BY THE U.S. GENERAL ACCOUNTING OFFICE

Report To Senator Lloyd Bentsen United States Senate

Regulatory Effects On R&D Are Better Assessed As Part Of The Innovation Process

Slow productivity growth has prompted concern that Federal regulations may be adversely affecting research and development (R&D) -- one part of the innovation process.

GAO reviewed numerous studies of effects of Federal environmental, safety, and health regulations on R&D and innovation. These studies indicate that investment in innovation activities depends on the expected profits the innovation will produce. Anything that tends to lengthen the time before benefits can be realized, limit those benefits, or increase the cost of investment, tends to reduce the rate of return to innovation, and therefore can reduce the amount of R&D performed. Regulation can do all of these things.

Whether the costs and benefits of regulation are positive to society depends on the value placed on the Federal policy goals that regulations attempt to achieve as against the goals implicit in a relatively free market.

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FEBRUARY 11, 1982

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UNITED STATES GENERAL ACCOUNTING OFFICE
WASHINGTON, D.C. 20548

PROGRAM ANALYSIS
DIVISION

B-203616
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The Honorable Lloyd Bentsen
United States Senate

Dear Senator Bentsen:

At your request, we examined the Federal regulatory process and the effect of this process on private sector research and development (R&D) activity. This report focuses on the effects of Federal environmental, safety, and health regulations on R&D. Trends in R&D over the last two decades are discussed and the measures of those trends are evaluated. The report also analyzes existing studies of the effects of regulation on R&D. Cost increases and changes in composition of the typical firms's portfolio of R&D projects are two of the most important regulatory effects on R&D. Finally, the report discusses the pharmaceutical industry, which is both regulated and intensive in R&D, as a case study of regulatory effects on R&D. We feel that the report provides a useful overview of the economic literature on the relationship of regulation and R&D and will be helpful in evaluating legislation in this area.

As arranged with your office, unless you publicly announce the contents earlier, no further distribution of this report will be made until 30 days after the report date. At that time, we will send copies to interested parties and make copies available to others upon request.

Sincerely yours,

Morton A. Myers

Morton A. Myers
Director

Enclosure

BY THE U.S. GENERAL ACCOUNTING OFFICE REPORT TO SENATOR LLOYD BENTSEN

REGULATORY EFFECTS ON R&D ARE BETTER ASSESSED AS PART OF THE INNOVATION PROCESS

D I G E S T

Senator Lloyd Bentsen requested that GAO undertake a series of studies on declining U.S. productivity. One of his concerns was the effect Federal regulation may have on private sector research and development (R&D) and innovation. This report addresses that concern.

RESEARCH AND DEVELOPMENT-- PART OF THE INNOVATION PROCESS

Research and development is the systematic investigation of natural phenomena with the objectives of expanding scientific and technical knowledge and of creating prototypes of new products and production processes. It is part of a complex sequence of events called innovation. Innovation is the process by which inventions or new ideas are redesigned and embodied in various outputs until something of commercial value is produced. Diffusion then occurs, the process by which the innovation achieves widespread commercial acceptance. Economic benefits begin with innovation and continue until the innovation becomes obsolete. In the innovation process, the Federal role may be paramount to success or failure.

The innovation process may begin with basic research (research with no specific commercial objective). The basic research may suggest a commercial possibility which then becomes the goal of applied research. Applied research may produce a working laboratory model of the new technology, which is refined in the process of development. Subsequent investments for pilot plants, marketing networks, and other expenses may lead the technology to become an innovation--a commercially feasible product or process. R&D activity may eventually, as is commonly believed, lead to increased growth rates of labor productivity and real income while reducing inflation. However, the benefits may be years away from the R&D process.

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MISDIRECTED CONCERN

Concern about the effects of regulations on R&D is generally misdirected. Most regulated industries in the United States face controls on rates of return, prices, entry into the industry, or controls on emissions of pollutants or safety of products. While these regulations may affect R&D, they are not restrictions placed directly on the R&D process. Since the results of R&D alone have little or no commercial value, unless sold as such, concern about the effects of regulation on R&D is really concern about regulatory effects on the innovation process. Since innovation occurs in a continuum, in which R&D is a part, if regulations adversely affect the innovation process they may tend to adversely affect certain types of R&D, especially development and applied research (but not defensive R&D). This is because, like any other investment, expected returns to innovative activities would be either lower or longer in coming--as would any productivity gains.

GAO'S APPROACH

GAO treats R&D as an investment and analyzes the effects of regulation on private sector R&D in terms of its effect on the rate of return to innovative activity. The report is a literature survey only, not an original empirical study, and it focuses on major economic studies available in this area. GAO believes the studies it examined represent fairly the concensus of professional judgment on this topic. However, the approaches used in the studies GAO reviewed are subject to criticism for a variety of reasons, such as inadequate data, technical statistical problems, aggregation problems, and inadequate consideration of quality changes in products or processes. GAO did not independently assess in detail the validity of the literature it examined. GAO particularly emphasizes the concept that because R&D activity is but one part of the innovation process, one must recognize that it is regulation's influence on the innovation process, not the R&D process, that is of fundamental importance. Also, at the Senator's request, GAO conducted a case study. GAO chose the pharmaceutical industry because it provides a concrete exposition of the concepts associated with regulation's effect on R&D spending. At the Senator's request GAO

did not obtain agency comments on the matters discussed in this report.

DIRECT EFFECTS OF REGULATION ON R&D

The direct effects of regulation on R&D embrace several distinct elements. Cost increases to meet regulatory requirements may affect the development of new products, processes, and services by forcing industries to increase capital spending. Regulatory delays can raise the costs of new product introduction (see chapter 3). Profits tend to be reduced, and thus R&D. Regulations may also cause increases in uncertainty, which may have a negative effect on investment in R&D. However, regulation may encourage R&D to develop new products and processes that help meet regulatory requirements (see chapter 3).

A primary effect of regulation has been to change the composition of the typical firm's portfolio of R&D projects. Firms are doing less basic research and less R&D on risky or entirely new products. R&D devoted to environmental safety and health regulations has accelerated (see chapter 3).

In many cases, Federal regulation deliberately attempts to force the introduction of new technology (see chapter 3). But this has resulted in a diversion of activity away from other forms of R&D activity. Furthermore, there is some evidence that technology-forcing regulations have reduced the likelihood of major advances in the state of the art in any particular industry because such advances would then become the new standard on which the regulation would be based.

INDIRECT EFFECTS OF REGULATION ON R&D

Regulation may affect R&D indirectly by reducing the number of firms in an industry, which in turn, may reduce R&D. If small firms are hurt by regulation, the industry may become more concentrated. If more concentrated industries spend less on R&D than less concentrated industries, then the regulation-induced increase in concentration will reduce R&D (see chapter 3).

However, in a wide range of industries, one or both of the pre-conditions for these indirect effects do not take place (see chapter 3). Even in the pharmaceutical industry, where the effect of regulation on increasing costs for small firms has led to a marked decline in innovation by small firms, the industry has not become more concentrated in terms of total sales. However, sales of innovative products are more concentrated in the largest firms (see chapter 4).

REGULATION AND R&D IN THE PHARMACEUTICAL INDUSTRY

The pharmaceutical industry has several special characteristics that highlight the effects of regulation on R&D:

- The R&D process itself is directly regulated by the Food and Drug Administration under laws passed in 1938 and 1962.

- A relatively good measure of the outputs of the R&D process is new drugs.

However, the peculiarities of this industry may cause conclusions drawn from GAO's examination to be unrepresentative of the effects produced in other industries. The U.S. pharmaceutical industry is research intensive, and regulation has had several marked direct effects on R&D. Specifically, since 1962, the private rate of return to drug industry innovation and the number of new drugs introduced has fallen, while the cost of introducing new drugs has risen (see chapter 4).

RESEARCH AND DEVELOPMENT AND THE GOALS OF REGULATION

Although regulation has adversely affected R&D through cost increase, delay, and the redirection of R&D away from newer or more risky projects, regulation was instituted to correct some important social problems--such as pollution, occupational disease, and introduction of products with unknown effects. Regulations that alleviate these problems have important social benefits. Of course, other Government policies and regulatory methods might encourage R&D and make regulation more

efficient, such as economic incentives (rather than normal command and control regulation), reducing regulatory delay, and performance standards rather than design standards. These alternative regulatory policies can help significantly in attaining society's goals while at the same time influence R&D activity not so negatively.

CONTENTS

TABLES

ABBREVIATIONS

CPSC	Consumer Product Safety Commission
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
GNP	Gross National Product
NCE	New Chemical Entity
NHTSA	National Highway Traffic Safety Administration
OSHA	Occupational Safety and Health Administration
R&D	Research and Development

CHAPTER 1

INTRODUCTION

In April 1979, Senator Bentsen asked us to undertake a series of studies on the decline in the growth rates of U.S. productivity. This report responds to the part of the request having to do with Federal regulatory processes. It focuses on the relationship between regulation and private sector research and development activity, and the effects of regulation on innovation--the introduction of new or improved products or services into the market place. The Senator also requested that we include a case study in our report.

Currently, there is great concern about lagging productivity in the United States. While most knowledgeable observers have not pointed to Federal regulation as the predominant cause, it does affect productivity. 1/ Similarly, the innovation process is often considered as affecting productivity and economic growth, and it too, is substantially affected by regulation. This report emphasizes the link between regulation and one component of the innovation process--research and development (R&D).

R&D SPENDING AND THE INNOVATION PROCESS

Some R&D does not result in research output. Furthermore, some R&D results in only minor improvements in products and processes while other R&D may result in radical breakthroughs. We must recognize that innovations occur in a continuum from the most minor modification of existing technology to the most important scientific and technological changes. R&D spending, for example, may be devoted to quick fixes of existing technology, or to risky projects with the objective of making fundamental changes. Since it is hard to determine exactly where along this spectrum we should begin or stop classifying activity as R&D, it is difficult to pin down the effect of regulation on R&D or the innovation process in general.

TRENDS IN R&D INVESTMENT DOLLARS

R&D spending has increased from $13.5 billion in 1960 to $51.6 billion in 1979. Total R&D from all sources as a share of the gross national product (GNP) has declined almost continuously since 1964, but two trends emerge, depending on the source of R&D funds. Between 1964 and 1979, R&D from all non-Federal

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1/The importance of regulation relative to other factors and its degree of impact is, however, not established in the economic literature. See, for example, Edward Denison, Accounting for Slower Economic Growth (Washington, D.C.: Brookings Institution, 1979).

sources rose as a percentage of the GNP, while R&D from Federal sources fell as a percentage of the GNP. Moreover, industrial R&D as a percentage of total national R&D from non-Federal sources has increased in recent years (table 1). Industrial R&D is also quite concentrated. In 1977, about 80 percent of all industrial R&D took place in five industries (chemicals including drugs, non-electrical machinery, electrical equipment and communications, motor vehicles, and aircraft and missiles) and 97 percent of it took place in manufacturing, which composed only about one-quarter of the GNP. 1/

OBJECTIVES, SCOPE, AND METHODOLOGY

Our objective in this assignment was to determine the potential effects of regulation on R&D in the private sector in some affected industries. We did not assess the relationship between R&D and productivity. An undertaking that would do justice to this subject would require a separate study and is beyond the current state of the art.

This report is a literature survey that reviews works on the relationship between private sector R&D activity and the Federal regulatory process, and problems of measuring returns to innovations in the private sector. It assesses the relationship between regulation and R&D as currently understood. We chose the pharmaceutical industry as a case study. We did not conduct original research on regulation and R&D, nor have we independently assessed in detail the validity of the literature we examined. However, we believe that the literature we reviewed does represent the concensus of professional judgment on the relationship between regulation and R&D. We chose not to conduct a more independent analysis of the effect of regulation on R&D because such a study is currently underway in the Office of Technology Assessment at the request of the Senate Committee on Commerce, Science, and Transportation.

For purposes of this report, we consider in a general sense health, safety, and environmental regulations administered by the Environmental Protection Agency (EPA), the Occupational Safety and Health Administration (OSHA), the Food and Drug Administration (FDA), the Consumer Product Safety Commission (CPSC), and the National Highway Traffic Safety Administration (NHTSA). We limited the scope to this set of regulatory objectives because we felt that these types of regulations have caused the greatest concern in terms of their effect on R&D.

Our approach is to treat R&D as a form of investment. We analyze the effect of regulation on R&D in terms of its effect on

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1/National Science Board, Science Indicators 1978: Report of the National Science Board (Washington, D.C.: U.S. Government Printing Office, 1979), NSB-79-1, p. 202.

Table 1

R&D Expenditures by Source and as a Percentage of GNP, Selected Years
(current dollars in billions)

Year	GNP	Total		Federal		Other*	
1960	$ 506.0	$13.5	2.67%	$ 8.7	1.72%	$ 4.8	0.95%
1962	563.8	15.4	2.73	9.9	1.76	5.5	0.98
1964	635.7	18.9	2.97	12.5	1.97	6.3	0.99
1966	753.0	21.8	2.90	14.0	1.86	7.9	1.05
1968	868.5	24.6	2.83	14.9	1.72	9.7	1.12
1970	982.4	25.9	2.64	14.7	1.50	11.2	1.14
1972	1,171.1	28.4	2.43	15.8	1.35	12.6	1.08
1974	1,412.9	32.7	2.31	16.8	1.19	15.9	1.13
1975	1,528.8	35.2	2.30	18.2	1.19	17.0	1.11
1976	1,700.1	38.8	2.28	19.6	1.15	19.2	1.13
1977 (prelim.)	1,887.2	42.9	2.27	21.6	1.14	21.3	1.13
1978 (est.)	2,100.0	47.3	2.25	23.8	1.13	23.5	1.12
1979 (est.)	2,325.0	51.6	2.21	25.7	1.11	25.9	1.11

*Other = industry, universities, and nonprofit institutions. Industry constitutes the biggest share.

Source: Science Indicators 1978, p. 170.

the rate of return to innovation activity, assuming that decisions by business people about how much R&D to finance are made primarily on the basis of the rate of return to innovations (see chapter 2). We ignored all non-economic influences of regulation on R&D, as well as certain economic effects, such as the effect of regulation on the supply of capital. We discuss the direct effects of regulation on R&D and the indirect effect on R&D caused by regulation's effect on changes in industry structure.

The remainder of this report is organized as follows. Chapter 2 presents our perspective on R&D and studies linking innovation to productivity. Chapter 3 considers the direct and indirect effects of regulation on R&D in industry generally. Chapter 4 examines the particular case of the effect of regulation on R&D in the pharmaceutical industry, where the effect of regulation is particularly significant and where the output of innovations is easily identifiable. Chapter 5 summarizes the report and suggests some innovative approaches to regulation that might help reduce the negative effects of regulation on innovation while still achieving regulatory goals.

CHAPTER 2

PERSPECTIVES ON R&D AND PRODUCTIVITY GROWTH

In this chapter we discuss the methods used to measure R&D, technological change, and productivity growth, and how they affect our approach in analyzing the relationship between R&D and regulation.

R&D IS ONLY PART OF THE INNOVATION PROCESS

Research and development is the systematic investigation of natural phenomena with the objectives of expanding scientific and technical knowledge and of creating prototypes of new products and production processes. It is but part of a complex sequence of events called innovation.

Innovation is the process by which inventions or new ideas are redesigned and embodied in various outputs until something of commercial value--an innovation--is produced. Diffusion then occurs. Diffusion is the process by which the innovation achieves widespread commercial acceptance. Economic benefits begin with innovation and continue until the innovation becomes obsolete. In the innovation process, the Federal role may be paramount to success or failure.

The innovation process may begin with basic research (research with no specific commercial objective). The basic research may suggest a commercial possibility which then becomes the goal of applied research. Applied research may produce a working laboratory model of the new technology, which is refined in the process of development. Subsequent investments for pilot plants, marketing networks, and other expenses may result in the technology becoming an innovation--a commercially feasible product or process. R&D activity is believed to increase the growth rates of labor productivity and real income while reducing inflation. However, the benefits may be years away from the R&D process.

A study by John Enos examining 46 major industrial innovations found that the average period between invention and innovation was 13.6 years. 1/ The interval varies considerably among innovations; for example, the fluorescent lamp took 79 years while streptomycin took only 5 years. 2/ A lag exists because there are numerous economic, social, and technological barriers

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1/John Enos, "Invention and Innovation in the Petroleum Refining Industry," The Rate and Direction of Innovative Activity, National Bureau of Economic Research (Princeton, New Jersey: Princeton University Press, 1962), pp. 299-321.

2/Nathan Rosenberg, Perspectives on Technology (Cambridge, England, Cambridge University Press, 1976), pp. 69-70.

to an invention's commercial success. The less formidable and the fewer barriers there are, the sooner diffusion occurs.

R&D activity undertaken by the private sector can be viewed as an investment. Experts on Federal Government regulation suggest that regulation may affect the decision to invest in R&D as opposed to some other capital asset, such as new plants or equipment. Since the decision to invest generally turns on the expectation that the investment will be profitable in the future, whether a firm decides to fund an R&D project depends on the likelihood of successful commercialization. This in turn depends upon the cost of the research itself; the availability of capital, trained personnel, and viable markets; the costs of market introduction, advertising, and demonstrations; and the going rate of interest. 1/ Any Government regulation that negatively affects these factors by causing uncertainty or delay in commercialization will probably reduce the appeal of investing in R&D. Commercial use of an R&D result requires that all institutions involved in the marketing, manufacturing, distribution, and end use of the technology accept the result. Regulations can affect any of these institutions. Therefore, the effect of regulation on R&D should be evaluated in the context of the innovation process.

ANALYSIS OF R&D, TECHNOLOGICAL CHANGE, AND PRODUCTIVITY GROWTH

There are enormous problems associated with measuring the contribution of R&D activity to productivity. Early studies of the relationship between technological change and economic growth used highly aggregated economic data and found that a large percentage (80 percent to 90 percent) of our labor productivity growth could not be explained by increases in the amount of capital per worker. 2/ These large residuals were then assumed to be due solely to technological change. However, this measure does not reflect only the effects of technological change. Some factors are excluded (e.g., changes in education, product mix, economies of scale, etc.) that contribute to these residuals. More recent studies have shown that "advances in knowledge" have contributed about half of the growth in output in the U.S. since 1929. 3/ This approach requires careful statistical sifting of

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1/Allan Mendelowitz, "Research and Innovation: Regulatory Impediments and Reform Alternatives," Proceedings of the 32nd National Conference on the Advancement of Research, Sept. 24-27, 1978, pp. 33-34.

2/R.M. Solow, "Technical Change and the Aggregate Production Function," Review of Economics and Statistics, 39 (1957), pp. 312-320; M. Abramowitz, "Resources and Output Trends in the U.S. Since 1870," American Economic Review, 46 (1956), pp. 5-23.

3/E.F. Denison, Accounting for United States Economic Growth, 1929-1969 (Washington, D.C.: The Brookings Institution, 1974), p. 136.

productivity data to determine the individual contribution of various economic factors to changes in aggregate productivity. There are numerous pitfalls--errors in data, errors in specifying the production relationships, and technical statistical problems. Precise measurements are illusive with this approach. Even after the components of productivity change are sorted out, measuring the R&D contribution accurately is probably impossible. There is unquestionably a contribution and possibly a large one, but pinning it down is beyond the current state of the art.

One cannot, for example, equate advances in knowledge with organized R&D activity since technological change can stem from sources other than organized R&D. 1/ One would expect that the contribution of R&D to growth is less than that of advances in knowledge. Also, much of the total U.S. R&D consists of defense and space-related R&D, which are probably less related to increasing private sector productivity than are other types of R&D. Furthermore, according to some researchers, there are serious measurement and aggregation errors in the more recent studies which could affect their results. For example, quality changes in outputs and inputs are still not adequately considered in these analyses. 2/

The problems with aggregate studies of U.S. productivity growth have led to another basic approach to estimating the effects of R&D on productivity. Rather than examining the aggregate economy, data on individual firms or innovations are analyzed to explore the complex interrelationships which might be obscured at a more aggregate level of analysis.

One of the first of these studies was made by Zvi Griliches estimating the returns from agricultural innovation. 3/ He found that the rate of return from U.S. agricultural innovations was between 35 percent and 170 percent from 1937 to 1951. Other studies such as Mansfield's indicated that the marginal rates of return to innovations in the chemical and petroleum industries were respectively about 40 percent and 30 percent. 4/ Recently, Mansfield has found that the median private rate of return for 17 selected

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1/E. Mansfield, "Contribution of R&D to Economic Growth in the United States," Science, 175 (1972), pp. 477-486.

2/Ibid., p. 478.

3/Zvi Griliches, "Research Costs and Social Returns: Hybrid Corn and Related Innovations," Journal of Political Economy, 66 (1958), pp. 419-431.

4/Mansfield, "Contribution of R&D," p. 482.

industrial innovations was about 25 percent, and the median social rate of return was much higher--about 56 percent. 1/

Several conclusions can be drawn from these disaggregated studies. The first is that the social rates of return from private sector expenditures on innovation appear to be very high. The second is that the social rates of return may diverge from the private rates of return, and may often exceed them by a significant amount. This implies that the private sector may be under-investing in R&D and innovative activity from a social point of view, if it is unable to capture the full benefits which privately financed innovations help to generate. Some studies of individual innovations are open to the criticism that their samples are unrepresentative and biased toward more successful innovations. However, the high rates of return to innovations which case studies generally find are evidence that innovation has an important positive effect on economic growth, even if the precise magnitude of the effect is in doubt.

In addition to the innovation case studies described above, studies by Terleckj, Mansfield, and Griliches analyze the overall relationships between industry or firm R&D spending and the rate of increase of total factor productivity. 2/ Output growth and productivity growth in agriculture, in manufacturing, and other industries were found to be positively related to R&D expenditures. These studies overcome the basic problem inherent in the aggregate residual method since R&D is specifically considered as an input in the production process.

On the basis of these prior studies, we know that the relationship between R&D and productivity is positive and significant, although the precise magnitude of the effect is in doubt. Thus, if the Federal regulatory process affects private sector R&D activity, it will to some extent affect productivity growth.

OUR APPROACH TO REGULATION'S EFFECT ON R&D

Our approach to assessing the relationship between regulation and R&D spending is to review the results of the literature to describe the ways in which the regulatory process affects R&D activity and to specify how this linkage is likely to influence the return to innovative activity. In this regard it is important to keep in mind that R&D activity is only part of the innovation process. In fact R&D may comprise only 10 percent of the total

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1/E. Mansfield, J. Rapoport, A. Romeo, S. Wergner, and G. Beardsley, "Social and Private Rates of Return from Industial Innovations, Quarterly Journal of Economics, 91 (1977), pp. 221-240.

2/E. Mansfield, "Contribution of R&D," p. 479.

expense associated with bringing a laboratory result to the commercial market. An R&D result is generally an intermediate output with little or no commercial value unless it is sold as such. Thus, studies describing the return to "R&D" are really referring to costs invested in bringing an R&D result to commercial success. This means that to the extent that regulations affect R&D either beneficially or adversely, it may be expected to affect the entire innovation process and consequently the rate of return to that process.

We believe that our approach to this problem has the potential to help improve policymaking on innovation by enabling policymakers to understand more fully the effects of the regulatory process on R&D which is part of the innovation process. If regulation adversely affects the returns to innovation, or causes the gap between social and private rates of return to widen because private rates of return decline, then the option exists to counter this by changing the regulations. Increasing the private rate of return to innovation activity should encourage more R&D, and the positive effects of innovation activity should increase economic growth and productivity.

CHAPTER 3

THE EFFECTS OF REGULATION ON RESEARCH AND DEVELOPMENT

Federal regulation has various objectives, as our past reports have indicated. 1/ Traditionally, regulation has focused on particular industries, e.g., Interstate Commerce Commission regulation of the railroad industry, or Federal Communications Commission regulation of the telecommunications industry. More recently, regulatory activity has focused on broad problems such as environmental pollution, occupational safety, and consumer product safety. Over the past 2 decades, much Federal legislation has been enacted and new Federal agencies have been created to effect regulatory solutions in these problem areas. 2/ While some industry-specific regulations are being dismantled, 3/ the new forms of regulation have generally expanded and are the ones most commonly alleged to have adverse consequences for economic growth and productivity. 4/ We will therefore focus on these new forms of regulation, emphasizing health, safety, and environmental quality, rather than the older forms of regulation which emphasize rate-setting and entry in particular industries. 5/

1/See especially U.S. General Accounting Office, "Government Regulatory Activity: Justifications, Processes, Impacts, and Alternatives" (PAD-77-34, June 3, 1977), and "Federal Regulatory Programs and Activities" (PAD-78-33, March 16, 1978).

2/These include the Consumer Product Safety Commission (CPSC) created in 1972 to enforce the Federal Hazardous Substances Act (15 U.S.C. 2051 et seq.), the Poison Prevention Packaging Act of 1970, and the Flammable Fabrics Act (15 U.S.C. 1191 et seq.), the Occupational Safety and Health Administration (OSHA) created in 1970 to enforce the Occupational Safety and Health Act of the same year (P.L. 91-596, Dec. 29, 1970. 84 Stat 1590, as amended), the National Highway Traffic Safety Administration (NHTSA) created in 1966 to enforce the National Traffic and Motor Vehicle Safety Act of that year (15 U.S.C. Chapter 38), and the Environmental Protection Agency created in 1970 to enforce what has become nine different pieces of legislation (42 U.S.C. Chapter 56).

3/See Public Law 95-504, the Airline Deregulation Act of 1978, 92 Stat. 1705, 95th Cong., October 24, 1978, and Public Law 96-296, the Motor Carrier Act of 1980, 94 Stat. 793, 96th Cong., July 1, 1980.

4/See, e.g., Arthur Andersen & Co., Cost of Government Regulation Study for the Business Roundtable, March 1979.

5/For a good discussion of the effect of regulation on innovation in some of these traditionally regulated industries, see William M. Capron, ed., Technological Change in Regulated Industries (Washington, D.C.: The Brookings Institution, 1971).

Regulation affects not only R&D but also the innovation process generally. Once a new technology emerges from R&D labs, further investment expenditures are normally necessary before the technology comes into commercial use (i.e., becomes an "innovation"). For example, R&D managers normally assume that R&D costs usually amount to about 10 percent of the total costs of bringing a product to market. 1/ The rest of the investment is required for such things as testing, production expenses, and marketing. Even in cases where regulation does not discourage the R&D leading to development of a technology, it may discourage the capital investment necessary to bring that technology into use. We are primarily concerned about the final outcome of the process (the innovation), not the R&D outcome (the new technology). We should pay attention to the effects of regulation on the full range of investment necessary to commercialize new technology, not just on the investments necessary to bring those new technologies into existence.

The effect of regulation on R&D is both direct and indirect. The direct effect includes the effect of regulation on reducing the profit rate on all of a firm's investments, including R&D. It also includes the effect of regulation on inducing the firm to carry out R&D it would not otherwise have carried out as a result of new regulations. The indirect effect includes the effect of regulation on industry concentration, which may in turn affect the amount of R&D carried out in a restructured industry. 2/

DIRECT EFFECTS OF REGULATION

R&D is an investment made by a firm that is expected to return benefits to the firm in the future. These benefits take the form of profits earned on new products and increases in profits due to cost savings attributable to new production processes. As an expenditure with long-term benefits, R&D thus constitutes an investment. The amount a firm invests in R&D will depend on the number of R&D projects whose expected return exceed the firm's opportunity cost of capital, adjusted for risk and the availability of financing for the project. The more R&D projects with high rates of return that are available to a firm, the more R&D projects the firm is likely to support. This would imply that, like any investment, the amount of R&D spending would increase if the relative rate of return on innovation activity increased.

1/"Vanishing Innovation," Business Week, July 3, 1978, p. 49. See also "Innovation: Has America Lost its Edge?" Newsweek, June 4, 1979, p. 62.

2/By "industry concentration" we mean the number and size distribution of the firms in the industry; in other words, how "concentrated" output is in a small number of firms.

However, anything which tends to lengthen the time before benefits can be realized, or limits the benefits when they are realized, or increases the costs of making the investment tends to decrease its rate of return and reduce the amount of R&D carried out. By this reasoning, Federal regulation can obviously affect the level of private sector R&D by affecting the rates of return it helps to generate.

Regulation may alter these returns either by changing the costs of producing a new product or by changing the demand for it. Alterations in the rate of return to innovations may be either positive or negative--that is, they may either encourage of discourage R&D. Regulation can also alter the risk associated with a new product or process, with either favorable or unfavorable effects on support for R&D. In some cases, regulation completely changes the environment within which the firm operates, and makes new technology and the R&D necessary to produce it essential for the firm's continued operation. These technology-forcing regulations may affect R&D carried out by firms without any explicit reference to the innovation's rate of return. Regulations may also increase total R&D spending, or leave it unchanged in total, but alter the composition of a firm's R&D portfolio by forcing it away from more basic or more long-term or more risky research and toward more applied, short-term, or safer R&D. 1/

Cost increases

Regulation may have an effect on the rate of return to innovation through its effect on the costs of developing, producing, and marketing a new product resulting from R&D. Drug regulations, for example, requiring clinical testing of the product prior to commercial introduction, generally increase the cost of developing the product. Environmental regulations governing production processes often increase the cost of producing the product. Federal Trade Commission regulations governing the selling of the product may increase marketing costs. On the other hand, regulations may reduce production and marketing costs through, for example, size standardization or quality grading.

One important form of cost increase is delay caused by regulation. A Senate Governmental Affairs Committee study found in a survey of lawyers that undue delay was the most frequently cited problem with Federal regulation. The length of time involved in making regulatory decisions is shown in table 2. Notice the number of days required for the classes of cases involving environmental, consumer protection, and safety issues. We can see that regulation in these areas may drag on for years before final decisions are reached. Although some new approaches are being

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1/See Edwin Mansfield, "Basic Research and Productivity Increase in Manufacturing," American Economic Review, vol. 70, no. 5, December 1980, pp. 863-873.

considered, it is doubtful that there will soon be significant decreases in the time involved in making regulations in these areas. 1/

Table 2

Classes of Agency Adjudication Where More Than Two Hearings Were Held and Where Average Hearing Time Exceeded 5 Days (Cases Ended FY 1975)

Types of Cases	Average Number of Days Between Being Referred for Hearing and Termination
NRC - Reactor Operating Licenses	786
EPA - Pesticide Registration and Cancellation	1089
NRC - Reactor Construction Permit	680
FTC - Consumer Protection	533

Source: Study on Federal Regulation, Volume IV: Delay in the Regulatory Process, Committee on Governmental Affairs, United States Senate, July 1977, 95th Cong., 1st sess., p. 33.

One example of regulatory delay from the Interstate Commerce Commission (ICC) will serve to illustrate this point. In the 1960s the Southern Railway tried to capture a larger share of the grain shipments in the Southeastern U.S. by purchasing specially designed railway cars to move grain at reduced costs. To compete more effectively, the railway planned to lower its freight rates. The lower rates were necessary to attract sufficient grain traffic to make the new cars profitable. However, the Southern Railway was forced to spend 4 years in court fighting ICC opposition to its reduced freight rates before the railway could obtain final approval. 2/

1/"Battling Carcinogens Systematically: New Strategies at OSHA and CPSC," Regulation, January/February 1979, pp. 7-9, and "Regulating Cancer - Fast, Fast, Fast Relief," Regulation, March/April 1980, pp. 4-7.

2/Aaron J. Gillman, "Surface Freight Transport" in William M. Capron, ed., Technological Change in Regulated Industries (Washington, D.C.: The Brookings Institution), 1971, pp. 175-178, 183.

An example of the increased costs associated with regulation is capital costs. In 1977, capital expenditures required to meet pollution abatement regulations were 7.0 percent of total capital outlays in manufacturing. In the chemical industry, this figure was 10.2 percent. 1/ Spending to meet regulatory requirements can reasonably be expected to reduce the number of new products a firm invests in, and hence the amount of R&D it invests to develop new products.

In the automobile industry, annual costs of regulation to meet fuel economy, pollution, and safety standards from 1978 to 1985 have been estimated by industry sources to be $0.8 billion for Chrysler, $1.0 billion for Ford, and $2.0 billion for General Motors. These regulatory costs per car produced will be $550, $340, and $345, respectively. 2/ In addition, General Motors has estimated that in 1976 it spent 20 percent of its R&D budget on research that was needed to meet only the federally imposed safety and emission standards. 3/ Insofar as these additional costs reduce the expected profit rates of these firms, they may have a depressive effect on all kinds of investments, including R&D.

The 1972 Federal Environmental Pesticide Control Act (P.L. 92-516, Oct. 21, 1972, 86 Stat. 973) has required firms that manufacture pesticides to register new pesticides with EPA. Apparently as a result of the increased costs associated with registration requirements, registration of new pesticides fell from 58 in 1975-76 to 9 in 1977-78. 4/ The industry also reports that its R&D has become more defensive, that is, concerned with protecting the present product line rather than with developing new products. 5/ One particular effect of regulatory costs on pesticide innovation has been to discourage innovation in pesticides with limited markets. "Biological" pesticides, for example, which use a pest's own hormones and sex attractants against itself, are less toxic to humans and animals, but are effective against only one or two species of insect, and thus have more limited markets than more toxic chemicals, such as Malathion and

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1/Economic Report of the President, January 1979, p. 127.

2/Kenneth W. Clarkson, Charles W. Kadlec, and Arthur B. Laffer, "Regulating Chrysler Out of Business?," Regulation, September/October, 1979, pp. 44-49.

3/Business Week, June 28, 1976, p. 55.

4/Henry G. Grabowski and John M. Vernon, The Impact of Regulation on Industrial Innovation (Washington, D.C.: National Academy of Sciences, 1979), pp. 19-20.

5/Ibid., p. 20.

parathion. 1/ Since the cost of EPA registration procedures rose to nearly $1 million per pesticide in 1978, it becomes more difficult to justify investments in R&D to develop pesticides with such limited markets. Chemical industry spokesmen assert that only those new chemicals that are targeted toward large markets can even be attempted. 2/

Cost increases by regulation do not always reduce profits

A regulation that increases costs may not reduce profits if it simultaneously increases the demand for the firm's product or reduces its other costs of production. If demand increases or other costs fall to a sufficient extent, the firm's profits may remain unchanged or actually rise. For example, in the automobile industry, it is widely believed that low fuel economy has resulted in decreased sales and, thus, low profits. But since Federal regulations have forced the automobile industry to improve fuel economy, and since the market now demands it, the impact of fuel economy standards put the automobile industry in a better position to respond to the demands of the market.

In the chemical industry, OSHA regulations governing exposures to polyvinyl chloride were widely expected to increase capital costs by nearly $2 billion when the standards were first promulgated in the fall of 1974. In fact, the capital costs necessary to comply with the standard turned out to be only about one-tenth of this estimate, and the new technologies installed may have reduced operating costs enought to have actually reduced total costs for at least some of the firms in the industry. 3/

Demand increases

A second direct effect of regulation may be to increase the demand for products and processes derived from R&D, which must be used to comply with the regulation. The new product or process may be the work of either the firm directly affected by the regulation, or of some supplier to it. The firm directly affected may seek to overturn the regulation or simply ignore it, but the supplier, unless he has a heavy investment in an existing technology, is likely to see the new regulation exclusively as a profitable opportunity to sell new equipment assuming he has the

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1/William Tucker, "Of Mites and Men," Harpers (August, 1978), pp. 44-46.

2/Ibid., p. 46. See also "Vanishing Innovations," Business Week, July 3, 1978, p. 48.

3/Susan Dirks-Mason, "The Effects of the OSHA Vinyl Chloride Standard on the Vinyl Industry," U.S. Occupational Safety and Health Administration Policy Office, August 1979.

ability to develop and produce the items. For example, while steel companies have sought to have pollution control requirements moderated or deferred, firms manufacturing pollution control equipment have seized the opportunity to develop and sell new pollution control equipment. This is particularly the case when, as with certain EPA regulations, the law requires the use of the "best available control technology." 1/ In this case, the firm that develops a new pollution control technology has a virtually guaranteed market among the firms subject to the regulation.

This effect of regulation also illustrates the increase in capital costs referred to earlier. What is an increased cost to one firm is a new market to another. The 7 percent capital outlays by manufacturers spent for pollution control equipment in 1977 represented a market of $4.2 billion. 2/

Changes in composition of R&D portfolios

Regulation may also be changing the composition of a typical firm's portfolio of R&D projects away from projects taking a longer time (risky) to complete to those promising results in a shorter period (less risky). The conventional viewpoint of industrial R&D is that, under pressure of higher costs and regulatory constraints, industry has shortened its time horizon for R&D results and is doing less fundamental research. 3/ This will supposedly result in fewer radical innovations. For example, it is alleged that fewer radical breakthroughs have been taking place recently as opposed to 20 years ago. 4/

Some evidence exists that firms in the United States have changed the composition of their R&D portfolios. Edwin Mansfield obtained information from 119 firms concerning the changes they made over the 1967 to 1977 period in the shares of R&D expenditures devoted to basic research, long-term projects, and risky and ambitious projects. 5/ These firms accounted for about one-half of all industrial R&D spending. Table 3 shows some of the survey results.

1/Russell V. Randle, "Forcing Technology: The Clean Air Act Experience," Yale Law Journal, vol. 88, no. 8, July 1979, p. 1717.

2/Economic Report of the President, 1979, p. 235.

3/Pascarella, Perry, "Our Technological Recession: Can We Again Brighten the Dark World," Across the Board, December 1979, pp. 60.

4/Science Indicators 1976, p. 93.

5/Mansfield, "Basic Research," pp. 863-873.

Table 3

Percentage of Company-Financed R&D Expenditures Going for Basic, Long-term, and Relatively Risky Projects: 1967-77

Industry	Basic research		Projects lasting 5 or more years		Projects aimed at entirely new products and processes		Projects with less than 50-50 chance of success	
	1967	1977	1967	1977	1967	1977	1967	1977
Ferrous and non-ferrous metals	6.2%	2.4%	26%	22%	28%	18%	18%	11%
Chemicals	7.3	5.9	43	39	37	33	37	30
Auto-mobiles	0.3	0.2	18	20	15	16	47	45
Drugs	20.7	16.4	63	66	76	68	46	40
Total for all in-dustries	5.6	4.7	34	34	36	34	28	25

Source: Mansfield, "Basic Research," p. 870. We do not include here all of the industries which Mansfield surveyed.

Mansfield's results show that the proportion of R&D expenditures devoted to basic research declined in almost every industry surveyed over the 1967-77 period. This proportion also declined for the sample as a whole. In most of the industries he examined, the proportion of R&D spending devoted to relatively risky projects declined; in some industries (such as metals, chemicals, and drugs) this reduction was rather large. Also, the "proportion of R&D expenditures aimed at entirely new products and processes (rather than improvements and modifications of existing products and processes) declined somewhat between 1967 and 1977." 1/ However, the proportion of R&D expenditures devoted to longer-term projects did not decline much overall and actually increased in both automobiles and drugs over the 1967-77 period. These last two cases can probably be explained by increased regulatory requirements. We show in chapter 4 that FDA regulation has increased the time required to develop new drugs. As for the automobile industry, evidence exists that regulatory requirements are

1/Ibid., p. 870.

forcing auto companies to increase their product planning time to 5 or more years. 1/ Moreover, Mansfield's respondents indicate that the primary reason for declines in spending on basic and risky research has been the increase in Government regulations, especially in the chemical and drug industries. 2/ Another reason may be the decline in Government-financed R&D performed by private firms and institutions.

Although we have noted that basic research and research on relatively risky projects seem to have decreased as shares of certain industry's R&D portfolios over the 1967-77 period, it is possible that in certain instances regulation may actually increase the payoff to basic research. 3/ Regulations that force firms to bear more of the costs of their own actions may induce firms to do more basic research to find out what the costs of their own actions are. It is generally acknowledged that scientific uncertainties and gaps in knowledge exist in many areas where regulatory actions are taking place. Questions are often unresolved, such as whether carcinogens are safe at any level of exposure and what are the precise effects of a particular toxic substance in the dosage to which particular people have been exposed. 4/

Regulation has increased the demand for toxicological research. Chemical firms, for example, might desire to keep abreast of scientific research that might lead to particular chemicals being suspected of causing cancer. This is mainly a defensive reason for supporting research. But such knowledge may give one firm an advantage over another, or enable firms to predict the biological effects of their products.

1/John B. Schnapp et al., Corporate Strategies of the Automotive Manufacturers (Lexington, Mass.: Lexington Books, 1979), p. xiv. Schnapp shows that "despite the efforts of the automakers to delay 'point of no return' decisions as long as possible in the cycle, they are nonetheless making many basic decisions without the confidence that a closer-in view of consumer interests and behavior would provide. This increases risks, especially for the smaller U.S. companies that cannot absorb any major product errors." Schnapp et al., Corporate Strategies of the Automotive Manufacturers, p. xiv.

2/Mansfield, "Basic Research," p. 871.

3/George Eads, "Regulation and Technical Change: Some Largely Unexplored Influences," American Economic Review, vol. 70, no. 2, May 1980, pp. 50-54.

4/For other examples of possible scientific questions, see "Regulating Cancer - Fast, Fast, Fast Relief," Regulation, vol. 4, no. 2, March/April 1980, pp. 4-7.

Regulation may have the effect of getting the leading firms in a particular industry to cooperate in funding generic research or research that is useful to several firms equally, as basic research might be. For example, the chemical industry has collaborated on funding a toxicological research institute, rather than having each company rely on academic research or increase its own research. 1/

Summarizing, we found some evidence to support the proposition that regulation caused a decline in basic research in industry and research on relatively risky projects but this evidence does not all point in the same direction. There has been a rise in research projects lasting 5 years or more in certain industries (e.g., automobiles and drugs) that are heavily affected by regulation. Also, evidence suggests that particular research fields, such as toxicology, have benefited from increased interest due to regulation. Thus, our conclusion should be that while overall basic risky and innovative research projects may have declined, other types of research, most notably long term and defensive projects, have increased. Nothing suggests a trend away from longer to shorter projects.

Uncertainty

A fourth direct effect of regulation may be to affect the uncertainty of R&D projects. If the regulatory environment is unstable, so that firms cannot predict what regulations will be in effect 3 to 5 years from now when the R&D carried out today will result in new products and processes, then they cannot predict whether the products or processes they might create will be legal under future regulations. This regulatory uncertainty can add an additional layer of uncertainty to that which already exists in any R&D project. Generally speaking, firms are risk averse--that is, they must be compensated for the burden of bearing additional risk by being able to make additional profits if the risky venture is successful. If regulation increases risk, then firms will require an R&D project to promise a higher potential return to compensate for the additional risk. Fewer R&D projects will meet this higher standard. 2/

Technology-forcing regulations

The discussion so far assumes that regulation may have a negative effect on the rate of return to innovation activities. By increasing the rate of return somewhat, regulation might increase

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1/William Reddig, "Industry's Preemptive Strike Against Cancer," Fortune, February 13, 1978, pp. 116-119.

2/Eads, "Regulation and Technical Change," pp. 52-53.

R&D. By reducing the rate of return somewhat, R&D might be discouraged. In many cases, however, this sort of explicit rate-of-return calculation never takes place. If compliance with regulation is legally required for a firm to stay in business, and if R&D is necessary to comply with the regulation, then the firm may do the necessary R&D without even considering explicitly what its rate of return to those projects is. On the other hand, to the extent that regulation reallocates resources away from non-regulated induced projects, fewer of those will be undertaken and they will be the ones with higher expected rates of return. (In some cases, of course, where the costs of compliance are high and the firm's business prospects are marginal anyway, the firm might well shut down rather than comply with the regulation.) Such regulations are often referred to as "technology-forcing." 1/

It is important to define exactly what is meant by the term "technology-forcing regulation." At least two possible meanings might be considered. First, regulations may force firms to use different processes and to produce products with different characteristics than they would otherwise have done. Second, regulations might lead to a major or minor advance in the technological state of the art in the regulated industry. In other words, regulations may simply involve substituting one well-known product or process for another to satisfy regulatory requirements without any significant advances in the particular industry. On the other hand, they might stimulate innovations (radical or not) in a particular industry.

Several examples of regulatory statutes which attempt to affect industrial technology follow. The Clean Air Act Amendments of 1970 (84 Stat. 1676) and of 1977 (91 Stat. 685) require that all new industrial capacity must use the best available control technology to reduce emissions. This requirement then results in new source performance standards for new sources of pollution and modified existing sources of pollution. These standards are technology related and depend on the equipment used in a particular plant. The Federal Water Pollution Control Act Amendments of 1972 (86 Stat. 816) also base standards on technology, requiring best practicable technology to be in place by 1977 and best available technology by 1983. 2/ According to Freeman, by

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1/See, for example, Randle, "Forcing Technology" Yale Law Journal, vol. 88, no. 8, July 1979, pp. 1713-34.

2/For discussion, see A. Myrick Freeman, III, "Air and Water Pollution Policy," in Current Issues in U.S. Environmental Policy, Paul R. Portney, ed. (Baltimore: Johns Hopkins University Press, 1978), pp. 16-17. See also Raymond S. Hartman, Kirkor Bozdogan, and Ravindra N. Nadkarni, "The Economic Impacts of Environmental Regulations on the U.S. Copper Industry," Bell Journal of Economics, vol. 10, no. 2, Autumn 1979, pp. 591-592.

basing standards on technology, regulators are relieved of any necessity to estimate how much pollution a particular body of water can take without exceeding water quality standards.

A recent evaluation of the technology-forcing aspects of the Clean Air Act Amendments of 1970 and 1977 found that these laws did force technical innovation, and lead to the development of new innovative pollution control technologies, especially in the copper smelting and electric power industries. 1/ However, these laws and the regulations interpreting them have also created barriers to innovation. Randle shows that the new source performance standards "discouraged utilities from seeking further improvements in removal efficiency, because these improvements might then serve as the basis for expensive new standards." 2/ Thus, there is a need for some mechanism to enable continuous progress in pollution abatement and control to overcome this problem.

The Clean Air Act Amendments also applied to mobile sources, such as automobiles. While delays in complying with these regulations have been granted to automobile manufacturers, the amendments have clearly stimulated much more rapid adoption of pollution control technology than would otherwise have taken place. However, some have argued that the regulations have induced U.S. automobile manufacturers to choose technologies (like catalytic converters) that minimize their risks, even if the technologies are more expensive to consumers than alternative, more radical approaches to pollution control (such as stratified-charge engines). 3/

EFFECT OF POLLUTION ABATEMENT ON R&D SPENDING

We can also examine the figures on overall industrial R&D spending for pollution abatement and control to observe regulatory effects on the industrial R&D portfolio. Table 4 gives us industrial R&D spending for pollution abatement and control for the 2 most recently available years. Note that industry is spending large amounts of money on R&D to satisfy just this one type of regulatory requirement. Thus, the total spending on all regulatory requirements would be even larger. Of course, some percentage of this money would have been spent in the absence of regulation. However, we are justified in assuming that regulation has tended to force R&D spending in directions that it would not have gone otherwise. The effects of regulation on the amount of overall R&D spending is less clear.

1/Randle, "Forcing Technology," pp. 1717-19.

2/Ibid., p. 1727.

3/Eugene P. Seskin, "Automobile Air Pollution Policy," Current Issues In U.S. Environmental Policy, Paul R. Portney, ed., (Baltimore: Johns Hopkins University Press, 1978), pp. 33-87.

Table 4

Industrial Expenditures for Pollution Abatement R&D Compared with all R&D Spending ($ in millions)

	1977	1978
Total all industry-financed R&D	19,407	22,098
All pollution types:	$918	$1,050
Air pollution (total)	685	787
Auto emissions	495	531
Electric power plant emissions	67	93
All other air pollution	123	163
Water pollution	105	114
Solid waste	28	30
Other pollution types	100	119

Source: Science Indicators 1978, National Science Board, 1979, NSB-79-1, p. 217, and National Patterns of Science and Technology Resources 1980, National Science Foundation, NSF-80-308, U.S. Government Printing Office, Washington, D.C., 1980, p. 25.

INDIRECT EFFECTS OF REGULATION

Regulation may affect R&D indirectly by changing the structure of an industry, which may in turn affect R&D levels in that industry. Grabowski and Vernon, for example, argue that innovation in the drug industry has become more concentrated in a small number of firms since the 1962 Kefauver-Harris amendments to the Food, Drug, and Cosmetics Act. 1/ Clarkson et al., make a similar argument in connection with the automobile industry, 2/ and this effect has also been noted in the lawnmower industry. 3/ The

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1/Grabowski and Vernon, "Structural Effects of Regulation," p. 192.

2/Clarkson et al., "Regulating Chrysler Out of Business?," p. 45.

3/Stanford Research Institute, An Analysis of the Proposed CPSC Lawnmower Safety Standard, Menlo Park, Calif., May 1977, p. S-1.

general argument has two parts. First, the costs of regulation are largely fixed costs, or at least rise more slowly than production volume. Thus, larger firms have lower regulatory costs per dollar of sales than smaller firms do, and therefore find that their costs of doing business are less, relative to those of their competitors. This gives a competitive advantage to larger firms, and tends to drive smaller firms out of business, thus increasing the degree of concentration in each regulated industry.

The second part of the argument is that more concentrated industries, composed of larger firms, tend to spend less on R&D than more competitive industries with smaller firms. This increase in concentration tends to reduce spending on R&D. If, however, more concentrated industries spend more on R&D, then the regulation would tend to increase R&D spending. We shall consider each part of the argument in turn.

Within the automobile industry, the argument is that the Chrysler Corporation has been at a disadvantage because it must shoulder the same absolute financial burden in meeting regulations along with General Motors and Ford, two larger firms. "Thus the inadvertent result may be to cripple the smaller firms and concentrate market share in the hands of the biggest and wealthiest corporations." 1/ It is not clear, however, that this has been the effect of regulation. According to industry estimates, the cost of regulation for the period 1978-85 is projected to be 4.6 percent of sales for General Motors, but only 4.2 percent for Ford, despite the fact that Ford is a much smaller firm, which should, according to the hypothesis advanced above, have higher regulatory costs per dollar of sales. However, Chrysler is expected to spend 7 percent of sales to meet regulatory requirements. 2/ Much of the regulatory burden involves costs of retooling capital equipment. Since the smaller firms in the automobile industry have historically had lower capital costs per vehicle sold than the larger firms, 3/ this portion of the regulatory burden would be lower for the smaller firms, both absolutely and per vehicle, than for the larger firms. One study found that Chrysler spent less per vehicle than either Ford or General Motors to meet two of the most expensive safety standards that auto companies must meet. 4/ It is not clear why these trends differ because we did not examine the types of expenses included by each firm or in each study.

1/Clarkson et al., "Regulating Chrysler Out of Business?," p. 44.

2/Ibid., p. 46.

3/U.S. National Highway Traffic Safety Administration, Office of Plans and Programs, The Effects of Automobile Regulations on Industry Competition, November 1979, p. IV-32.

4/Ibid., p. IV-27.

The same argument has been made in connection with the lawnmower industry. The Consumer Product Safety Commission has proposed lawnmower safety regulations that would become effective in June 1982 (16 CFR 1205). The Stanford Research Institute (now SRI International) has projected that these regulations would lead to the failure of some of the 55-70 manufacturers currently producing lawnmowers, thus resulting in a more concentrated industry. 1/

Finally, Birnbaum has argued that regulations issued in 1974 by the Bureau of Radiological Health (now part of the Department of Health and Human Services) governing the manufacture and testing of x-ray devices have tended to increase concentration in the x-ray manufacturing industry. 2/

The second part of the argument rests upon the assertion that larger firms perform less R&D per dollar of sales than smaller firms. This issue was first raised by Schumpeter nearly 40 years ago. 3/ The literature has been summarized recently in detailed surveys, 4/, 5/, but they are beyond the scope of this report and too voluminous for us to summarize in detail. Their general conclusion is that while very small firms may be disadvantaged in performing R&D, very large firms spend no more, per dollar of sales, and are no more effective at R&D than medium-sized firms. Kamien and Schwartz, for example, conclude that "studies over the last 10 years have typically shown that while there may be certain advantages of size in exploiting the fruits of R&D, it is more efficiently done in small to medium size [sic] firms than in large ones." 6/ Scherer concludes:

1/Stanford Research Institute, CPSC Lawnmower Safety Standard, pp. E-33-E-35. See also The New Republic, December 27, 1980, pp. 17-18.

2/Philip H. Birnbaum, "The Choice of Strategic Alternatives Under Increasing Regulation in High Technology Companies," paper presented to the Operations Research Society of America, October 1979, pp. 15-16.

3/Joseph A. Schumpeter, Capitalism, Socialism, and Democracy (New York: Harper and Row, 1942), ch. 8.

4/Morton I. Kamien and Nancy L. Schwartz, "Market Structure and Innovation: A Survey," Journal of Economic Literature, vol. 13, no. 1, March 1975, pp. 1-37.

5/Frederic M. Scherer, Industrial Market Structure and Economic Performance (Chicago: Rand McNally, 1980), ch. 15.

6/Kamien and Schwartz, "Market Structure," 1975, p. 9.

> "A bit of monopoly power in the form of structural concentration is conducive to invention and innovation, particularly when advances in the relevant knowledge base occur slowly. But very high concentration has a favorable effect only in rare cases, and more often it is apt to retard progress by restricting the number of independent sources of initiative and by dampening firms' incentive to gain market position through accelerated research and development." 1/

This pattern varies somewhat from industry to industry. Several studies have found that the larger firms in the chemical industry seem to do more R&D than the smaller firms, but it is not clear whether these results could be generalized for any other industry. 2/ In the automobile industry, Chrysler spends less on R&D per dollar of sales than either Ford or General Motors. 3/ And in the x-ray manufacturing industry, innovation is apparently concentrated among the largest firms. 4/ Kamien and Schwartz point out that "most small firms do not engage in research and most very large firms do." 5/ In several industries, therefore, in which regulation may cause industry concentration to increase, the effect on R&D spending seems likely, if anything, to be positive.

1/Scherer, Industrial Market Structure, 1980, p. 438.

2/See, for example, Edwin Mansfield, "Rate of Return from Industrial Research and Development," American Economic Review, vol. 55, May 1965, pp. 310-322, and Henry G. Grabowski, "The Determinants of Industrial Research and Development: A Study of the Chemical, Drug, and Petroleum Industries," Journal of Political Economy, vol. 76, no. 2, March/April 1968, pp. 292-306. Link has recently found a similar relationship between size and the rate of return to R&D in the chemical industry, but he finds that it does not obtain for firms in the industry with annual sales of more than $297 million (in 1975 dollars), which includes the majority of the firms and the vast majority of the output of the industry. See Albert N. Link, "Firm Size and Efficient Entrepreneurial Activity: A Reformulation of the Schumpeterian Hypothesis," Journal of Political Economy, vol. 88, no. 4, August 1980, pp. 771-782.

3/U.S. NHTSA, Effects of Automobile Regulations, p. IV-49.

4/Birnbaum, "The Choice of Strategic Alternatives," October 1979, pp. 14-16.

5/Morton I. Kamien and Nancy L. Schwartz, "Market Structure and Innovation: A Survey," Journal of Economic Literature, vol. 13, no. 1, March 1975, p. 3.

REGULATION AND THE SOCIAL RATE OF RETURN

Since the effect of regulation on R&D is positive in some cases and negative in others, it is difficult to determine its net effect. The effect largely will be not to change the overall level of spending on (or rate of) R&D, but rather to change its direction--away from some types of R&D and toward others. Whether this change in direction is desirable or not depends on the "social rate of return" from this activity.

While the private rate of return is the flow of profits and other benefits (as a percentage of the original investment) to the firm which incurred the costs of innovation, the social rate of return is the flow of benefits to society as a whole. The private, unregulated economy will tend to direct resources towards R&D projects that promise high private rates of return. The rationale of regulation, insofar as it affects R&D, is to redirect R&D toward projects with high social rates of return, even if they have low private rates of return. This is accomplished in part by actively discouraging R&D projects with high private rates of return but low, and possibly negative social rates of return. Any assessment of the efficacy of regulation, therefore, must consider the relative social rates of return of the R&D encouraged and discouraged by regulation.

Private and social rates of return may diverge for a variety of reasons. In the absence of regulation, external costs such as pollution would not enter into calculating the private rate of return, but they would enter, as a cost or benefit, into calculating the social rate of return. Social costs, like pollution, can drive the social rate of return below its private rate of return, and perhaps even render it negative. Other forms of market failure, such as imperfect information, may also cause private and social rates of return to diverge. Products harmful to consumers, such as thalidomide, may find a market for a time because of imperfect information. In the absence of complete and equally shared information, the producers of such products may be able to earn a substantial private rate of return despite the fact that the social rate of return is negative.

While the costs and benefits to the private performers of R&D can only be measured with some degree of accuracy, after the innovation has wide market acceptance the costs and benefits to society are more difficult, if not impossible, to measure. Even when an R&D project may hold the promise of a worthwhile advance, it may also hold some small possibility of a societal disaster. Even if we could accurately measure all the costs and benefits, before the fact, it is still essentially a political decision to decide how much risk society is willing to bear to achieve a given advance. The political dimension of these decisions is accentuated by the fact that the costs and benefits generally fall on different people.

SUMMARY

Based on the literature we reviewed, regulation has both positive and negative effects on research and development. Often it increases the costs of developing, producing, and marketing a product. In some cases, however, regulation may reduce costs. Regulation normally increases the demand for technologies that are needed to comply with regulation, and thus stimulates the R&D necessary to develop such technologies. A major effect of regulation is to change the direction of R&D toward that designed to satisfy regulatory requirements. On the other hand, R&D devoted to new and risky products may have decreased. Regulation may increase the uncertainty facing a firm, and thus discourage R&D, or it may reduce uncertainty and encourage R&D. In some cases, firms perceive regulation as requiring that R&D be performed, without regard to costs. Regulation may also have indirect effects on R&D by changing the concentration of an industry, but the direction of this effect is uncertain.

It is difficult to assess the net effect of regulation on R&D. For the most part, the effect is to change the direction of R&D rather than the total amount of R&D spending. Whether this change in direction is desirable depends upon the value placed on the Federal policy goals regulations attempt to achieve as against the goals implicit in a relatively free market.

CHAPTER 4

REGULATION AND RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY

Most regulated industries in the United States face controls on rates of return, prices, entry into the industry, or controls on emissions of pollutants or safety of products. While these regulations may affect R&D, they are not restrictions placed directly on the R&D process. However, the pharmaceutical industry, a research-intensive sector with much innovation, has had regulatory control imposed directly on its innovation process by the Food and Drug Administration (FDA) because drug safety and effectiveness are of conern to the public. The effects of regulatory requirements are much more visible in this industry because it is R&D intensive, both in R&D spending and in new drugs discovered; and because regulatory stringency increased during the last 2 decades. In addition, we have a good measure of innovative output in the pharmaceutical industry: new drugs. 1/ This measurement allows one to draw conclusions about possible regulatory effects on R&D with more confidence. The high visibility of regulation on the innovation process in the drug industry provides insight into those effects which are not quite so evident in other industries. For these reasons we chose to more closely examine the pharmaceutical industry for the effects of regulation on R&D.

However, the peculiarities of this industry may cause conclusions drawn from our examination to be unrepresentative. Other industries may not be as deeply affected by regulation, or if affected strongly, may not show such dramatic effects on R&D.

THE DRUG INDUSTRY IN HISTORICAL PERSPECTIVE

In the 1920s and 1930s, the U.S. pharmaceutical industry was structured very differently than it is today. Since most of the medicines sold did not require prescriptions, most drug industry advertising was directed at consumers, rather than medical doctors, as it is today. Pharmaceutical companies did little

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1/The economic and medical value of new drugs varies greatly. In this chapter we consider new chemical entities (NCEs), a small fraction of total new drugs but including all important therapeutic discoveries. A therapeutic breakthrough in the drug industry will be reflected in the statistics. This is not always true for other industries, which may rely on secrecy to protect their innovative discoveries.

research. Medicines were compounded by pharmacists, not by drug companies. 1/

This situation changed drastically in 1938, when one of the new sulfa drugs (sulfanilamide) was marketed in a liquid form. The liquid in which the sulfanilamide was dissolved proved to be poisonous; more than 100 people died after taking the drug. 2/ The disaster led to the passage of the Federal Food, Drug, and Cosmetic Act of 1938. This law required that drugs sold had to be proved safe, and that much more information had to be included on drug labels than had previously been the case. FDA regulations accompanying the Act effectively prohibited consumers from obtaining newly discovered drugs without a prescription. This major change in the mechanics of obtaining drugs was legislatively ratified in 1951. 3/ This change also prompted drug companies to direct their advertising toward physicians and away from consumers.

In 1962, the second major stimulus to pharmaceutical regulation was the thalidomide case. Thalidomide was used as a sleeping pill and an anti-emetic. It was distributed commercially in Europe, primarily in Britain and West Germany between 1959 and 1962. Its use by pregnant women caused birth defects. Between 2,000 and 6,000 deformed babies were born in West Germany, and about 500 in Britain while the drug was distributed. 4/ Although thalidomide was never distributed for clinical use in the United States, some doctors obtained it and used it for experimental purposes. FDA estimated that 10 deformed children were born in the United States as a result of thalidomide use. 5/ This drug disaster spurred passage of the 1962 Kefauver Amendments to the Food, Drug, and Cosmetic Act, requiring proof of effectiveness in all drugs, in addition to the proof of safety formerly required. 6/ Also, the testing procedures for a new drug were made

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1/Peter Temin, "Technology, Regulation, and Market Structure in the Modern Pharmaceutical Industry," Bell Journal of Economics, vol. 10, no. 2, Autumn 1979, pp. 433-434.

2/Peter Temin, "The Origin of Compulsory Drug Prescriptions," Journal of Law and Economics, vol. 22, no. 1, April 1979, pp. 94-95.

3/Ibid., pp. 96-102.

4/Morton Mintz, By Prescription Only (Boston: Beacon Press, 1967), revised edition, chapter 12. See also The New Encyclopedia Britannica: Micropaedia (Chicago: Helen Hemingway Benton, 1974), vol. 9, p. 920.

5/Mintz, By Prescription Only, p. 261.

6/Mark Nadel, The Politics of Consumer Protection (Indianapolis: Bobbs-Merrill, 1971), pp. 121-130.

subject to FDA regulation. These changes significantly lengthened the time required to gain FDA approval of a new drug for marketing purposes.

MEASUREMENT OF R&D IN THE DRUG INDUSTRY

In the pharmaceutical industry, it is possible to obtain measures of innovation activity--new drugs introduced since 1951. 1/ The measures of new drugs can be divided into three main groups: new chemical entities (NCEs), other new drugs, and new dosage forms. New chemical entities are new drugs that have not been previously marketed and which contain a single chemical formula. NCEs include the vast majority of important therapeutic breakthroughs. 2/ "Other new drugs" tend to be combinations of older, previously marketed NCEs and duplications of NCEs sold under a new brand name. 3/ Sometimes "other new drugs" are marketed to treat a new symptom or disease; often they are sold by a new manufacturer. The third category of new drugs is new dosage forms, such as a liquid form of a drug previously sold as a pill. Table 5 compares the average annual number of each of these types of drugs introduced from 1963-70. Although the "other new drugs" and "new dosage forms" are innovations, we will concentrate on the NCEs, since these drugs cost more to develop and represent the more important therapeutic breakthroughs.

Table 5

Average Annual Number of New Drugs Introduced, 1963-70 a/

Type of drug	Number
New chemical entities (NCEs)	16.1
Other new drugs	94.4
New dosage forms	26.4
Total	136.9

a/Peltzman, "The 1962 Drug Amendments," p. 1053.

1/Sam Peltzman, "An Evaluation of Consumer Protection Legislation: The 1962 Drug Amendments," Journal of Political Economy, volume 81, no. 5, September/October 1973, pp. 1053-54.

2/Peltzman, "The 1962 Drug Amendments," p. 1054.

3/Ibid., p. 1053.

DIRECT EFFECTS OF REGULATION

In chapter 2, we noted that R&D is regarded as an investment and is directly affected by the influence of regulation on the rate of return on the innovation. Studies on this subject have shown that the increased costs due to regulatory requirements changed the rate of return to innovation efforts in the pharmaceutical industry from the period prior to 1962 (the date of the Food and Drug amendments) to the post-1962 period. A study by Henry Grabowski and John Vernon found that the average development costs for an NCE rose by a factor of 10 between 1962 and 1972. 1/ In addition, they found that the average NCE took 7-1/2 to 10 years to obtain approval from FDA, as opposed to about 2-1/2 years before 1962. 2/ Lasagna found that the average cost of introducing an NCE into the U.S. market is now over $50 million, and takes 8 to 10 years. 3/ In the United States, the number of NCEs per R&D dollar fell by a factor of six between the 1960-61 and 1966-70 period. 4/ Baily pointed out that the rate of innovation between 1962 and 1969 was somewhat less than half the pre-1961 level, because 224 NCEs were developed by the pharmaceutical industry from 1954 to 1961, while only 86 were developed from 1962 to 1969 with a much larger expenditure of R&D. 5/ A more recent study found that the expected return to pharmaceutical

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1/Grabowski and Vernon, "Structural Effects," pp. 185-186.

2/This 7-1/2 to 10 year period for developing a new drug is divided into two major phases, the relatively long clinical investigation phase and the relatively shorter new drug application for marketing phase (NDA). When enough data on a drug°s safety and efficacy are available from clinical studies, an NDA is submitted to the FDA for approval. The above studies look at the sum of the two phases.

3/Louis Lasagna, "Who Will Adopt the Orphan Drugs?" Regulation, November/December 1979, pp. 27-32. See also Ronald W. Hansen, "The Pharmaceutical Development Process: Estimates of Current Development Costs and Times and the Effects of Regulatory Changes," in Issues in Pharmaceutical Economics, Robert I. Chien, ed. (Lexington, Mass.: Lexington Books, 1979), pp. 178-180.

4/Grabowski and Vernon, "Structural Effects," 1976, p. 187. See also William Wardell, "Rx: More Regulation or Better Therapies," Regulation, September/October 1979, p. 28.

5/Martin N. Baily, "Research and Development Costs and Returns: The U.S. Pharmaceutical Industry," Journal of Political Economy, vol. 80, no. 1, January 1972, pp. 70-85.

innovations fell from 11.4 percent to 3.3 percent under the most likely assumptions. 1/

Reduction in NCE output

The increased costs of and decreased returns of innovations since 1962 have been paralleled by a decrease in innovations as measured by the average annual number of new drugs introduced from 1951 to 1970. 2/ See table 6. We can see that after 1962 there was a large drop in the rate of introducing new drugs. This drop is also noted by Wardell, who reported a 40 percent drop in NCEs introduced between 1974 and 1976. Wardell found that the "average effective patent life for NCEs that received FDA approval fell from 13.8 years for those approved in 1966 to 8.9 years for those approved in 1977." He attributes this decline to the greatly lengthened FDA approval process. 3/

Table 6

Average Annual Number of New Drugs Introduced, 1951-70

Period	NCEs	Other new drugs
1951-54	39.0	303.0
1955-58	42.0	351.5
1959-62	43.5	239.3
1963-66	17.0	120.0
1967-70	15.3	68.8
1951-62	41.5	297.9
1963-70	16.1	94.4
Ratio (1963-70/1951-62)	0.389	0.317

1/David Schwartzman, The Expected Return from Pharmaceutical Research (Washington, D.C.: American Enterprise Institute for Public Policy Research, 1975), pp. 34, 43.

2/Sam Peltzman, "An Evaluation of Consumer Protection Legislation: The 1962 Drug Amendments," Journal of Political Economy, vol. 81, no. 5, September 1973, p. 1053.

3/William Wardell, "Rx: More Regulation or Better Therapies?," Regulation, vol. 3, no. 5, September/October 1979, American Enterprise Institute for Public Policy Research, p. 28.

In a recent report 1/ we found that the new drug application (NDA) process required about 20 months. We also found that some important drugs have been approved by foreign countries in less time than the United States has taken, even when those drugs provided a major therapeutic advance. All these studies support the conclusion that there has been a decline in innovation in the drug industry, but not that there has been a decline in R&D spending.

Isolating regulation as a cause

A combination of factors may have led to the decreased introduction of NCEs recently. One possible factor is that the great rate of innovation in the immediate post-World War II period represented a rapid series of breakthroughs that could not be expected to continue at the same pace. The situation can be visualized as an underlying stock of research opportunities that have been "depleted" by the great breakthroughs of the 1940s and 1950s. 2/

One way to hold constant the role of basic scientific knowledge is to compare the United States with other countries on roughly the same scientific plane. Comparisons of regulatory effects have revealed several differences between the United States and other countries, especially the United Kingdom. Presumably the same scientific knowledge is available in both countries, but between 1960-61 and 1966-70, the number of NCEs introduced in the United States per R&D dollar fell by a factor of six, while in the United Kingdom the number fell by a factor of only three. 3/ Thus there is a relative decline in U.S. drug innovation relative to British innovation, which cannot be blamed on the lack of biomedical knowledge. Grabowski, Vernon, and Thomas found that, although some factor has been at work depressing the

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1/U.S. General Accounting Office, FDA Drug Approval--A Lengthy Process that Delays the Availability of Important New Drugs (HRD-80-64, May 28, 1980). Unlike some of the studies cited previously which look at the sum of the times for both the drug development and approval (NDA) process, the GAO report refers to only the approval process, the shorter of the two processes.

2/For a discussion of this point, see Henry Grabowski, Drug Regulation and Innovation (Washington, D.C.: American Enterprise Institute for Public Policy Research, 1976), p. 19.

3/Henry G. Grabowski, John M. Vernon, and Lacy Glenn Thomas, "Estimating the Effects of Regulation on Innovation: An International Comparative Analysis of the Pharmaceutical Industry," Journal of Law and Economics, vol. 21, no. 1, April 1978, p. 151.

productivity of pharmaceutical knowledge worldwide, in the United States an additional factor is at work depressing U.S. research productivity. That factor is associated with regulation. 1/ Another study found that the rate of return to pharmaceutical innovations in the United Kingdom consistently exceeds the rate of return to U.S. pharmaceutical innovations. 2/ These factors have led U.S. drug firms to introduce relatively more drugs into foreign markets than into the U.S. market, compared to the pre-1962 situation, and to switch R&D expenditures from domestic R&D to R&D performed abroad. 3/ These factors have helped contribute to the depressing effects of the U.S. regulatory environment on innovation in the pharmaceutical industry.

Although the foregoing evidence illustrates depressing effects of regulation on R&D and innovation, there are grounds for optimism in recent research developments. Recently, pharmaceutical companies have developed new drugs using knowledge in biological sciences. The rigorous drug testing required by regulation has led drug companies to hire more researchers and to use scientific breakthroughs more systematically. It appears that these developments may lead to important drug discoveries in the future, reversing the downward trend in drug innovations. 4/

INDIRECT EFFECTS OF REGULATION ON STRUCTURE OF THE DRUG INDUSTRY

Regulation can alter the structure of an industry. The structure of the drug industry changed as a result of the combination of R&D, FDA regulation, and the patentability of new drugs.

1/Grabowski et al., "Estimating the Effects of Regulation," p. 159.

2/Susan A. Simmons, S.C. Shull, and Mickey C. Smith, "Rates of Return on Research and Development Expenditures in the U.S. and U.K. Pharmaceutical Industries," paper presented at the annual meeting of the American Economic Association, Atlanta, Georgia, December 28-30, 1979.

3/Harold A. Clymer, "The Economic and Regulatory Climate: U.S. and Overseas Trends," in Robert B. Helms, ed., Drug Development and Marketing (Washington, D.C.: American Enterprise Institute for Public Policy Research, 1975), pp. 137-154. See also Henry G. Grabowski and John M. Vernon, "New Studies on Market Definition, Concentration, Theory of Supply, Entry, and Promotion," chapter 3, in Issues in Pharmaceutical Economics, Robert I. Chien, ed. (Lexington, Mass.: Lexington Books, 1979), p. 48.

4/Wall Street Journal, "Strong Medicine: Pharmaceutical Firms Prepare to Introduce New 'Wonder Drugs'," vol. 197, no. 15, January 22, 1981.

First, the technical and regulatory changes led the drug firms to perform R&D and to manufacture the drugs they developed, rather than license their discoveries to other firms. This resulted in a large rise in the size of drug firms over the 1945-72 period. However, these changes did not cause the profitability of the drug industry to increase or decrease relative to that of other industries. In addition, there was no rise in concentration as it is typically measured (four-firm or eight-firm concentration ratios) from 1947-72. 1/

In chapter 3, a two-part argument about the indirect effects of regulation on R&D was developed. First, although we do not agree in all cases, it has been maintained by some analysts that regulatory costs are fixed costs to some extent, and thus rise less quickly than production volume. To the extent that this is true, larger firms have lower regulatory costs per dollar of sales than small firms. This results in a competitive advantage for large firms, and the degree of concentration in the industry could be expected to increase. Secondly, it has been argued that more concentrated industries spend less per dollar of sales on R&D than less concentrated industries, and that increases in industry concentration tend to reduce R&D. The total indirect regulatory effect on R&D is therefore hypothesized to work through changes in concentration of industry sales among the top firms.

While we found a reduction in innovation in the drug industry, we did not find a rise in industry concentration over the 1948-73 period. Thus, the previous argument does not apply exactly to the drug industry. We find a slightly different effect, which is that increased costs of drug development have reduced innovation and led to fewer firms producing new drugs. We found evidence that the reduction in drug innovation has been disproportionately borne by smaller firms.

We would expect that the more strict the regulations on new drug approval and the higher the attrition rate of possible new drugs, the more concentrated drug innovation would become among the largest drug firms. Small firms would have difficulty in coping with expensive and risky R&D projects. This is in fact what we found. Over the 1957-71 period, the number of firms that produced at least one NCE fell by over half. 2/ Thus, there were fewer sources of NCEs during the period that regulations were significantly strengthened. Table 7 shows measures of NCE output

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1/Temin, "Technology, Regulation, and Market Structure," p. 430-432.

2/Grabowski and Vernon, "New Studies in Market Definition," p. 45.

in the U.S. drug industry. 1/ When comparing the four largest firms' shares of NCEs and sales, we found that by the 1967-71 period, these firms had a much larger share of NCE output than total sales. This conclusion is reinforced by examining the percentage of innovative output in the four most innovative firms (not necessarily the four largest). This measure has had a significant upward trend over time. Finally, we can see that the value of innovative output as measured by NCE sales for 3 years after introduction shows a significant downward trend over time. This suggests that innovative output was a much smaller share of drug sales in the 1970s than in the 1950s. 2/

Table 7

Measures of NCE Output in the U.S. Drug Industry

	1957-61	1962-66	1967-71
Number of firms having at least one NCE	51	34	23
Four largest firms' ratio of NCE output	46.2%	54.6%	61.0%
Four largest firms' share of NCE sales	24.0%	25.0%	48.7%
Four largest firms' share of total sales	26.5%	24.0%	26.1%
Total NCE output (NCE sales during 3 years after introduction) ($ million)	$1,220.3	$738.6	$726.8

1/Ibid. See also Henry G. Grabowski and John M. Vernon, The Impact of Regulation on Industrial Innovation (Washington, D.C.: National Academy of Sciences, 1979), pp. 16-17.

2/See also Henry G. Grabowski, John M. Vernon, and Lacy Glenn Thomas, "Estimating the Effects of Regulation on Innovation: An International Comparative Analysis of the Pharmaceutical Industry," Journal of Law and Economics, vol. 21, no. 1, April 1978, p. 138.

PHARMACEUTICAL REGULATION AND THE SOCIAL RATE OF RETURN

Evidence suggests that current pharmaceutical regulation has reduced the number of new drugs, delayed their marketing, and in general lowered rate of return on NCEs. This does not necessarily indicate a reduction of social welfare, however. Since the 1962 amendments established a proof of efficacy requirement, a decline in NCEs would be expected and might indicate that the amendments were having their intended effect in eliminating ineffective new drugs. While critics of the Food and Drug Administration have contended that regulation has deprived American consumers of some useful and even life-saving new drugs, FDA has maintained that the decrease in NCEs has been concentrated in drugs that would have offered little if any improvement over existing substances. After classifying new drug approvals by degree of therapeutic importance, the FDA concluded that nearly all of the post-1962 drop-off was composed of drugs of "little or no therapeutic gain." 1/

Indeed, critics of the pharmaceutical industry charge that much pharmaceutical R&D results in only very slight modifications of existing products, and is imitative rather than directed toward developing important new therapeutic advances. Even if R&D is directed toward imitative research, that is not necessarily bad. Imitative drugs eliminate the monopoly position of the breakthrough drug and spur greater price competition. The presence of large profits on any single new patented drug which represents a breakthrough stimulates R&D in other companies in the same general area, who are typically able to find somewhat different drugs with the same general purpose.

Another issue of social concern is posed by the so-called "orphan drugs." This category consists of those significant advances that combat only diseases of very low incidence, so that large markets for these drugs are not available. Thus, sufficient sales may not occur to pay for the high cost of development and regulatory approval. As a result, drug R&D is being redirected toward research projects with large payoffs and broad applicability. Five cases of promising drugs which fell victim to this and other problems were cited in a study by Lasagna. 2/

1/U.S. Senate Subcommittee on Health, Committee on Labor and Public Welfare, Examination of the Pharmaceutical Industry 1973-74, part 7, Hearings on Legislation Amending the Public Health Service Act and the Federal Food, Drug and Cosmetic Act, 93rd Congress (1974), testimony of Commissioner Alexander Schmidt, p. 3049.

2/Louis Lasagna, "Who Will Adopt the Orphan Drugs?" Regulation, November 1979, pp. 27-32.

In summary, while the private rate of return on innovation in the pharmaceutical industry has declined, the effect on social welfare is less clear. While some limited-use drugs may not be developed, the net benefits of removing ineffective and/or dangerous drugs may be an offsetting welfare gain.

CHAPTER 5

RESEARCH AND DEVELOPMENT AND THE GOALS OF REGULATION

ADVERSE EFFECTS OF REGULATION

In the previous four chapters, we discussed some of regulation's effects on R&D. Regulation has adversely affected R&D and innovation in several ways. Among these are cost increases and regulatory delay, the redirection of research away from projects that focus on new products and processes and toward regulatory requirements, and increases in uncertainty due to future regulation. These effects probably hurt the ability of the U.S. economy to increase productivity and real income.

Cost increases have been one of the major effects of regulatory actions on the innovative process. For example, drug industry development and regulatory clearance costs for new chemical entities rose by a factor of 10 between 1962 and 1972, and new drugs now average 7-1/2 to 10 years for development. The capital expenditures required for pollution abatement R&D and pollution control equipment have reduced the funds available for other types of R&D and capital investment. Firms thus initiate fewer new R&D projects and market fewer innovations. The two leading examples of these trends are the pharmaceutical industry and the chemical industry. In both industries, only those new products with potentially large and assured markets can be introduced due to increased regulatory requirements. Regulatory uncertainty has been added to the normal uncertainty of the research process, which will tend to lead risk-averse firms to do less R&D. Edwin Mansfield has shown that industry is doing less basic research, less R&D aimed at new products and processes, and less R&D aimed at relatively risky projects. His results have been echoed by other surveys. At the same time the National Science Foundation's statistics show increased pollution control R&D spending.

THE BENEFITS OF REGULATION

Regulations were established to satisfy important social goals. The recent rise in regulation in the environmental, safety, and health fields has developed because, left to its own devices, the market system did not prevent excess pollution, occupational disease, dangerous products, and other problems. Correcting these problems has become the major goal of regulatory action for such agencies as EPA and OSHA. These regulatory goals can be realized in different ways, each of which has differing implications for efficiency and equity. Later in this chapter we discuss possible modifications in the means by which regulatory goals may be achieved without the deleterious effects described above.

Regulation can have positive effects on R&D. Redirecting R&D toward pollution abatement and product and occupational safety should lead to technological advances being achieved in pollution abatement and other areas, and these advances should benefit society. Also, the large R&D and capital costs incurred for pollution abatement regulations present a growing market to firms engaged in producing and selling pollution control equipment. In some cases basic research has benefited from regulatory requirements (one example is toxicological R&D in the chemical industry). Even though industry in total has cut back on basic research, Mansfield shows that the percentage of R&D going toward long-term projects (5 or more years) which are not necessarily basic in nature did not decrease over the 1967-77 period.

Another major regulation benefit is exemplified by the decline in introduction of unsafe drugs and pesticides caused by regulatory controls on R&D and new products. These controls are an attempt to deal with the unknown problems which new substances introduced into the environment might possibly cause. In these uncertain situations, many believe it is desirable to proceed with caution, at least until information becomes available to clarify the hazardous potential of new products and processes.

Equity issues also must be considered when deciding how far and in what areas to pursue regulatory actions. In the safety area, society might find it desirable to prevent accidents to stop heavy costs from falling on certain persons who may be considered less able to bear those costs, even if those persons are aware of the risks and are willing to bear them. In environmental regulation, one observer has estimated that the benefits of pollution control will be concentrated in the metropolitan areas most heavily affected while the costs will be more evenly spread. 1/ This may be desirable to prevent residents of these areas from bearing the brunt of the pollution costs, even if they do not pay the full cost of the benefits they receive.

R&D is a type of investment with unknown payoffs. As the cost of this investment increases the likelihood of less R&D investment increases. Edwin Mansfield shows that society may benefit even more from industrial innovations resulting from R&D than private firms do, which suggests that society ought to encourage more industrial R&D than firms would pay for on their own. 2/

1/Henry M. Peskin, "Environmental Policy and the Distribution of Benefits and Costs," in Current Issues in U.S. Environmental Policy, Paul R. Portney, ed. (Baltimore: Johns Hopkins University Press, 1978), p. 151.

2/Edwin Mansfield, John Rapoport, Anthony Romeo, Samuel Wagner, and George Beardsley, "Social and Private Rates of Return from Industrial Innovations," Quarterly Journal of Economics, vol. 91, no. 2, May 1977, p. 234.

On the other hand, the fact that drugs and toxic chemicals are regulated suggests that in the absence of regulation, the social benefit from R&D in those areas would be lower or negative. If this is true, some action restricting R&D in those areas may be indicated. Thus, even though drug innovation has been shown to be adversely affected by regulation, which is a social cost, the posssibly unsafe drugs kept off the market will be a corresponding social benefit.

The relationship between R&D and productivity can also be affected by regulation. In general, research advances will stimulate productivity increases. However, the relationship is unclear because many research advances are not measured in productivity statistics, and productivity can increase for other reasons. Regulation which redirects research into areas with lower private than social returns such as pollution control R&D, may benefit society while actually reducing measured productivity. This is because the innovation resources used to reduce pollution will be measured, but the economic value of increased clean air will not be. Thus, regulatory policy ought not be based solely on whether it can increase measured productivity. Mansfield's results suggest, however, that in general a stimulus to R&D would benefit society, since for a broad range of manufacturing innovations, the social return is higher than the private return.

R&D projects which may lead to a promising new product may also have unintended impacts. It may be impossible to measure all the costs and benefits of a project accurately. A political decision must be made to decide how much uncertainty must be borne to achieve a given advance. In addition, costs and benefits of regulation generally fall on different members of society. A change in direction of R&D spending may or may not be worthwhile, depending on how strongly society feels about the goals and means of regulation versus the goals and methods involved in a relatively free market.

POSSIBLE REGULATORY METHODS TO PROMOTE R&D AND INNOVATION

Several possible regulatory approaches might be taken in the future to encourage R&D and innovation. These include such policies as using economic incentives to attain regulatory objectives rather than normal command and control regulation, reducing regulatory delay, and using performance standards rather than design standards. No one policy will make regulations costless, but implementation of some of them should lead to increased efficiency in attaining regulatory goals.

Economic incentives can make regulatory goals attainable in a more efficient manner. To begin with, the 1970 and 1977 Clean Air Act Amendments require the use of best available control technology in reducing emissions of pollutants from industrial plants. Thus, if a firm invests in research to develop a pollution-reducing device and applies it to one of its several plants, the firm would

then have to install the device in all its plants, as would its competitors. So, any incentive the firm had to develop new pollution control technology might be reduced unless the firm could sell the innovation to other firms. If, on the other hand, a tax were placed on emissions of pollutants, any reduction in emissions by any firm would save taxes paid, and the firm's incentive to install new pollution control devices and to do R&D in pollution control might be increased. Of course, an increase in the degree to which firms buy pollution control research results and technology from other firms may tend to reduce this problem.

Reductions in regulatory delay may also lead to increased innovation. One example of regulatory delay is the FDA drug approval process, which has been shown to increase the time required to bring new drugs to market. 1/ Reducing this regulatory delay would increase the number of people who can benefit from new drugs, and reduce the costs of bringing those drugs to market. This would lead, in turn, to a higher return on the research done in the pharmaceutical industry, and might stimulate more research. Increases in the speed with which new products, processes, and services are brought to the market will reduce the costs of innovation and/or raise the rates of return to innovations.

The increased use of performance standards in regulation, rather than design standards, may stimulate innovation and R&D. With these standards, regulated businesses may reduce compliance costs by determining the most efficient means of attaining regulatory goals, and the need to change regulations to meet new conditions can be reduced. One example of the use of these standards is EPA's "bubble" policy which allows firms to use any type of control on pollutants to achieve an overall standard, rather than specifying limits for each pollution source and each level of technology used. The U.S. Regulatory Council estimated that the "bubble" policy will save "between 15 and 20 percent of the total compliance costs for air pollution..." and will encourage the development of innovative pollution control methods. 2/ In this case, the effect of performance standards on R&D spending is ambiguous, since part of the compliance costs saved may be R&D. But performance standards do have the potential to make the regulatory process operate more efficiently, although they are not the solution to all regulatory problems. The policies discussed here can make the innovation process work more efficiently. However, we are not sure of the precise magnitude of these effects. It is often hard to show where innovations have not been made, or where

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1/U.S. General Accounting Office, FDA Drug Approval--A Lengthy Process that Delays the Availability of Important New Drugs (HRD-80-64, May 28, 1980).

2/United States Regulatory Council, Innovative Techniques in Theory and Practice: Proceedings of a Regulatory Council Conference, July 22, 1980, p. 21.

R&D spending has been foregone. The evidence suggests that changes in regulatory policies may tend to lead to significant economic gains in new products, processes, or services, even if the exact location and degree of these gains are not predictable.

As arranged with Senator Bentsen's office, we did not obtain agency comments on the matters discussed in this report.

CONCLUSIONS

Regulation in the environmental, safety, and health areas can provide society with benefits which may not be obtainable through the market system, such as cleaner air or safer products. These benefits are not costless; one important cost is adverse regulatory effects on R&D and innovation. Regulatory attempts to achieve social goals have had some negative effects on R&D. Cost increases resulting from regulation have reduced the rate of return to innovations in some cases, thereby leading to less R&D and innovation. In other areas, regulation has induced changes in the composition of industrial R&D, away from riskier and more basic research.

Offsetting the adverse effects on R&D, there are some positive effects of regulation. Technical change has been achieved in pollution abatement, and fewer unsafe drugs and pesticides are being introduced into the marketplace. In addition, regulations encourage the performance of R&D with a potentially high social return, even if the private return is low.

Using economic incentives rather than current regulatory standards may reduce regulatory delay, and using performance standards rather than design standards can make the innovation process work more efficiently and can reduce the negative effects of regulation.

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