**THE EFFECTS OF FEDERALREGULATION ON CHEMICAL INDUSTRY INNOVATION**

INTRODUCTION

The extent to which federal laws and regulations, particularly the Toxic Substances Control Act (TSCA),' have adversely affected the development of new chemical products, has become a matter of considerable interest and controversy. The question is both important and complex.

The importance of the question has at least two dimensions. First, the question is important because of its implications on how environmental health laws are administered. If it becomes generally accepted that these laws significantly impinge on innovation, it is then likely that the implementing regulations, and perhaps even the laws themselves, will be modified so as to impose less of a burden on industry. Modifications of TSCA regulations for reviewing new chemicals have already been proposed.

The second reason the regulation-innovation question is important is that it highlights in a dramatic way the need to consider the interaction and relationship between private sector economic processes and governmental regulation. In the health and safety area, the interaction between the two major institutions of society, government and industry, has been largely neglected except for rhetorical purposes. Society is beginning to realize that the true effects of regulations cannot be understood without understanding how the regulations relate to the decision making process, the flow of money, and other characteristics of the private sector.

The relationship between regulation and innovation is quite complex. It has been examined in detail only in the context of new drugs, an area that will not be covered in this article. The complexity derives from the many different regulations,the diversity of the chemical industry, and the differences among types of innovation. Each of these factors will be discussed briefly.

A. Types of Regulations

There are a large number of health and safety statutes that have an impact on the chemical industry. For the purpose of considering their impact on innovation, three general types of regulatory schemes should be distinguished. These schemes should be labeled as follows: environment-oriented, product registration, and product oversight. Environment-oriented statutes are the most common, and they are focused on the level of contamination of some aspect of the environment. Included in this category are the Clean Air Act, the Clean Water Act, the Occupational Safety and Health Act, the Safe Drinking Water Act, the Resource Conservation and Recovery Act, and the Comprehensive Environmental Response, Compensation

and Liability Act.

Product registration statutes require that particular kinds of products be approved by the government before they can be manufactured or marketed. The Federal Food, Drug, and Cosmetic Act' and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) are the only two health and safety statutes in this category.

Product oversight statutes focus on particular products but do not require government approval for new products. The Hazardous Substances Act, the Consumer Product Safety Act, the Flammable Fabrics Act, and the Toxic Substances Control Act are examples.

The reason for making these distinctions is that the different types of regulatory

schemes may have quite different effects on innovation. Some of these differences

will be described later.

B. Diversity of the Chemical Industry

The chemical industry produces a vast array of products which are used by all other industries in the economy.

**EFFECTS** ON INNOVATION

List more than 55,000 chemicals, and this inventory excludes thousands of drugs, pesticides, food additives, and cosmetics.' 8 Some chemical products are used only to make other chemicals. Others are sold to processors who incorporate them into consumer goods. Many major chemical companies, such as Dow and DuPont, sell some of their products directly to the buying public.

The Standard Industrial Classification Manual contains eight major divisions of chemicals and allied products: industrial inorganic chemicals; plastics, synthetic rubber, and man-made fibers; drugs; soaps, detergents, and cosmetics; paints, varnishes, and allied products; agricultural chemicals; industrial organic chemicals, and miscellaneous chemical products.

Some chemical companies only produce one product or one type of product. Many companies produce products in several or all of the major industry divisions. Many companies that make chemicals are not primarily chemical companies. Four of the top ten chemical producers in 1981 (Exxon, Shell Oil, Gulf Oil, and Occidental Petroleum) were oil companies. Another two of the top ten had only about half their total sales attributable to chemicals (Union Carbide, 57%; W.R. Grace, 45%).The top twenty-five included a photographic equipment company (Eastman Kodak), a dairy products company (Borden), and U.S. Steel.

A total of 11,500 companies are estimated to be involved in producing and processing chemicals. About 1,000 companies are in the basic chemical industry and 3,100 in allied products with the remaining 7,400 in chemical processing. In 1980, thirty-six companies had chemical sales of over $1 billion. But there are thousands of chemical companies with annual sales of less than $1 million. In 1981, DuPont spent $575 million on research and development, and Dow spent

$404 million. But thousands of companies do no research and development. Some companies depend on innovation for their continued existence. Many do not innovate at all. In short, the industry is so large and diverse that it is almost impossible to subject it to valid generalizations.

C. Varieties of Innovation

Most broadly, innovation can be described as the creation and introduction of something new. Technological innovation has been defined as "a conscious attempt to bring about, through technology, a change in the way man lives.

LAW **AND** CONTEMPORARY PROBLEMS

Innovation is the process by which technological knowledge is developed and transformed into

specific products, processes, and services to meet human needs.

This article defines innovation to include the sequence of steps in the conception,development, testing, production, adoption, and diffusion of a technology.

The focus, however, will be on the stages between invention and widespread diffusion because these are the stages most likely to be affected by regulation.

Distinctions must be made among the kinds of innovations as well as among the stages in the innovation process. Most important is the distinction between product and process innovations. Much of the innovation in the chemical industry is changed processes, that is, improved methods for making the same product.

However, will concentrate on the innovation of new products because this topic has been the subject of primary concern with respect to the chemical industry.

Given the different types of regulatory schemes, the diversity of the chemical industry, and the varieties of innovation, it should not be hard to understand why the interrelationship of the three is very complex.

ADVERSE EFFECTS OF REGULATION ON INNOVATION

To understand how regulation affects innovation in the chemical industry it is first necessary to understand the dynamics of the innovation process in the industry. This is difficult, however, not only because of the complexities discussed above, but also because there have been very few empirical examinations of the innovation process in the chemical industry. To understand chemical innovation, three interrelated levels or models must be considered: the industry level, the company level, and the product level.

A. Industry-Level Effects: Market Concentration

Government regulation may have the effect of increasing concentration in an industry by increasing the cost of developing and marketing products and thereby eliminating all but large firms from the market. This effect, if it occurs, will probably influence the rate and type of innovation that takes place in the industry, although the existing literature contains contradictory findings on the relationship between innovation, on the one hand, and industry concentration and the size of a firm, on the other.

Manufacturing industry between 1972 and 1977 found that ten companies started manufacturing basic pesticide ingredients for the first time in the period between 1972 and 1977 while thirteen companies stopped manufacturing pesticides. Three of the companies that stopped produced only very small amounts of one chemical.

The above data are not intended to imply that small companies are not precluded from manufacturing pesticides. In fact, they are. But the barriers to entering the market are the large capital investment required for manufacturing facilities, the large cash reserves necessary either to purchase patent licenses or to sort through a large number of chemicals looking for a suitable pesticide, and the network of salesmen to distribute the product. Regulatory requirements are also a barrier to entering the market, but if all of the regulatory requirements disappeared,

it would still be impossible for a small firm to get into the pesticide manufacturing business.The concentration data cited above indicate that increases in regulatory requirements during the 1970's have not had a significant concentrating effect.

Research and development is probably more concentrated than sales or production in the chemical industry. Over 60% of the research and development funds for industrial chemicals are spent by four companies. DuPont alone accounts for about one-fourth of all research and development in the chemical industry. Seventy-one percent of the new chemical notifications under TSCA were submitted by companies with sales over $500 million. Only 2% of the notifications were submitted by companies with sales under $10 million. This would suggest that small companies do little new chemical innovation. One, therefore,need not worry too much about regulation impeding innovation in small companies.

However, some industry representatives have interpreted the TSCA figures to indicate that regulation has already put an end to small companies developing new chemicals, and that in the good old days, perhaps before 1976, many small companies developed many new chemicals.

B. Company-Level Effects: Research and Development

There are two types of innovation-related decisions that are applicable to an entire company, not just to an individual product. The first is the philosophy or strategy that the firm wants to pursue with respect to innovation. The second is the annual decision of how much to invest in research and development. The specific decisions within a firm regarding innovation are governed, implicitly or explicitly, by the corporate strategy of innovation. Such strategies are of great importance, but they are also elusive because they can take a variety of forms, and only rarely are they explicitly documented. The most basic strategy choice, in the realm of innovation, is whether a firm wants to engage in innovative product activity at all. All firms within some industries, and many firms within innovative industries such as the chemical industry, choose to compete for market share by marketing at a lower price rather than by developing new products. Sometimes the pricing strategy itself depends on making process innovations that permit more efficient production. Another strategy choice may involve the choice of product lines where research emphasis will be placed. Still another choice is between conducting research in-house or

buying patent rights from other, sometimes foreign, firms. One effect of health and safety regulations may be to place more emphasis on minor improvements in existing products than on more radical innovations.

Because existing products have been on the market their health and environmental effects are presumed by some to be better known than those of a completely new compound. Also, government regulators are likely to give more careful scrutiny to major new products than to minor improvements. The time delay involved in government regulation may also discourage radical innovations.

**EXTENSION AND** THE **PHARMACEUTICAL INDUSTRY** 26 (1982).

Slight decline in the average number of new pesticide chemicals registered since the late 1960's, but the pattern is erratic, and the largest number of registrations was in 1975 when the 1972 amendments to FIFRA34 were beginning to have their full impact. Similarly, the number of new pharmaceutical chemicals declined sharply in the early 1960's, but most of the decline was in drugs that represented little or no therapeutic gain. Chemical industry research and development expenditures have generally increased over the past decade, even when inflation is taken into account. This is true not only for the industry as a whole, but also for its most intensely regulated

sectors, drugs and pesticides**.** For both pesticides and drugs, research and development expenditures as a percentage of sales has remained constant at about **8%,** but there has been continuing real growth in sales. The result has been continuing real growth in research and development. It is undoubtedly true that a larger portion of this research and development is more "defensive" than it was ten or fifteen years ago, but there are no good data on the way the research and development expenditures are apportioned. Mansfield found that in the chemical

industry the proportion of research and development expenditures going for basic research had declined in the last decade and that the proportion devoted to long term (more than five years) projects had also declined. 37 The ratio of industry research and development to sales for chemicals as a whole has also declined significantly.

C. Product-Level Effects: The Commercialization Decision

The analysis done by a firm to decide whether or not to commercialize a new product depends on the type of product line, the size of the firm, and the amount of investment necessary to bring the new product to market. A specialty chemical firm deciding to make fifty pounds of a new chemical may not do much more than a back-of-the-envelope calculation to determine the selling price. At the other extreme, a large firm may spend months analyzing alternative scenarios of cash flow, return on investment, etc., before deciding to proceed with a major new

product. The three elements that are crucial to any decision to commercialize are cost, time, and uncertainty. All three may be adversely affected by regulation. The impact of regulation on direct costs depends on the nature of the regulatory requirement and on the type of firm or product impacted. Pollution control costs for industry as a whole amounted to $31.5 billion in 1980.

These pollution control costs can adversely affect innovation in two ways. First, by using capital funds which might otherwise be invested in new plants or new equipment, pollution control investments may retard or prevent the introduction of process changes. Second, the costs of operating the pollution control equipment may reduce profits, which may in turn reduce the amount of money devoted to research and the development of new products. Regulations directed at new products, such as the manufacturing notification requirements under TSCA or the pesticide registration requirements under FIFRA, increase the direct cost of marketing a new product. The increase in direct costs may result in a decision by a firm not to market a new product or even not to develop new products at all.

The average research and development cost for each new pesticide registered under FIFRA is estimated to be $6.9 million. Of the $450 million total pesticide industry research and development expenditures in 1981, 67% was devoted to development of new products, 25% to product expansion, and 8% to reregistration and product defense.42 The average cost of filing a TSCA pre-manufacturing notification has been estimated to range from $5,000 to $7,800. The impact of direct regulatory costs on product innovation is roughly proportional to the percentage that such costs bear to the total investment necessary to commercialize the product. For a large firm deciding whether to market a major new product, the direct regulatory costs are unlikely to significantly influence the decision. Data obtained from one large company on typical costs for developing a new pesticide indicate that added regulatory costs of $1 million would not significantly influence the decision to market the pesticide. On the other hand, for a firm deciding whether to make a single small-volume batch of a new chemical, at a cost of maybe $10,000 to $30,000, almost any regulatory costs may influence the decision to proceed. The decision may hinge on the extent to which the costs can be passed on to the customer. For major products involving large capital investments, time delay is likely to be a more important regulatory impact than direct costs. The same data on typical costs for a new pesticide cited above indicate that a two-year delay in registering the pesticide would reduce the cumulative net income from the product over its total commercial life by more than 50%. 45 The National Agricultural Chemicals Association (NACA) estimates that in 1981 the average time consumed

from submission of a registration application for a new pesticide chemical to granting of a conditional registration was twenty-four months. On the average, more than seven years elapsed between initial discovery and conditional registration. FIFRA and the Federal Food, Drug and Cosmetic Act are the only health safety statutes that impose significant time delays on new product development. The ninety-day waiting period for new chemicals under TSCA is not likely to be a major impediment to the devleopment of new chemicals except in the case of some small-volume chemicals needed rapidly for a particular customer's use. Small volume exemptions now being considered by the EPA probably would eliminate all cases when the TSCA time delay impeded innovation. Uncertainty about what the regulatory requirements are, or will be, and

whether regulatory action will be taken, is often cited by industry as the aspect of regulation that most impedes innovation. To a great extent the impact of uncertainty is psychological. It may lead corporate decisionmakers at all levels to be more cautious, to avoid radical innovations, and to resist putting large amounts of capital into development because liquidity is the best hedge against an uncertain future.

The impact of uncertainty may show up in more concrete ways than just affecting corporate psyches. The minimum acceptable return on investment may be adjusted for the degree of uncertainty, and thus a higher rate of return may be demanded from regulated products. For example, Rohm & Haas calculates the minimum rate of return for a proposed new chemical at rates varying from 15% to 25%, depending on the anticipated riskiness of the venture.47 Regulatory, technical, and marketing uncertainties contribute to riskiness.

Whether uncertainty has a major effect on innovation is not really known. There is some evidence that, for example, commercial disposers of hazardous wastes have not installed new and improved methods of waste disposal because of the uncertainty over regulations to be issued by the EPA to implement the Resources Conservation and Recovery Act. 48 On the other hand, at times when industry has been faced with a choice between uncertainty and potentially more stringent regulations, such as, for example, the testing requirements for new chemicals under TSCA, the industry has chosen uncertainty.

D. Studies of TSCA Impact on Innovation

The most recent focus of concern about the impact of regulation on innovation has been the effect of premanufacturing notification requirements under TSCA on the introduction of new chemicals. Four studies have attempted to determine this effect.

The first study, completed in December 1978, was done by Arthur D. Little, Inc. (ADL) for the EPA.49 The study was done quite rapidly under pressure from the EPA, and it is methodologically flawed to the point of being useless. The key data on the economic impact of TSCA is based on a nonrandom sample of seven chemicals. 50 Ten chemicals are listed in the table, but two are the same chemical made by two different manufacturers, and two others are research and development chemicals excluded from TSCA. The problems with the ADL report were sufficiently great to be the subject of several days of Congressional hearings. The ADL study predicted that if TSCA notification costs were $10,000 per chemical then the number of chemicals currently being commercially introduced would be reduced by 50%. If notification costs were $40,000 innovation would be reduced by 90%. In response to the problems with the ADL study, the EPA commissioned ICF, Inc., another consulting firm, to do a similar study. The EPA issued the results in

September **1980. 53** The ICF study declined to predict the adverse impact of the premanufacturing notice requirements on innovation, noting that "[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.* -154 The study estimated the direct costs of reporting a new chemical to range from $1,000 to $9,000, but stated that the direct cost "is the least important cost factor influencing chemical company decision making **. . .** the uncertainties associated with possible EPA actions will generally outweigh the direct costs of complying with notice requirements.

FAVORABLE EFFECTS OF REGULATION ON INNOVATION

Although the negative effects of regulation on innovation have received the most attention, there are major favorable effects as well. The most obvious favorable effect is the shift in corporate strategies and procedures so that new products and new plants are safer and healthier. Pollution control at new plants and toxicological testing of new products are now important considerations which have been institutionalized in the structure of most major corporations. The effect may

not be to increase the number or dollar value of new products or processes, but the quality of innovations has been changed and the decision making processes leading

to innovations also have been changed.

A. Process Innovations

Pollution control and other environmental or health regulations have stimulated the development and adoption of a number of innovative production processes. For example, a number of electrolytic caustic soda-chlorine plants have converted from using mercury cells to diaphragm cells, and from using graphite anodes to dimensionally stable anodes. Although costly, these changes have substantially reduced pollution problems and control costs and have increased plant efficiency within the industry. The new processes have helped domestic producers remain competitive with foreign producers and have reduced pressures for manufacturers to relocate abroad.

Many industries have found that the cost of complying with new regulations can be reduced through reclaiming and recycling material that previously was discharged into the air or water. The electroplating industry, for example, was expected to be one of the industries hit hardest by regulations covering toxic water effluents. Since the industry consisted primarily of small, local operations and, at the same time, was the largest contributor of toxic metal wastes into public sewage treatment plants, the EPA estimated that up to 20% of all electroplating firms would be forced out of business by the water regulations. This has not happened because technological advances, both in production processes and recycling techniques, have enabled many electroplaters to reduce their discharges of toxic wastes. This has not only reduced the toxic waste problem but has also led to major cost savings through the recycling of expensive metals.

Many chemical firms have introduced process changes in response to environmental regulations. A number of these changes have led to more efficient production. However, it should not be implied that firms typically save money bycomplying with pollution control regulations.

B. Product Innovations

Regulations can also result in product innovations. This innovation can happen in three ways. First, new markets may be opened because regulatory action removes existing products from the market or threatens to do so. The banning of DDT and the likelihood that other chlorinated hydrocarbon pesticides would be removed from the market encouraged the development and commercialization of alternative kinds of pesticides. Proposed regulations to limit the uses of

asbestos have led to a search for alternative materials. Second, apart from any direct regulatory action or threat, the existence of health and safety regulatory mechanisms may encourage companies to develop and market products whose commercial superiority rests in part on their being less hazardous for humans and the environment. The development of so-called biorational

pesticides is an example. Third, regulation can encourage the development of products necessary for implementing regulatory action. A wide variety of new pollution control products has been developed over the past fifteen years. Also, a number of devices for monitoring and analyzing chemicals have been invented and marketed because of the demand created by regulations.

STRIKING A BALANCE

Although regulation may have stimulated the development of some new products or processes, it is clear that health and safety regulation must be justified on the grounds of improved health and safety, not as an obscure and indirect way of stimulating innovation. How does one strike a balance between greater health protection and more innovation? Unfortunately, it cannot be done through cost benefit analysis.

For almost all health and safety regulations the benefits in greater health protection are not known even within an order of magnitude. The costs of innovation are even less quantifiable. The problems of determining whether and to what extent innovation has been reduced by various regulations. But even if one knew exactly how many new chemicals were not produced because of TSCA regulations, one would not be able to express the cost in dollar figures. Such a calculation would require knowing the consumer's surplus and the producer's surplus of the chemicals not produced and subtracting from the sum of these two figures the sum of the consumer's and producer's surpluses of the existing chemicals that would have been replaced by the new chemicals. No one has even made, or is likely to make, the crudest estimates regarding any of these numbers. In the absence of any good analytical methodology for balancing health benefits and economic costs, personal and institutional values will play a crucial role in any decisions that are made. In fact it is probably a waste of time to try to pass some overall judgment about the benefits and costs of health and safety regulation. If one accepts the basic premise that some regulation of chemicals is socially desirable then the more relevant question is how the existing regulatory framework can be changed so that its benefits are increased and its costs reduced.

The exploration of how the regulatory framework can be improved is a discussion that is beyond the scope of this article. It needs to follow three broad paths. First, the statutes themselves should be examined for ways to make the legislative framework of regulation simpler and more efficient. If the debate over the Clean Air Act is any example, such an examination is not likely to happen in a constructive way in the near future. Second, new ways of implementing the statutes through innovative approaches such as regulatory negotiation, market mechanisms,

and better intergovernmental relations must be developed and tried. Third, and probably most important, the quality of the civil service and of the administration of the federal government must be improved. Any regulatory scheme can be undermined by administrators who are poorly qualified for their jobs or by good people who are forced to work under impossible constraints. The current administration is simply the latest and most extreme force in a decade-long

effort to obstruct, denigrate, and paralyze the federal civil service. The so-called regulatory reform legislation which came close to passage in the last session of Congress would strike another blow in this direction. It will "reform" regulation by making it more time-consuming and cumbersome and by making the regulatory process still more byzantine and inflexible. The time has come to try to restore the integrity and efficiency of government service. Such a restoration would be a crucial step in improving the effectiveness and efficiency of regulation and in reducing any adverse effects on innovation.