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REGULATION AND TECHNOLOGICAL INNOVATION IN THE CHEMICAL INDUSTRY

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I

INTRODUCTION

Economists, social theorists, and those concerned with technology each bring different perspectives to an analysis of environmental, health, and safety regulation. Environmental, health, and safety regulation, as seen by economists, has as its purpose the correction of market imperfections in order to internalize the social costs of industrial production. The effects of regulation result in a redistribution of the costs and benefits of industrial activity among manufacturers, employers, workers, consumers, and citizens in general. Within the traditional economic paradigm, economically efficient solutions of the proper balance between costs and benefits of any given activity are the major concern. The distributive effects are considered secondary to considerations of economic efficiency. Quite understandably, therefore, the techniques of cost-benefit analysis and cost-effective analysis have arisen to aid in the decisionmaking process of what and how much to regulate.

In contrast, in viewing regulation the social theorist not only focuses on the distributive effects of regulation, but in some cases also sees regulation serving a redistributive function between the regulated industry and the intended beneficiaries of regulation, such as workers, consumers, and the general public. Costs and benefits are not necessarily to be balanced according to criteria of economic efficiency or cost effectiveness. Rather, questions of justice and fairness drive the decisionmaking process. As a result, a trade-off analysis, involving an articulation of those who "win" and "lose" from a regulatory action, becomes the analytical tool rather than traditional cost-benefit analysis.

Regulation may also have a significant redistributive effect between and within different industrial sectors because it affects the use and development of technology. Furthermore, regulation may be more effectively implemented if the decisionmaker gives careful thought to the *mechanisms* by which the technological change necessary to implement regulatory goals is effectuated, rather than merely

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specifying a risk reduction requirement. Technological innovation and diffusion are essential for regulation to succeed, and deliberate attention must be paid by regulators to encourage *specific* kinds of technological change in the *appropriate* industrial sectors. However, before decisionmakers can begin to fashion regulations that elicit appropriate technological responses from industry, it is necessary to understand how regulation has affected technological change.

The Center for Policy Alternatives (CPA) at the Massachusetts Institute of Technology has been involved with this question within the context of the chemical and pharmaceutical industries for almost ten years. This article reviews the work of CPA as well as other published work on this question. The article seeks to accomplish four purposes: (1) describe technological innovation in the chemical industry; (2) construct a conceptual framework within which to view the effects of regulation on technological change; (3) evaluate these effects, based on empirical work and observation; and (4) suggest conclusions concerning the effects of regulation on technological change emerging at this time.

II

TECHNOLOGICAL INNOVATION

A. Basic Concepts

Technological innovation is the first *commercially* successful application of a new technical idea.[1] By definition, it occurs in those institutions, primarily private profit-seeking firms, that compete in the commercial marketplace. Innovation should be distinguished from invention, which is the development of a new technical idea, and from diffusion, which is the subsequent widespread adoption of an innovation by those who did not develop it. Line drawing between innovation and diffusion is complicated by the fact that innovations can rarely be adopted by new users without modification. When these adaptations become extensive enough, another innovation may have in fact occurred.

There are different types of innovation. A convenient separation is often made between product and process innovation, the former being a saleable new end product, and the latter a change in the production process. In addition, there are differences in degree: major, revolutionary changes are called radical innovations, whereas smaller evolutionary developments, which actually comprise the bulk of innovative activity, are incremental changes.

The totality of activities by which new products and processes are developed and used may be termed the "innovation process" and should not be confused with an "innovation" which is the result of the process. This process thus encompasses research and technological diffusion. A considerable body of scholarship has developed over a number of years that describes and characterizes the innova-

1. Previous studies of innovation have used various definitions, ranging from invention on the one hand to widespread adoption of technology on the other. Definitions used herein draw on a history of several years' work at CPA, beginning with a five-country study, CENTER FOR POLICY ALTERNATIVES, MASSACHUSETTS INSTITUTE OF TECHNOLOGY, NATIONAL SUPPORT FOR SCIENCE AND TECHNOLOGY: AN EXPLANATION OF THE FOREIGN EXPERIENCE (1975) [hereinafter cited as NATIONAL SUPPORT FOR SCIENCE AND TECHNOLOGY]. The definitions appear in the *summary* at pages 1-12.

tion process. It is important to have at least a brief acquaintance with this literature to understand the relationship between regulation and innovation. Empirical studies of this relationship show that regulation is simply one of many external stimuli that affect a firm's technological strategy and that responses to regulation are often consistent with the historical patterns of technological change in a given industrial context.[2]

When technological innovation first became the subject of serious study, the innovation process was typically depicted as a *sequence* of more-or-less discrete steps. In this formulation, basic research led to applied research, invention, prototype development, and ultimately, commercialization and diffusion. Although the steps in the model might be characterized differently by different writers, a common conceptual thread was the emphasis on the sequence of an innovation's development. This view of the process spawned studies focusing on individual innovations and their histories.

This sequential view of the innovation process, although valuable in some respects, is too simple to be realistic. Its value lies principally in identifying certain discrete activities which *can* contribute to innovation. Although valuable in this sense, one may be misled by this intellectual model into assuming that all the enumerated steps in the process are necessary and that they proceed neatly in prescribed sequence. In fact, neither is the case. Innovation often occurs without research and development (R&D),[3] prototypes, or basic research, and it is frequently a trial-and-error process that contains many false starts. From a policy standpoint, the sequential model is misleading because it focuses too much on the innovation process per se and too little on the complex set of factors which can influence the process. Policymakers may thus mistakenly emphasize individual elements of the process, such as R&D, and ignore the aspects of the broader social and economic environment that can either encourage or discourage innovation. Finally, the sequential model is of limited value in understanding the relationship between regulation and innovation because it does not describe the external environment in which innovation takes place and of which regulation is a part.

Some of the first research that went beyond the confines of a sequential model was done by Myers and Marquis in 1969.[4] Their concern was with the factors that motivate individual innovations. The concepts of "market-pull" and "technology-push" innovation were used as shorthand for the dichotomy between, in the former case, innovations developed as response to customer demand and, in the latter case, exploitation of a research-based technology whose market value was not yet demonstrated in the area in which innovation was being considered. This

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2. CENTER FOR POLICY ALTERNATIVES, MASSACHUSETTS INSTITUTE OF TECHNOLOGY, SUPPORTING INNOVATION: A POLICY STUDY (1980) (prepared for the U.S. Environmental Protection Agency) [hereinafter cited as SUPPORTING INNOVATION].

3. The observation that innovation often occurs without R&D has important implications for the argument that, because regulation may divert resources from R&D, innovation is necessarily adversely affected. *See infra* section III(D)(1)(e).

4. S. MYERS & D. MARQUIS, SUCCESSFUL INDUSTRIAL INNOVATIONS: A STUDY OF FACTORS UNDERLYING INNOVATION IN SELECTED FIRMS (1969) (Report to the National Science Foundation); *see also* Myers & Sweezy, *Why Innovations Fail,* TECH. REV., Mar.-Apr. 1978, at 40.

research showed that most successful innovations were motivated by market-pull. Its conclusions suggest that a high degree of customer orientation is important to a firm's technological strategy. The work is also important from a policy standpoint because it shows that market stimuli—of which regulation is one—are the most effective elicitors of new technology, and it thus provides a theoretical underpinning to the idea of regulation as a "technology-forcing" strategy.

B. Recent Research: A New Conceptual Approach

More recent research on the innovation process has focused on the "dynamic" of innovation in different industrial segments and throughout the economy. In particular, the work of Abernathy and Utterback offers an important model of the differences in the nature of innovation across industries and over time.[5] The model, capsulized in the following diagram (see figure 1), refers to a "productive segment" in industry,[6] which is defined by the nature of its technology. Over time, both the nature and rate of innovation in the segment will change. Initially, the segment creates a market niche by selling a new product, often one whose performance is superior in many respects to the old technology it replaces. Nevertheless, the new technology is typically unrefined in many respects, and thus a high rate of a product change occurs as technology improves.[7] Because of the high rate of product change, process improvements are neglected in the early period; but later, as the product becomes better defined, process change is emphasized. In this middle period, the high rate of process change reflects the need of various firms to compete on the basis of price more than in the earlier period, when product performance characteristics tend to be the principal competitive factor. In the latter stages, both product and process change decline significantly, and the segment becomes relatively static (rigid). At this point in its life cycle, the technology may be subject to invasion by new ideas or disruption by external forces that would cause a reversion to an earlier stage.

A few implications of this model of innovation are particularly relevant to the consideration of regulation and innovation. First, the model suggests that innovation—both its rate and character—is a predictable phenomenon in any given industrial context. Second, it implies that the characteristics of the particular technology are the main determinant of the nature of technological change in the segment and that one can predict those changes that are likely to occur by understanding the dynamics of that technology. Third, the model addresses a process of industrial maturation which appears to be relatively uniform across widely different productive segments. The model, however, does not describe at all the sources of innovation (the premodel stages), nor does it elucidate the forces (the external environment) that may transform a mature segment into a more innovative mode.

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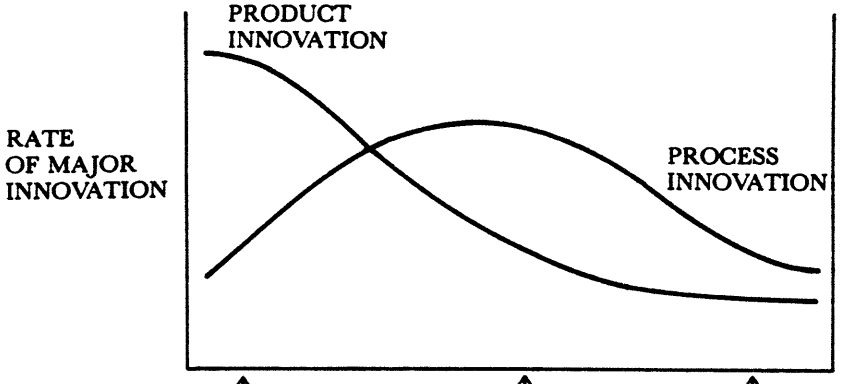
5. *See, e.g.,* Abernathy & Utterback, *Patterns of Industrial Innovation,* TECH. REV., June-July 1978, at 41.

6. Automobile engine manufacture would be a productive segment, as would vinyl chloride monomer production, but neither the automobile industry nor the vinyl chloride industry would be since they both encompass too many diverse technologies.

7. It might also be noted that it is typical for the old technology to improve as well, although incrementally, when its dominance is challenged by the new approach.

FIGURE 1

A MODEL FOR THE DYNAMICS OF INNOVATION IN INDUSTRY



STAGE OF DEVELOPMENT	FLUID	TRANSITION	RIGID
Predominant type of innovation	Frequent major changes in products	Major process changes required by rising volume	Incremental for product and process, with cumulative improvement in productivity and quality
Competitive emphasis on	Functional product performance	Product variation	Cost reduction
Innovation stimulated by	Information on users' needs and users' technical inputs	Opportunities created by expanding internal technical capability	Pressure to reduce cost and improve quality
Product line	Diverse, often including custom designs	Includes at least one product design stable enough to have significant production volume	Mostly undifferentiated standard products
Production processes	Flexible and inefficient; major changes easily accomodated	Becoming more rigid, with changes occuring in major steps	Efficient, capital-intensive, and rigid; cost of change is high
Equipment	General-purpose, requiring highly skilled labor	Some subprocesses automated, creating "islands of automation"	Special-purpose, mostly automatic with labor tasks mainly monitoring and controlling
Materials	Inputs are limited to generally-available materials	Specialized materials may be demanded from some suppliers	Specialized materials will be demanded; if not available, vertical integration will be extensive
Plant	Small-scale, located near user or source of technology	General-purpose with specialized sections	Large-scale, highly specific to particular products

Source: Abernathy & Utterback, *Patterns of Industrial Innovation*, TECH. REV., June-July 1978, at 2-9.

The work of Burton Klein[8] best describes the kind of industry and economy-wide environment in which innovation flourishes. Klein's work concerns the concept of dynamic efficiency, as opposed to the static economic efficiency of the traditional economic theorists. In a situation of static efficiency, resources are used most effectively within a given set of alternatives. Dynamic efficiency, in contrast, implies a constantly shifting set of alternatives, particularly in the technological realm. Thus, a dynamic economy, industry, or firm is one which is flexible and which can respond effectively to a constantly changing external environment.

Several conditions are apparently critical to the achievement of dynamic efficiency. At the firm level, there needs to be a flexible organizational and technological format, a relatively nonhierarchical structure, a high level of internal and external communication, and a willingness to redefine organizational priorities as new opportunities emerge. Dynamic efficiency mandates that the structure of industry groups be open to new entrants with superior technologies and that "rivalrous" behavior exists among those already in the sector. In particular, it is necessary to have an environment that is conducive to risk taking, that is, entrepreneurship, and one that does not reward those who adhere to the technological status quo. Thus, Klein's main emphasis is on structuring a macroeconomy in which there are strong incentives for firms to change, adapt, and redefine the alternatives facing them. Regulation is one of several stimuli which can cause such a restructuring of a firm's strategy.

C. The Relevance of Innovation Research to Regulation in the Chemical Industry

The body of research on innovation contains a number of broad lessons relevant to the design of regulatory policy. First, from the early research and the sequential model, one gets a sense of the complexity of the innovation process, the number of activities involved, and the time necessary if major breakthroughs are to be achieved. This research implies that a simplistic search for "innovation" as the solution to regulatory problems is unrealistic. Radical innovation, as the early research shows, may require a great deal of time and resources, thus sometimes leaving incremental innovation or diffusion of known techniques as a preferred approach to the solution of regulatory problems. On the other hand, later research shows that in some instances radical innovation can occur rapidly—and without following a prescribed sequence of steps in a hypothetical innovation process. The work focusing on market-pull as a motivation for innovation suggests that regulation, like any other market stimulus, can be the driving force behind innovation. Whether over the short or long term, consideration must be given to how regulation affects the rate-determining elements of the innovation process in a particular instance.

The Abernathy-Utterback model[9] gives regulatory policymakers a framework from which to predict the kinds of technological responses that may be elicited by

8. B. KLEIN, DYNAMIC ECONOMICS (1977).
9. *See supra* text accompanying note 5.

a regulatory stimulus.[10] The strength of the model's predictive value supports the argument that underlying technological characteristics fundamentally determine what kinds of changes will occur in response to a particular regulation. Klein's work[11] is most useful in going beyond the confines of the firm-level or industry-level innovation process, and it provides a framework for considering the external stimuli which drive the innovation process. Regulation may, in Klein's terms, provide the "hidden foot" which is the impetus for an industry or firm to revise its perception of the strategic alternatives it faces. To the extent that regulation modifies the tacit ground rules within which an industry has operated, it should be a force stimulating rivalry, new entrants, and the search for new technological solutions. There is the danger, however, that regulations themselves, if they are drafted poorly and do not create incentives for continual change, may modify the operating constraints of an industry in such a way as to fix them more rigidly.

An examination of the structure of the U.S. chemical industry, and the current patterns of innovation within it, illustrates many of the concepts taken from the research just described.[12] As a whole, the industry is highly diverse, comprising twenty-eight different four-digit classes within Standard Industrial Classification (SIC) 28, as well as a number of firms in SIC 29 (petroleum refining and related industries). On the surface, competition in the industry appears to be strong with moderate concentration.[13] More realistically, however, the industry should be divided into three distinct product types: basic chemicals, intermediates, and finished products. Basic chemicals, a technologically mature sector, consists of large producers, many of which are integrated into the petroleum industry. In contrast, the intermediates chemical sector has experienced the highest growth rates in the industry. This category includes many smaller firms that market a variety of specialty products which are highly profitable but often short-lived in the market. The intermediates sector appears to be highly dynamic with discoveries occuring with most frequency in this sector. The finished products sector is the most diverse segment of the chemical industry. This market typically defines the needs for new products to which intermediate manufacturers then respond. Subsectors of the finished products sector are frequently very innovative as well—adhesives, specialty chemicals, and photochemicals provide examples. Whereas some of the older regulatory systems such as air and water pollution control were of greatest concern to the basic chemicals industry, the more recent regulatory pressure being applied to the industry—toxic substances control—is being felt most directly by the finished productors sector.

Profiles of the chemical industry show that its R&D is higher than the U.S.

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10. *See infra* text accompanying notes 26-31.

11. *See supra* note 8 and accompanying text.

12. The description of the industry is drawn largely from *Innovation in the Chemical Industry,* in SUPPORTING INNOVATION, *supra* note 2, app. B.

13. The four-firm ratio in the industry is 35% and the ten-firm ratio is 50%. These ratios are convenient measures, used by economists, of the degree of concentration in a particular sector. Thus a four-firm ratio indicates the market share held by the largest four firms in the chemical industry.

average.[14] Although R&D has continued to climb since 1960, in both current and constant dollars, the R&D/sales ratio has declined. The following graph (see graph 1) shows the trend in R&D as a percentage of sales over this period. Although the obvious decline may result from many causes, it is important to note that it began well before the period of intense regulatory activity occurred. Post-1980 data appear to show an upturn, at least for 1981 and 1982, in the R&D/sales ratio.[15] A Battelle study projects a 19% increase in 1983 R&D spending for the entire industry.[16] In recent years, funding has grown fast for applied research and moderately for development, while basic research funding has fallen behind the rate of inflation. It also appears that in the late 1970's a shift in the nature of innovation began to occur as new product initiatives began to be replaced to some extent by process development.[17] A number of studies have attempted to measure innovation in the industry more precisely, although none has a good enough data base to be authoritative.[18] Nevertheless, it is still possible to conclude that:

(1) The rate and nature of chemical innovation can be expected to vary greatly among the sectors of the chemical industry. Small firms and new entrants play an important, though largely unmeasured, role in innovation especially in newer or more rapidly developing sectors.

(2) As firms become mature, their R&D efforts become more risk averse, process change becomes more important, and they face displacement if they do not recognize the need for continued innovation.

(3) Established chemical firms have demonstrated a shift toward process change, product modification, and new uses for old products.

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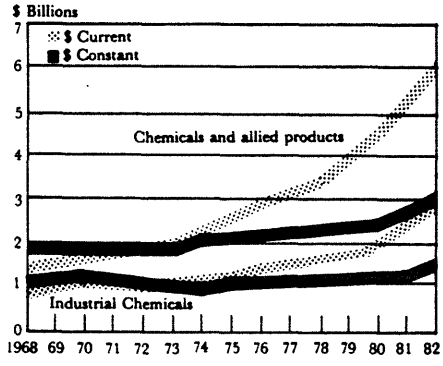
14. The most complete R&D statistics for the chemical industry can be found in the CHEMICAL RESEARCH HANDBOOK (1982) (available from the Stanford Research Institute, Menlo Park, Cal.)

15. Graphs 2 and 3 below show the latest R&D statistics for the industry. It is important to note that the 1982 statistics are estimates made by *Chemical and Engineering News* (C&EN), a trade journal. Since C&EN frequently bases its estimates on interviews with large firms, these data may be somewhat biased.

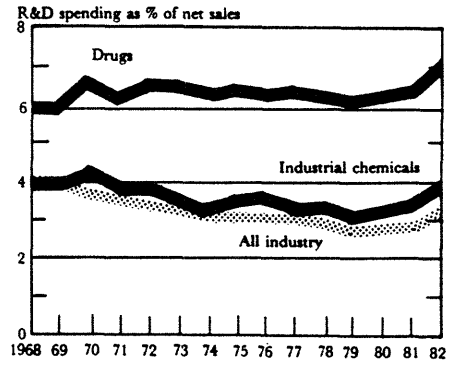
GRAPH 2

CHEMICAL INDUSTRY KEEPS R&D OUTLAYS AHEAD OF INFLATION



GRAPH 3

R&D'S SHARE OF INDUSTRY SALES RISES AS SALES STAGNATE IN RECENT RECESSION



Source: CHEM. & ENG'G NEWS, July 25, 1983, at 43.

16. *A Projected Leap in R & D Spending,* CHEM. WEEK, Jan. 5, 1983, at 52.

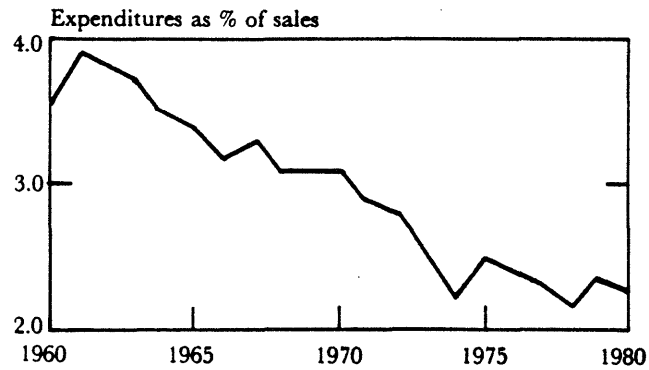
17. Landau & Brown, *The Chemical Industry 2000 A.D.,* CHEM. ENG'G PROCESS, Oct. 1978, at 22.

18. Twelve such studies are summarized in SUPPORTING INNOVATION, *supra* note 2, app. B, table B.6.

(4) Large firms in the industry have traditionally been best at product modification and process innovation, but not at product discovery.
(5) Small innovative firms are more dependent on new products and are, therefore, more likely than large firms to be adversely affected *if* regulation inhibits the development of new products.

GRAPH 1

EXPENDITURES FOR RESEARCH AND DEVELOPMENT BY CHEMICAL AND ALLIED INDUSTRIES 1960 — 1980



Sources: NATIONAL SCIENCE FOUNDATION, ANNUAL SURVEY OF MANUFACTURES (1980); estimates by C.H. Kline & Co.

In the future, it appears that several trends will dramatically change the business environment of the chemical industry. First, there is much more international competition, most notably from a developing chemical industry in oil-producing countries. Second, the growth in the industry is expected to be considerably slower than previously experienced, due to both cyclical and long term factors. Third, the high cost of feedstocks (oil and natural gas) will persist, leading to a search for new alternatives. Lastly, public scrutiny, regulatory and otherwise, will undoubtedly continue to shape demand for the industry in the foreseeable future.

Overall, these trends seem to suggest that in responding to regulation, the industry should exhibit both diversity and vitality in the coming years. The greatest resistance to regulatory change is likely to come from the more mature sectors, where commitments to large-scale existing technologies or product markets are strong. If, however, regulation tends to augment changes that future market trends are already generating, then it may in fact benefit the industry. More flexible sectors should experience the least difficulty in responding to regulation. The danger here, however, is that regulation may impose disproportionate costs on the most innovative firms and sectors by defining its requirements (and hence the market) too inflexibly.

In any event, effects at the industry or sector level are only one aspect of the regulation-innovation relationship. Perhaps, unfortunately, this level of analysis

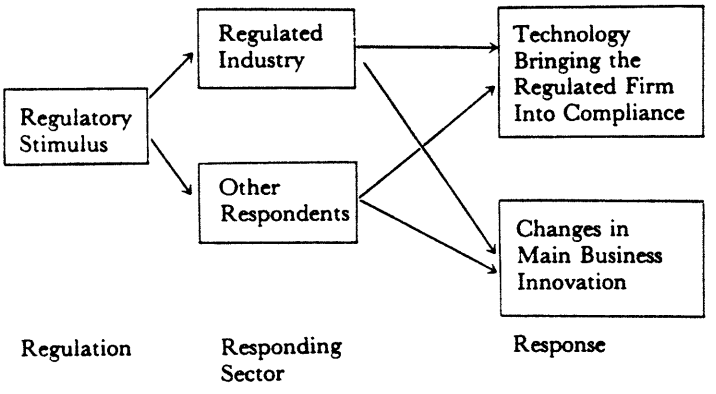
has been the primary focus of innovation research. Equally important, however, are the differences in innovative capabilities among firms. These differences stand out as strongly in the responses to regulation as they do in other competitive areas. To understand the differences in responses to regulation between firms and between different sectors of the chemical industry, a conceptual framework is needed to relate regulation to technological change.

III

REGULATION AND TECHNOLOGICAL CHANGE: A CONCEPTUAL FRAMEWORK

A. Model for Regulation-Induced Technological Change

The basic purpose of regulation is to protect the public health, safety, and the environment. Technological change in industry is not per se a goal of regulation, but rather, the principal means by which regulatory purposes are effectuated. Regulatory decisionmakers, therefore, must rely on their abilities to understand, predict, and direct technological change. The model presented in this section explains how regulatory stimuli produce technological changes among the various actors that respond to regulation. The following schematic shows the basic components of this model.



In this model, the regulatory stimulus is perceived by industry as requiring some change in the nature of industrial production. The way in which this demand is perceived depends not only on the characteristics of a particular industry and its technology, but also on the individual situation of each firm affected. Two kinds of industrial sectors are important to distinguish: the regulated industry and the other respondents. The regulated industry can be defined as the industry to which regulatory requirements apply directly, as well as its closely related suppliers and customers. The universe of other potential respondents is usually large and may include the regulated industry's competitors (for example, makers of a substitute product) as well as manufacturers of compliance technology.

The third element in the model, responses, is the most complex. Obviously, regulation requires compliance, which typically involves a change in technology.

Nevertheless, in many instances, compliance has been delayed for long periods of time as a result of litigation, variances, or exemptions, and in some cases as a result of changes in legislation or regulation. This need to comply with regulation often changes the nature of activity *inside* the firm: R&D may be redirected; new organizational units created; and a different set of alternatives may be faced. In addition, regulation changes patterns of activity in the world *outside* the firm by establishing new patterns of competition in a new market framework. Each of these three elements of the regulation-technological change model is discussed in more detail below.

B. The Regulatory Stimulus

The kinds of environmental, health, and safety regulations most relevant to the chemical industry include controls on air quality, water quality, solid and hazardous waste, pesticides, food additives, pharmaceuticals, toxic substances, workplace health and safety, and consumer product safety.[19] These regulations vary considerably in that they control different aspects of development or production, change over time, and are "technology-forcing" to different degrees.[20] Thus, one expects the effect on technological innovation to be different for regulations which:

(1) require product safety to be demonstrated *prior* to marketing (pesticides, food additives, pharmaceuticals, and new chemicals);

(2) require the efficacy of products to be demonstrated *prior* to marketing (pharmaceuticals);

(3) require safety to be proved or require the control of the use of products *after* products have been marketed (existing chemicals under the Toxic Substances Control Act, worker protection, and consumer products);

(4) require the control of production technology to reduce workplace safety and health risks; and

(5) require effluent, emission, or waste control (air, water, and hazardous waste regulation).

In addition, the format and timing of regulations will affect the outcome. For example, regulations relying on detailed specification standards may leave little room for innovation in compliance; however, they will prompt rapid diffusion of

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19. The statutes from which these regulatory systems derive their authority are as follows (listed as ordered in the text): Clean Air Act, 42 U.S.C. §§ 7401-7626 (Supp. V 1981); Clean Water Act, 33 U.S.C. §§ 1251-1376 (1976 & Supp. V 1981); Resource Conservation and Recovery Act, 42 U.S.C. §§ 6901-6986 (1976 & Supp. V 1981); Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. §§ 136-136y (1982); Food, Drug and Cosmetic Act, 21 U.S.C. §§ 321-360dd (1976 & Supp. V 1981); Toxic Substances Control Act, 15 U.S.C. § 2601 (1982); Occupational Safety and Health Act, 29 U.S.C. §§ 651-678 (1976 & Supp. V 1981); and Consumer Product Safety Act, 15 U.S.C. §§ 2051-2081 (1982).

20. "End-of-the-pipe" effluents are, for example, the main focus of air and water pollution. OSHA, in contrast, regulates chemical exposures incident to the production process. The FDCA, FIFRA, and TSCA impose a premarket approval process on new chemicals. Most of these statutes have undergone significant revision since their enactment. For example, in 1977, both the Clean Air Act (CAA) and Clean Water Act (CWA) amendments passed Congress. The degree of technology forcing ranges from pure "health-based" mandates such as that in the ambient air quality standards of the CAA to a technology diffusion standard (such as "best available" technology) under the CWA. For a discussion of this issue and comparison of statutes, see LaPierre, *Technology-forcing and Federal Environmental Protection Statutes,* 62 IOWA L. REV. 771 (1977).

state-of-the-art technology. Similarly, a phased-in compliance schedule may prompt incremental improvements in technology rather than a major change, but this allows compliance technologies to be put in place sooner.

The perception by business of the need to change its technological course typically precedes the actual promulgation of a regulation. Most regulations are promulgated after a rather extended scrutiny of a potential environmental, health, or safety problems not only by government but also by citizens, workers, and industry. These informal stimuli, as studies done by CPA have found,[21] are often more important than formal rulemaking since the anticipation of regulations first stimulates change. For example, the formal regulation of polychlorinated biphenyls (PCBs) did not occur until years after the government's initial concern about these substances. Aware of this concern, both the original producer and other chemical companies had begun to search for substitutes prior to regulation. Similarly, most firms in the asbestos products industry were in substantial compliance with the Occupational Safety and Health Administration (OSHA) asbestos regulation years before it was promulgated.[22] This preregulation period is important since it allows an industry sufficient time to develop compliance technologies, process changes, or product substitutes, while giving leeway for adjustments to be made to ensure continued production or future innovation for commercial purposes.

The initial show of concern by the government is often, however, an uncertain stimulus to technological change. Uncertainty as to the ultimate regulatory requirement may be caused both by technical uncertainties and by the extent to which interested parties apply pressure for accommodation through both formal and informal means. But regulatory uncertainty is often necessary and beneficial. It is a necessary consequence of administrative flexibility, which allows regulations to be improved. Although too great a regulatory uncertainty may result in inaction on the part of industry until the outcome is definite, too much certainty about the final standard is not likely to result in the development of technology which exceeds the minimum requirements. Similarly, too frequent change in regulatory requirements may frustrate technological development efforts.

Regulations also differ greatly in stringency—the extent to which they "force" the development of new technology for compliance. The relevant statutory mandate will lead to different degrees of stringency because some statutes are based on environmental, health, and safety considerations alone, others on existing technological capability, and still others on the technology within reach of a vigorous R&D effort. Regulatory stringency appears to be the single most important factor

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21. CENTER FOR POLICY ALTERNATIVES, MASSACHUSETTS INSTITUTE OF TECHNOLOGY, ENVIRONMENTAL/SAFETY REGULATION AND TECHNOLOGICAL CHANGE IN THE U.S. CHEMICAL INDUSTRY (1979) [hereinafter cited as CPA CHEMICAL INDUSTRY STUDY]. Results of this study were published as Ashford & Heaton, *The Effects of Health and Environmental Regulation on Technological Change in the Chemical Industry: Theory and Evidence,* in FEDERAL REGULATION AND CHEMICAL INNOVATION 45 (C.T. Hill ed. 1979) [hereinafter cited as FEDERAL REGULATION AND CHEMICAL INNOVATION].

22. W. PRIEST & S. BENGALI, A MICROECONOMIC STUDY ON PRODUCTIVITY: IMPACT OF OSHA REGULATION OF THE ASBESTOS INDUSTRY, A COLLECTION OF CASE STUDIES (1981) [hereinafter cited as THE ASBESTOS STUDY].

influencing the extent of the technological response. In fact, however, most environmental, health, and safety regulations have been set at a level consistent with existing technological capabilities.[23] This fact reflects both the limits of legislative authority and the substantial industry input which influences the drafting of standards.

Lastly, it is important to see the regulatory stimulus within a larger sociopolitical context. Regulations are, to some extent, a reflection of the desires of society rather than the narrow interests of an agency administrator. The "environmental movement," which has undoubtedly stimulated much regulation, has also created the kind of consciousness about the environment that encourages voluntary action. In addition, private rights of legal action coexist and overlap with regulation. The existence of these other pressures means that the demands that underlie regulation are often inescapable and would prompt some technological change even if there were no regulations. What regulations can do better than private actions, however, is more sharply define social demands and create timetables which remove some uncertainty as to what is required of the industry and when.

C. The Industry and Firm Context

Regulatory requirements lead to technological change on two levels. On the macrolevel, they demand change in technologies in widespread use throughout an industry. More particularly, however, individual firms must respond to the regulation's demands. To the extent that their individual situations differ from the norm, each firm will be affected differently. The tension between an industry's compliance capability and the situations of individual firms recurs frequently in regulatory case law. Almost uniformly, the courts have held that technological feasibility is an issue to be determined at the industry level and that, if individual firms cannot comply, they will be forced to close.[24] Thus, the characteristics of both industries and firms must be assessed in order to understand the impact of regulation.

1. *The Regulated Industry.* The regulated industry is comprised of those industrial sectors that are legally bound to comply with regulations as well as those so closely related to the legally bound sector that the regulations are effectively imposed on them as well. For example, regulations on gasoline lead content technically apply only to the manufacturers and marketers of gasoline, but they are effectively imposed on the manufacturers of tetraethyl lead (the lead fuel additive) as well.

Perhaps the most important variable influencing the regulated industry's

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23. LaPierre, *supra* note 20.

24. In the water pollution context, EPA v. National Crushed Stone Ass'n, 449 U.S. 64 (1980), held that variances for individual firms were generally not available on the basis of technological or economic infeasibility with regard to the 1977 "best practicable technology" requirement. Similarly, the courts have held that, under occupational safety and health regulations, individual firms can be expected to go out of business although the requirements must be feasible on an industrywide basis. *See* Industrial Union Dep't v. Hodgson, 499 F.2d 467 (D.C. Cir. 1974). In United Steelworkers of Amer. v. Marshall, 647 F.2d 1189 (D.C. Cir. 1980), in upholding the OSHA occupational exposure standard for lead, the court said in *dicta* that the only way for an individual firm to be excused from an industrywide standard was for the firm itself to prove that the standard was infeasible for the industry taken as a whole.

response to regulation is its technology. (Technology is also, of course, a principal variable influencing the industry's response to other external stimuli.) Following the work of Abernathy and Utterback,[25] it is possible to characterize the technology in a regulated industry in terms of its stage of development: fluid, transitional, or rigid. Using these characterizations, one can then make reasonably accurate predictions about the kinds of responses to regulation the industry will make—how regulation will change its technology. In fact, as will be discussed below, empirical work supports this hypothesis.

The principal aspects of the technology that are most important in predicting its response to regulation are its position and rate of change along a developmental continuum. At one extreme of the continuum are evolving fluid product lines and uncoordinated production technologies, and at the other extreme, mature, commodity-like products and highly integrated, cost-effective production technologies. This continuum can be called "technological rigidity." Industrial sectors can also be placed along the continuum of rigidity according to a set of objective criteria. Because these criteria, the three technological stages, and the entire notion of technological rigidity are a synthesis of earlier work by many in the field, it is important to discuss the derivation of these concepts at some length.

There have been three principal contexts in which analysts have attempted to characterize technologies: economics, organizational sociology, and management science. Economists typically specify the technology of a firm using a production function. The production function can generally tell the following things about a technology: (1) the inputs to the process and their relative contribution to the final product; (2) the elasticity of substitution among the inputs; and (3) the "returns to scale" inherent in the technology.

Unfortunately, this abstract characterization does not capture the detailed qualitative differences among technologies which may be crucial in determining the differential responses to regulation. Further, it is a *static* model, and the important issue is the change that may be likely to emerge from a particular technology under regulation.

Sociologists have been interested for some time in the role played by technology in determining the organizational structure of the working group or firm. In the course of investigating this issue, they have developed methods of characterizing technologies. Thomson and Bates suggested "rigidity" as a characterization of technologies.[26] To them, rigidity is "the extent to which the appropriate mechanics, knowledge, skills, and raw materials can be used for other products:" the less the transferability, the greater the rigidity.[27]

Joan Woodward has identified eleven categories of production technologies. The categories consist of a nine-point scale of "technical complexity" and two "mixed categories" which involve combinations of the others.[28] Woodward also points out that the scale is one of chronological development: "the production of

25. *See supra* note 5 & figure 1.
26. Thomson & Bates, *Technology, Organization and Administration*, 2 AD. SCI. Q. 325 (1957).
27. *Id.* at 325.
28. J. WOODWARD, INDUSTRIAL ORGANIZATION: THEORY AND PRACTICE 35-49 (1965).

unit articles to customers' individual requirements being the oldest and simplest form of manufacture, and the continuous-flow production of dimensional products, the most advanced and complicated."[29]

Charles Perrow has suggested that technologies be placed along a continuum from "routine" to "nonroutine."[30] He distinguished two dimensions to the notion of routineness: (1) the number of exceptional cases encountered in the work; and (2) the degree to which logical analytical procedures are employed to deal with exceptions when they do arise.

Amber and Amber have developed a tenfold characterization of the "order of automaticity" of a technology.[31] The factor which determines the order of automaticity is the human attribute which is mechanized.

Perhaps most important among the sociologists, David Hickson and his colleagues at the University of Aston distinguish three facets of technology: operations technology, materials technology, and knowledge technology.[32] They go on to develop a detailed characterization of operations technology. Their characterization, called "workflow integration," consists of four subconcepts: automaticity, continuity, workflow rigidity, and specificity of evaluation of operations.

In the management literature, the work of primary importance for the purpose at hand is that of Abernathy and Utterback.[33] Described to some extent in the preceding section, their work uses the term "rigidity" to mean both the inherent physical rigidity of a technology and also the historical change or lack of change in a productive segment. That is, a fluid segment is characterized both by an inherently fluid product and an uncoordinated process and by a recent history of frequent product change; a rigid segment is characterized both by a standardized product and a highly integrated process and by a recent history of little product or process change. Further, Abernathy and Utterback's work suggests that the likely future pattern of change can be predicted based on the recent past and hence can also be predicted based on the physical rigidity of the technology at a given point in time.

Taken together, these various studies suggest that the following kinds of objective criteria can be used to characterize an industry's technological rigidity:

(1) narrowness of equipment functions and interdependence of process steps (Thomson and Bates, and Hickson, et al.);

(2) degree of automaticity (Amber and Amber);

(3) continuity of the production process (Woodward and Hickson, et al.);

(4) degree of standardization of inputs (Perrow) and outputs (Abernathy and Utterback); and

(5) price versus quality as the basis of competition (Abernathy and Utterback).

The purpose of this exercise, from a regulatory point of view, is to understand the

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29. *Id.* at 40.
30. Perrow, *A Framework for the Comparative Analysis of Organizations,* 32 AM. SOC. REV. 194 (1967).
31. G.H. AMBER & P.S. AMBER, ANATOMY OF AUTOMATION 2 (1962).
32. Hickson, Pugh & Pheysey, *Operations Technology and Organizations Structure: An Empirical Reappraisal,* 14 AD. SCI. Q. 378 (1969).
33. Abernathy & Utterback, *supra* note 5.

technology being regulated well enough to predict with reasonable assurance the extent of change that is possible and the nature of the changes likely to occur in response to regulatory demands.

2. *Other Respondents.* Regulation creates new markets and transforms existing ones, thus establishing a set of incentives in which firms different from those theretofore in the industry may profit. The obvious *new* market created by regulation is in the field of compliance technology, currently a multibillion dollar industry. The transformation of *existing* markets occurs by virtue of requirements that decrease the attractiveness of an existing product or process relative to its potential substitutes. Thus, regulation creates a new competitive environment in which some firms (or industries) are relatively advantaged and others relatively disadvantaged. In this new environment, some firms may perceive regulation as a market constraint, whereas others will certainly see it as a market opportunity. Hence, they will respond to regulation because it makes business sense to do so rather than because of any legal compulsion.

The pollution control industry is the principal respondent to regulation outside of the regulated industry. Its development was entirely anticipated, and in fact, much of this industry, for example, the municipal waste treatment companies, predated the regulatory movement. In many industrial contexts, the line of demarcation between the regulated and the pollution control industries is clear. An example is the steel industry. In such instances, the effect of regulation on innovation may be minimal because there has been little cross-fertilization between compliance technology development and the development of the technology basic to the regulated industry.[34] Diffusion of pollution control technology is often the predominant response.

In the chemical industry, the line between the regulated industry and its pollution control counterpart is often difficult to draw. Regulated firms often develop compliance solutions themselves, and these technologies appear to diffuse rapidly throughout the affected sector. Furthermore, firms within the chemical industry frequently see regulation as a way to capture new markets. For example, as the need to control the uses of PCBs became apparent, chemical and petroleum firms, other than the PCB producers, developed substitutes, and petroleum firms developed innovative disposal techniques. Regulation has also created some opportunities for the chemical industry to expand beyond existing confines. For example, automobile emissions control regulation provided the stimulus for materials and chemical companies to develop catalytic converter technology. In all these instances, firms other than those in the regulated sector have responded to regulation as a market stimulus from which they can profit.

Responses to regulation from outside the regulated industry are not unexpected events. On the contrary, the theoretical models of the innovation process

34. Indeed, other policies, taxation in particular, have perpetuated this dichotomy by favoring add-on pollution control devices over process changes or product substitutions. For a detailed analysis of the tax provision pertaining to pollution control, see M. MCINTYRE, AMORTIZATION OF POLLUTION CONTROL FACILITIES—SECTION 169 (ENV'T REP. (BNA) Monograph No. 13, 1980).

discussed earlier suggest why and when such responses are likely to occur. Many historical case studies of innovation show that radical technological changes frequently develop outside the industrial context in which they are later to be used. For example, transistors were not developed by vacuum tube manufacturers, and computers were not developed by those who manufactured mechanical adding machines. Often, the primary industry does not initiate these developments because it has too much invested—both economically and intellectually—in the old technology. The likelihood of technological invasion from outside appears to be particularly high in the case of technologically rigid sectors where change of any type is an infrequent event. Significantly, these sectors are often the ones that present environmental, health, and safety hazards of the greatest magnitude. Responses from outside these industries are likely to arise when the environmental, health, or safety problems are particularly severe and, thus, the regulation in question quite stringent. This statement must be qualified, however, by the recognition that these outside responses will not be forthcoming unless they present a potential market opportunity that firms perceive as relatively certain. (Banning asbestos for certain uses, for example, would provide a relatively certain market opportunity for new products with favorable physical or chemical properties.) Thus, continual unpredictable changes in the regulatory agenda would impede the development of innovative outside responses.

In addition to developing new technologies to solve regulatory problems, respondents from outside the regulated sector have the effect of prompting improvements in the existing technology. Proponents of the existing technology are likely to perceive themselves as being threatened by the new ideas and often these technological invasions lead to creative developments in the old technology—developments that were not believed possible shortly before. For example, the addition of photosensitizers to polyethelene, in order to enhance biodegradability, was stimulated by the better biodegradability of competing plastics. Again, this phenomenon is most likely to occur in mature, rigid sectors.

3. *Firm Characteristics.* The individual character of each affected firm is another important factor influencing responses to regulation and the nature of the impacts on innovation. Regulation inevitably affects individual firms differently, creating "winners" and "losers" among the firms to which it applies. Some companies obviously benefit directly—for example, if they sell compliance technology. Even among the regulated industry, however, some firms will become relatively better off if they can comply more easily than their competitors. The firms that can reap neither the direct benefits of regulation nor the indirect benefit of relatively easier compliance are the competitive losers. The differential competitive consequences of regulation arise because firms are poised differently to respond to the agency rules. Four relevant areas of difference condition these consequences:

(1) technical product and process characteristics;
(2) market strategy towards innovation in general;
(3) organizational and political strategy; and
(4) compliance costs.

In the technological realm, some firms may in fact be able to meet regulatory

requirements without significant technological change; whereas, in others, compliance may necessitate major product or process modifications.[35] The companies that must change most will tend to be disadvantaged, at least in the short term.[36] More subtly, however, regulation interacts with the *momentum* of technological change already going on within the firm. If one company is in the process of undergoing technological change, regulatory requirements can often be accommodated relatively easily, provided that the regulatory requirement is consistent with the new technology. In a company not undergoing such change, regulatory compliance will be out of phase with change and can result in costly retrofit.[37]

Firms' organization characteristics, particularly their flexibility and political astuteness, will also give rise to competitive consequences in responding to regulation. Flexible firms respond to regulation more easily than others, just as they respond more creatively to stimuli of all kinds. Flexibility in companies tends to be in part a result of their size, in part a question of manufacturing process design, and in part attitudinal. Another organizational feature of importance is the attitude of firms toward their political environment. In some cases, firms may be able to influence or manipulate the regulatory environment. Influence over the regulatory process can have important competitve implications if the result is a regulation favorable to one firm or group of firms' interests.[38] It is reasonable to assume that firms which object strenuously to regulatory requirements in principle will also comply less effectively (all other things being equal) than firms which accept the necessity of accommodating regulatory demands with good grace.[39]

Regulation also has competitive consequences because of the differential ability of firms to absorb the costs of compliance. In many industries, economies of scale in production appear to be particularly pertinent in reducing the unit costs of regulatory compliance technology, and in general the larger firms seem to be better able to capture these economies (assuming that all firms must make equal changes in technology).[40] To the extent that regulation standardizes the product or production process in question, it especially rewards the least-cost producer

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35. Indeed, it is common for environmental or safety regulations to be based on the "best practice" in a given industry. Lagging firms are, thus, supposed to be brought up to the standards of the industry leader. Although this obviously works to the competitive advantage of the leading firm, to do otherwise would effectively penalize the most socially responsible company. The Supreme Court recently addressed this issue and approved the general practice, as exemplified in water pollution regulation, in EPA v. National Crushed Stone Ass'n, 449 U.S. 64 (1980).

36. On the other hand, there is a strong argument to be made that, over the long term, a firm that lagged behind best practice before regulation was imposed can leapfrog itself into a position of leadership by implementing needed innovations in connection with compliance. Of course, this depends on whether the firm has the foresight and can amass the resources to do so.

37. CENTER FOR POLICY ALTERNATIVES, MASSACHUSETTS INSTITUTE OF TECHNOLOGY, AN INTERNATIONAL PERSPECTIVE ON AUTOMOBILE REGULATION: PUBLIC POLICIES AND TECHNOLOGICAL RESPONSES (1981).

38. See, for example, B. OWEN & R. BRAEUTIGAN, THE REGULATION GAME (1978), for a somewhat tongue-in-cheek analysis of how companies can make strategic use of the administrative process.

39. *See* R. COLE & P. TEGELER, GOVERNMENT REQUIREMENTS OF SMALL BUSINESS (1980). This study showed, among other things, that the firms which were most negative about regulation also tended to be those hurt worst by it.

40. *See* Clarkson, Kadlec & Laffer, *Regulating Chrysler Out of Business,* REGULATION, Sept.-Oct. 1979, at 44-49.

because it effectively eliminates some dimensions of competition. On the other hand, if regulation creates new market demands, it will establish another dimension within which to compete. Lastly, firms' differing abilities to finance the costs of regulatory compliance can also lead to competitive effects. Other things being equal, the least creditworthy companies are likely to be penalized when regulatory compliance necessitates large infusions of borrowed capital, which may be difficult to obtain and very expensive.

In sum, one can be sure that the economic impacts of regulation will fall unevenly on the individual firms within a given industrial sector. Static economic analysis suggests that, other things being equal, firms with reduced financial resources, fewer economies of scale, and higher compliance costs will be relatively penalized. A dynamic perspective (drawing on Klein's ideas) suggests, however, that a firm's technological base and market strategy, if relatively consistent with regulatory requirements, can work significantly to its competitive advantage. Moreover, a flexible and politically astute firm, able to influence and respond quickly to its external environment, can exploit regulatory opportunities. Whatever the effects, they are likely to be different over the long and short terms. In the long run, regulatory burdens that once seemed onerous may be accommodated with relative ease. Moreover, those firms that in the short term were disadvantaged by significant cost impacts may, if they cope successfully, emerge stronger and more flexible in the future.

D. Responses to Regulation

It is useful for analytical purposes to view regulation as eliciting two different types of technological responses from industry. One type, compliance, is straightforward in concept but often difficult and costly. Compliance may or may not require technological change, depending on the firm's preregulatory position, and the changes required may or may not be innovative, depending on whether the regulation is technology-forcing or based on existing techniques. A second type of response is exhibited in the many complicated and diffuse reactions to regulation that occur in the firm's main business activities. In this latter case, regulation changes the character of the firm's traditional activities; whereas in the case of compliance activity, it demands technological changes not previously within the scope of the firm activity.

The dichotomy between technological development in the areas of a firm's main business and those in its compliance activities is a useful way of separating the many effects regulation creates. It is also, at this point in time, an accurate reflection of the way regulatory issues are often perceived. Richard Stewart terms these different areas "market innovation" and "social innovation," to refer to the motivation behind the technological changes that occur in each instance.[41] Nevertheless, it is likely that this dichotomy will tend to disappear over time as long-standing regulatory demands become so internalized that they are effectively part

41. Stewart, *Regulation, Innovation and Administrative Law: A Conceptual Framework*, 69 CALIF. L. REV. 1263 (1981).

of the firm's "main business" consciousness. To the extent that this internalization occurs, many of the effects of regulation described herein will dissipate, industrial practices will be restructured, and a new technological equilibrium reached.

1. *Effects of Regulation on Innovation for Main Business Purposes.*

a. Changes in expected profitability. Regulation may change the profitability expected from a portfolio of R&D investments by affecting either the expected rate of return or the perceived risk. As a result, the firm may modify its level of investment in R&D. To the extent that R&D is perceived to be less profitable or less certain to pay off, investment may be cut back and fewer main business innovations may be produced.

Profitability may decrease as a result of regulation-induced costs, delays, or uncertainty. David Schwartzman has cited several studies which indicate an increase of 100 to 1000% in R&D costs per new chemical entity as a result of pharmaceutical regulation.[42] These costs are attributable to toxicological testing, premarket testing, and increased paperwork required by the Food and Drug Administration for drug registration and approval. Higher development costs have also been reported in the pesticide industry[43] and in the chemical industry as a whole, which has been required to install pollution control equipment on some pilot plant facilities.[44] In the drug development process, Ronald Hansen found that significant economic burdens also arise from the costs of tying up capital during the approval period.[45] Others point out, however, that greater concern over toxicological effects among the population at large, especially in light of the thalidomide disaster, might have caused the tests for safety to be introduced even in the absence of regulation in order to avoid litigation.[46] Thus, these studies are limited like many others in the area by their failure to articulate a proper preregulatory baseline against which to compare the effects of regulation.

Delay decreases the potential profitability of new products, and regulatory requirements undoubtedly increase the amount of time required for introduction of new products. However, because delayed market entry is a risk that all competitors face, decreases in profitability may be minimal. The other side of the question is displayed in the pharmaceutical industry, where an issue of particular concern has been the impact of regulatory delay on patent protection. If patents are applied for early in the development process, long before regulatory approval

42. D. SCHWARTZMAN, INNOVATION IN THE PHARMACEUTICAL INDUSTRY (1976).

43. Wechsler, Incentives for Research and Development in Pest Control (1976) (prepared for the National Bureau of Standards by Arthur D. Little, Inc.).

44. W. Boucher, Federal Incentives for Innovation (1976) (prepared by Denver Research Institute, Univ. of Denver).

45. Hansen, *The Pharmaceutical Development Process: Estimates of Current Development Costs and Times and the Effects of Regulatory Change,* in TECHNOLOGICAL INNOVATION AND GOVERNMENT REGULATION OF PHARMACEUTICALS IN THE U.S. AND GREAT BRITAIN (1978).

46. N. Ashford, S. Butler & E. Zolt, Comment on New Drug Regulation and Innovation in the Pharmaceutical Industry (1977) (prepared for the U.S. Department of Health, Education and Welfare Review Panel of New Drug Regulation) (available through Center for Policy Alternatives, Massachusetts Institute of Technology).

has been granted, then regulation effectively decreases the effective patent term.[47]

The costs of regulation will reduce profitability unless these costs can easily be passed on to the consumer—as may be done with unique pharmaceuticals, with essential chemicals, or with commodities with no close substitutes or with low price elasticities. Monopolistic industries can also pass on regulatory costs so that the profitability in a highly regulated industry may not decrease.

High risk associated with the development of a new product or process can deter innovation, and regulatory uncertainty may be one element of this risk. Although uncertainty can be attributed, in large part, to industry attempts to modify, avoid, or eliminate standards, regulatory agencies can also create uncertainty by issuing ill-defined standards or by failing to recognize and resolve interagency conflicts over regulatory goals and procedures. Conversely, regulatory standards can reduce uncertainty. Because standards both provide a definite statement of legal requirements and encourage the development of safer products, they may limit highly unpredictable products liability suits.

Agency actions other than the promulgation of standards can change the profitability of investment in innovation in subtle ways. For example, requiring the submission of confidential technical data may disturb trade secret protection, which may penalize technological innovation because it decreases the legal protection (and hence the rewards) available to new technologies. Whether such fears, often cited by industry, are real or imagined, they may chill the desire to develop new products or processes, especially when they are not patentable. On the other hand, it must be recognized that some technologies present enough risk to the public that their components must be disclosed. In such cases, whatever chilling effect occurs toward innovation may be justified by the public benefit of disclosure. Moreover, such disclosure is likely to provide an incentive to redirect innovation along competing, but safer, technical lines.

b. Changes in the number of innovations that fail for environmental, health, and safety reasons. Otherwise successful innovations may ultimately fail if they are found to pose unacceptable environmental, health, or safety problems. Regulation can increase the number of such failures by imposing new requirements on products. On the other hand, regulation may actually reduce the number of innovations which fail in the marketplace for environmental, health, or safety reasons. Indeed, the stated purpose of some regulatory systems is to increase the rate of failure for products that are unsafe. Sometimes, the regulatory requirement for premarket testing can eliminate the failure of a fully developed product by catching problems early. For example, practocol, a cardiovasacular drug which has not been approved for use in the United States, was found to cause long term toxic effects, including blindness, during its sale in Britain.[48] It was subsequently removed from the British market.

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47. OFFICE OF TECHNOLOGY ASSESSMENT, CONGRESS OF THE UNITED STATES, PATENT-TERM EXTENSION AND THE PHARMACEUTICAL INDUSTRY (1981) [hereinafter cited as OTA].

48. This incident is recounted by Donald Kennedy (former FDA commissioner) in Kennedy, *A Calm Look at 'Drug Lag,'* 239 J. A.M.A. 423 (1978).

In analyzing this issue, care must be taken to distinguish observations of decreased innovation during the period of transition to new regulatory demands (when existing, but never-before-scrutinized products are taken off the market) from an equilibrium or final state (when the developer scrutinizes products more thoroughly for possible problems during the development process). Overall, the change in failure rate is likely to reduce the output of harmful new products. It is not clear to what extent regulation leads to a compensating effect by bringing safer products to market. This effect may vary with the innovativeness and characteristics of the particular responding industry.

c. Changes in investment opportunities due to increased environmental, health, or safety risks. The chance that a new product or process might be unable to enter or remain on the market because of environmental, health, or safety problems may discourage investment in innovation. This may be particularly true for products with limited market potential, such as specialty chemicals. While the existence of regulation may increase commercial risk and discourage investment in some cases, in other cases the lack of regulation itself can deter new investment. For example, development of new, high-risk, large-scale processes, such as shale oil production, may be hindered by the fact that environmental or workplace regulations are undefined. Here, regulations that specify acceptable emission targets are needed to reduce uncertainty. Regulation undoubtedly changes investment opportunities; however, the ultimate effect is not generalizable across all industries. Industries which historically have been highly innovative may merely shift the type of products developed. On the other hand, noninnovative industries may find themselves competing with more innovative new entrants. Thus, governmental regulation is both a creator and destroyer of business opportunities.

d. Diversion of managerial personnel. What may be termed "transition diversion" of management time from more traditional activities will occur as emergent regulations create new and taxing problems with which management must deal. After a strategy has been developed to address these problems, much of the transition diversion will disappear. What will remain, however, is a need to monitor the compliance efforts and regulatory developments that follow as a matter of course. This function will accompany management as long as the problems to which regulation is addressed remain. Because much of the discussion of the diversion of management is typically addressed to the transition problem rather than to the long run effects of regulation on management, it is particlarly difficult to access the magnitude of the diversion that in fact occurs. In any event, the term "diversion" is not really an appropriate characterization of the compliance function, which is better seen as an important, legitimate management task.

e. Diversion of R&D resources. Regulation causes some firms to redirect resources away from conventional innovative activities such as R&D into compliance-related activities. This resource reallocation may in some instances tend to reduce main business innovation. Its impact on the overall R&D budget has been a major focus of attention. A number of studies cite the decline of effective R&D

budgets in the chemical industry[49] and attribute this effect to regulation. Although regulatory actions may be responsible for some of this decline, it is important to recognize that changes in corporate strategy, changing technological opportunities, and perhaps other factors play a more important role. In fact, the R&D/sales ratio declined steadily in industrial chemicals between 1960 and 1980. Some have suggested that there was overinvestment in R&D during the 1960's and that now there is a return to more realistic levels.[50] As a result, the regulatory impact is unclear.

When compliance diverts resources which would otherwise be used for innovation, the diversion represents an opportunity cost. If, as some say, the long term marginal rates of return on R&D investment are as high as 30 to 50%,[51] this highly productive use of resources is not likely to be significantly reduced by the firm. Instead, other ways to reduce spending may be found, and the opportunity cost of regulation will be more likely reflected in a cutback in outlays for expansion and acquisition. Moreover, early scrutiny of the environmental effects of new technologies can offset much of the diversionary impact on R&D. Edwin Mansfield points out that in the chemical industry 83% of the costs of new product develoment occur after the applied research stage and 57% occur after the pilot plant stage.[52] This finding would imply that rejection of new products early in their development would not be especially costly.

Even if R&D resources are diverted as a result of regulation, it does not follow that there is a corresponding proportional decrease in total innovative output. In small firms, incremental reductions in R&D could have significant results, especially if the firms have limited access to capital. On the other hand, such incremental decreases may not lead to particularly dramatic results in large firms, which may already have surpassed the advantages of economies of scale in R&D.[53] Furthermore, the productivity of R&D for innovation may be improved in other ways if regulation encourages the more efficient use of resources. In sum, the effect of resource diversion on innovation is firm-specific, and aggregate effects are not well established.

Whatever the effects of regulation on R&D, the extent of the impact is very uncertain. Moreover, it is not clear that the chemical industry's situation differs greatly from that of other industries. On the average, approximately 3% of industrial R&D is spent on pollution abatement. The chemical industry, according to some observers, spends only slightly more of its R&D on pollution abatement than the overall industry average—probably about 4%.[54] Nevertheless, such figures are

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49. Iverstine & Kinard, *The Impact of Environmental Protection Regulations on Research and Development in the Industrial Chemical Industry,* in FEDERAL REGULATION AND CHEMICAL INNOVATION, *supra* note 21, at 67.

50. Schweitzer, *Regulation and Innovation: Short-Term Adjustments and Long-Term Impacts,* in FEDERAL REGULATION AND CHEMICAL INNOVATION, *supra* note 21, at 179.

51. Mansfield, *Federal Support for R&D Activities in the Private Sector,* in JOINT ECONOMIC COMMITTEE COMPENDIUM, PRIORITIES AND EFFICIENCY 97-99 (1976).

52. E. MANSFIELD, RESEARCH AND INNOVATION IN THE MODERN CORPORATION 118 (1981).

53. Schmookler, *The Size of Firm and Growth of Knowledge,* in PATENTS, INNOVATION AND ECONOMIC CHANGE (1972).

54. Landau, *Chemical Industry Research and Innovation,* in AMERICAN CHEMICAL SOCIETY SYMPOSIUM ON CHEMICAL INDUSTRY RESEARCH AND INNOVATION (1979).

subject to some question. Other, higher estimates are frequently advanced, but accounting problems, such as separating "pollution control" R&D from R&D generally, make reliable estimates hard to come by.

f. Ancillary innovation from redirected R&D. Some research suggests that when regulation redirects R&D activities in some companies, this can actually result in more innovation. A study of government influences on innovation in five foreign countries found that innovations for ordinary business purposes were much more likely to be commercially successful when environmental, health, and safety concerns were present as an element in the planning process than when they were absent.[55] Furthermore, technological changes far beyond the scope of the compliance effort were found to have been associated with the need to comply.

These ancillary innovations often appear, in individual instances, to be unexpected or serendipitous results of regulatory compliance efforts. Nevertheless, there are enough of them to suggest that they are, overall, a predictable phenomenon. They may arise most often in industries not previously innovative and may occur because of the necessity, brought on by regulation, to rethink established and previously unquestioned modes of operation.[56]

g. Regulation-induced R&D and process improvement. Regulation appears to create opportunities for firms to make a variety of process improvements unrelated to compliance. These process improvements will occur more frequently as greater technological change is required to achieve compliance. Two examples from the CPA chemical industry innovation study provide good illustrations of the pattern. In one instance, the petroleum refinery industry developed improved catalysts and, consequently, a more efficient system as a result of the R&D which went into the effort to comply with lead-in-gasoline regulations.[57] Similarly, the need to limit employee exposure to vinyl chloride monomer led to the creation of a tighter production system and to some increase in output among the firms that polymerize this chemical.[58] Similar phenomena have been uncovered in other studies.[59] Iverstine and Kinard reported that 33% of their study's respondents cited process improvements resulting from regulatory changes, principally the development of closed systems and better process instrumentation.[60] The Denver Research Institute also found that regulation provides an opportunity to make process improve-

55. NATIONAL SUPPORT FOR SCIENCE AND TECHNOLOGY, *supra* note 1.

56. Allen, *Government Influence on the Process of Innovation in Europe and Japan,* 7 RESEARCH POL'Y 124 (1978).

57. In petroleum refining and gasoline production, crude oil is distilled and processed mainly through catalytic cracking and reforming. Because the use of anti-knock compounds such as lead reduces the need for cracking and reforming, the regulatory restrictions prompted increased cracking and considerable expense. The development of new catalysts made the cracking process more efficient and less costly.

58. Employee exposure typically results from nonclosed processes, for example, a reactor vessel that has to be opened periodically and cleaned manually, or a leak in a production line. One response to regulation consisted of improving reactor cleaning by making it automatic. Another was to monitor more closely for leakage. Both responses had the effect of improving yield somewhat since less material was now lost during processing.

59. Schweitzer, *supra* note 50, at 180.

60. Iverstine & Kinard, *supra* note 49.

ments in areas outside the compliance sphere.[61]

The explanation for this phenomenon is simple. Because it is usually easier to make multiple changes simultaneously rather than individually, the imposition of regulation-based change can be used to introduce other improvements as well. The technologies installed, such as safer closed systems with greater yields, will often be complementary to the regulatory purpose, and they may often be suggested by the R&D which was necessitated by regulation. Although these improvements might have occurred eventually in the absence of regulation, regulation can be viewed as having accelerated the course of normal business innovation in such instances.

h. Rechannelling creativity. The innovative potential of a firm is to a large extent a function of the creative energies and abilities of its personnel. Although one effect of regulation is to divert personnel attention from the normal business of the company, there also appears to be an opposite effect: the creative potential of the firm can be rechannelled, augmented, or enhanced by regulation. Because compliance with environmental, health, and safety regulations involves a large component of technical expertise, new people have been brought into firms to assist with compliance. Typically, they are environmental scientists or engineers; often they possess advanced degrees. If this new source of expertise can be integrated into the normal R&D process, innovative products and processes are likely to result. One such effect was cited by companies during the CPA chemical industry innovation study: interviewees believed that the sophisticated analytical chemistry work done to assess health and environmental risks also created a better knowledge of the properties of their products and suggested new uses for them.[62] In addition, they believed that this new analytical capability would be important in the future in developing new products and processes. Thirty-three percent of the interviewees in Iverstine and Kinard's study noted this phenomenon;[63] a study by Oslosky and Keller found the same effect.[64]

A general explanation for the increased creativity that firms may exhibit under regulatory conditions has been offered by Thomas Allen and colleagues, who argue that regulation, by adding new dimensions to older problems, "increases the problem space of the engineer."[65] This new need to optimize along several dimensions is likely to foster more creative solutions than those which prevailed under less complex conditions. This effect is especially likely to occur in older, more rigid, industries where few external stimuli have demanded creative responses. Allen's hypothesis is entirely consistent with Klein's theories[66] which suggest that "negative feedback" from regulation is a factor that leads to more innovation.

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61. W. Boucher, *supra* note 44.

62. NATIONAL SUPPORT FOR SCIENCE AND TECHNOLOGY, *supra* note 1.

63. Iverstine & Kinard, *supra* note 49.

64. Oslosky & Keller, *Impact of the Toxic Substances Control Act on the Reactive Polymer Industry,* in TSCA's IMPACT ON SOCIETY AND THE CHEMICAL INDUSTRY 213 (1983) [hereinafter cited as ACS 1983].

65. Allen, *supra* note 56.

66. *See supra* note 8 and accompanying text.

i. Changes in industry structure. Because regulations have differential impacts upon the firms within an industry, the composition of that industry may be changed as a result. There may be entry and exit of firms, and the size mix may change. Such structural changes are likely to affect innovation. Distinguishing between effects of regulation and other influences on industry structure, such as changing technology or inflation, presents difficult methodological problems. Furthermore, the relationship between industry structure and innovation varies significantly from industry to industry.[67]

2. *Compliance Responses and Innovation.*

a. Saleable compliance technologies. The great majority of compliance technologies are apparently developed in the firms subject to regulatory requirements; still, many regulated firms have been able to market the technologies developed to solve their own in-house control problems, thus providing themselves with new products to sell.[68] Iverstine and Kinard's study confirmed this fact but, on the other hand, also indicated that the uniqueness of each firm's environmental, health, and safety problems often necessitates adaptations before the technology can be transferred successfully to other companies.[69]

b. Compliance technologies with ancillary benefits. Technological change to comply with regulation can yield ancillary benefits of various kinds to the complying firm. These benefits are more likely to arise when compliance responses are innovative and comprehensive in scope. Typically, ancillary benefits result when the firm can transfer the technologies developed for compliance purposes to other uses. For example, the use of microprocessors in automobiles to regulate fuel consumption and emissions has opened the door to other applications of this technology for improving performance. The documentation of ancillary benefits in several studies leads to the conclusion that this phenomenon is, in the aggregate, to be expected, although it certainly does not occur in every case. Moreover, the ancillary benefits deriving from compliance efforts can be consciously sought and achieved by firms. For instance, Bell Laboratories announced in May 1978, a new computer-controlled electroplating system that both reduces pollution and conserves raw materials.[70] The system used an enclosed processing method which has reduced gaseous exhaust by 97%, chemical waste by 90%, and gold consumption by 50%. Because it increases production dramatically, the payback period is about six months. Similarly, the Denver Research Institute study reported that there is a strong link between management's commitment to compliance and the nature of the impact from regulation.[71] Such commitments tended to result in both lower compliance costs and favorable impacts on innovation.

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67. For a review of this difficult issue, see Kamien & Schwartz, *Market Structure and Innovation: A Survey,* 13 J. ECON. LIT. 1 (1975).

68. These two findings were made by both the Denver Research Institute, W. Boucher, *supra* note 44, and the CPA studies.

69. Iverstine & Kinard, *supra* note 49.

70. *Current Developments,* ENV'T REP. (BNA), May 26, 1978, at 101.

71. W. Boucher, *supra* note 44, at 53.

c. Joint R&D efforts for compliance. Joint R&D efforts designed to produce compliance-related technologies may be a way to reduce the aggregate cost of technology development and perhaps yield more innovative solutions. This strategy appears to hold most promise when the cost of technology development is high or there is little economic benefit to individual firms in undertaking the necessary R&D. Joint R&D can be undertaken by an industry or trade association or by private arrangement among individual companies. Industry associations, in particular, appear to be doing more R&D on environmental issues; for example, the Chemical Industry Institute of Toxicology (CIIT) was established a few years ago to perform toxicological tests on chemical products. One study indicates that this is the major kind of cooperative endeavor occurring in response to regulation.[72] The study shows that because compliance technology changes are often unique to individual firms, most of the shared research occurs in preparing environmental impact analyses and in toxicity testing. These efforts may affect the introduction of new technologies because they reduce the costs associated with regulation. However, the history of trade association R&D in other countries, where it is more common than in the United States, indicates that it is not likely to become a major source for the development of new products or processes.[73]

Firms within an industry often share the results of their compliance research—especially with respect to difficult regulatory problems—even when they do not undertake it jointly. Iverstine and Kinard found that such sharing occurred in 53% of the firms in their sample.[74] Although this phenomenon is not likely to have a major impact on the development of innovative new compliance technologies, it may have an important impact on the diffusion of state-of-the-art solutions.

d. Reorganization of firms to meet compliance requirements. It has been widely reported that regulation has fostered organizational change in companies. For example, the CPA chemical industry innovation study found that about 65% of the chemical firms interviewed had formal environmental affairs groups.[75] The Conference Board also reports that 78% of a sample of chemical and pharmaceutical firms have government relations units.[76] These groups often serve primarily as liaisons between the regulators and the companies. They participate regularly in the public regulatory decisionmaking process, often indicating to the regulatory agencies the technical limits of existing compliance capability. This interaction is seen by some as a way of tempering potentially strict technology-forcing regulatory standards by considerations of "feasibility" and also as a way by which the holders of certain compliance technologies can "capture" the regulatory standard for their particular compliance method.[77] The environmental affairs unit often functions as a quasi-regulatory agency within the firm. Environmental review procedures may

72. Iverstine & Kinard, *supra* note 49.

73. NATIONAL SUPPORT FOR SCIENCE AND TECHNOLOGY, *supra* note 1.

74. Iverstine & Kinard, *supra* note 49, at 69.

75. CPA CHEMICAL INDUSTRY STUDY, *supra* note 21, at 62.

76. *More Firms Set Up Government Relations Units,* CHEM. ENG'G NEWS, July 2, 1979, at 18.

77. Eads, *Chemicals as a Regulated Industry: Implications for Research and Product Development,* in FEDERAL REGULATION AND CHEMICAL INNOVATION, *supra* note 21, at 1.

be established, with the environmental affairs unit able to "pass" on the acceptability of various products or processes, particularly in their early stages of development. Thus, these groups will encourage the development of safer technologies.

Environmental affairs units are more common in large corporations. They are typically located in the central corporate headquarters rather than in production facilities. They may be staffed with young environmental scientists rather than engineers. As such, it apears they often do not play a major role in development of new compliance technology or in the engineering aspects of compliance. These functions are more typically within the realm of the engineers at the plant level, or R&D personnel. Nevertheless, personnel assigned to the regulatory compliance functions can play an important informational role. In the regulatory area, these individuals provide liaison between the firm and outside technical knowledge, which can be a force for innovation in both compliance and noncompliance areas.[78]

IV

REGULATION AND INNOVATION IN THE CHEMICAL INDUSTRY: THE EVIDENCE

Public concern about technological innovation in U.S. society developed into a pressing national issue during the mid- and late-1970's. This concern resulted in large part from evidence that American economic performance was lagging. Domestic productivity improvements appeared to be nil, and international competition had eroded the traditional market position of many U.S. industries.[79] Coincident with these declines, a massive expansion of environmental, health, and safety regulation took place. In the search for explanations and solutions to the national economic dilemmas, a number of commentators noted the coincidence of regulation and economic downturn and argued that there was a causal relationship.[80] Indeed, this presumed causality was a major aspect of the Reagan campaign to reduce government regulation. Simplistic though this argument may be, it has claimed many adherents and generated a great deal of literature. On close examination, however, most of this writing cannot be taken very seriously: a great deal of it is simply opinion, based on an ideological position rather than evidence. A developing body of more solid evidence does exist, however. Much of it is anecdotal, based on the individual experiences of business people and regulators, but some detailed studies have been undertaken.

This section reviews and comments on the evidence accumulated to date about the regulation-innovation relationship in the chemical industry. Section A looks at studies of general applicability to the chemical industry, section B focuses on pharmaceuticals, and section C on the Toxic Substances Control Act.

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78. They may function as the "gatekeepers" described in Allen's work. Allen, *supra* note 56.

79. For a general overview and analysis of these issues, see I. MAGAZINER & R. REICH, MINDING AMERICA'S BUSINESS: THE DECLINE AND RISE OF THE U.S. ECONOMY (1982).

80. M. Weidenbaum, Cost of Federal Regulation of Economic Activity (May 1978) (pamphlet available from the American Enterprise Institute).

A. Regulation and the Chemical Industry: Studies of General Applicability

A number of studies have taken a "macro" view of the regulation-innovation relationship in an attempt to understand how, in general terms, regulation is influencing technological change in the chemical industry. The first effort, completed in 1975, was a review and synthesis of the then-available literature. It concluded that in spite of the large amount of writing, there was little of substance known: "Unfortunately, almost no work has appeared in the literature which has attempted to measure or even to model in a rigorous way the impacts of environmental regulation on technological innovation."[81]

In 1976, the Denver Research Institute completed a study of the impact of the Environmental Protection Agency (EPA) regulation and administrative practice on innovation in various industries, including chemicals.[82] Researchers found a widespread *perception* among industry that regulation did indeed create barriers to innovation; however, the industry interviewees were unable to offer much concrete evidence in support of this proposition. A similar study, completed by Battelle in 1980, looked in particular at the impact on small firms.[83] The study found that the negative impact of regulation tended to be strongest among those firms that had the most negative attitude toward regulation before its requirements were imposed.

A number of studies indicate that regulation often makes little difference to most of the firms in an industry because their own environmental, health or safety standards have long met or exceeded those imposed by regulation. For example, a study of ammonia production, completed in 1977, concluded that at that time governmental health and safety standards were consistent with prevailing industry practice.[84] More recently, a study of the effects of the 1972 occupational exposure standard for asbestos, based on interviews with the industry, concluded that the impact on the asbestos industry has been minimal, in large part because as early as 1960 most plants had incorporated extensive ventilation and dust collection systems sufficient to meet the later requirements.[85] These two cases are apparently not rare events. On the contrary, the CPA chemical industry study (discussed in detail below) found that because most regulations are based on considerations of technological feasibility and/or best available technology, by the time a regulation is finalized, many, if not most, firms are already in compliance. This phenomenon results sometimes from the legislative mandate—which may not permit technology forcing—and often from the nature of the regulatory decisionmaking process, which typically gives firms long lead times before requirements are imposed and

81. 1 C. HILL, E. GREENBERG & D. NEWBURGER, A STATE OF THE ART REVIEW OF THE EFFECTS OF REGULATION ON TECHNOLOGICAL INNOVATION IN THE CHEMICAL AND ALLIED PRODUCTS INDUSTRIES (1975).

82. DENVER RESEARCH INSTITUTE, THE IMPACT OF EPA ADMINISTRATIVE PRACTICE ON THE INNOVATION PROCESS IN U.S. COMPANIES: A CASE STUDY OF REGULATORY BARRIERS TO INNOVATION (1976).

83. *See* R. COLE & P. TEGELER, *supra* note 39.

84. E. GREENBERG, C. HILL & D. NEWBURGER, REGULATION, MARKET PRICES AND PROCESS INNOVATION: THE CASE OF THE AMMONIA INDUSTRY (1979).

85. W. PRIEST & S. BENGALI, *supra* note 22.

allows them to have substantial input in formulating the substance of the requirements.

In late 1978, the American Chemical Society (ACS) sponsored a symposium to examine the effects of regulation on innovation in the chemical industry, and in 1979 the symposium was published as a book.[86] Taken as a whole, the studies presented at the symposium reflect a recognition on the part of authors of diverse political views that regulation has fundamentally and irrevocably changed the business environment of the chemical industry[87] and that as a result the nature of the innovation process will be changed as well. Nevertheless, as the book's editor observed:

> [T]he reader looking for a definitive understanding must continue to search. Despite the importance of both regulation and innovation to industry and society, and despite the hours that have been devoted to discussion of their interactions, there is still much to learn. Problems of description, definition, and measurement plague serious research in the field. Reasonable arguments can be made on theoretical grounds that regulation would inhibit or stimulate innovation, and empirical confirmation is available to support both sides. Furthermore, some participants in the debate confuse the impacts of regulation on innovation with the larger question of whether regulation's costs are worth the benefits.[88]

Some of the studies in the ACS book deserve particular mention. One, by Iverstine and Kinard,[89] examined the impact of regulation on R&D among large companies in the chemical industry. It concluded that regulation is "diverting" R&D from the ordinary pursuit of new product and processes, as evidenced by the fact that R&D/sales ratios declined between 1970 and 1976.[90] Nevertheless, the study was careful to offer other plausible explanations for this change, such as inflation and less corporate emphasis on R&D, and it noted a variety of benefits that have resulted from regulation-related R&D, such as safer products, marketable control technologies, new information, and new skills. The thesis that R&D is diverted is also argued by some of the other authors in the book. For example, Glenn Schweitzer notes a "dampening influence" on innovation for main business purposes but a coincident increase in innovation in control technology.[91] The combination of these two effects suggests that innovation is indeed being changed by regulation, but that there is a redirection of innovative effort into more socially approved areas, rather than an absolute decline.

One of the most problematic issues in these studies is the question of how regulation is affecting the structure of the chemical industry. Iverstine and Kinard found that large chemical companies reacted to regulation in a very similar manner. From this finding, they then inferred that the impacts of regulation were relatively uniform across this class of companies.[92] Eads took issue with this position, however, and saw regulation as a strategic opportunity for some firms.[93]

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86. FEDERAL REGULATION AND CHEMICAL INNOVATION, *supra* note 21.
87. *See* Eads, *supra* note 77.
88. Hill, *Preface* to FEDERAL REGULATION AND CHEMICAL INNOVATION, *supra* note 21, at xi.
89. Iverstine & Kinard, *supra* note 49, at 67.
90. In fact, the decline was constant over the 1960-1980 period. *See supra* figures and discussion at note 15.
91. Schweitzer, *supra* note 50, at 179.
92. Iverstine & Kinard, *supra* note 49, at 72.
93. Eads, *supra* note 77.

Most of the studies asserted that regulation disadvantages small firms, although none had good data to support this proposition. No study of the chemical industry, unfortunately, attempted to look specifically at the kind of restructuring effects regulation may have within an industrial context or among industries.

Also in 1979, CPA's staff completed an empirical study examining regulation and technological change in the chemical industry.[94] The study focused on the regulation of lead, mercury, PCBs, and vinyl chloride and sought to uncover the technological changes that had arisen in response to these regulations. Investigating the regulatory stimuli in these four cases, which included numerous individual regulatory events, researchers found that informal regulatory procedures including research, investigation, early versions of rules, and hearings were as important, or more so, than formalized rulemaking. Because these events took place long before the eventual compliance deadline, companies were usually afforded the necessary leadtime in which to develop their technological responses. Even more important, these informal aspects of the regulatory process gave industry substantial opportunity for input to agency decisionmaking. In observing the final regulations that emerged with regard to these four substances, researchers found that, with few exceptions, they were based largely on considerations of technological feasibility or best available technology. In addition, although the format of the regulations, such as a performance or specification standard, did not appear to be a major factor influencing the nature of technological responses, the *stringency* of the regulation—its cost, disruptiveness, and time phasing—was a significant factor.

A major hypothesis underlying the CPA research was that the characteristics of the technology in different productive segments would be a major factor determining the nature of the technological response to regulation. The hypothesis is based on the research of Abernathy and Utterback and is borne out by a variety of specific findings.[95]

First, it was found that, in qualitative terms, the kinds of technical changes that firms within a productive segment made in order to comply with a given regulation were highly uniform. This uniformity cannot be attributed to the fact that the regulations only permitted one compliance technology because most of the regulations investigated were performance standards. Rather, the response uniformity within productive segments suggests that the character of the existing technology does indeed dominate the character of the technological response to regulation. Second, it was found that the proportion of product and process responses to regulation closely resembled the expected balance of product and process innovations that would have occurred in the segment absent regulation. Thus, fluid-stage industries tended to respond to regulation with product modifications, and rigid segments tended to have more process responses than product changes. This again suggests the dominant role technology plays.

Perhaps the most interesting result linking technology characteristics to the

94. CPA CHEMICAL INDUSTRY STUDY, *supra* note 21.

95. *See supra* text accompanying notes 5-7.

nature of the response concerned the relationship between the novelty of the response and the rigidity of the segment. Although one might have expected to find the most novel responses in fluid segments and the least novel in rigid segments, this expectation did not turn out to be true. Instead, regulation of rigid segments often elicited responses that were as novel as those in fluid segments.[96] This finding lends some support to the idea that regulation can change the overall character of innovation in rigid industries—that it may cause a dynamic readjustment of the industries, innovative records. Creative response to regulation may occur especially when the regulation precipitates "crisis" conditions for the industry. In addition, many creative responses arise from new entrants to the industry, whose entry was occasioned by regulation.

It was found that most of the compliance reponses to regulation were in a late stage of technological development and required only moderate adaptations for compliance purposes. This was particularly true for air and water pollution regulations, which tended to be based on existing technological capability. Thus, one might say that most responses were drawn from technology already "on the shelf." Consistent with this finding, the data from the study showed only a very few examples of radically new technologies. One such innovation, "gasohol," a gasoline substitute, was a much-discussed response to both market and regulatory conditions. Developed outside the regulated segment, it has proved unsuccessful thus far in replacing the established product. However, although radical change was rare, several highly creative solutions—new polymerization techniques for vinyl chloride and several PCB substitutes—did in fact arise.

The CPA study also uncovered a variety of systemic or ancillary changes, defined as organizational or technological responses that went beyond what was necessary for compliance, that appear to be important. One common phenomenon, new firms entering the business, has been mentioned already. However, important organizational changes took place inside the regulated firms as well. For example, most of the companies interviewed had established environmental affairs groups. The new capabilities which these groups have injected into companies may have important long term implications for the pattern of innovation in the primary lines of business. Lastly, many firms had found that technological changes ancillary to the compliance effort offered important avenues for improving products or processes in their main areas of business.

A number of more recent papers have also addressed the general relationship between regulation and innovation. Unfortunately, few do so from the basis of empirical findings. Nevertheless, the writing on this issue has tended to become prescriptive as it has been drawn into the context of the nationwide debate about regulatory reform. Two recent publications serve as examples of this trend. An article by Richard Stewart appearing in the *California Law Review*[97] contains a long

96. For example, gasohol, an innovative new fuel, was developed by the rigid petroleum industry. On the other hand, fluid segments offer utilized technology "on the shelf" to comply, showing little novelty. An example of this response was demonstrated when paint manufacturers simply used existing, well-known lead substitutes when concern about lead in paint arose.

97. Stewart, *supra* note 41.

and thoughtful analysis of ways to change regulation in order to promote innovation. Many of his suggestions, which for the most part focus on the regulatory decisionmaking process, are quite sensible. Stewart attempts to redefine the essential regulatory "problem" of today: creating innovative new industries to respond to social demands rather than having existing industries respond more creatively to regulation. In spite of the assumption running through the work that regulation is a barrier to innovation, no evidence to support this proposition is offered.

Another examination, completed by Hoerger, Beamer, and Hanson[98] in late 1982, looked in general at the impact of regulation on the chemical industry. Its main conclusion is that "scientific and technical manpower have been diverted from traditional chemical R&D into HE&S [health, environmental, and safety] activity. *Observations of the authors* suggest that perhaps 10 to 20% of chemical industry R&D is motivated primarily by HE&S concerns."[99] These authors argue not from systematic empirical observation but rather from their own impressions. They assert that the existence of numerous regulatory statutes necessarily *implies* a resource diversion with negative impacts on innovation, and they point to a "general acceptance" of the validity of this hypothesis with respect to drugs and pesticides as proof that it is true. In spite of the paucity of data, these authors are remarkably bold in their policy conclusions. They argue that regulatory concepts of the past, such as generic regulations and technology-forcing standards, should be discarded in favor of less public involvement in decisionmaking, greater control of regulatory decisions by scientists, and more preregulation analysis.

Lastly, two recent works have, by looking at general trends in chemical industry innovation, shed some light on the relationship between regulation and innovation even though they do not address this issue directly. J. Clarence Davies, after surveying R&D data for the chemical industry as a whole during the last decade, concludes that R&D has generally increased throughout the industry, even after inflation is taken into account.[100] He asserts, however, that the nature of R&D is changing, moving more toward applied projects of a shorter term nature, and that the R&D/sales ratio for the industry as a whole is declining since sales have been growing faster than R&D.[101]

An analysis by Ralph Landau basically supports these assertions.[102] He estimates that the composition of chemical R&D funding is broken down as follows.

98. F. Hoerger, W. Beamer & J. Hanson, *The Cumulative Impact of Health, Environmental, and Safety Concerns on the Chemical Industry During the Seventies,* LAW & CONTEMP. PROBS. Summer 1983, at 59.

99. *Id.* at 96 (emphasis added).

100. Davies, *Overall Costs and Benefits,* in ACS 1983, *supra* note 64, at 213.

101. Davies relies heavily on a number of studies by Edwin Mansfield of the University of Pennsylvania as the basis for these conclusions.

102. Landau, *supra* note 54.

Topic Area	Expenditure Allocation (%)	
	1978	1978
Improving Existing Products	58	62
New Processes	16	20
New Products	26	18
Pollution Control	5	4
Energy Related	4	3

These data show a 30% drop in new product investment by the industry from 1978 to 1979 and may indicate that a major decrease is occurring in new product investment by the chemical industry. According to Landau's interpretation, this decline is occurring because funding is being shifted toward product and process improvements, not towards environmental or regulatory demands.[103] Whether these studies actually establish that the pattern of chemical innovation is changing, irrespective of regulation, is much less than clear. Taken together with the studies of regulation, however, they lead one to conclude that major changes are taking place in the chemical industry, although their genesis is multifaceted and often obscure.

B. Studies of Regulation and the Pharmaceutical Industry

The impact of regulation in the pharmaceutical industry has been studied more, and these studies have created perhaps more controversy than similar studies in any other industrial context. The controversy arises in part from the fact that drug regulation is a relatively old and comprehensive regulatory system and in part from evidence suggesting a change in the rate and nature of innovation in this important industry.[104] Some of the earliest studies addressing this issue, conducted in the early 1970's, argued simplistically in a monetary cost-benefit framework that the numbers of new drugs had been reduced by regulation, especially by

103. Of course, one should be very careful about data based on such a short time period and on a more-or-less subjective categorization of research areas. On the other hand, Landau is a knowledgeable observer whose interpretations should be noted.

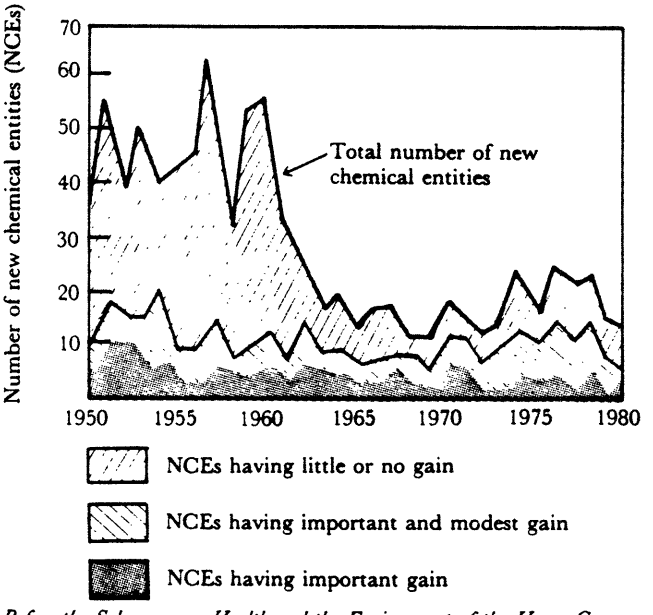
104. The figure below (graph 4) has been widely cited to indicate a change in the level of pharmaceutical innovation. Nevertheless, it raises many questions of interpretation. For example, it is not at all clear that counting NCEs is a valid measure of innovation. Furthermore, the mere fact of change is no indication of any causality.

the legislatively mandated efficacy requirement which was enacted in 1962.[105] Later work began to undertake a more serious and thorough examination of the relationship between regulation and pharmaceutical innovation.[106] A number of important findings arose from this body of work. Several of these writers emphasized the increased cost and delay that regulation imposes on new drug development. Schwartzman, for example, maintained that there has been a 100 to 1000% increase in R&D costs per new chemical entity and that the average rate of return for new drugs has fallen from 15 to 6.3%. Similarly, he cites reports of an average increase of 3.9 years in pharmaceutical development time.[107]

Conclusions of this sort are intriguing, but dangerous. To begin, such conclusions are subject to considerable uncertainty. Even assuming their partial correctness, they present many problems of interpretation. Some of the analytical

GRAPH 4

ANNUAL APPROVALS OF NEW CHEMICAL ENTITIES (NCEs) REFLECTING FDA'S JUDGMENT OF THERAPEUTIC POTENTIAL



Source: *Hearings Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 97th Cong., 1st Sess. 277, 292 (1981) (testimony of J. Richard Crout), *reprinted in* OTA, *supra* note 47, at 26.

105. *See* Baily, *Research and Development Costs and Returns: The U.S. Pharmaceutical Industry*, 80 J. POL. ECON. 70 (1972); Peltzman, *An Evaluation of Consumer Protection Legislations: The 1962 Drug Amendments*, 81 J. POL. ECON. 1067 (1973); J.M. Jadlow, Jr., The Economic Effects of the 1962 Drug Amendments (1970) (unpublished Ph.D. dissertation, Univ. of Va.); J.M. Jondrow, A Measure of the Monetary Benefits and Costs of the Regulation of Prescription Drug Effectiveness (1972) (unpublished Ph.D. dissertation, Univ. of Wis.).

106. *See* H. GRABOWSKI, DRUG REGULATION AND INNOVATION: EMPIRICAL EVIDENCE AND POLICY OPTIONS (1976); IMPACT OF PUBLIC POLICY ON DRUG INNOVATION AND PRICING, PROCEEDINGS OF THE THIRD SEMINAR ON PHARMACEUTICAL PUBLIC POLICY ISSUES (S. Mitchell & E. Link eds. 1976); D. SCHWARTZMAN, *supra* note 42; W. WARDELL & L. LASAGNA, REGULATION AND DRUG DEVELOPMENT (1975).

107. D. SCHWARTZMAN, *supra* note 42, at 65-70.

difficulties in considering the relationship between regulation and pharmaceutical innovation were addressed in detail in 1977 by Ashford, Butler, and Zolt.[108] They concluded that the following five research areas were in particular need of clarification:

(1) *Problem Definition*—that is, selection of the appropriate governmental actions and responding portion of the pharmaceutical industry as well as the choice of alternative bases against which to compare the consequences of government action;

(2) *Difficulties in Analytical Approaches*—for example, with regard to conceptualizations of investment strategies by firm, the determiners of demand, and opportunity costs of continuing the utilization of ineffective drugs;

(3) *Difficulties in Assessing Regulatory Effects*—for example, the appropriateness of New Chemical Entities (NCEs) as a measure of innovative activity and the problem of defining objective criteria of drug efficacy and safety;

(4) *Alternative Hypotheses for the [Alleged] Decline*—for example, the examination of the mismatch between models of disease causation and pharmaceutical action, and the possible distortion of the market by both regulatory and nonregulatory intervention by the government; and

(5) *The Nature of the Trade-Offs*—that is, the identification of the winners and losers from government intervention, equity and efficiency consequences, and the characteristics of the elements of costs and benefits.

An interesting, recently developed subquestion within the regulatory debate has focused on the relationship between regulation and effective patent terms for pharmaceuticals.[109] Effective patent terms have apparently decreased, from about 13.6 years in 1966 to 9.5 years in 1979. This decline is due in part to delays in marketing associated with regulatory compliance and in part to other factors, such as Patent Office slowness. The Office of Technology Assessment (OTA) believes, however, that the decrease is likely to end or be reversed in the near future as a result of changing regulatory procedures.[110] In any event, effective patent protection has much to do with the competitive environment for the drug in question; for example, effective patent lives for the top-selling drugs range from 11 to 17 years.[111] If, in fact, the effective patent life has been decreased, this may be a disincentive to innovation.

During the last three years, members of CPA have been investigating further the relationships among pharmaceutical regulation, innovation, and therapeutic benefits. The following preliminary conclusions emerged from the first phase of

108. N. Ashford, S. Butler & E. Zolt, *supra* note 46.

109. This issue is dealt with extensively in the OTA, *supra* note 47, which is a synthesis of a considerable number of specific studies on the issue.

110. OTA, *supra* note 47, at 30-31.

111. *Id.*

their work[112] and are supported by analysis now underway in a second phase of the project:

(1) The post-1962 period has seen a relative shift in NCE output away from drugs providing no advance or only very modest increment advances over previously available therapies to an increased proportion of drugs offering at least some appreciable therapeutic advantage in comparison to earlier members of the therapeutic class.

(2) In the post-1962 period there is a suggested increase in the proportion of new drugs discovered through the "astute" discovery mode (recognition of the potential importance of an unexpected biological activity in a chemical being tested for other purposes).

(3) Therapeutic classes without post-1950 prototypes have had a particularly serious decline in overall NCE output in the post-1962 period. For these classes, depletion of *commercially* exploitable opportunities for new drug research in the 1950's may have contributed appreciably to the overall drop in innovative output since 1962. As another indicator of relative stagnation, in these classes there has been no increase in the proportion of drugs offering appreciable therapeutic advantages over previous therapies.

(4) In the post-1962 period, a larger proportion of new drugs has been characterized as having the benefit of reduced adverse effects compared to earlier drug therapies. These pre- versus post-1962 shifts were much more evident in drugs with chronic, rather than acute, modes of use.

(5) There were interesting and unexpected patterns in the data on total processing time from Investigational New Drug (IND) submission through NDA approval. Outside of the anti-infective and anticancer classes, average total processing times were significantly shorter for prototype than nonprototype drugs (approximately 49 versus 79 months, respectively). Also outside the anti-infective and anticancer group, there was a trend in the data suggesting a bimodel distribution in total processing times for chronic-use drugs. These drugs appeared to have either particularly long or particularly short total IND submission through NDA approval times. Acute-use drugs did not display this pattern.

These detailed findings, based on a disaggregate analysis of different therapeutic classes, led to the more general conclusion that the process of drug innovation has probably undergone some fundamental changes in the postregulatory era. Nevertheless, the changes are not all negative—on the contrary, many appear to be desirable—and they are not uniform across therapeutic categories.

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112. CENTER FOR POLICY ALTERNATIVES, MASSACHUSETTS INSTITUTE OF TECHNOLOGY, RELATIONSHIPS BETWEEN ASPECTS OF PHARMACEUTICAL REGULATIONS, INNOVATION, AND THERAPEUTIC BENEFITS (1980) (this report is currently being supplemented by a second phase of analysis which is nearing completion).

C. Impact of the Toxic Substances Control Act on Innovation

The Toxic Substances Control Act (TSCA),[113] enacted in 1976, was the last major regulatory system to be applied to the chemical industry. TSCA was debated for several years before its passage, and the long debate led to a detailed and sophisticated statute, which exhibits a strong consciousness about the effects it may have on technological innovation. Indeed, TSCA is the only regulatory statute that addresses this issue directly. The Act states at section 2(b)(3):

> Authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this Act to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment.

This concern for innovation has a number of origins. First, a major purpose of the Act is to encourage safer, more healthful new chemicals as substitutes for hazardous chemicals now on the market. Second, the Act recognizes that new chemicals are the basis for the historic pattern of rapid growth in the chemical industry and for its contributions to the national economy. Thus, a healthy climate for innovation is necessary both to achieve the environmental goals of the Act and to preserve the position of U.S. industry.

TSCA can be seen as a statute that "fills in the gaps" left by other regulatory systems.[114] In addition, however, it contains significant new authority of an omnibus nature, applying to all chemicals,[115] as well as a premarket clearance system specifically for new chemicals.[116] This last feature of the statute has caused the Congress, EPA, and the business community particular concern about its impact on innovation. Even before the Act was passed, studies were instituted in an attempt to assess its likely impact. In 1975 the first such attempt, by Foster D. Snell, Inc., was completed.[117] Using a survey and inteviews, it estimated that up to 2200 new chemicals were marketed each year. Of these, about 70% were exclusively for R&D purposes, thus leaving only about 30% potentially subject to TSCA.[118] These numbers, though widely cited, are subject to considerable uncertainty. The study also tried to portray the innovation process, emphasizing the important role of small firms in developing new products. It cited soaps, plastics, and industrial organics as sectors dominant in new chemical development.

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113. Pub. L. No. 94-469, 90 Stat. 2003 (1976) (codified at 15 U.S.C. §§ 2601-2629 (1982)).

114. The inability of other regulatory statutes to deal with certain kinds of problems (such as PCBs) constituted a major argument in favor of TSCA's passage. See R. DOULAY & G. ORDWAY, THE TOXIC SUBSTANCES CONTROL ACT (1977), for a reproduction of various items in the legislative history. Section 9 of the Act, 15 U.S.C. § 2608 (1982), deals in some detail with the problem of statutory coordination and in general defers action under TSCA to other statutory authority except when that authority fails to adequately address the issue.

115. For example, section 5 of TSCA, 15 U.S.C. § 2604 (1982), permits regulation of manufacture, processing, distribution, or disposal of existing chemicals.

116. *See* 15 U.S.C. § 2604 (1982).

117. Foster D. Snell, Inc., Study of the Potential Impacts of the Proposed Toxic Substances Control Act as Illustrated by Senate Bill S. 776 (Feb. 20, 1975) (paper prepared for the Chemical Manufacturers Association, Washington, D.C.).

118. Section 5(h)(3) of TSCA, 15 U.S.C. § 2604(h)(3) (1982), exempts scientific experiments and R&D.

Overall, the study is useful principally for its survey of trends in innovation rather than for meaningful projections about the impact of TSCA.

Subsequent to the passage of the Act, several studies tried to assess its impact. A study for EPA by Arthur D. Little, Inc. (ADL), completed in 1978, estimated that 1000 new chemicals per year were developed prior to TSCA, of which only 300 would potentially be subject to the Act.[119] ADL estimated that if premarket notification (PMN) costs were $10,000 per chemical, new commercial introductions would be reduced by 50%. However, the methodology of this study, based on a nonrandom small sample, was highly flawed. In fact, the study's deficiencies were widely publicized in congressional hearings.[120]

Another EPA-sponsored study, by ICF, Inc. in 1980, declined to predict with any exactness the impact of TSCA on innovation: "[E]ven with all of the necessary data to measure the current rate (of new chemical introductions) and the likely reduction (data that industry has been reticent to provide), it is doubtful that the level of the reduction could be predicted *ex ante*."[121]

The study estimated that the direct costs of PMN reporting were likely to range from $1000 to $9000. The researchers believed, however, that the uncertainties associated with EPA regulation might outweigh these direct costs as a deterrent to innovation.

The continuing concern about the impact of TSCA on chemical innovation had led EPA to undertake the above-mentioned studies of TSCA's economic costs. To address the policy issues more directly, in 1980 EPA contracted with the CPA to consider ways in which it might promote innovation in the implementation of the Act without sacrificing the principal goal of the legislation—protection of the public from unreasonably dangerous chemicals.[122] The resulting study's purpose was not to assess the impact of TSCA (in fact, as other studies had indicated, reliable data did not exist to do so), but rather, it was to provide a framework for anticipating how TSCA might affect innovation and how its avoidable negative impacts could be eliminated or neutralized. After a thorough survey of the then-available evidence, the study concluded:

> There is not a good understanding of the nature and sources of chemical innovation. For example, there are no sound data on the number of new chemicals marketed each year, or on the contributions of small and large firms or new entrants to chemical innovation. A few studies have found that large firms are more innovative than small ones, but even these results are open to serious question. A variety of factors in the scientific, financial, and competitive environment of the chemical industry are changing, and even if the TSCA has not been passed, historic trends in chemical innovation are unlikely to be followed in the future. Contributing to this is the fact that developments in products liability and in other environmental and occupational health and safety regulation are influencing chemical innovation quite apart from the TSCA's effects.

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119. U.S. ENVIRONMENTAL PROTECTION AGENCY, IMPACT OF TSCA PROPOSED PREMANUFACTURING REQUIREMENTS (1978).

120. *See* SUBCOMM. ON OVERSIGHT AND INVESTIGATIONS, HOUSE COMM. ON INTERSTATE AND FOREIGN COMMERCE, COST-BENEFIT ANALYSIS: THE POTENTIAL FOR CONFLICT OF INTEREST, H.R. DOC. NO. 218, 96th Cong., 2d Sess. (1980).

121. U.S. ENVIRONMENTAL PROTECTION AGENCY, ECONOMIC IMPACT ANALYSIS OF PROPOSED SECTION 5 NOTICE REQUIREMENTS, *executive summary* at x (1980).

122. SUPPORTING INNOVATION, *supra* note 2.

> Superimposed on the uncertain future of chemical innovation are the variety of effects that the TSCA regulatory requirements may have.[123] Environmental, health, and safety regulation can act through a variety of mechanisms to inhibit, stimulate or redirect technological innovation, depending on the circumstances. Since the TSCA features several different regulatory stimuli, and since the "chemical industry" is in fact a combination of many very different kinds of industries in various stages of maturity whose products differ greatly in the hazards they present, it is to be expected that inhibition, stimulation, and redirection will all occur at the same time. However, the current understanding of the interaction of regulation and innovation does not allow one to predict the quantitative impact of TSCA on the rate of chemical product innovation.
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> The inhibition of innovation by TSCA could arise, for example, from the marketing delays, testing costs, resource diversions, and commercial uncertainties it would introduce into the innovation process. The stimulation of innovation could arise, for example, from the increased staff diversity and revised corporate decisionmaking process required to comply with the TSCA. Redirection could arise from firms electing to seek safe substitutes or abandon lines of research into chemicals expected to pose a high risk to health.
>
> The main purposes of the TSCA are to slow the rate of introduction and/or encourage the more prudent use and operation of products and processes that pose unreasonable risks of injury to health and the environment. Thus, some inhibition and some redirection of chemical innovation was expected due to TSCA—it was part of the social bargain struck by Congress. Therefore, an observation that the rate of chemical innovation has declined, or that the nature of chemical innovations has shifted is not, by itself, grounds for determining that EPA has acted "unduly" or "created unnecessary economic barriers to innovation." Offsetting policies should not attempt to return the rate and direction of chemical innovation to some hypothetical pre- TSCA baseline.[124]

A suggestion and analysis of a "comprehensive program opportunity" then followed, focusing on the following seven different types of programs:

(1) EPA dissemination of chemical information-test results and labeling;
(2) Generic PMN for classes of new chemicals;
(3) Government support to develop new, better test methods;
(4) Direct cost subsidy for testing and compliance costs of new chemical development via a grant mechanism;
(5) "Fast track" PMNs for both safe and major innovations;
(6) Government support for education and training programs; and
(7) Direct cost subsidy for testing and compliance costs of new chemical development via a loan mechanism (or loan guarantee).

In 1981 and 1982, the question of the costs and impacts of the PMN process was again raised when two studies were completed by the Regulatory Research Service. One was for the Chemical Manufacturers Association[125] and the other for the Chemical Specialties Manufacturers Association.[126] The first study estimated, by extrapolating from the numbers of PMNs submitted during a selected 1980-1981 period and adjusting this number to account for intermediates and early-stage products, that the number of new chemicals was reduced by 71 to 88% from the pre-TSCA period. The second study estimated that, for ingredient suppliers, new substance development was on average 26% lower for 1979-1981 than in 1976-

123. Regulation in this context includes both procedural requirements, such as premanufacturing notification, and substantive requirements, such as use restrictions or testing requirements.

124. SUPPORTING INNOVATION, *supra* note 2, at 9-11.

125. E. Heiden & A. Pittaway, A Critique of the EPA "Economic Impact Analysis of Proposed Section 5 Notice Requirements" (1981) (report prepared for the Chemical Manufacturers Association).

126. E. Heiden & A. Pittaway, Impact of the Toxic Substances Act on Innovation in the Chemical Specialties Manufacturing Industry (1982) (report prepared for the Chemical Specialties Manufacturers Association).

1978. About 98% of this decline was believed to have occurred in smaller firms (sales under $100,000,000).

These two studies are subject to considerable question, not only methodologically, but also with respect to the assumptions on which they are based. First, their estimates of pre-TSCA innovation levels—indeed any numerical estimates of the level of chemical innovation—are highly suspect. Second, extrapolations from these pre-TSCA numbers to post-TSCA numbers (as measured by PMNs) are dangerous. The immediate post-TSCA period is likely to be unrepresentative. Levels of new product introduction may look low because many new products were introduced just before regulation occurred or because it took industry and government some time to become familiar with PMN procedures. In any event, so many factors influence chemical innovation that a decline in innovation cannot necessarily be attributed to TSCA. Lastly, simply counting numbers of chemicals is not an adequate basis for drawing an evaluative conclusion: chemicals differ too markedly in terms of their market and social value for increases or decreases in the numbers of new products to be a reliable indicator of economic or social welfare.

In spite of the deficiencies of the several studies referred to above, there are certain common themes running through them which appear to be important for policy purposes. One of the themes that emerged in the CPA study, as well as in others dealing with the issue, is that the impacts of TSCA regulation may fall disproportionately on certain elements of the industry. Several recent studies have elaborated on this theme. One study concerning the effect of TSCA on small chemical companies was addressed in a paper by J.R. Yost of Muskegon Chemicals.[127] Yost defines small companies as those with $20,000,000 or less in sales and fewer than 100 employees. He argues that small companies can ill-afford the cost and time involved in complying with TSCA, particularly its premarket notification requirements which, he believes, reduce the small company's great advantages: speed and flexibility in responding to customer needs. His evidence for this position is anecdotal, based on his own experience, rather than on any empirical findings, and his argument rests on the intuitive analysis that "the mathematics of a larger company make [regulatory] costs a lot less proportionately."[128]

Another study by Dan Harlow examined what kinds of corporate structures, procedures, and personnel impacts have resulted from TSCA compliance.[129] His analysis, which differentiates the compliance responses of very large, large, medium, and small firms, suggests that small firms spend very much less than large ones on TSCA compliance. Often they rely on trade association help as a supplement to in-house personnel assigned part time to TSCA compliance. Large firms, in contrast, often have large regulatory affairs staffs. He maintains that it is impossible to separate TSCA-related functions from those involving other regulatory legislation and that, although additional costs have been incurred, these "will be

127. J.R. Yost, Effects of TSCA on Small Chemical Companies (Mar. 1982) (unpublished paper presented at the American Chemical Society Symposium).

128. *Id.* at 2.

129. Harlow, *TSCA: Impacts on Corporate Structure and Procedure,* in ACS 1983, *supra* note 64, at 121-32.

expressed in the cost of products and services provided by the corporation."[130]

A somewhat different view is offered by Oslosky and Keller, who have examined the reactive polymer industry,[131] which in areas such as coatings, plastics, inks, and adhesives, manufactures a wide range of products to meet fast-changing market needs. They have found that the impacts of TSCA are both positive and negative from the point of view of a corporation in this sector. Since 1979, when TSCA regulation effectively began,[132] nearly all the corporate compliance activity has been directed toward the PMN process for new chemicals. One of the negative impacts of TSCA has been the alleged diversion of a substantial but immeasurable amount of facilities and personnel from ordinary new product activities. The industry sees PMN, particularly the interpretation of what is a commercial product, as unduly restrictive since only about 29% of reactive polymer PMNs are actually marketed. The remaining 71%, called "protective" filings, are seen as unnecessarily burdensome to the companies. Other negative impacts include testing costs and uncertainty about regulatory directions. Oslosky and Keller, on the other hand, found some significant positive impacts arising from TSCA, although these are even harder to quantify than the negative effects. First, because corporate resources are now diverted away from traditional activities, new opportunities are likely to be uncovered and new uses found for old products. This tendency is reinforced by the virtual absence of TSCA regulations pertaining to existing products, even when they are applied to new uses. Second, it appears that the need to scrutinize products more carefully leads to better communication and planning in many corporations. Thus, Oslosky and Keller conclude that "nearly every negative impact discussed has some positive aspect that the manufacturer committed to health and safety can maximize to reduce the total adverse effects."[133]

The most recent series of assessments of the impact of TSCA on chemical innovation took place under the auspices of the American Chemical Society (ACS) in the spring of 1982. At that point, two-and-a-half years since the imposition of the PMN requirement, about 1100 PMNs had been submitted, thus providing a substantial data base for analysis. The fact that 1100 PMNs were submitted over a two-and-a-half-year period was the subject of much concern among industry commentators. For example, Carl Umland compares this figure (actually, he uses an annualized PMN rate of 600 to 700) to the ADL and Snell estimates of 1000 and 2200 new chemicals per year. He infers from this that the PMN process has created "an apparent drop in new substance introduction on the order of 35-70%."[134] He believes that this drop results from the direct PMN costs, $12,000 according to his estimate, and the uncertainty created by the PMN process at an economically

130. *Id.* at 15.

131. Oslosky & Keller, *supra* note 64.

132. The premarket notification requriements (PMNs) did not become effective until July 1, 1979, thirty days after the inventory of existing chemicals were published. *See* 45 Fed. Reg. 50,544 (1979). The final premanufacture notification regulations were not published until May 19, 1983. *See* 48 Fed. Reg. 22,694 (1983).

133. Oslosky & Keller, *supra* note 64, at 154.

134. Umland, *Future for Innovation,* in ACS 1983, *supra* note 64, at 29.

vulnerable point early in the life cycle of new products. Umland argues that these costs and uncertainties are most likely to affect small-volume and financially risky new products. This means in turn that specialty producers and small companies will be most adversely affected. Umland's prescription for these problems, which is also advocated by the Chemical Manufacturers Association, is to exempt from the PMN requirements many polymers, site-limited intermediates, and production volumes below 25,000 pounds per year.[135]

Umland's paper makes a good case for the economic importance of small-volume, specialty chemicals. He documents, to some extent, their uses, the pattern of their development (many are discontinued within a few years), and their importance to the overall process of innovation in the chemical industry. Furthermore, his argument that this sector of the industry is most hurt by TSCA has logical appeal. Nevertheless, the facts that Umland presents certainly do not prove that innovation or small-volume chemicals have been especially hurt by TSCA. The pre-TSCA innovation studies are too methodologicaly flawed to be reliable baselines, and the two-and-a-half-year period of experience to date is too short and unrepresentative to yield anything more than hypotheses about TSCA's impacts.

In any event, there are alternative explanations of the PMN data. Douglas G. Bannerman, an EPA official, has presented and analyzed these same data in some detail.[136] He shows that the rate of PMN submittal has increased dramatically: from only about 30 per calendar quarter in the early quarters to about 200 currently. This suggests that the negative impacts that occurred may have been a transition phenomenon or the result of massive new introductions in anticipation of the PMN requirement. Bannerman's data also show that the great majority of PMNs are submitted by large companies.[137] Through 1981, those with sales over $500,000,000 have submitted about 70% of all PMNs filed and those with sales of $100,000,000 to $500,000,000 have submitted 15%. These findings, as Bannerman admits, lend some support to the Umland position that small companies are being hurt. Nevertheless, both EPA and the Chemical Specialties Manufacturing Association have found that small companies frequently misperceive the regulatory requirements—they tend to believe testing is required for PMN submittal when in fact it is not—and therefore are mistakenly deterred from filing a PMN.[138] The PMN submittal record is further skewed by the fact that a relatively small number of companies file a relatively large percentage of all PMNs. Thus, although 186 companies have made submittals, 6 companies' filings comprise 28% of the total number of new chemicals. Bannerman concludes that there is no way really to know whether TSCA is affecting chemical innovation positively or negatively. He believes, however, that TSCA is creating significant benefits: the chemicals

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135. The industry has sought an exemption for polymers since 1979. In response, the EPA has developed several versions for such an exemption, and a final version is now reportedly under review. *See OPTS Approves Policy to Allow Production of Structural Polymers without EPA Review,* 1983 CHEM. REG. REP. 1275.

136. Bannerman, *Impact of TSCA on Market Introduction of New Chemicals,* in ACS 1983, *supra* note 64, at 7.

137. Bannerman is apparently unable to distinguish, however, between small, independent companies and small subsidiaries or affiliates of very large companies.

138. Bannerman, *supra* note 136, at 8.

entering the market are now safer. On the other hand, EPA recognizes the need to guard against the potential for uneven negative impacts on some segments of the industry, and it is currently implementing a program to address this issue.[139]

Another ACS symposium paper, by Hurst, ties together the experience with PMN submittals to date with broader trends in chemical innovation.[140] Hurst argues that the experience with the first 1100 PMNs shows that "the Agency has found reason to question only a very few chemicals as presenting unreasonable risks."[141] This suggests that the PMN submittal rate probably approximates the actual development rate of commercially viable new chemicals. Hurst's examination of available PMN data also leads him to the conclusion that most new chemicals are actually modifications of existing substances and that "our industry's R&D effort is not producing 'new chemistry.' "[142] His conclusions seem in accordance with the findings of Landau, who suggested that there is a general shift in the industry toward process-oriented R&D and away from new products.[143] The inference to be drawn from both writers is that TSCA is less important to the future of chemical innovation than market factors.

V

CONCLUSIONS

The evidence that exists about the relationship between regulation and innovation in the chemical industry strongly suggests that an understanding of this interaction lies more in the investigation of particular cases than in generalizations about overall effects. The need for disaggregated analysis arises from the fact that individual regulations and regulatory systems differ too much in terms of their purposes, operational mechanisms, and histories of implementation to be treated as a group. Similarly, the chemical industry is too complex and varied an industrial sector for its responses to regulation to be uniform. Changes over time complicate the problem even further, making the transient and long term effects difficult to distinguish. Finally, existing empirical data are either too sparse or inconclusive to prove conclusions of general applicability. However, much is known about the regulation-innovation relationship if one focuses individually on the various subcategories of the industry and on specific regulation. A number of particular cases have been well-documented. In addition, one can make clear distinctions and contrasts among these different examples, thus yielding a relatively well-defined taxonomy for approaching the overall issue.

Within the diversity of regulations applicable to the chemical industry, three generic regulatory mechanisms should be distinguished. One type of regulation is based on governmental premarket approval of new chemical substances. This group includes the regulation of pharmaceuticals, food additives, pesticides, and most other new chemicals, via the new chemical provisions of TSCA. A second

139. *See* SUPPORTING INNOVATION *supra* note 2.
140. Hurst, *TSCA—After Five Years—An Overview,* in ASC 1983, *supra* note 64, at 81-94.
141. *Id.* at 92.
142. *Id.*
143. *See* Landau, *supra* note 54.

group of regulations, directed principally at process control, includes air and water pollution control and control of workplace technologies. The third type is focused on existing products, including consumer product safety regulation and the regulation of existing chemicals under TSCA. The differences among these three broad types of regulations are important in terms of their relationship to technological innovation. For the most part the regulations pertaining to new chemicals are based on a risk-benefit analysis conducted by the regulators. Since this analysis is imposed uniformly on new substances, it generally necessitates the development of environmental, health, or safety data by the manufacturer.[144] The regulations for existing products, although based on a similar risk-benefit framework, require the government to amass evidence about the chemical hazard in question or, as in the case of TSCA, very infrequently impose testing requirements on the manufacturer through imposition of a chemical-specific rule before taking any regulatory action.[145] The regulations directed principally at processes are based on one of two rationales: health objectives[146] or some concept of technology forcing.[147]

Based on the evidence currently available, it appears that regulations of the first type, such as premarket approvals, may simultaneously be having an adverse competitive impact on certain kinds of firms while increasing the likelihood of success for new products which are offered on the market by industry as a whole. The adverse effects appear to be felt most by the small and newer firms, particularly those that produce specialty chemicals for limited, dynamic markets. These effects derive principally from the following factors: the ability of large firms to monitor or influence the political and legal climate; the economies of scale in compliance that large firms may enjoy; and the disproportionate emphasis these regulations place on new as opposed to existing products. Regulation under TSCA perhaps best illustrates this problem. Data about PMNs submitted to EPA as well as other evidence *suggest* that small companies and specialty chemicals have suffered a decline relative to the situation of large companies, particularly those whose products are targeted to large markets.[148] The larger companies are not only better able to understand and comply with regulatory requirements but also

144. For example, there is no general duty to test new chemicals under TSCA. The registrant need only submit the information in its possession, and from that information the EPA decides whether or not to impose additional testing requirements.

145. Similar language can be found in both TSCA and section 7 of the Consumer Product Safety Act, 15 U.S.C. § 2057 (1982), to describe the protection to be afforded the public by the regulations promulgated thereunder—protection from "unreasonable risk."

146. For example, ambient air quality standards are intended to protect public health "with an adequate margin of safety," section 109(b)(1) of the Clean Air Act, 42 U.S.C. § 7409(b)(1) (Supp. V 1981) and were not intended to take into account, during their promulgation, issues of economic or technological feasibility. *See* Union Elec. Co. v. EPA, 427 U.S. 246 (1976).

147. For example, effluent standards in the water pollution context are based on "best practicable technology" or "best available technology." Clean Water Act, 33 U.S.C. §§ 1311(b)(1)(a) & (2)(a) (Supp. V 1981). These concepts are meant to move forward the level of control technology used in the industry. *See* EPA v. National Crushed Stone Ass'n, 499 U.S. 64 (1980). Standards for occupational exposure to toxic substances are driven by health concerns but limited by technological feasibility. *See supra* note 22.

148. It should be emphasized that this evidence is only suggestive. Bannerman's data, *see supra* note 136 and accompanying text, the only published analysis, does not prove that small company innovations have decreased because it has no pre-TSCA baseline for comparison. Similarly, these data do not distinguish between small, independent companies and small subsidiaries of large firms.

may be better able to influence the regulatory process. In addition, economies of scale and scope may make the large companies more able to bear the associated costs. The situation under TSCA is exacerbated by the disproportionate emphasis regulatory action has placed on new chemical substances, as opposed to problems associated with existing products. Were strong regulatory actions under TSCA directed at existing products, this would create an incentive for the introduction of new, safer substitutes. Given the history of innovation in the chemical industry, it is to be expected that many such substitutes would be developed by specialty producers. As it is, however, the incentives for the production of safer substitutes are weak, and, as a result, the regulatory requirements fall disproportionately on the introduction of new chemicals by new, small, and specialty firms.

At the same time, the regulatory premarket approval process may be benefiting many companies by increasing the likelihood that their new products will be successful in the marketplace. Studies from both the pharmaceutical and TSCA areas indicate that the testing and analysis which is now routinely undertaken in the development of the application for government approval often also yields a much better idea of the characteristics of the product under development. In addition, a variety of studies have shown that regulation-related R&D often suggests new uses for products and sometimes new product lines. It appears that these benefits are most likely to occur among companies with significant research establishments where these costs can be absorbed relatively easily, where speed in new product introduction may not be critical to capturing a market, or where the regulatory constraint has promoted new, creative thinking.

The regulations directed at existing chemical products seem to prompt one of two types of reponses. In a number of instances, an existing chemical has simply been substituted for a regulated one.[149] This substitution is typically accomplished by firms in the industry. In other instances, however, new products have been developed, often offered by new entrants.[150] This appears most likely to occur when the regulation is most stringent and challenges the technological status quo.

Regulations based principally on a health or technology forcing rationale also appear to be having diverse effects on innovation. For example, regulations based on "best available technology," or a variant of this concept, tend to promote the diffusion of known technology more than the development of the new.[151] On the other hand, the few regulations that have gone beyond the technology available at the time of promotion, or which have stretched that technology's capability to some extent, appear to have led to the development of innovative products and processes.

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149. For example, nonmercury pesticides were substituted for mercury-based products; and in paints, nonlead pigments and driers quickly came into use when lead became a health concern. *See* CPA CHEMICAL INDUSTRY STUDY, *supra* note 21.

150. PCB substitutes—of which there are several—are the best examples. None were developed by Monsanto, which is the sole U.S. producer of PCBs.

151. In theory, the necessity for regulators to base requirements on the best existing technology should provide an incentive for innovators, especially in the compliance technology sector, to produce new, better technology on which new, more stringent regulations will be based. In fact, this does not appear to have occurred.

The differences between premarket and postmarket regulation are also further affected by differences in the technological "stringency" of the regulatory requirements. Stringency can be viewed as a measure of the technological difficulty entailed in complying with regulation. To some extent, stringency measures the degree of development required. In addition, however, changes that are well within the realm of existing technical capabilities, but quite costly, should also be thought of as stringent. Stringent regulations, such as those pertaining to PCBs or vinyl chloride, appear to be more likely to prompt the development of innovative new technologies than regulations based on existing technology or on risk-benefit criteria for approval or disapproval of new products. On the other hand, the costs and difficulties associated with stringent regulations often lead to significant political and legal controversy, which may result in delays in the development of compliance technology or abortive technological responses.

Overall, the regulations based on premarket approval of new chemicals represent a more comprehensive but often less stringent regulatory regime than the regulations for existing products and processes. The existing chemical regulatory actions, of course, have not been uniformly stringent. On the contrary, many of these regulations have been relatively easy to comply with and thus have prompted little or no technological change other than diffusion.

In considering the relationship between regulation and technological change, the characteristics of both the applicable regulations and the technology in question must be taken into account. Investigations of responses in industry lead to the general conclusion that the particular characteristics of the technology in productive segments would be a major factor determining the nature of the technological response to regulation. This general hypothesis is based on a variety of studies of the innovation process which explore the concept of technological "rigidity" as a determinant of the nature of technological change in a given industrial context.[152] Studying the technology in use before regulation often allows one to predict the subsequent industrial response. Of course, variations among individual firms are to be expected, but, in general, responses appear to be fairly predictable and consistent across the sector in question.

Other more specific findings support this basic hypothesis. First, in most sectors, the kinds of technical changes that firms within a productive segment have made to comply with a given regulation have been highly uniform. This uniformity cannot be attributed to regulatory signals which required a single compliance technology because most of the regulations investigated were performance standards. Rather, the response uniformity within productive segments suggests that the character of the existing technology does indeed dominate the response to regulation, as would be the case for other market stimuli. Second, the proportion of product and process responses to regulation closely resembles the expected balance of product to process innovations occurring in the segment absent regulation. Thus, "fluid" industries tend to respond to regulation with product modifications, and "rigid" segments tend to have more process responses than product changes.

152. *See supra* text accompanying notes 25-33.

"Transition" industries, in contrast, exhibit both product and process changes and a greater overall amount of change than fluid or rigid segments. These responses to regulation are highly consistent with the usual pattern of innovation in the absence of regulation.

One of the most interesting linkages between the technological characteristics of the regulated segment and the nature of the response pertains to the issue of technological novelty. Although it might be expected that the most novel responses would arise from fluid segments and the least novel from rigid segments, this does not appear to be true. On the contrary, regulation of rigid segments often elicits reponses as novel or more so than those in fluid segments. This finding lends some support to the idea that regulation can change the overall character of innovation in rigid industries and that creative responses to regulation may occur when the regulation precipitates "crisis" conditions for the industry. Again, Klein's analysis of the conditions necessary for dynamic change seems to be supported by empirical findings.

Findings with respect to specific parts of the chemical industry and how they have responded technologically to regulation vary greatly. There are a wide diversity of responses—major and minor, innovative and noninnovative. In addition, responses have arisen in many sectors other than those initially affected by the regulations in question. Often, these sectors have developed the most innovative responses. There appears to be a distinct and widespread perception in industry that regulation is detrimental to innovation. Little evidence exists to support this perception as a general proposition, and indeed, most of the business people surveyed have been unable to document their perception with reliable data. On the other hand, a number of studies have shown that regulations have only rarely required major changes of industry. Even some of the most controversial regulations, such as regulation of asbestos in the workplace, appear to have caused little or no technological change in most of the affected industry.

The chemical industry does, however, seem to be undergoing a period of transformation. For example, R&D appears to be shifting away from basic research and toward more applied work. Certainly, regulation, or more precisely, the sum of the many diverse regulatory regimes that apply to chemicals, has played a major role in the transformation; but the traditional market forces have been transformed as well, and it is not possible to separate the effects of these two different stimuli. Many of the longer term impacts of regulation appear to be "systemic" or ancillary to the compliance effort. For example, changes in the skill mix of personnel involved in the new product development, such as the involvement of more toxicologists or analytical chemists, may lead to the development of safer products as well as more discoveries, given the new diversity of approaches to product evaluation. Changes of this nature seem to be occurring in the pharmaceutical industry, causing for many therapeutic classes a relative increase in the proportion of prototype drugs and drugs of significant therapeutic value.

The foregoing conclusions have focused on specific subparts of the chemical industry and particular types of regulatory impacts. It is also important to recognize that each of the types of impacts enumerated above will be felt differentially

across the firms that comprise a particular segment of the chemical industry. As mentioned earlier, it is to be expected that regulation will produce differential competitive impacts, given that some firms will be more technologically predisposed or more able to mount effective and less costly compliance activities.

Were the competitive effects of regulation to fall at random throughout an industry, it would be of little concern to policymakers. The issue is of concern, however, because some evidence, and many commentators, suggest that adverse effects are in fact being felt among the more innovative segments of the industry—principally new firms, small firms, and specialty producers. The evidence of this phenomenon is suggested most strongly by the experience with TSCA. Small firms seem to be least likely to understand regulatory requirements and least able to cope with them. There appear to be two reasons for this phenomenon. First, under TSCA particularly, new chemical regulation has been emphasized and regulation of existing chemicals almost ignored. This lopsided regulatory emphasis in turn creates incentives for firms to maintain the status quo of existing chemicals and effectively penalizes to some extent the proponents of new products. Second, the relative financial and technical weakness of small or new firms appears to impede their responses to regulation. Having concluded that the detriments to small, new, or specialty firms are an important issue in some contexts, it should not be implied that this is uniformly the case. Indeed, when regulations have effectively challenged the technological status quo, these firms often make best use of the opportunity to introduce new, innovative, and socially desirable products.

Going beyond the question of what the impacts of regulation have been, it is necessary to distinguish between impacts that are transient and those that will persist over the longer term. A great deal of the discussion and concern to date seems to have been about impacts which are likely to be transient, such as R&D "diversion" or managerial time devoted to compliance. Little attention has been paid to the long term agendas and effects of regulation. Thus, it should be acknowledged that the long term purpose of all the regulatory systems applicable to the chemical industry is to change, in a fundamental way, the nature of the technology the industry employs. In particular, this means changing the perspectives engineers and others bring to the design process so as to incorporate, as the standard way of doing business, the many social concerns that environmental, health, and safety regulations exemplify. It should also be acknowledged that this process of change will be disruptive. Individual regulations will inevitably displace the market position of particular entrenched technologies, and the new design ethos will, of course, supplant those who continue to subscribe to the old. Over the long term, however, these displacements may be all to the good, even for reasons other than those concerning the environment, health, and safety. As Klein's work so persuasively suggests, a dynamic, innovative economy is built on a continual push toward change, based on stimuli that provide "negative feedback" to those firms that adhere to the status quo. Over the long run, regulation may provide one such important stimulus.