success ratios characterize most R&D projects. The probability of commercialization on clinical development projects in the drug industry, for example, is now estimated to be about 1 in 10 (Wardell, 1978).

Another finding emerging from several economic studies is that the annual R&D expenditures of corporate firms tend to be significantly related to their level of retained earnings and internally generated cash flows. This result emerges from cross-sectional studies by Mueller (1967), Grabowski (1968), Branch (1974), Grabowski and Mueller (1972), and Wilson (1977). The positive link of R&D outlays to internally generated sources of finance is generally attributed to the much greater uncertainty and gestation periods of investments in R&D and the desire of corporate managers to have a very secure underpinning for such investments.

Of course, externally generated funds also play an important role in the funding of innovational activity. This is particularly so for new, smaller innovative firms that have relatively little or no internally of developing the inventions of these small firms to the point of commercial introduction were frequently undertaken by a larger more established firm with greater technical, financial, and managerial resources. However, there are also many examples of the opposite kind, especially in the semiconductor and electronics industries, in which entrepreneurs have launched new firms based on technical ideas originating in the laboratories of larger companies. The costs of regulation, however, appear to be particularly burdensome to small, entrepreneurial companies.

To sum up, research studies by economists suggest that no single firm size is necessarily optimal for innovation. The activities of different-sized firms have frequently operated in a complementary fashion in bringing important new products and processes into the marketplace.

#### **RECENT TRENDS IN INNOVATION**

As noted at the outset of this paper, there has been increasing concern in the United States about several adverse developments relating to the country's current and future capacity for technological change. Much of this discussion has focused on trends in various aggregate indicators. For example, total societal R&D outlays as a percentage of GNP peaked at 3 percent in the middle 1960's and has been on a declining trend line since that time. Furthermore, industrially financed R&D has grown at a rate of less than 2 percent in real terms since 1967, which is significantly slower than the earlier postwar period.

Growth in productivity has been another area of concern. Technological innovation is one of the principal factors underlying productivity advances. The U.S. productivity growth rate over the last decade has declined significantly below the historical trend line and also compares unfavorably with most other advanced Western economies. Using an aggregative economic approach, Edward Denison (1978) has estimated a decrease of almost one-half of a percentage point in U.S. productivity because of increased regulation in the industrial sector. (Annual increases in U.S. productivity averaged 2.1 percent from 1948 to 1969.)

Other indicators frequently cited include sharp declines in newventure technology companies (Hannay, 1978) and a large increase in the percentage of patents granted to foreign residents (i.e., from 20 percent in 1962 to 45 percent in 1978). The latter indicator is of doubtful value, however, as the increase in U.S. filings coincided with greater entry into U.S. markets by foreign firms, which would lead to

### SOCIAL REGULATION

#### INTRODUCTION

Government regulatory controls in the health, safety, and environmental areas have increased dramatically over the past decade and a half. Since the early 1960's Congress has passed a succession of laws imposing and strengthening regulatory policies for these social objectives over a wide spectrum of market situations.

Some of the major pieces of legislation include the 1962 Kefauver-Harris Amendments, which made the premarket approval process for new pharmaceuticals more stringent in nature; the 1968 Delaney Amendments requiring the FDA to ban any food additive found to be carcinogenic in animals, regardless of foregone benefits; the 1970 Amendments to the Clean Air Act and the 1972 Amendments to the Federal Water Pollution Act, which authorized EPA to set national standards for air and water pollution; the creation of the Occupational Safety and Health Administration (OSHA) in 1970 and Consumer Product Safety Commission (CPSC) in 1972 as major new federal agencies to set health and safety standards for workers on the job and for products in various industry classes; and the Toxic Substance Control Act in 1976, which authorizes stringent EPA regulatory controls over new chemical substances.

The growth of federal regulation in the health, safety, and environmental areas has occurred at a truly explosive pace over recent years. The Center for the Study of American Business, for example, has calculated that federal expenditures for these regulatory activities more than quadrupled between 1970 and 1977 and now exceed \$3 billion in value (Wallace and Penoyer, 1978). The number of employees at federal agencies administering these regulations has grown

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manufacturers were required to demonstrate the therapeutic efficacy as well as safety of a new drug prior to obtaining FDA approval.

The fact that new drugs can cause serious unforeseen toxic side effects as well as provide therapeutic benefits is the legislative justification for these strong regulatory controls. At the same time, however, the regulatory decisionmaking process at the FDA has been characterized by an extreme form of safety imperative. As FDA Bureau of Drugs Director Richard Crout has indicated:

> I would emphasize very strongly that the Food and Drug Administration regulates health policy, not economic matters. That is terribly important to understand. We do not pay any attention to the economic consequences of our decisions and the law does not ask us to. (Crout, 1975, pp. 196-197).

and

... The issue isn't whether ... regulation cuts down on innovation. Indeed it does. It hardlv must. There's any way that regulation can stimulate innovation. Those are cross purposes. The issue is whether the regulation accomplishes some higher purpose and does so with minimum inhibition of research. That's hard. I won't say it's easy. (Crout, 1976).

While few would question the need for regulatory controls over drug safety and the clinical investigation process, it is also important to recognize that society also receives important health benefits from new drug innovation. The pharmaceutical industry has been the source of over 90 percent of the new drug therapies or new chemical entities (NCE's) introduced in the United States since 1950. The industry has also discovered a correspondingly high percentage of those NCE's classified as important therapeutic advances by the FDA and other evaluators (Schwartzman, 1976).

The cumulative advance in drug therapy has resulted in impressive declines in the death rate and associated personal losses in several disease categories. In addition, new drug introductions have U.S. firms is now done abroad. A recent NSF study shows that roughly one third of all American-owned NCE's are now first investigated clinically abroad, where clinical investigations are permitted at an earlier stage (Wardell et al., 1978).

5. NCE Introductions Available Abroad before the United States. Professor William Wardell, a clinical pharmacologist, has documented many cases in which new drugs developed abroad (and even many American drugs first introduced abroad) generally take several additional years to gain FDA approval for use in the United States (Wardell and Lasagna, 1975). Wardell's findings are consistent with Grabowski and Vernon's (1978) analysis of the international diffusion of new drug therapies across four countries (the U.S., U.K., France, and Germany). Specifically, the latter found that a majority of all the new chemical-entity drug introductions into the United States over the period 1965-1975 had a prior introduction in the U.K., France, or Germany. Moreover, if one considers only the 27 new drugs introduced in this period that were specifically classified by the FDA in 1974 as important therapeutic advances, 15 had prior introduction in one of these foreign countries, 8 became available here and abroad in the same year, and only 4 were initially available here first. This was true despite the fact that the majority of these therapeutically important drugs were discovered in U.S. research laboratories (Grabowski and Vernon, 1978).

Increased regulation has not been responsible for all these adverse trends in the pharmaceutical industry. Other factors, both scientific and economic, have had important effects on pharmaceutical innovation in recent periods. However, a number of studies have concluded that regulation has been one of the more important factors underlying these adverse trends in pharmaceutical innovation. The most persuasive evidence that this is the case comes from comparative international studies that analyze drug costs and innovation here and abroad over similar periods. (For a survey see Grabowski, 1976.)

At the present time, FDA officials do not have much incentive to be concerned about possible negative impacts of their policies on innovation. As Dr. Crout's statements above emphasize, the regulatory mandate is drawn in rather narrow terms--to protect consumers against unsafe or ineffective drugs. There is no corresponding mandate dealing with drug innovation, or in particular, with the need for improved medical therapy.

In addition, the incentive structure confronting the FDA regulator is strongly asymmetric. The regulator stands to bear heavy personal wishes to encourage a more balanced decision-making process before expanding FDA regulatory control further, it should consider putting some institutional mechanisms into the bill that would encourage a more balanced decision-making process that gives greater weight to the effects of regulation on innovation at all phases of the innovational process. In the final chapter of this report, we will consider some general policy measures that might be utilized for accomplishing this objective.

#### Premarket Regulatory Controls in the Chemicals, Medical Devices, and Nuclear Power Industries

A number of other industries have been singled out by Congress for special regulatory controls over product safety. In this section we consider three such industries--chemicals, medical devices, and nuclear power. Like pharmaceuticals, these industries have been among the most innovative in the U.S. economy. However, regulation of these industries is much more recent in origin. Hence, it is still too soon for much data to have accumulated on the effects of regulation on innovation. Some preliminary case studies and analyses will be considered below.

#### 1. Chemicals

Two acts have imposed significant, rather recent controls on the chemical industry. The 1972 Federal Environmental Pesticide Control Act requires that, prior to marketing, all pesticides must be registered with the Environmental Protection Agency along with supporting test data demonstrating their safety and efficacy. EPA's Office of Pesticide Programs then undertakes a regulatory review of benefits versus environmental risks before deciding on marketing approval. In 1976, Congress passed the Toxic Substances Control Act which requires manufacturers of all new chemical substances (not already previously regulated as drugs or pesticides) to give notification to EPA 90 days in advance of first manufacture. The EPA Administrator can then require manufacturers to test any substances, prior to marketing, which he deems to have potentially unreasonable risks to health or the environment or for which significant human or environmental exposure may take place.

The 1972 Act regulating pesticides is obviously patterned afterregulation in the pharmaceutical industry. There is evidence that it has led to similar negative effects on the time and R&D costs of developing These trends are likely to intensify as the number and scope of product regulations increase under the Toxic Substances Control Act. Obviously the environmental problems associated with chemicals are serious in nature and warrant government regulatory attention. But an excessively rigid or stringent regulatory process for new chemicals could have a number of adverse consequences, including discouraging on economic grounds the development of many new chemicals that have more favorable benefit to risk characteristics than chemicals currently in use.

#### 2. Medical Devices

Congress, in the 1976 Medical Device Amendments, has also extended the FDA's regulatory controls over a very large spectrum of medical products. The FDA is now in the process of classifying all medical devices into those that will be governed by premarket approval versus standards or labeling requirements. All body implants and lifesustaining devices will be required to undergo premarket approval as well as some other important types of medical products.

If the FDA brings a "safety imperative" regulatory philosophy to bear on this sector similar to that which it has exhibited in pharmaceuticals, the costs in foregone innovation are likely to be quite high indeed. This is particularly so because innovation in many medical device fields (such as heart pacemakers) has not been characterized by large economies of scale. Several major new products have emanated from small firms. Such firms would be least able to finance or bear the costs and risks of an expensive, lengthy, and uncertain premarket regulatory approval process. Moreover, as we have shown elsewhere, the rapid increases in research and development costs that occurred in pharmaceuticals over the post-Amendment period has operated to concentrate innovation in the very largest drug firms (Grabowski and Vernon, 1976). One might expect comparable, but perhaps even more dramatic, structural changes for many medical devices, if the regulation proceeds along lines similar to FDA regulation of pharmaceuticals. This would appear to be an important question for future research study and investigation.

#### 3. Nuclear Power

The Nuclear Regulatory Commission (NRC) was created in 1975 to replace the Atomic Energy Commission (AEC) in its role as a regulatory agency. The research and development role of the AEC is "the full benefits of standardization will only be realized if both government and industry management are firm in their commitment to limit changes to an approved standard design to those clearly needed for public health and safety reasons." This seems to imply that cost reductions resulting from innovations unrelated to safety would be discouraged by this policy. The potential gains from a standardization policy are also conjectural, since Montgomery and Quirk's analysis indicates that government mandated changes in nuclear plants have been the primary factor underlying past increases in costs and time delays.

#### **Regulation by OSHA and CPSC**

In order to reduce health and safety hazards associated with consumer products and the work environment, Congress created two new regulatory agencies at the start of the 1970's. These were the Occupational Safety and Health Administration (OSHA) established in 1970 and the Consumer Product Safety Commission (CPSC) in 1972. Prior to the establishment of these agencies, safety regulation was concentrated in a few industries thought to pose special safety problems, such as drugs, transportation, and nuclear power. However, in establishing OSHA and CPSC, Congress vested these agencies with broad authority to develop and enforce safety standards over virtually all segments of the U.S. economy. The regulations emanating from these agencies have affected business costs and investment in new plant and equipment facilities and hence, have had a potentially significant derivative effect on innovation across a large number of industry classes.

#### 1. OSHA

The law establishing OSHA was enacted with great expectations in Congress. One of the authors of the OSHA Act, for example, expressed the hope for a 50 percent reduction in industrial accidents by 1980. Within a short time, over 4,400 standards had been promulgated under the OSHA Act. However, many of these regulations, which were adopted as consensus standards from voluntary industry codes and other sources, were outdated and at most bore a tenuous relation to occupational health and safety (Zeckhauser and Nichols, 1978). OSHA itself has recognized this and has recently moved away from some of these regulations.

the means of OSHA's intervention and safety and health. Regulatory procedures and standards that can not be shown to be linked to occupational safety and health should be written off the books. Finally, we would urge that OSHA be required to generate information systematically on the costs of its regulatory interventions, in that way guaranteeing that such information attention political receives in and administrative proceedings (Zeckhauser and Nichols, 1978, p. 236).

These policy recommendations, which are directed toward a more market-oriented approach to encouraging occupational health and safety, are in general accord with the policy recommendations that have been advocated by economists in the environmental-regulation area (considered below).

#### 2. CPSC

The CPSC also was given a broad mandate by Congress to develop safety standards for consumer products to prevent undue risk of injury. The Commission was given jurisdiction over all consumer products not already firmly in the domain of an established agency (such as food, drugs, cosmetics, cigarettes, and autos). The Commission has been estimated to have jurisdiction over some 10,000-12,000 different products that account for about \$750 billion in annual sales.

In contrast to the OSHA, however, CPSC has implemented mandatory safety standards for only a handful of products (e.g., bicycles, matchbooks, swimming pool slides). Consequently, its impact on firm costs to date have been minimal compared to OSHA. Nevertheless, some of the proposed standards of CPSC, such as those for power lawnmowers, have been challenged by the President's Cost and Wage Price Council as inflationary in that they involve much greater costs than expected benefits. In this regard, a study undertaken by the Stanford Research Institute (Brockett et al., 1977) indicated the proposed standard would have increased mower prices by approximately 24 percent and the estimated benefits were less than half these costs. Furthermore, they estimated that the regulations would require over \$40 million in capital costs for plant and equipment changes and force several small manufacturers out of the mower business. enacted that introduced the idea of standards, first at the state level and then at the federal level. Standards were initially applied to the ambient air and water quality, but difficulty in identifying a particular polluter as causing the substandard air or water led, in the early 1970's, to specific emission standards being developed for each point-source polluter. The Environmental Protection Agency was set up in 1970 to take responsibility for setting such standards.

#### Water Pollution

In the case of water pollution, amendments to the Federal Water Pollution Control Act amendments of 1972 require EPA to develop permissible effluent levels on water-borne pollutants and to issue permits based on such standards. The law gives EPA specific guidelines to use in granting discharge permits. The "best practicable discharge control technology" was to be implemented by 1977 and the "best available technology economically achievable" by 1983. The law has the objective of eliminating all pollution in navigable waters by 1985.

In a broad sense, therefore, EPA is supposed to take economic considerations into account in determining the appropriate pollutionreduction approach for each individual source. However, it has been estimated that there are 62,000 point sources of water pollution in the United States. These vary greatly in the production processes used, age of plant and equipment, and other factors relevant to determining the "best technology economically achievable." available As a consequence, EPA, in issuing permits, has become quite involved with the specific production and control technologies, as well as the investment and expansion plans, of each individual pollution source. The magnitude and complexity of EPA's task is therefore enormous. This process also creates many opportunities for court challenges and legal delays. In 1976, for example, requests for administrative hearings were pending for over one tenth of the 45,000 permits issued by the EPA.

Professor Edwin Mills of Princeton has observed that a typical consequence of this complex regulatory process is to mandate an approximately uniform percentage discharge abatement from previous discharges for existing plants, or a uniform percentage abatement from some hypothetical discharge level for new sources. But this general outcome is generally accomplished only after "months or years of costly and demoralizing negotiation with government officials and litigation" (Mills, 1978).

tend instead to channel the firm's efforts toward those approaches that have been sanctioned by regulatory authorities and that will avoid trouble in gaining their approval. Charles Schultze of the CEA has pointed out that laws that mandate regulatory authorities to impose the "best available technology" operate as a strong deterrent to experimentation with new techniques and technologies. He asks in this regard, "will firms in polluting industries sponsor research or undertake experimentation to develop a new means of reducing pollution still further if its very availability will generate new and more stringent regulations?" (Schultze, 1977, p. 53).

The point, of course, is not that environmental legislation has not created a substantial demand for new pollution-control technologies. There is no question that this legislation has accelerated the development of numerous new technologies for pollution control. There are even instances in which innovation in pollution-control equipment has had positive spillover effects on firm efficiency and profitability as well as yielding broader social gains. But there is also ample evidence from which we conclude that the centralized mode of direct regulatory controls used in this country is not the best approach for encouraging such pollution-reducing technologies. The experiences in regulating air pollution from auto emissions (discussed below) provides a particularly good case illustration of this point.

In place of the present centralized bureaucratic system of regulatory controls, economists have almost unanimously advocated the more decentralized process of effluent fees on water polluters. This would affect the economic incentives of firms to pollute. This approach has a number of advantages over current procedures. First, it would eliminate the uncertainties, delays, and legal court battles now associated with the bargaining and granting of regulatory approval. Given any particular effluent fee, a firm would elect the pollutionabatement method that is most efficient for its own circumstances without the lengthy information exchanges and bargaining with regulators that now occurs (in very imperfect fashion). Furthermore, using this approach, the effluent fee can be adjusted to achieve any particular quality level at minimal compliance costs to the private sector.

Firms would also have a continuing incentive to find new methods to reduce pollution levels, since they are taxed on the residual amount of pollution remaining at any point in time. Thus, in contrast to the current system, in which there is no further incentive to reduce pollution levels once a standard is met and a permit obtained, the effluent system would set strong incentives in motion to experiment plant facilities in electrical-generating and other industries comparable to those discussed above for the water pollution area.

The Council on Environmental Quality (1978) estimates society's annual *incremental* pollution-abatement expenditures. This is defined as those costs or expenditures made each year pursuant to federal environmental legislation beyond those that would have been made in the absence of such legislation. Such incremental expenditures are now estimated to be approximately 2 percent of GNP with private airpollution-abatement costs accounting for the dominant portion of societal expenditures (\$12.2 billion of the \$19.3 billion of the total costs in 1977).

One unique aspect of the air-pollution problem is the role of mobile sources (automobiles and other motor vehicles) as major contributors to air pollution. In response to this particular problem, Congress mandated in the 1970 Amendments specific emission standards on new automobiles manufactured after 1975. Specifically, Congress declared that new automobiles must achieve a 90 percent reduction in hydrocarbons and carbon monoxide emission by 1975 and a corresponding decrease in nitrogen oxides by 1976. The setting of such standards by legislative fiat without much knowledge about either the benefits or costs of such reductions was an unprecedented act. Moreover, a 90 percent reduction in auto emission was beyond the known technical capabilities in 1970, so Congress was deliberately attempting to speed up automakers' research and design of auto emission-control technology. Stiff penalties (e.g., the shutdown of a firm's manufacturing operations) were incorporated for noncompliance. At the same time, an escape clause was included to cover the eventuality that firms would make a "good faith" effort to comply with the standards but fail to achieve this goal.

The subsequent history of this experiment in the congressional regulation of auto pollution has been extensively analyzed elsewhere in the literature. Clearly the level of auto emissions has been significantly reduced since 1970. However, the imposition of standards in this fashion has led to brinksmanship-type negotiations between the manufacturers and the EPA that have created great uncertainties and repeated time delays. The originally proposed standards have not been achieved and have now been postponed by Congress until the 1980's.

A number of studies have emphasized that the attempt to legislate technical advances in the control of auto emissions under very demanding time deadlines leads to counterproductive incentives in the strategic choices by firms to meet these standards. In particular, firms selected a "quick fix" technology, the catalytic converter, which had a National Academies of Science and of Engineering, nine years after the start of the federal policy of standard-setting.\*

Mills and White also conclude that a properly structured system of effluent fees could have avoided these adverse incentive effects and more appropriately channeled the automakers' activities toward the development of a more efficient, less polluting automobile engine.

### SUMMARY AND OVERVIEW OF SAFETY AND ENVIRONMENTAL REGULATORY POLICY

Government regulation relating to safety and the environment obviously differs significantly across various industries and product classes. Nevertheless, it is useful at this point to consider some of the common characteristics of government intervention revealed by the survey undertaken here.

First, in drafting and funding new product safety legislation, Congress has strongly favored *direct regulatory controls* (e.g., product standards, premarket approval, prohibitions of very risky products, etc.) over other policy instruments that might be employed to achieve health and safety objectives. *Economic incentives* to achieve these goals--as for example, in the form of effluent fees for polluters--have been virtually ignored, despite the fact that this approach has a number of demonstrated advantages over direct controls in many circumstances. Likewise, the use of government policy to generate and provide *better information* to consumers and jobholders about health and safety hazards has been given little attention as an alternative to product bans and minimum safety standards.

Second, the decision-making process at the various agencies appears to embody a strong "safety imperative." That is, there is strong resistance to the notion that the benefits of greater health and safety stemming from a particular policy must be weighed against the costs that might be entailed by that policy. By costs, we mean all costs, not just dollar costs; thus, one important cost is foregone innovation (e.g., of new drug therapies that themselves provide health benefits). To a considerable degree, the regulatory agencies have probably reflected the desires of Congress in this regard. Until very recently the enabling legislation and annual budgets of the agencies have generally provided

\*That this study fell short of its goal is beside the point, which is that even an attempt at such an analysis had not been previously made.

### **ECONOMIC REGULATION**

#### INTRODUCTION

In contrast to the newer health, safety, and environment regulations, economic regulation of profits and entry has had a rather long history in the United States. Generally, the reason for initiating regulation was a concern over excessively high and/or discriminatory prices or other abuses due to monopoly power, or a fear of the results of destructive competition.

While many of the categories of regulation discussed in the previous section directly affect innovation in a rather obvious manner, e.g., the FDA premarket approval process for new drugs, the regulation-innovation relationship in economic regulation is often indirect and subtle. As we shall observe, in many cases it can be demonstrated that economic regulation can affect innovation simultaneously in both positive and negative ways. Only in exceptional cases can the effect of regulation on innovation be clearly documented. The reason is that the standard of performance must be based on a conjecture of what the rate of innovation would have been in the absence of regulation. Thus there is considerable uncertainty and ignorance about the general relationship between regulation and innovation in economically regulated industries. Of course, in certain cases reasonably sound conclusions can be drawn, as we shall indicate.

The industries subject to economic regulation include electric power, telephone, natural gas, oil and gas pipelines, railroads, trucking, airlines, and radio and television broadcasting. For convenience, we shall group the industries under three main headings: rate-of-return regulation of public utilities, regulated competition in transportation, 2. They tend to be subject to significant economies of scale, and it is often the case that a single firm can supply the output at the lowest possible unit cost.

3. They tend to be relatively capital-intensive. For example, capital assets as a percentage of annual revenues is usually three to four times greater than for general manufacturing industries.

This last feature--that utilities tend to be relatively capitalintensive--complicates the problem of understanding the regulationinnovation relationship. As Capron and Noll observe, "one of the factors that give rise to regulation--natural monopoly arising from capital-intensive economies of scale--also tends to be intimately connected with a high potential for relatively easy and rapid technological advance. The above-average technological progress in regulated industries is a powerful counterargument, at least in the eyes of politicians and regulatory commissions, to theoretical arguments that regulated firms are less progressive than they should be" (Capron and Noll, 1971, p. 221).

Although we have grouped all the public utilities together for purposes of exposition, it should be recognized that each industry is unique. The industries differ in market structure, technology, and historical development, as well as in the pattern of their regulation, making it very difficult to isolate the effects of regulation. For one example, consider the differences in structure between the electricpower and telephone industries. Electric-power supply is organized into more than 100 independent firms, none of which is vertically integrated backward into electrical-equipment manufacturing. Most of the research and development is carried out by the electrical-equipment manufacturing industry. In contrast, the telephone industry has historically been dominated by a single firm, the American Telephone and Telegraph Company. This company not only dominates the supply of telephone services but also manufactures much of its own equipment and performs all of its own research and development. Also. technological innovation in electric-power supply results in greater efficiency in the supplying of service, and the incentive to the utility lies in cost savings. In the supplying of telecommunications service, there is a similar incentive for cost reductions, but there is also a wealth of opportunity for new revenues through the supplying of new kinds of service.

Bearing in mind the difficulties of making comparisons, there do appear to be some common mechanisms through which rate-of-return To date, regulatory commissions have not employed regulatory lag as a conscious policy instrument. Rather, the increased incentives for regulated firms to innovate have been brought about in an almost accidental manner. The close similarity of patent life to regulatory lag as devices for encouraging innovation should be noted. A zero lag or a zero patent life would provide little or no incentive for innovation. At the other extreme, a very long lag or patent life provides too much protection for monopoly returns. Hence, a conscious attempt to reach some intermediate "optimal" length of lag should be made and not left as an accidental by-product of the regulatory process.

As a variant of this idea, Scherer (1970) and others have argued that the allowed rate of return should be systematically related by commissions to a firm's operating efficiency, thereby creating specific incentives for cost-control and cost-reducing innovation. In particular, utilities achieving above-average efficiency would be allowed a rate of return above the market cost of capital, while those having belowaverage efficiency would be permitted a rate less than the market cost of capital. Scherer acknowledges that there are difficult practical problems in implementing such an approach, but feels that greater efficiency would be maintained than the current capricious system associated with the regulatory-lag phenomenon.

It should also be recognized that delays by regulatory agencies in making decisions can in certain cases lead to lower rates of innovation. One such case is the decision on whether to authorize a utility to provide new services. The FCC, for example, delayed for a number of years a decision on domestic satellites because it could not decide who should provide them. The ICC has also been a source of this type of delay, as we shall observe in the next section.

Another type of positive stimulus to innovation has been termed the "fishbowl" effect. This refers to the view that firms are reluctant to engage in public hearings before regulatory commissions in order to obtain rate increases. To avoid this situation, cost-reducing innovations may be given high priority by firms.

Another way in which rate-of-return regulation can affect innovation has become known widely as the Averch-Johnson (AJ) effect (Averch and Johnson, 1962). The AJ effect has to do with the direction that innovation may take, i.e., capital-using, rather than with the amount of innovation. The basic argument is that a monopoly that seeks to maximize profit subject to a rate-of-return constraint, where the allowed profit rate exceeds the cost of capital, will produce a given output with a higher capital-to-"other inputs" ratio than an A different, though somewhat related, aspect of the regulationinnovation relationship in electric power has been explored by William R. Hughes (1969). In his view, regulation could have its major influence on innovation by encouraging mergers among electric utilities in order to create some 20 to 30 large systems. The present organization of the industry has too few systems large enough to take advantage of available scale economies in power generation. Hughes estimated that potential scale economies unrealized because of the present structure of the industry account for 4 to 10 percent of wholesale power costs. (For a more recent econometric study that estimates unrealized savings to be 3.2 percent, see Christensen and Greene (1976).) Of course, mergers would be unnecessary if power pooling were more thoroughly integrated, but, as Kahn's point above suggests, this is an unlikely outcome.

To conclude this review of ways by which rate-of-return regulation can affect innovation, we report an example given by Aaron J. Gellman concerning regulation by the ICC of petroleum pipelines.

> ... if the rate base--that is, the capital investment on which the rate of return is computed--includes carrier property either completely or partially at its reproduction cost, the estimated rate of return will be substantially lower than the rate based on capital actually invested. The substantial given weight to reproduction costs encourages management use older to equipment as long as possible, especially when there is an inflationary trend or when the evaluators are generous (Gellman, 1971, p. 183).

Thus, as stated at the beginning of this section, generalizations about the impact of rate-of-return regulation on innovation are hard to reach. However, we do subscribe to Capron's general conclusion in describing the majority view of the 1969 Brookings Institution conference on this subject:

> ...of least importance in the long-run development of regulated industries have been the controls placed on the general price level, such as limiting the rate of return.

At least two general influences of regulation on innovation can be distinguished. The first influence arises from the entry-restriction characteristic. According to Burton Klein, a major factor in determining the rate of technical progress in an industry is the entry of new firms into the industry. "As long as new firms continue to enter an industry, progress is likely to be rapid; when entry becomes closed, progress is likely to slow down" (Klein, 1978, p. 11). Klein cites automobiles, aircraft, and aircraft engines as examples in which many of the important advances were made by relative newcomers to the industry. An important factor, according to Klein, is to maintain an environment that, by featuring a high degree of risk and uncertainty, favors the generation of a wide diversity of ideas.

Hence, according to the foregoing argument, regulated competition has an adverse effect on innovation through entry restrictions. A second identifiable influence, however, tends to offset this negative impact. If regulated firms cannot compete through price reductions, advertising and innovation become major competitive weapons. If one firm should introduce a new innovation, then there will be strong pressures on the other firms to imitate quickly. Thus, regulated competition can have the effect of encouraging the rapid diffusion of an innovation. The airlines industry is an often-cited example of this phenomenon.

Capron and Noll have summarized the views of a 1969 Brookings Institution conference on this particular point as follows:

> The conferees agreed that the principal impact of regulation on technological change in the civilian air transport industry in this country has been an indirect one. Regulation has prohibited price competition among the air carriers and has thus channeled the rivalry among them toward service improvement. Some conferees suggested that innovation actually has been too rapid or of the wrong kind. One example is the pace at which jet transports were introduced into civil air transport in this country. In an oligopolistic industry in which price competition is suppressed, when one competing carrier adopts a faster and longer-range aircraft, rivals flying the same

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existing services. As a result, the profits to be gained by the railroads from capturing business from other modes (notably water transport) by offering unit train service were more than offset by the reductions in profits they would have experienced by offering the service to existing customers who had no opportunity to use other modes and who, therefore, were being charged very high prices for the old service.

Although less convincing than the MacAvov-Sloss analysis because of the absence of actual cost and revenue data, it still seems clear on the basis of published research that the ICC did severely retard two other innovations: the Big John hopper car and piggyback truck-rail shipping. The Big John case...involved the introduction of a new, large car for hauling grain that enabled the user of the car, the Southern Railway, to reduce rates about sixty percent if shippers agreed to use the entire car and to ship directly from origin to destination, waiving transit privileges. Other grain shippers, notably the barge lines who really had no effective competitive response, bitterly fought the Big John system, and twice the ICC vacated the new rates. Eventually, under pressure from adverse court rulings, the ICC permitted the new rates and thereby made possible the adoption of Big John cars: however they had succeeded in delaying full use of the innovation for more than four years.

The piggyback case...involved a similar type of conflict among freight modes, and a similar result in terms of retarding a costsaving innovation. For various reasons having to do with the technical problems of attaching trucks to railroad cars, handling flat cars in switchyards, and accommodating car design to the realities of the roadbed, the 45

has identified five kinds of losses that he attributes to regulation. These include increasing costs within a particular mode, increasing costs by shifting traffic from low-cost to high-cost modes, increasing prices above marginal costs, and increasing distortions in other sectors of the economy due to price discrimination. However, as Moore observes,

> A fifth--and possibly the largest--loss from regulation is the dynamic loss caused by a reduction in incentives to innovate. If regulatory inertia and pricing umbrellas inhibit innovation, higher costs and a less progressive industry posture are the results (Moore, 1975, p. 57).

#### **REGULATION OF BROADCASTING**

The radio and television broadcasting industries are subject to detailed regulation by the Federal Communications Commission (FCC), although the regulation is not of prices or profits. The key regulatory power is that of licensing, i.e., the power to control entry. The FCC has used its power to control entry in such a stringent manner that the result has been to retard the diffusion of technical developments such as cable TV, pay TV, and satellites.

The rationale for regulation of broadcasting is easily understood by reviewing its historical development. The first public radio broadcast occurred in Pittsburgh in 1920. Initially, radio broadcasting was open to all entrants; it was only necessary to obtain a license from the Department of Commerce. By 1922, however, interference became a serious problem as numerous broadcasters tried to use the same frequencies. Eventually, the Federal Radio Commission was created in 1927 and was given the authority to assign wavelengths and determine the power and location of transmitters. In 1934 the Federal Radio Commission became the FCC.

The 1934 legislation that created the FCC charged it with distributing licenses so as to provide "equality of radio broadcasting service" to "each of the States and the District of Columbia." As Noll, Peck, and McGowan point out in their 1973 analysis of television regulation:

This provision underlies what has come to be known as the FCC's "local service"

# SUMMARY, CONCLUSIONS,AND GENERAL DISCUSSION

There is widespread agreement among businessmen, government officials, and academicians that the declining trend in innovation in the U.S. is a serious economic problem. While the reasons for the decline are varied and complex, there is in our opinion convincing evidence to support the hypothesis that government regulation is an important contributing factor in many circumstances.

There is solid documentation to support this hypothesis in a number of cases. Examples we have cited include the substantial decrease in the number of new drugs, the sharp decline in the number of new pesticides, abandonment of R&D on some classes of new chemical compounds, and delay of various innovations in railroad shipping services. In other cases in which a decrease in innovation is indicated, it cannot be stated quite so positively what would occur in the absence of regulation. Examples are the delay in development of CATV, retarding of innovations in nuclear-power-plant design, reductions in labor productivity, and the diversion of funds to meet OSHA and CPSC regulations.

Finally, in connection with some kinds of regulation both negative and positive effects on innovation are observed or are suspected; it is not clear in some of these which effects predominate. Prominent in this class are environmental regulations. The indicated negative effect is the use of R&D and capital funds to meet regulations rather than for the innovation of new products, and delays in the construction of plants using new technology or to make new products; on the positive side is stimulation of the development of new pollution-control equipment.

In economic regulation a number of partially offsetting effects are observed or postulated: regulatory lag may delay innovative technologies and services or may offer profit inducements for innovation; monopoly regulation may reduce incentives to innovation

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#### **Evaluating the Benefits Versus Costs of Regulatory Actions**

First, Congress should broaden the mandate of the various regulatory agencies to require them to consider the benefits as well as the costs, or undesirable side effects, of regulatory actions. Most of the laws now are governed by only a "safety imperative," with the agencies giving little or no attention to the impact of their actions either on firm productivity, or innovation, or the effect on consumers of higher prices and less product choice. Concern over possible inflationary effects of costs resulting from regulation led to an Executive Order in 1974 requiring an inflation-impact statement for new regulations, and this has caused some agencies to undertake cost-benefit analyses.

With respect to minimizing the adverse effects of regulation on innovation, it would seem particularly important that agencies now directly regulating new products or processes prior to marketing (e.g., FDA regulation of pharmaceuticals and medical devices, EPA regulation of new plants in various industries, etc.) be required to consider the potential effects of their actions on the incentives for innovation.

The Administration's proposed Drug Regulatory Reform Act of 1978 has some features consistent with this objective. As noted in Chapter 3, considerable evidence has now been accumulated that the policies and regulatory actions of the FDA in policing drug safety and efficacy have contributed to a significant slowdown in new drug innovation and long lags vis-á-vis other countries in obtaining significant new drug therapies. This in turn has resulted in unfavorable effects on national health and patient well-being (Wardell and Lasagna, 1975). In response to these developments, the new bill declares at the outset that the encouragement of innovation is an important objective of public policy relating to pharmaceuticals. This type of mandate could be incorporated into the charters of other regulatory agencies that also significantly affect industrial innovation.

Of course, in the final analysis the organizational incentives and attitudes of regulatory officials will have a crucial effect on how such a mandate would in fact be carried out. Thus, Congress should also institutional mechanisms consider creating some specific for accomplishing this objective. For example, in the case of pharmaceuticals, it has been suggested that Congress might set up a distinguished panel of medical experts from elsewhere in the health community to review annually the FDA's progress on new medicines. and also to consider potentially valuable new medicines in use abroad. The various agencies might also be required to include in their annual

the use of taxes or effluent fees would appear to have a number of advantages over direct controls.

As discussed in Chapter 3, EPA, in granting licenses to firms on new and existing plants, has in fact become directly involved in the production and investment planning process of firms at thousands of separate locations. As one might expect, this regulatory process has in turn become characterized by long delays and considerable uncertainty. This is especially true in the case of new plants, in which the options and uncertainty about pollution-control methods are obviously great and in which regulatory officials have generally attempted to impose on firms the greatest increases in pollution abatement. As a consequence, firms often choose to challenge EPA regulations in the courts, further increasing the lags and uncertainty associated with regulation.

The substitution of an effluent tax approach for the current system of direct controls would appear to have a number of significant advantages. This market-oriented approach would alter the economic incentives of firms to pollute by imposing a tax directly on emission levels. Each firm would then be free to choose the mode and level of pollution abatement consistent with its own situation. The agency would be responsible for setting the effluent-fee schedule that would reduce pollution in the aggregate to socially desirable levels and to monitoring the sources to ascertain the actual level of pollution emitted. Direct regulatory controls would be maintained in the case of extreme pollutants, of which relatively small concentrations can produce catastrophic or potentially irreversible consequences.

This decentralized approach to pollution abatement would not be prone to the uncertainties, delays, and legal battles now associated with the direct regulatory controls used by EPA. Charles Schultze, currently the Chairman of the President's Council of Economic Advisors, has emphasized that perhaps the most significant advantage of an effluenttax approach would be in its incentives for the discovery and adoption of pollution-reducing technology. He argues that "in the long run, the future of society is going to hinge on the discovery and adoption of ever-improving technologies to reduce the environmental consequences of expanding production." But he also points out that, under the current system of pollution controls, there is little incentive for a firm to deviate from the control methods favored by regulators or to reduce pollution levels once a standard is met and permit obtained. On the other hand, if a firm is taxed on its residual level of pollution, as would be the case under the effluent-fee approach, there would be continuing incentives for the firm to experiment with and develop new pollutionregulation on the incentives for innovation in such products, some offsetting policies offering a positive stimulus to innovation would seem warranted. For example, in the case of pharmaceuticals, it has been suggested elsewhere that the patent life be started at the time when regulatory approval is granted, thereby restoring the effective patent life to the nominal life of 17 years. Obviously several variants of this scheme would be possible. It illustrates, however, how patent incentives might be employed to offset the negative impact on R&D incentives in highly innovative sectors like drugs and medical devices, which are also likely to be subject to particularly stringent forms of regulation over the foreseeable future.

Beyond such policies geared to special situations like drugs, it might also be appropriate to consider increasing the length of the patent life on all manufactured products. The United Kingdom has recently increased the patent life from 18 to 20 years. In light of the adverse tendencies in the innovational process noted in Chapters 2 and 3 and the general role that increased health, safety, and environment regulation and other government policies have played in this process, this may be one type of offsetting policy action toward innovation worth examining. However, further research on this question is clearly warranted and the efficacy of this type of policy action should clearly be compared with other policy alternatives.

All these suggested policy reforms in health, safety, and environment regulation would require to one degree or another legislative action by Congress before they could be fully implemented. However, some movement in the directions indicated could also be accomplished through executive or administrative action. This is so because the existing legislation generally allows great discretionary authority to the individual regulatory agencies. Hence, to the extent that the Interagency Task force on Innovation were able to effectively educate and convince other members in government, as well as the general public, of the nature and serious character of the regulationinnovation problem, it would be a very important first step toward changing priorities and organizational incentives at the different agencies. This could, in turn, lead to administrative actions that would have important positive benefits even prior to any major legislative changes in this area.

#### ECONOMIC REGULATION

Economic regulation is restricted to a much narrower range of industries than those significantly impacted by the health, safety, and

which a promising new innovation that had the potential of adversely influencing existing broadcasting stations was significantly retarded by a regulatory agency.

Because of the strong discretionary power that regulatory agencies have in limiting new technologies that threaten the status quo, it would seem especially important that regulation be limited only to those situations in which a strong rationale for regulation can be made, for example, in situations of natural monopoly or on economic-efficiency grounds. Unfortunately, the history of regulation shows many cases in which regulation, once established, tends to expand and become more rigid in character, even when the original rationale for regulation no longer applies because of changes in technology and other developments occurring over time. This historical development of regulation in the transportation sector dramatically illustrates this phenomenon.

At the outset of this paper, we noted that a considerable movement toward regulatory reform and deregulation has recently developed in the transportation sector, as well as in some other areas, including cable TV. Economic studies suggest that a greater role for market forces in these industries would be highly desirable. Our analysis in Chapter 4 also suggests that improved incentives for innovation are likely to be one of the important expected gains from deregulation of those sectors in which current conditions provide no strong rationale for continuing regulation as it now exists. We therefore would strongly support the movement toward deregulation in sectors where economic regulation exists, such as transportation and cable TV, and would predict that it would have favorable effects on innovation over future periods.

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environment regulations discussed above. In particular, economic regulation is primarily confined to the utility, transportation, and telecommunication sectors. These sectors account for less than 10 percent of overall GNP. However, they also form part of the critical infrastructure of the economy so that the effect of regulation on innovation in these sectors can strongly influence overall societal welfare.

As emphasized in Chapter 4, the net effect on innovation of the rate-of-return regulatory approach in these sectors is complex and subject to several sometimes offsetting factors. It is quite ironic that probably the most significant positive stimulus to innovation under rate-of-return regulation is the regulatory-lag phenomenon. In particular, if a firm can reduce costs through innovation below those projected in the rate-setting process, it can retain the savings as higher profits until the Commission acts to readjust prices and rates of return (the regulatory lag). This is generally considered to be a major stimulus toward cost-reducing innovation among the regulated utilities. However, it also leads to the paradoxical result that, if commissions were to become more efficient in their deliberations and actually reduce regulatory-lag, it would also reduce the incentives for innovation in many cases.

This fact and the rather capricious character of the regulatorylag phenomenon in general suggests that a more systematic set of incentives for innovation should be developed and incorporated into the rate-of-return regulatory process. Along these lines, Scherer (1970) has suggested allowing those utilities with above-average operating efficiencies to earn rates of return above the cost of capital while those with below-average efficiency would be permitted only rates below the cost of capital. While there are considerable practical problems in implementing such incentive approaches, it is probably worth experimenting with them rather than leaving the incentives for innovation tied to the vagaries of the regulatory-lag phenomenon as at present.

From a broader perspective, the analysis in Chapter 4 suggests that regulation has had its severest effect in retarding innovation in those situations in which new technologies have emerged that threaten the market shares or competitive positions of groups already under regulation. Thus, in the case of transportation, both the Big John hopper car and piggyback truck-rail system involved intermodal distributions of wealth. These intermodal conflicts resulted in long delays in the introduction of these innovations. Similarly, the constraints imposed on cable TV by the FCC is another example in control methods in order to reduce its costs and increase its profitability.

For all these reasons, we believe that a strong case can be made for a gradual shift toward greater use of the effluent-fee approach and away from the direct system of controls now prevalent. As noted in Chapter 3, perhaps the best place to begin such a shift in policy might be in areas such as water pollution on which a great deal of research and background information on the probable effects of an effluent-fee system is already available in the literature. However, over the long run, if this approach proved successful, it might be applied quite widely in health, safety, and environment regulation, including regulation of occupational hazards and industrial accidents. A number of recent studies have examined the administrative feasibility of the effluent-fee approach for the environmental area. The reader is referred to those studies for further details on how this approach could be implemented under various conditions (e.g., Ruff, 1978).

# The Use of Patent Incentives and Other Economic Incentives to Offset Adverse Regulatory Effects

Finally, a third set of general recommendations involves the potential use of the patent system and other incentive schemes to offset adverse effects of regulation on the incentives to innovate. This would appear to be especially warranted in those situations in which regulation directly and strongly affects the innovational process. For example, in the case of the pharmaceutical industry, it has been estimated that FDA regulation has more than doubled the cost of producing a new drug and also added several years to the development process. An additional adverse consequence is that the effective patent life in pharmaceuticals is now only 9 to 12 years. While some of the regulatory reforms discussed above might eventually mitigate the severity of regulation on costs and development times, it also seems clear that there are still going to be products like pharmaceuticals that will be subject to particularly stringent premarket controls over R&D and product introduction. This in turn is likely to have particularly adverse effects on the economic incentives to undertake R&D and innovational activities in connection with these products.

In addition to drugs, medical devices (like heart pacemakers) and certain kinds of industrial chemicals have also recently been made subject to premarket controls requiring proof of safety and efficacy. Allthese products emanate from one of the most innovative sectors of the American economy. To offset the potentially severe effects of reports specific evaluations of how actual and proposed regulatory policies affect innovation. To date, most analyses of this type have been performed by outside academics with very limited resources and access to the data. Usually the agencies have much better data than academic researchers for analyzing this question and could commission or undertake studies of a much more comprehensive character. Moreover, the fact that the agencies would have to undertake such studies, and annually publish summaries of them, might encourage these bodies to take a more balanced perspective in the regulatorydecision process.

It is also important that agencies with broad discretionary power to intervene across different industries (i.e., OSHA, CPSC, and EPA) use benefit-cost analysis as an aid to setting agency priorities. We are not advocating that a benefit-cost analysis be used in an inflexible manner. Obviously, there are uncertainties and conceptual difficulties in measuring the benefits in the health and safety area that would make rigid use of a benefit-cost ratio as the ultimate basis for regulatory action unwarranted. Quantification of the value of life and limb, or of a clean environment, is both difficult and controversial. Nevertheless, benefit-cost analyses can be employed to help guide the agency in deploying its limited resources so that it can give higher priority to regulations that yield relatively high levels of net benefits. As noted in Chapter 3, agencies like OSHA and CPSC have generally not been considering cost at all in setting priorities or making regulatory a consequence, these agencies have frequently decisions. As undertaken regulatory initiatives or priorities with very low benefit-cost ratios while postponing action on projects with much higher benefit-cost ratios. Such an approach obviously leads to wasted resources and lower levels of benefits from these regulatory programs than could otherwise be achieved if benefit-cost analyses were employed to help set priorities and guide agency intervention in various areas.

#### **Direct Regulatory Controls Versus Taxes and Effluent Fees**

Another recommendation based on our analysis in Chapter 3 is that efficiency and innovation would be promoted by greater use of economic incentives (e.g., through effluent fees and taxes) to accomplish regulatory objectives in health and safety. Regulation almost invariably has taken the form of direct controls and standards. While there are many situations in which direct controls are the only feasible method of regulatory intervention, there are also many situations, especially in the area of environmental pollution, in which We emphasize that government regulation varies widely in both intent and method. The early economic regulation was undertaken primarily to control monopolistic practices, as we observed in Chapter 4. The more recent wave of social regulation, described in Chapter 3, includes among its objectives the protection of individuals from excessive pollution and unsafe products and working conditions. Some 120 different departments, bureaus, and agencies in the federal government, and many more in the states, are charged with administering regulatory programs.

The economic and social justification for regulation in many instances is clear and uncontroversial. Few would quarrel with the need for regulating natural monopolies, pollution, or safety. In these cases the appropriate public policy should be to seek methods that accomplish the benefits of regulation but also give due weight to the impact of these methods on innovation and other costs.

In this chapter, we summarize the main findings that emerge from our analyses of social and economic regulation in Chapters 3 and 4 and present our recommendations for policy changes in each of these areas.

# HEALTH, SAFETY, AND ENVIRONMENT REGULATION

Because of externalities and information imperfections, an unregulated market system will generally not provide adequate incentives to market participants in environmental pollution and product and worker safety. Moreover, problems in these areas tend to grow and become more severe in character as a society grows industrially and becomes technologically more complex. It was therefore necessary for the government to intervene in the market and establish regulatory processes to deal with these problems, as it has done to an increasing degree over the last few decades.

Although there is therefore a strong justification for government intervention in the health, safety, and environment areas, the analysis undertaken in Chapter 3 suggests that the *process* of regulation is not working out very well. We present below some of the directions for policy changes that we believe are important and necessary to improve this situation.

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objective--establishment of stations in as many localities as possible (Noll, Peck, and McGowan, 1973, p. 99).

The FCC pursuit of the local service objective is a major explanation of the retarded development of cable TV, pay TV, and satellites. Thus, to protect local broadcasting stations from loss of revenues due to the competition from new technologies, the FCC has severely restricted entry. The case of cable TV is an example in point.

In 1966, in response to the growth of cable TV and the threat to the survival of certain television stations, the FCC forbade the creation of new cable systems in the largest 100 television markets. It also prohibited the importation of additional distant signals by existing systems. In 1972, the FCC removed the freeze but substituted further restrictions in its place. First, it limited the number of distant signals that could be imported. Second, it imposed exclusivity rules that required blacking out certain programs. And, third, it limited pay-cable services to providing sports events not generally televised over the air. (This last restriction is no longer in effect as a result of a 1977 court decision.)

Without trying to weigh the benefits and costs of FCC regulation, there seems to be little doubt that the costs of foregone innovation have been high. In pursuing a policy of localism, the FCC has surely retarded the development of many potential technological options that are only dimly perceived today. For example, as cable TV develops more fully, consumers can expect "refined two-way signalling, information and entertainment banks, free public access" and "as cable technology matures, it may converge with local telephone technology" (Wilcox and Shepherd, 1975, p. 458). The FCC has recently become more receptive to such criticisms of regulatory policies on cable TV and has announced plans to relax significantly its controls over this industry in the near future. cheapest technology for piggybacking was to use a very short flatcar, large enough for but one truck, and to transport only the freight container of the truck instead of the entire trailer. But the ICC policy of establishing rates on the basis of historical average costs prevented the rails from adopting the best technology, since they could not set a low price to encourage of enough use piggybacking if they carried only one truck per car nor could they incorporate into the price structure an incentive from truckers to detachable trucks with freight use containers. Consequently, piggybacking is more expensive and less fully utilized than it could be. Unlike the Big John case, there is no indication that the ICC actively used average-cost pricing to retard the innovation and thereby reduce the incursion of railroads into the long-distance shipping business of truck firms. Nevertheless, the ultimate consequence was similar: to blunt the extent to which an innovation was permitted to produce intermodal redistributions of wealth (Montgomery and Noll, 1974, p. 189).

Gellman (1971), after reviewing the impact of regulation on innovation in transportation, argues that the best short-run improvement could be effected by explicitly requiring regulators to consider the relation between regulation and innovation, both in general and in each relevant case. In this regard, he advocates strengthening the staffs of these agencies with specially trained personnel to analyze these issues and also establishing a special advisory group within the federal government to offer analyses and forecasts across agencies.

In the long run, according to Gellman, the innovative performance of the transport sector would be improved most effectively by a gradual elimination of economic regulation. This is an opinion held by a substantial majority of economists in this field, and we share

Of course, deregulation of transportation is not advocated by economists solely to improve innovation. Thomas G. Moore (1975)

routes are forced to do the same as quickly as possible (Capron and Noll, 1971, p. 213).

Even this tentative inference that airline regulation may have served to accelerate the introduction rate and diffusion of jet transports is debatable. In particular, if the demand for air travel is quite priceelastic (as many studies seem to suggest), then the excessive prices due to regulation would operate to reduce the overall market demand for air travel, and, correspondingly, the demand for jet transports. This would have, ceteris paribus, a negative effect on the incentives for aircraft manufacturers to engage in more rapid development of new airplanes. This negative effect would have then to be compared empirically with the positive "rivalry effect" mentioned in the above citation before one could determine the net effect of regulation on the rate of introduction of new aircraft.

In late 1978 President Carter signed a bill that will eventually lead to complete deregulation of the airlines. As deregulation proceeds in the airlines industry the distortions that exist in the innovative process due to regulation should be eliminated.

The ICC substantially delayed innovation in three welldocumented railroad cases. One common ingredient in these cases seems to be the ICC's policy of maintaining existing rate structures in a rather rigid and uncompromising fashion, giving little or no weight to the social benefits of innovation to the public. An additional factor seems to be its decisions to protect the various transportation modes under its jurisdiction from each other, e.g., to protect water transport from losing business to the railroads.

The description of these three cases--the unit train, the Big John hopper car, and piggyback truck-rail shipping--is taken from the 1974 National Science Foundation sponsored study, *Government Policies and Technological Innovation*, undertaken at the California Institute of Technology.

> ...In a study of the ICC's response to the unit train, MacAvoy and Sloss show that the innovation was economically warranted and desired by the industry about forty years before it was widely adopted. But adoption was delayed because the ICC demanded that new services be offered to all customers at comparable costs, whereas it made no attempt to undo price discrimination in

While rate-of-return regulation probably creates a bias toward capital-intensive technology, this appears to be far more important in affecting static efficiency decisions than in influencing technological change (Capron, 1971b, p. 7).

Finally, it should be noted that in recent years there has been an increasing policy interest in the possibility of injecting competition into the traditional natural monopolies. That is, if certain submarkets in electric power and telecommunications can be shown not to have large-scale economies relative to market demand, there is the possibility that removing entry restrictions would produce improved economic performance. Weiss (1975) has suggested as one possibility the introduction of competition into the supply of bulk electric power. Similarly, Waverman (1975) has examined the possibility of competition in intercity telecommunications--that is, the transmittal of messages from one local distribution network to another.

#### **REGULATED COMPETITION IN TRANSPORTATION**

In contrast to the rate-of-return regulation of natural monopolies discussed above, a number of *multifirm* industries are subject to economic regulation, i.e., controls over price and entry/exit. The main examples provided here are in the transportation sector and include ICC regulation of railroads and trucking and CAB regulations of the airlines.

The economic rationale for such regulation is usually said to be the need to prevent excessive or destructive competition. The concern is that competition would produce wide swings in prices and output that would be too costly for consumers and producers. Industries that are thought to be most likely to experience excessive competition are those characterized by high overhead costs and subjected to severe random or cyclical business fluctuations. It should be noted that true natural monopoly is generally viewed by economists as a much more legitimate reason for regulation than is excessive competition.

Of course, as reported earlier, the original regulation of railroads was justified partly on natural monopoly grounds--the desire to prevent price discrimination and the concern that extensive scale economies made it unlikely that competition would work well. Trucking and airlines, however, would not appear to possess similar natural-monopoly elements. unregulated, cost-minimizing firm would use. If one then applies this to innovation, it can be argued that the firm will have an incentive to develop new technology that requires adding to the stock of plant and equipment, thereby increasing the rate base.

While the formal AJ argument does provide a very specific prediction about the influence of regulation on innovation, it has been subject to some criticism. Joskow and Noll (1977) have criticized the assumptions and structure of the model on three grounds.

First, they argue that the AJ model fails to capture the essence of the regulatory process. The model assumes that the commission regulates profits only when, in fact, the commission actually regulates prices. "The calculation of an allowed profit is a way station along the way to determining how much increase in revenues and prices will be allowed. Once set, the regulated firm's prices, not its rate-of-return, are fixed, pending additional regulatory review" (Joskow and Noll, p. 13).

Second, Joskow and Noll observe that the AJ model ignores the fact that the commission sometimes disallows certain costs because the firm appears to be operating inefficiently. Third, they point out that the investment-planning horizon implicit in the AJ model is short compared to the interval between regulatory reviews, and this is unrealistic.

A number of empirical tests of the AJ effect have been published. The tests have all been econometric studies of the electric-power industry. Three studies, Spann (1974), Courville (1974), and Petersen (1975), concluded that the AJ hypothesis had been confirmed, while Boyes (1976) and Baron and Taggart (1977) reached the opposite conclusion.

In contrast to the inconclusive econometric work just cited, some writers have described specific examples that appear to be consistent with AJ behavior. Alfred E. Kahn (1971, p. 50) has observed that the companies utility "considerable resistance bv electric to the thoroughgoing regional planning of investment that represents the most highly integrated form of power pooling" is consistent with the AJ model. The argument is that when one company purchases power from one of its partners, it receives nothing more than reimbursement for those actual expenses, whereas if it generates the power itself it has an expanded rate base on which it can earn a return. This implies a bias in favor of the installation of several smaller, high-cost plants in lieu of a single large, low-cost plant.

The net effect of rate-of-return regulation on the rate and direction of innovation is complex and consists of several sometimes offsetting factors. A key factor is simply that the regulators seek to prevent the firms from making excessively high profits. Hence, it might be expected that managers would not have as great an incentive to engage in high-risk, high-payoff innovative activities as would managers in the unregulated sector of the economy. This would appear to describe the performance of the electric utilities, but it would hardly describe that of the Bell Laboratories, which has an outstanding record of innovation.

Related to the point above is that the regulated monopolies do not face as great a risk of loss as do unregulated firms. While the regulatory commission does not guarantee a fair rate-of-return to the monopoly, often it does permit the firm to include investments in its "mistakes" in the rate base. Hence, given its monopoly position, the firm is likely to recover most of its investment. A monopoly position might therefore encourage a firm to take a long-term view in its R&D and to be innovative.

As William Capron has put it, rate-of-return regulation "tends to cut off both the upper and lower ends of the profit-possibility distribution a firm faces. On the one hand, the regulated firm is protected against the risks of loss inherent in technological change; on the other, it is denied the supernormal profit that the unregulated, successful innovator can expect to earn" (Capron, 1971, p. 9). The net effect of these two factors on innovative performance is, of course, impossible to predict a priori.

A further factor complicating the problem of predicting whether rate-of-return regulation increases or decreases a firm's propensity to innovate is "regulatory lag." Regulatory lag refers to the period of time between rate adjustments by the regulatory commission. The commission normally tries to set prices that will yield the approved rate-of-return on capital, given some best estimates of future costs and demand. If the firm can reduce costs through innovation below these estimates, it can retain the savings as higher profits, at least until the commission acts to adjust prices again. Hence, the slower the commission is in effecting this readjustment, the greater is the firm's incentive to innovate. On the other hand, this slowness of the commission could retard innovation if the action required is the authorization of a new service. and regulation of broadcasting. We omit any discussion of general price controls.

# **RATE-OF-RETURN REGULATION OF PUBLIC UTILITIES**

Regulation of natural monopolies, such as the public utilities (electric power, telephone, and oil and natural gas pipelines), is characterized by the granting of a franchise to a firm as the sole supplier and then setting prices, or rates, such that the firm can earn no more than a "fair" rate-of-return on its invested capital, or "rate base." As noted previously, the rationale for regulation is that large-scale economies make it inefficient for more than one firm to produce in these naturalmonopoly situations.

While regulation of utilities is nominally rate-of-return, it should be noted that it is generally prices that are regulated. The rate-ofreturn may occasionally be examined and set, but regulatory commissions are primarily concerned with prices. During the 1960's, for example, electric utilities experienced cost decreases and had no need to request higher prices. Their fixed nominal prices yielded increasing rates-of-return, and regulatory commissions seldom intervened to force price reductions. Apparently, commissions were quite content with high rates-of-return as long as nominal prices were not increasing (Joskow, 1974).

State regulatory commissions handle much of this type of regulation, although the federal government is concerned with the interstate operations of the utilities. Each state has some form of regulatory commission responsible for controlling entry, approving price of service. reviewing quality Typically state levels. and the commissions are composed of a staff of permanent inspectors, and economists under the direction of accountants. engineers, commissioners who are either appointed by the governor or elected directly by the people. The commissions hold hearings--for example, a utility may present evidence at a hearing seeking to justify a price increase--and then render decisions. Decisions may be appealed to the courts in certain cases.

Three general features of the utilities listed above constitute economic characteristics that are important in addition to the fact that they are natural monopolies:

1. They tend to supply important inputs or services that are generally not storeable and must be supplied on demand. Hence, sufficient capacity must be in place to meet peak demands.

few incentives for decisionmakers to introduce cost considerations in establishing priorities or developing standards. Consequently, agencies often undertake projects with low benefit-cost ratios while ignoring other projects with much higher benefit-cost ratios.

Third, the process of regulation in the United States has developed a strong adversarial character that is heavily influenced by legal considerations and strategic maneuvers. This legal emphasis increases the volume and complexity of documentation required as well as the lags and uncertainties associated with the regulatory process. Moreover, many regulations are now being challenged in the judicial system, which further compounds the costs and uncertainties of regulation.

As a consequence of these factors, the process of regulation relating to safety and the environment is generally not working out very well. Our analysis above suggests numerous instances in which regulation has resulted in excessive costs and wasted resources as wellas diminished resources for innovation and productivity gains over the long run. As noted at the beginning of this chapter, government regulation of product and worker safety and the environment is clearly necessary and provides important benefits to society. While this is so, some changes in the process of regulation now appear warranted to reduce the adverse effects of regulation without sacrificing the intended benefits. In the final chapter, we will consider various policy changes for achieving this goal. high probability of success but was also very costly. The total-life costs of meeting the original 1975 standards using catalytic converters have been estimated by the National Academy of Sciences in 1974 to be over \$400.00 per car (in 1974 dollars). On the other hand, other technologies such as the Honda stratified-charge engine, which had lower apparent probability of success in 1970, eventually proved able to meet the 1975 standards at less than half the costs of the catalytic converter. Had the regulations been structured differently, automakers would have had incentives to look at a wider variety of technological solutions, including even more fundamental changes in engine design.

Mills and White (1978) have noted several other adverse incentive effects associated with our regulatory policy in auto emissions. In particular:

The delays granted in the enforcement of the standards have undermined the credibility of the program. They have been granted at scattered and uncertain intervals; they have introduced needless uncertainty, which is simply not good policy.

Standards regulating a number of pollutants simultaneously have impeded research. Most engine technologies involve trade-offs between emissions of HC and CO and those of  $NO_x$ ; efforts to reduce the former frequently lead to increases in the latter....

The standards policy has placed the burden of virtually all control efforts on the manufacturers. Incentives for motorists to maintain their cars properly are totally lacking...

The policy of standard-setting has institutionalized disregard for considering costs and benefits. It is shocking that the first full study of costs and benefits, with rigorous efforts to quantify and compare both, was conducted only in 1974 by the

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with and develop new pollution-control methods in order to increase firm profitability (Ruff, 1978).

Of course, effluent fees are neither practical nor desirable in all types of circumstances. Where one is dealing with very hazardous pollutants (like Kepone) for which relatively small concentrations can produce severe, long-lasting, or even potentially irreversible effects, direct regulatory controls have obvious advantages over effluent fees.

The effluent-fee system of regulating water pollution does have the advantage, however, that it could be introduced gradually and could be used in tandem with direct regulatory controls for certain types of extreme pollutants. A number of studies by Professor Allen Kneese and others on particular river basins provide a great deal of background knowledge on what level of effluent fees might be necessary to achieve particular water-quality objectives. A now classic government study of the Delaware River estuary (Kneese and Bowers, 1968) illustrates the cost-saving potential of the effluent-fee approach. Specifically, they estimate that a policy of effluent fees could meet quality objectives in the Delaware estuary at less than half the direct cost of a uniform percentage discharge abatement policy. In addition, the effluent-fee approach, by minimizing the regulatory uncertainties associated with constructing new plant and equipment, should also have favorable long-term effects on the rate of innovation.

# Air Pollution

The pattern of developments for environmental regulation of air pollution is similar to that for water pollution. The general failure of early federal attempts to encourage state development and policing of air-quality standards led to successively more stringent policies at the national level. This culminated in the 1970 Clean Air Act Amendments authorizing EPA to set federal standards with respect to maximum permissible concentrations of air pollutants. Specifically, EPA was directed to set primary standards for the protection of human health, which were to be implemented rapidly by federal and state agencies. EPA was also to determine more stringent secondary standards to protect property and welfare, which were to be implemented over a longer time period.

The Clean Air Act Amendments also directed EPA to develop maximum emission standards for new generating plants and other facilities that embody the "best adequately demonstrated controltechnology." This has resulted in time delays and uncertainties for new The resulting uncertainties and time delays have particularly adverse effects on the new plants or new technologies that frequently accompany the introduction of a significant product or process innovation. Regulators generally impose much higher standards on new plants since the abatement cost per pound of pollutant is frequently lower for such plants. However, as the President's Council of Economic Advisors has pointed out, "regulations can inadvertently add to the economic costs of an industry by applying excessively large differentials to new processes compared with existing ones. If the differential is too large, firms deciding between continuing production in older facilities or converting to new ones may be biased against the new ones. Since investment in new and expanded facilities strongly affects the rate at which productivity grows, overly large differences in standards can slow productivity gains and raise costs" (Council of Economic Advisors, 1978).

In addition to the tendency of regulators to impose higher differentials on new plants (Council of Economic Advisors; Mills; Schultze), it is also true that the number of options and the degree of uncertainty about pollution-control methods are obviously much greater for new than for existing plants and processes. As a consequence, government regulatory officials tend to become deeply involved in the most detailed aspects of new plant design. This has added to the above average risks and uncertainties, which tend to characterize investments in innovations involving significant additions to new plant capacity.

Data collected by the Council on Environmental Quality indicate that the direct expenditures by industry for water-pollution abatement are now very large in the aggregate. 'CEQ data indicate that private expenditures for water-pollution abatement (operating and capital costs) were \$5.7 billion in 1977, and this is expected to nearly triple over the next 10 years to meet the ambitious goals of the Water Pollution Control Act for the 1980's. Numerous benefit-cost studies of environmental regulations in particular waterways have been undertaken. Some of these studies of local and regional waterways clearly point to positive net benefits from government intervention (Mills, 1978, p.120-9). However, in line with our discussion above, these studies also indicate that the prevailing mode of regulatory controls in this country has led to unnecessarily high costs and time delays in obtaining the social benefits of pollution abatement.

A number of studies have also pointed out that the direct regulatory control procedures used by the EPA in water (and air) pollution do not provide strong positive incentives for firms to develop pollution-reducing technological advances. Rather, the current laws

Grabowski and Vernon's analysis of the Commission's priority rankings for 21 product classes under consideration for standards in the 1977 Mid Year Review obtained similar findings in benefit-cost ratios. Only 5 of the 21 projects had estimated benefit-cost ratios greater than 1 in value. Furthermore, a number of projects with quite low benefitcost ratios (for example, less than .10 in the case of television sets and extension cords) received high-priority rankings and were slated for standards during the coming year. At the same time, other product classes with much higher benefit-cost ratios received lower priority ranking bv the Commission (Grabowski and Vernon, 1978) Admittedly, benefit-cost calculations have distinct limitations, but we believe they can be used to help guide the setting of priorities for regulatory activities; this will be discussed further in Chapter 5.

Hence, the decision-making procedure adopted by the Commission clearly does not embody a cost-effective approach to preventing injuries and deaths from product-related accidents. Economic side effects are almost totally ignored in setting priorities. If this approach is maintained, the likely resource misallocations associated with Commission decisions will tend to multiply over time as regulatory standards are extended to several product classes now under review.

At this time, the exact impacts of OSHA and CPSC regulations on innovation are not fully known. This is because these regulatory activities are relatively recent in origin and their effects on innovation are somewhat indirect. There is evidence, as noted in the previous section on OSHA, that these policies have had a significant effect on the investment expenditures for new plant and equipment in many industries. Thus, it is likely that there have been important derivative effects on the investment decision in innovation (i.e., through effects on the returns, risks, and availability of funds to undertake such investment). This is clearly an important topic for further research work.

### ENVIRONMENTAL REGULATION

Government regulation of air and water pollution started in the late 1950's. Initially, the main purpose of the 1956 Federal Water Pollution Control Act and the 1963 Clean Air Act was to fund studies of the effects of pollution and to respond to findings of high levels of pollutants by holding conferences, giving advice, and, as a last resort, initiating court action. As these measures proved ineffective and pollution continued to worsen during the 1960's, amendments were

Several studies of OSHA's aggregate effect on job safety have now been undertaken. They suggest its influence in this respect has been minimal. Post-OSHA injury rate data fail to reveal any significant impact on injury rates from OSHA's regulatory standards. Even studies of the Target Industry Program (in which inspection rates are much higher than for industry as a whole) have failed to show a consistent reduction of injuries (Zeckhauser and Nichols, 1978).

On the other hand, OSHA's current and proposed regulations imply sizable costs for many industries in expenditures for new plant and equipment as well as from losses in worker productivity. This can operate to contain the availability of funds for new technological developments and counteract potential advances in productivity. The inflationary impact statement prepared for the Coke Emission Standards, for example, estimates that these standards would lead to a reduction in average productivity per worker of at least 18 percent, and possibly as much as 29 percent. In addition, it is estimated that the steel industry will have to incur capital costs of between \$451 and \$860 million in complying with these standards. The proposed noiseabatement standards are even more costly. It has been estimated that the 90 dBA standard would require capital costs of \$10.5 billion spread over five years and the more stringent 85 dBA standard would lead to capital costs of \$18.5 billion. (For further analyses of cost effects see Zeckhauser and Nichols, 1978.) The 1978 McGraw-Hill Third Annual Survey of Investment in Employee Safety and Health suggests that annual capital expenditures by firms to comply with OSHA's regulations now exceed \$3 billion, or approximately 3 percent of all capital costs.

Zeckhauser and Nichols (1978) have prepared a comprehensive analysis of OSHA's performance for the Senate Committee on Government Operations. They have made the following basic recommendations for policy changes in OSHA operations.

> OSHA. and other federal agencies promoting OSH, should channel their resources in three directions: (1) generating, gathering and disseminating information about conditions that promote OSH, (2) of **OSH-promoting** increasing the use incentive mechanisms as an alternative or complement to direct regulation; and (3) intervening in the market directly in those areas, and only in those areas, in which there is a demonstrated relationship between

now a function of the new Department of Energy. The NRC is charged with ensuring the safety of nuclear power plants and with maintaining environmental quality at nuclear plant sites. It has directly affected the cost and diffusion of nuclear power.

The NRC administers an extremely comprehensive licensing process for nuclear reactors that encompasses safety and environmental factors, safeguarding the nuclear materials and facilities, and antitrust reviews. Safety issues dominated the licensing process until the late 1960's, but since then environmental issues have also become important.

Licenses are required from the NRC for both construction and operation of a nuclear plant. As a result of frequent interventions in the process by public interest groups and local governments, as well as "bottleneck" problems in construction, equipment-supplying industries, and in the licensing process, the capital cost of nuclear plants has increased dramatically in recent years. Montgomery and Quirk (1978) have calculated that nuclear capital costs increased 136 percent between 1972 and 1976. This compares with increases of only 34 percent in the GNP price index and 49 percent in the construction price index for the same period.

Based upon their research, Montgomery and Quirk offer these general conclusions:

In the early years of commercial development of the nuclear power industry (1966-1970). the bottleneck hypothesis accounts for most of the cost increases that occurred; but, since 1970, while bottleneck effects are still present, the procedural and substantive effects of intervention in the licensing processes have dominated the cost picture.

At present, the time required for a utility to initiate action to construct a nuclear plant until it is in commercial operation is on the order of 10 years. In an attempt to reduce this long lead time, the NRC has been pursuing a "standardization" policy. The basic idea of the policy is that if utilities mainly would replicate earlier plants already approved by the NRC and incorporate only changes that the NRC thinks would increase health or safety, the reviewing time could be shortened. The NRC published a general policy statement on standardization in the Federal Register on July 5, 1977. In this statement the NRC observed that

new pesticides and increased the economic risks of such activity (Decker, 1978). Chemical firms also indicate that their R&D activity has now become much more defensive and less innovative in nature (i.e., more oriented toward alleviating possible problems with existing pesticides). In addition, R&D activity is increasingly being directed to new pesticides with very large markets that can offset the higher costs and risks of innovational activity.

An analysis of EPA data on new pesticides introduced over recent years shows that a strong decline has occurred in recent years. Over the past two fiscal years, for instance, there have been only 9 new pesticides registered with the EPA versus 58 pesticides in the 1975 and 1976 period.

While the regulatory controls on the chemical industry from the Toxic Substances Control Act are more discretionary and selective in character, they potentially may affect a much broader segment of the chemical industry than the controls on pesticides. The Act has been in operation for only a short time so that any analysis of its effects would be necessarily limited in nature. However, Schweitzer (1978), former EPA Director of Toxic Substances, has collected some survey data from chemical firms on the growing effects of environmental regulations on chemicals during recent years. He detects a change in both the objectives and orientation of R&D activities. Expenditures for environmental and health activities now typically exceed 10 percent of the R&D budget. Greater emphasis is placed on marginal improvements in established products and broadening their uses, with less emphasis on new-product development. As an example, Schweitzer (1978) cites one major company in which 25 percent of its R&D budget was spent on new ventures in the mid 1960's, while now it spends less than 10 percent in this manner.

Some companies have also decided to avoid certain classes of chemicals altogether, if their molecular structure is subject to many regulatory problems, e.g., chlorinated hydrocarbons. One company has abandoned about 100 commercially interesting chemicals since they appeared on the suspected list. In other words, one could summarize these effects as a reduction in the diversity of chemicals being developed and tested.

The number of new chemicals that have been commercialized in recent years has declined, especially those that are produced in response to the needs of small markets. In large companies the trend is clearly to emphasize a limited number of new chemicals directed at large potential markets (Schweitzer, 1978).

costs if there is a bad outcome associated with the approval of a drug with unforeseen adverse effects. On the other hand, the social costs associated with time delays in obtaining important new drug therapies and lower rates of innovation are less visible and are borne completely by external parties. Hence, the regulator has strong incentives to be risk averse and err on the side of caution and delay.

At the beginning of last year, the Administration had introduced in the Congress the Drug Regulation Reform Act of 1978. This bill addresses at least in part the problem of declining pharmaceutical innovation. In particular the bill declares at the outset that it is in the national interest to encourage the development and introduction of new pharmaceutical agents and also to encourage scientific freedom in the drug-investigational process. It also contains a provisional approval process for "breakthrough drugs" involving life-threatening conditions that is designed to expedite the approval process for important new therapies. This bill therefore provides one mechanism for reducing the long lags that have characterized the approval even of breakthrough drugs.

At the same time, however, there are several provisions in the new bill that could provide increased regulatory disincentives for drug innovation. An extensive analysis of the potential negative effects of the bill on pharmaceutical innovation has been undertaken elsewhere (Grabowski, 1979) and will not be repeated here. It should be noted, however, that the bill would significantly increase FDA discretionary authority at every point in the life cycle of a developing new drug product. It would institute tighter FDA regulatory controls over the drug-investigational process, give FDA new powers to decide which drugs should be expedited through the various regulatory pathways, and also give significant new authority to the FDA over postmarketing testing and distribution of drugs. At the same time, there are few, if any, institutional mechanisms in the bill for changing the incentive structure at the FDA in order to ensure a more balanced decisionmaking environment for evaluating the benefits as well as risks of new pharmaceutical products. Granting the FDA more discretionary authority under these circumstances could very well operate to slow down the drug-approval process and further increase the costs of developing new drugs. It could thus have the exact opposite effect on pharmaceutical innovation from that claimed by its advocates.

In the final analysis, the attitudes of and organizational incentives operating on regulatory officials will have a key influence on how regulation affects drug innovation and the supply of new medicines for treating health problems in this country. Accordingly, if the Congress provided a relatively low-cost method of treating disease. This is in sharp contrast to other areas of the health sector that have been characterized by very high rates of cost inflation over recent years. Where drug therapies have replaced other forms of treatment, there have often been dramatic cost savings; examples are drug therapies for polio and tuberculosis.

As the regulatory control of this industry has become more stringent since 1962, a number of adverse trends in pharmaceutical innovation have become increasingly apparent. These include:

1. Increased Costs and Lower Yields on New Drug Introductions. A recent study by Ronald Hansen (1979) indicates that the average cost of introducing an NCE into the U.S. is now over \$50 million. In addition, the average time to develop and gain FDA approval for an NCE is now between 8 and 10 years. This is over an order of magnitude higher than cost estimates for the early 1960's (see Grabowski, Vernon, and Thomas, 1978). A number of studies have further analyzed the costs versus sales revenues from recent NCE introductions and found relatively low average yields on R&D drug investment (Schwartzman, 1975).

2. Declining Rates of New Product Introductions. The annual rate of new drug introductions in the U.S. has fallen to less than one third the rate that existed in the early 1960's. Moreover, an analysis of total market shares captured by new drug products indicates that these shares have fallen at a comparable rate (Grabowski, Vernon, and Thomas, 1978). This underscores the extent to which new product innovations have declined as a competitive factor in the drug industry.

3. Fewer Independent Sources and Increased Concentration of NCE Introductions. This analysis also indicates that the number of independent sources of NCE introductions has declined sharply over time. While 51 separate firms had at least one NCE over the period 1957-61, only 23 firms had an NCE a decade later in the period 1967-1971. At the same time, it was found that the percentage of NCE introductions and sales accounted for by the very largest firms has risen sharply over time (Grabowski and Vernon, 1971). The costs of regulation have discouraged innovations by smaller firms, in the view of economists and of the industry.

4. Declining Growth Rates for Domestic R&D and Shifts in R&D Abroad. In contrast to the very high rates of growth in drug industry R&D activity that characterized the earlier post World War II period, R&D outlays in real terms have experienced little, if any, growth in the 1970's. In addition, an increasing percentage of R&D supported by at a comparable rate. Nevertheless, these developments reflect only the "tip of the iceberg" in quantifying the increased magnitude of social regulation since the effects of the resulting regulations on the private sector generally far exceed the direct governmental costs of administering the programs.

This vast increase in regulatory activity is directed at remedying some long-standing "market failure" situations of a serious nature. Pollution is a classic example of externalities. A free market will produce excess levels of pollution, which will become more serious over time as an economy grows larger. Similarly, the rationale for government intervention in the occupational and product-safety areas derives from the presence of both externalities and market information imperfections that result in excessive or unforeseen hazards to consumers and workers. Few would guarrel with the basic rationale or objectives of government regulation in the health, safety, and environmental areas. However, a number of studies have concluded that our current approach to social regulation has led to unforeseen and excessive costs in the private sector. One of the most significant of such costs are the long-run adverse effects on the country's incentive and capacity for innovation. This is the main concern in this chapter and of the examples provided.

In our review of this subject, we first consider the case of FDA regulation of the pharmaceutical industry. This sector is characterized by the most direct and stringent controls over new product introductions. We then turn to an analysis of the effects of occupational and product-safety regulations on innovation in other industries. The final section deals with environmental regulation.

# HEALTH AND SAFETY REGULATION

#### FDA Regulation of Pharmaceuticals

Government regulation of pharmaceuticals started in 1906 and has since evolved into a very stringent system of premarket controls over new drug development and introduction. While early regulation was directed at patent medicine abuses, the sulfanilamide tragedy in 1938 led to passage of the Food, Drug and Cosmetic Act, which required FDA approval of all new drugs as "safe" before they could be marketed. Then, in 1962, as the disastrous effects of thalidomide were becoming apparent in Europe, the Kefauver-Harris Amendments were passed. This law extended FDA controls to the clinical testing and development process for new drug compounds. In addition, In addition, a number of research directors have also pointed to changes in quality of R&D activity. Specifically, they have indicated that R&D is increasingly being directed at shorter-term, less risky projects. Firms are focusing more attention on marginal improvements over existing products and processes rather than major advances. One fact consistent with this view is that basic research funded by industry fell 21 percent in real dollars between 1966 and 1976 according to NSF data. In addition, there was a drop of 77 percent in federally financed basic research performed by industry.

Increased government regulation has been among the factors prominently cited as contributing to this basic shift in business attitudes and strategies toward innovation. In particular, it has been argued that the dramatic increase in safety and environmental regulations in the U.S. since the mid 1960's has significantly increased the expected costs and uncertainties associated with investments in new products and plant facilities in many industries. In addition, these regulations have often required large new capital outlays to meet regulatory standards. This development, combined with the general decline over time in real after-tax profits and cash flows, has made many firms less willing to undertake discretionary investments for basic research and longer-term, higher-risk, investment projects. Moreover, there is evidence that these effects of government regulation on innovation for smaller newly established firms has been especially dramatic in nature (Grabowski and Vernon, 1977). In some cases, the added costs due to regulation have effectively precluded innovation by small firms; in others, regulatory requirements may have encouraged the formation of firms supplying specialized equipment and instruments.

In the chapter that follows, we will consider postulated effects of increased social regulation on innovation for several different types of regulatory activities and industry classes. We will then turn in Chapter 4 to an examination of the effects of economic regulation on innovation for the public utility and transportation sectors.

n na seneral s Seneral generated funds. Such firms must rely almost completely on external sources to generate the capital necessary to support investment in a new product or process innovation.

# SOURCES OF INDUSTRIAL R&D AND INNOVATION

Statistics collected by the NSF indicate that U.S. industry expended about \$17.5 billion for R&D for commercial markets in 1977. NSF data further indicate that these expenditures are highly concentrated within certain industry classes. Eighty-five percent of the R&D outlays occur within six broad industrial groupings--electrical equipment and communications. chemicals and allied products (including pharmaceuticals), electrical and mechanical machinery, motor vehicles, aircraft and missiles, and scientific instruments. There is a large variation across industry classes in the amount of R&D invested as a sales. Certain high-technology percentage of industries (pharmaceuticals, scientific instruments, electrical communications, etc.) invest 5 percent or more of their sales, whereas many nonprogressive industries (food, textiles, primary metal) invest only a fraction of 1 percent.

A number of studies by economists have been directed to uncovering the relation between firm size and investment in R&D and innovation in particular industries. These studies have found that a threshold relation characterizes most industry classes. That is, below a certain size (which is different for each industry) firms spend little on organized R&D activity (as defined by the NSF). However, above this threshold size level, there is no tendency for R&D expenditures to increase disproportionately with firm size in most industries.

While small firms perform relatively little of the nation's total organized R&D activity, case studies of past inventions and innovation have frequently found that such firms have made a disproportionately large contribution at the early, more inventive, but frequently less expensive stages of the innovational process (Charpie, 1967). This has often been attributed to the fact that small firms tend to have a more flexible, less conservative attitude to experimenting with new technologies characterized by high levels of uncertainties. In this regard, Jewkes, Sawers, and Stillerman (1959) conducted a very detailed analysis of the sources of invention for a sample of the most important new products and processes commercialized in the twentieth century. They found numerous instances in which the original inventor was a small firm or even an individual entrepreneur (e.g., xerography, cellophane, the wankel engine). At the same time, the significant task

# 2 THE INDUSTRIAL INNOVATION PROCESS

In this chapter, we review briefly what is known about the determinants and sources of industrial innovation (Mansfield, 1971; Charpie, 1967). Our purpose is to provide a general background for the analysis of particular regulatory policies on innovation in the chapters that follow.

# INNOVATION AS AN INVESTMENT DECISION

Economists define technological innovation as the initial commercial application of a new product or process. From the standpoint of the industrial firm, the activities leading to innovation involve a long-term investment decision process. This process incorporates the various development, research. capital investment. and stages of A firm's investment in these activities are commercialization. influenced by the same basic forces that govern outlays on other investment projects. Thus, investments for R&D and innovation will be determined by their perceived profits and risks relative to alternative investment opportunities as well as the cost and availability of funds for investment.

A number of empirical studies by economists have found aboveaverage returns on investments in industrial innovation. For example, this finding was obtained in studies of the returns to industrial R&D and innovational activity performed by Griliches (1958), Mansfield (1965), Terleckyj (1974), and Grabowski and Mueller (1978).

Most prior empirical work has examined the private returns to innovation--i.e., the returns to the innovating firm. However, because a significant portion of the benefits from innovation accrues immediately to outside parties--consumers as well as other industrial firms--the total social rate of return to innovation will usually be much higher than the private rate of return. Consistent with this expectation, that society would be better off if regulatory controls over prices and entry were removed from the airline and trucking industries.

Recently, a number of evaluative studies and cost-benefit analyses of regulation for safety and environmental goals also have been conducted. These have uncovered many instances of unsatisfactory regulatory performance. In particular, they point to the large, often excessive, costs to the private sector as well as lengthy delays and unforeseen difficulties in achieving the intended social benefits of regulatory policies. These experiences also have spawned a number of policy recommendations for changes in the current regulatory process in the safety and environmental areas. One prominent thrust of such proposals, espoused by the President's Council of Economic Advisors and others, is to place greater emphasis on policy measures that attempt to utilize economic incentives to achieve social objectives, effluent fees in pollution control, for example. This approach could be substituted in many circumstances for current regulatory procedures relying mainly on direct bureaucratic controls and administrative standards. While such an approach has considerable analytical appeal and the support of certain policymaking groups, it so far, however, has not progressed much beyond the proposal stage.

As noted at the beginning, one of the long-term, more subtle costs of regulation is its possible effect as a disincentive to innovation. In the setting of regulations, whether by Congress or by regulatory agencies, no consideration has been given to the effects of the regulations on innovation, as the purposes of the regulations were quite different. Although this has not been the central focus of attention in most current discussions of regulatory reform, a number of studies suggest it as an important issue for public attention.

The task of this monograph is to examine the evidence concerning the effects of regulatory policy on innovation and consider what modifications of regulatory policies, actions, or mechanisms appear warranted to improve regulatory performance in this regard. In many of the cases to be discussed, the connection between regulation and innovation is found in the costs entailed in meeting regulatory requirements, as these reduce the availability of R&D funds for innovative new products, the capital available for new plant to manufacture such products, or the competitiveness of the products in U.S. and world markets. It should be emphasized at this point that the effect of regulation on innovation is not always negative in character. In certain situations the effect can be neutral and in others it can be positive. Nevertheless, our interest here is in those regulatory situations in which there is potential for improving innovative consumers. This type of market situation has been thought likely to occur, for example, by some opponents of proposed regulatory reforms that would allow more competition in the airline industry. However, most economists would agree that destructive competition of the sort described above has been a very rare situation historically, and there are few, if any, current circumstances in which regulation is warranted to prevent firms from engaging in too much competition.

Regulation is often instituted to remedy the problem of "externalities," as well as market situations in which property rights to a public resource are not well defined. Environmental pollution provides a classic example of external side effects arising from market activities--costs that are not directly captured in any market prices. Similarly, government regulation of broadcasting has been justified on grounds of preventing spillover effects from potential users of the spectrum and thereby causing significant quality deterioration in the use of this scarce public resource.

Another type of market failure that has been used to rationalize government regulation is "information imperfections." This underlies most consumer-protection regulation. For example, the Food and Drug Administration has been given the responsibility to screen all new drugs on grounds of safety and efficacy before they can be made available to the public. In effect, a regulatory agency has been empowered to prohibit or restrict certain voluntary market transactions. Presumably, these transactions are expected to lead to losses in consumer welfare that might occur in the absence of regulation because of imperfect information provided to consumers. A comparable rationale underlies the activities of the Consumer Product Safety Commission, the Occupational Safety and Health Administration, the Federal Trade Commission, and other federal and state regulatory agencies.

In addition to these considerations concerning economic efficiency, government regulation often becomes a mechanism for income redistribution. Thus, for example, rate regulation often leads to cross subsidization in which prices are set below costs for some services or markets and the resulting losses are made up by the profits from some other market or services. Telephone service to rural areas provides one standard example of such cross subsidization. Commoncarrier obligations in transportation furnish another commonly cited example.

Furthermore, there may be a diversion of R&D funds away from productive innovative activities; capital that might have been used for new plant for innovative products is preempted for equipment to meet regulatory requirements; or, the added costs may make the proposed product economically unattractive or uncompetitive in world markets. Other mechanisms are more subtle and indirect, and often the firm is subject to several regulatory influences that tend to be offsetting in nature. In this monograph we examine the evidence concerning the impact, often unintentional, of regulation on innovation and make recommendations for changes in regulatory methods that could better foster innovation without sacrificing the intended benefits of regulation.

As background for the study, the remainder of this chapter provides a brief overview of the development of regulation. Chapter 2 reviews what is currently known about the determinants of industrial innovation and considers the above developments in more detail. Chapters 3 and 4 are the heart of the paper. They examine the impacts of the government's social and economic regulatory policies on innovation in considerable detail. The final chapter presents general findings and policy recommendations.

# THE HISTORICAL DEVELOPMENT OF AND RATIONALE FOR REGULATION

The first significant regulation of business in the United States began in 1887 with the passage of the Act to Regulate Commerce. This Act established the Interstate Commerce Commission (ICC) and empowered it to regulate the railroads. An important reason for the creation of the ICC was to curb the monopoly power of the railroads and end the highly discriminatory railroad freight rate structure that existed at that time. The Act made it illegal to discriminate among customers, to charge more for short hauls than for long, and to practice secret, collusive price cutting.

In ensuing years the original legislation was amended and broadened. As trucking became an important competitive force in the 1930's, it was brought under ICC jurisdiction. In the 1930's, direct regulation by the federal government spread to other industries, including electric power, telephone and telegraph, natural gas pipelines, and air transportation. This type of regulation was generally concerned with such economic factors as rate levels, rate structures, and entry and exit by firms in those industries. Similar regulation by states began even earlier. For example, Wisconsin and New York began regulating electric power in 1907.

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per se. Quite the contrary--if the regulatory process can be improved, it can only strengthen the case for regulation.

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government policies and practices that affect technological innovation. In the present phase of the study, efforts were undertaken in three areas:

- 1. "The Impact of Regulation on Innovation"
- 2. "The Impact of Tax and Financial Regulatory Policies on Industrial Innovation," and
- 3. "Antitrust, Uncertainty, and Technological Innovation."

This monograph is the first of this series. A word is in order about the methodology. The committee utilized a workshop format in order to a) involve additional experts in the field, b) obtain views of representatives of various government agencies, and c) provide a forum for discussion among the committee members, academic and private industry specialists, government personnel, and the authors. The workshop was held on May 2, 1978 in New York City. In order to give some structure to the workshop, the following questions were given to the panel:

1. What do we know about the effect of regulation--economic, environmental, and health and safety--on the innovation process and on the private and social returns from technological innovation?

- a. What do we know about the social costs and benefits of regulations that directly affect innovation?
- b. Have there been patterns of major intended and unintended effects with respect to innovative activity in regulated industry?

c. What have been the experiences of third parties as a result of regulations?

6.2. What are the possibilities either for modification or for improved implementation of regulations that will achieve the same social or economic objectives of some existing regulatory policies but with fewer undesired effects on innovation?

3. What are some suggestions for the direction of future research on the effects of federal regulation on innovation?

- a. What are some of the limitations of current research?
- b. What are some of the appropriate topics for future research?

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NOTICE: The project that is the subject of this report was approved by the Governing Board of the National Research Council, whose members are drawn from the Councils of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine. The members of the committee responsible for the report were chosen for their special competences and with regard for appropriate balance.

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