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APPENDIX C

BALANCING ENVIRONMENTAL, HEALTH, AND SAFETY REGULATION WITH THE NEEDS OF RESEARCH, DEVELOPMENT, AND TECHNOLOGICAL INNOVATION

A SPECIAL REPORT ON
THE NEED FOR FURTHER REGULATORY REVIEW

The President's Commission on Industrial Competitiveness

Committee on Research, Development, and Manufacturing

December 7, 1984

INTRODUCTION

The need to regulate new technologies and products is reflected in the explosive growth in Federal health, safety, and environmental regulations over the last three decades.[1] Regulation is certainly legitimate and necessary to protect public interests. With the extensive growth of regulation, however, every major industry now faces thousands of social regulations, many of which unnecessarily impede the competitiveness of American firms, especially in high-technology sectors of the economy. It is therefore worryisome that regulation now threatens to slow the emergence of entirely new industries.

Clearly, societal benefits arise from governmental regulation, but in recent years a large number of well-documented economic and policy studies point to the fact that in all too many cases the costs to society of so much regulation, if imprudently conceived and implemented, could far exceed the apparent benefits. Many of these studies also demonstrate that regulation can have a powerful negative impact on technological innovation. For example, the Advisory Committee on Industrial Innovation, U.S. Department of Commerce, found:

> There is no doubt in impacted industries that regulation has a serious negative effect on industrial innovation and on productivity and contributes to inflation.[2]

And a National Academy of Sciences study reports that:

> . . . the connection between regulation and innovation is found in the costs entailed in meeting regulatory requirements, as these reduce the availability of R&D funds for innovative new products, the capital available for new plants to manufacture such products, or the competitiveness of the products in the U.S. world markets.[3]

Industrial innovation is crucial to the continued vitality of the U.S. economy and our ability to compete in world markets. The United States must therefore safeguard its comparative advantage in high technology if our Nation is to remain a world leader. In 1980, high-technology trade contributed a large surplus to the U.S. balance of trade--approaching $40 billion.[4] Nine out of the ten fastest growing industries are technology-intensive. Moreover, real output growth for high-technology industries is more than double that for all businesses in the United States.[5] Poorly conceived regulation, however, poses a potential threat to our continued leadership.

Regulation is a significant factor, but not the only factor, affecting innovation and product development. Economic factors, such as market size, and other factors also have important roles. The negative impact of regulation on product research, development, and technological innovation is particularly apparent for the high technology industries discussed in this paper (see exhibit 1). They illustrate how industrial innovation is adversely affected by health, environmental, and safety regulation. The impact is felt not only in these industries, but throughout our economy. Increased business uncertainty, delays in research and development, decline in product approvals, slower productivity growth, and the diversion of capital resources put U.S. industry at a competitive disadvantage. Thus, infeasible regulations not only erode our technological lead but result in fewer jobs for U.S. workers, and delay the availability of new products for consumers.

Ultimately, the issue is not whether regulations should exist. Their benefits are clear and the public supports the concept of regulation. The public has the right to be informed on the level of risk relating to new products. Workers have the right to a safe work place or at least to an informed opinion as to the associated risk. The Government's role in securing their rights through the regulatory process is not in issue. However, there are many unnecessary or unintended regulatory constraints on innovation, research, development, and product approval which should be eliminated. The problem of excessive regulation has developed primarily from regulatory mandates which do not call for a balance between competing national public policy objectives. Specifically, issues of international competitiveness and technological innovation have been neglected in the regulatory process. As a result, the mature regulatory process is excessively devoted to a single purpose and often regulates substances and conditions that it should not. Also the regulator should be dependent on good technological advice. This advice, however, often can constitute nothing more than uninformed opinion. If a reliable source of advice is not available, or if the regulatory mandate does not require or permit an appropriate balancing of interests, the inevitable result is overregulation.

Concern about overregulation is not new. A national consensus has emerged that inept Federal regulation in too many instances has become more of a hindrance to progress than a solution to the problems it addresses.[6] In fact, the last four Administrations have reviewed the problem and taken actions to ease specific economic regulations. The pace of new regulations has slowed. Little has been achieved, however, in the review of existing health, safety, and environmental regulations as they affect the innovation of new products. It is, therefore, critically important that the new Administration place this issue high on its agenda in 1985.

The following discussion examines the impact of health, safety, and environmental regulations on product innovation, research, development, and product approval. The findings and recommendations are limited to the impact of regulation on these narrow but highly important areas. They also do not address the issue of regulatory codes that other countries use to achieve similar objectives. Since many regulations adversely impact innovation and competitiveness, the challenge is to identify those that are unnecessary. A regulation-by-regulation analysis is beyond the scope of this paper, but the examples presented here indicate that such a review is

needed. Regulations should be applied with skill and reasonableness. The major recommendation in this paper calls for an expansion of the role of the Office of Science and Technology Policy in the regulatory process to take actions in the regulatory process in balancing the need to enhance industrial innovation and competitiveness, while continuing to protect public health, safety, and the environment.

THE IMPACT OF HEALTH, SAFETY, AND ENVIRONMENTAL REGULATION ON SELECTED IMPORTANT INDUSTRIES

The relationship between regulation and innovation is complex and varies from industry to industry. A summary of current U.S. regulatory policy in selected industries highlights the damage done to technological innovation and competitiveness (see also exhibit 1). Chemicals, pesticides, and pharmaceuticals have been under mature and intense regulation for many years. The ever-growing regulatory barriers faced by these industries are indicative of problems shared by many U.S. businesses. They also reveal what the future may hold for two other highly innovative industries--medical devices and biotechnology--if Government regulation follows the same policies and practices of overregulation and attempts to protect against all possible risks as in the past. All point to the need for a more balanced regulatory process, which also considers the need to enhance research and technological innovation.

REGULATION OF BIOTECHNOLOGY

Biotechnology is one of today's most promising new industries, with the market for genetically engineered products expected to leap from less than $100 million this year to tens of billions of dollars annually during the 1990's.[7] The United States has taken the lead in the worldwide race to develop new genetically engineered products. This technology promises new advances ranging from disease-resistant plants to microbes that clean up oil spills. Because only one genetically engineered product--human insulin--has been developed to the point where it is sold on the market, the regulation of biotechnology is still in its incipiency. The specter of overregulation, however, is threatening to stifle innovation and affect strategic decisions by U.S. firms. Therefore, regulation could have a major impact on the ability of the United States to compete in this infant industry.

For the past 8 years, most Federal Government oversight of genetic engineering has been exercised by the Recombinant DNA Advisory Committee (RAC) of the National Institutes of Health (NIH). RAC's purpose is to review proposals for publicly funded research and construct guidelines for the safe handling of recombinant DNA material in the laboratory. It is believed that private companies have also voluntarily complied with NIH guidelines and both public and private researchers have made requests to the RAC to release genetically altered organisms into the environment for field testing.

To date, two regulatory issues threaten the United States' preeminence in this field: (1) export restrictions that could severely limit the ability of American firms to market products abroad, and (2) the turf fight among several Federal regulatory agencies for control over biotechnology.

EXHIBIT 1

Impact of Regulation on Research, Development, and Innovation in Selected Important Industries

Industry	Value[a] (in millions)	Principal Regulations/Regulator	Impact	Effect
Biotechnology	less than $100[b]	NIH—research regulations EPA—proposing regulations FDA—drug approval regulations USDA Antitrust/Export Laws	—jurisdictional squabble over which agency will regulate research and commercialization —inability to export products licensed abroad but not in U.S —uncertain effect of antitrust laws on joint R&D	—stifling product development, marketing and commercialization —threat of foreign competition in research and commercialization
Medical Devices	$5,000	FDA—new device regulations HHS—DRG regulations	—increasing degree of regulation as FDA continues to issue regulations under Medical Device amendments —increasing impact on use as HHG implements DRGs —export restrictions	—when fully implemented, impact on innovation is likely to be severe because economies of scale do not apply to many of these specialty products
Chemical	$142,000	EPA—TSCA	—70-90% reduction in rate of new product innovation since TSCA[c] —$5,000-12,000 cost of filing a premanufacture notification[d]	—rising R&D costs —greater competition from abroad —small manufacturers hurt
Pesticide	$16,000	EPA—FIFRA	—over $20 million cost in developing a new pesticide[e] —14-22 year delay from discovery to full production[e]	—rising R&D costs
Pharmaceutical	$22,000	FDA—drug approval process Export Laws	—$70 million in R&D costs per marketed new drug[f] —since 1962 doubling of R&D investment required for a new drug[g] —greatly increased time from discovery to marketing	—declining rate of new product introductions —rising R&D costs —declining effective patent life of new drug —U.S. lags behind other countries in approving new drugs for use—"drug lag"

[a] Value of industry shipments for 1981 (in millions of dollars). 1981 Annual Survey of Manufacturers, Bureau of Census

[b] Represents estimated sales. "Biotech: Will the United States Lose Its Edge?", *Dun's Business Month*, August 1984

[c] OTA, *Technological Innovation and Health, Safety, and Environmental Regulation*, VIII-53 (1981)

[d] Davies, "The Effects of Federal Regulation on Chemical Industry Innovation", 46 *Law and Contemporary Problems* 51 (Summer 1983), Chemical Manufacturers Association, "Preserving Innovation Under the Toxic Substances Control Act," p. 18 (January 20, 1982)

[e] *Ruckelshaus v. Monsanto*, 52 U.S.L.W. 4886, 4889 (June 26, 1984)

[f] OTA, *Commercial Biotechnology: An International Analysis* 361 (1984)

[g] Statman, *Competition in the Pharmaceutical Industry: The Declining Profitability of drug Innovation* (American Enterprise Institute 1983)

Reacting to congressional concern that deliberate release of modified organisms could pose risks to the environment, Federal agencies have begun to formulate a comprehensive plan to regulate biotechnology. Under the recent direction of the White House Office of Science and Technology Policy, agencies, including Environmental Protection Agency, NIH, U.S. Department of Agriculture, Food and Drug Administration, and Occupational Safety and Health Administration, have met to clarify the regulatory path that a company would follow to meet Federal health and safety requirements.

EPA is also moving to regulate biotechnology by changing the review procedures for pesticides and toxic chemicals. New regulations would no longer exempt living microorganisms from the current regulations for field tests of small quantities of chemicals used solely for R&D.[8] These proposed rules have the potential for becoming inflexible and bureaucratized, as discussed in the later sections on chemicals and pesticides. Improperly conceived and administered, they would have a high probability of delaying or altogether extinguishing the research efforts needed to maintain biotechnology innovation.

Lengthy court battles by opponents of genetic engineering over the interpretation of regulations could also stifle innovation. This spring, with the scientific community's overwhelming support for the experiment, scientists planned to field-test a modified bacterium that could save farmers as much as $1.5 billion a year by protecting crops from frost damage.[9] Environmental activists, however, obtained an injunction to stop the scientific experiments already approved by the NIH. Now results from this key experiment will be delayed at least a year.

In order to maintain U.S. competitiveness in biotechnology, Federal agencies must work to develop a coherent interagency strategy for clear and expeditious regulation based on rigorous scientific data. Agencies must avoid a patchwork of conflicting, overlapping, and unnecessary rules. Awkwardly conceived and poorly managed regulation would have a particularly damaging effect on smaller biotechnology firms, which are leaders in innovation but lack the financial resources to contend with governmental regulation. Unilateral regulation could lead to the removal of research and testing facilities to countries where oversight is less stringent and damage the fragile lead the United States has over its competitors in the global biotechnology race.

REGULATION OF MEDICAL DEVICES

The medical device industry is affected primarily by the 1976 Medical Device Amendments, which extended FDA's regulatory control over a large spectrum of medical products, and by the Department of Health and Human Services (HHS) new regulations for Diagnostic Related Groups (DRG) aimed at containing health care costs.

The device industry is currently facing a number of new FDA regulatory pressures. Many regulations required to implement the 1976 Medical Device Amendments are still pending. With increased pressure coming from Congress, consumer groups, and Federal agencies such as the General Accounting Office, several major regulations are expected to be implemented in the next year. Industry observers fear that medical device innovation and technology will

be affected by excessively cumbersome regulations that will attempt to control the industry along lines similar to FDA regulation of pharmaceuticals (discussed below). Furthermore, a study from the National Academy of Sciences concludes:

> If the FDA brings a "safety imperative" regulatory philosophy to bear on this sector similar to that which it has exhibited in pharmaceuticals, the costs in foregone innovation are likely to be quite high indeed. This is particularly so because innovation in many medical device fields (such as heart pacemakers) has not been characterized by large economies of scale. Several major new products have emanated from small firms. Such firms would be least able to finance or bear the costs and risks of an expensive, lengthy, and uncertain premarket regulatory approval process.[10]

The 1976 Medical Device Amendments also impose new requirements regarding the export of unapproved devices. These controls pose problems for medical innovation and technological progess in this industry. Delays for obtaining export permits act as a disincentive to trade.

The emphasis on health care cost containment has led to the recent enactment of new DRG regulations. Whereas the DRG's have a useful purpose in promoting competition in hospital services, they are also forming a potential barrier to the development and dissemination of new medical devices. Cost constraints tend to create disincentives for innovation in virtually all medical technologies, regardless of their cost. This difficulty is illustrated by examining the prospective payment system under the Department of Health and Human Services.

Prospective payment is an attempt to force cost-conscious management upon hospitals by capping overall reimbursement. Based on the illness diagnosed, hospitals will be paid a fixed rate per patient admitted. In contrast to the "fee for service" system of payment, prospective payment gives hospital administrators a vested interest in controlling all costs. If costs are higher than the specified reimbursement, the hospitals will incur a "loss."

Under prospective payment, health care technology will have to compete for hospital resources with salaries, malpractice insurance, energy, cleaning supplies, and the like. Moreover, some of these costs, such as salaries and wages, are responsive to vocal constituencies well entrenched in the hospital. In contrast, innovative technology, being new, is unlikely to have many effective champions to press its case. Furthermore, medical technology represents a very small part of total hospital costs. In 1981 drugs constituted only 2.6 percent of these costs, and surgical and medical instruments and supplies were 2.1 percent. By contrast, wages and salaries were the largest item at 56.6 percent and employee benefits were next with 8.2 percent.[11]

The high-quality, leading-edge technology of U.S. medical devices should permit continuation of innovation and export growth, unless overregulation in the United States restricts opportunities for expansion. Recent regulatory initiatives for the industry, however, seem likely to have a negative impact on future medical innovation, as they have had on chemical and

pharmaceutical innovation. Unless the DRG regulations are changed, industry observers think that the development of many useful new technologies will be slowed or stopped. Therefore, allowances for medical innovation should be made within the reimbursement system to recognize technology's pivotal importance in the future health care system of this country. Innovation in health care is of vital importance not only for our technological prowess but for the standard of living and quality of life as well.

REGULATION OF CHEMICALS

The chemical industry is affected by an array of Federal regulations, based on the Clean Air and Clean Water Acts, the Worker Safety Act, Resource Conservation and Recovery Act, and perhaps most important, the Toxic Substances Control Act (TSCA). This act requires manufacturers of all new chemical substances (not already regulated as drugs or pesticides) to give notification to the Environmental Protection Agency 90 days in advance of their first manufacture. Prior to marketing, EPA can then require manufacturers to test any substances deemed to have potentially unreasonable risks to health or the environment, or for which significant human or environmental exposure may occur. In recent years at least four studies--ADL,[12] ICF,[13] Regulatory Research Service for CMA,[14] and CSMA[15]--have concluded that the review mechanism and testing requirements under TSCA have an adverse impact on innovation in the chemical industry.

The costs imposed by these acts--including business uncertainties about regulatory actions, required paperwork, and additional testing--have had adverse effects on the chemical industry, particularly on innovation and the introduction of new products. Prior to the passage of TSCA and the introduction of complex screening requirements, chemical companies were developing and introducing between 1,000 and 2,200 new chemicals annually. By 1981, however, new chemical introductions, as measured by premanufacture notifications, had plummeted to only 627, a decline of as much as 72 percent.[16] The Office of Technology Assessment has also reported that the Toxic Substances Control Act "has already reduced the rate of new product introductions by 70 to 90 percent."[17]

Industry studies report that R&D activity has become less innovative, with over 10 percent of R&D budgets directed at environmental and health activity.[18] Emphasis is being placed on peripheral improvements in product lines, to the detriment of developing new ones. In the chemical industry, as in others, technological progress is usually incremental, consisting of small improvements over time--improvements now being made less frequently. Classes of chemicals are being disregarded totally if their molecular structure presents the possibility of incurring rigorous regulatory examination.[19] The decrease in R&D discourages the development of new chemicals with more favorable risk benefits than those currently on the market. Increased costs, which manifest themselves in many ways, put innovative products at a severe disadvantage when competing with existing products.

Where these trends are caused by unnecessary regulation, they pose potentially long-term problems and strong disincentives to the innovation process. Such regulation contributes to a reduction in the rate of new chemical innovation and to rising research and development costs. The impact of regulation on the innovative stature of this industry cannot be ignored if it is to remain competitive in global markets.

A more flexible regulatory apparatus should be developed in the United States to balance risks against innovation and product development. The British regulatory approach, which rests on a foundation of trust, cooperation, and dialogue between industry, academia, and Government, merits examination. Environmental regulations in Britain are formulated through mandatory consultation among government officials, outside consultants, and industry. The outgrowth of this concept termed "cooperative regulation" is a less adversarial, more realistic atmosphere in which many factors--including innovation and competition--are taken into account.[20] Its effectiveness and feasibility, however, have not been evaluated.

REGULATION OF PESTICIDES

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires that, prior to marketing, all pesticides must be registered with the EPA along with test data demonstrating their safety and efficacy. The review mechanism and testing requirements under FIFRA increase the direct cost of marketing new products and impose significant time delays on new product development.

The average research and development cost for each new pesticide registered under FIFRA is high.[21] In a June 1984 decision, the Supreme Court of the United States accepted as "findings of fact" the following regulatory environment in which American companies try to develop new pesticides to protect the world's food supply. The process includes expenditures of $5 million to $15 million annually during the "development process," which "may take between 14 and 22 years." The success rate is infinitesimal: "For every manufacturing-use pesticide the average company finally markets, it will have screened and tested 20,000 others." A major cost in this process flows directly from regulation. The Supreme Court noted that one manufacturer "had incurred costs in excess of $23.6 million in developing the health, safety, and environmental data submitted by it under FIFRA."[22]

The increase in direct costs may result in a company's decision not to market a new product or develop any new products. The impact of this Act is demonstrated by an analysis of EPA data on new pesticides introduced before and after the full impact of FIFRA, which shows a marked decline in new product development. In 1978-79, for example, there were only nine new pesticides registered with the EPA against 58 in 1975 and 1976.[23] Of the $450 million total pesticide industry R&D expenditures in 1981, 67 percent was devoted to development of new products, 25 percent to product expansion, and 8 percent to reregistration and product defense.[24]

The failure of pesticide producers to develop and market "narrow spectrum" pesticides also illustrates the consequences of the cost barrier to the development of new chemical products. Specialized pesticides have long been favored over "broad spectrum" products that kill not only a particular pest but many other organisms in the same terrain. But the high cost of obtaining a license under FIFRA makes such selective products commercially unattractive.[25] As of 1978, more than 125 biological chemicals had been discovered that were not submitted to the EPA because of the high cost of regulation.[26]

The impact of direct regulatory costs on product innovation is roughly proportional to the percentage such costs bear to the total investment necessary to commercialize a product. For a large firm deciding whether to market a major new product, the direct regulatory costs are unlikely to influence the decision significantly. On the other hand, for a firm deciding whether to make a single small-volume batch of a new chemical, at a cost of $10,000 to $30,000, almost any regulatory costs may influence the decision to proceed.[27]

For major products involving large capital investments, time delays are a more important regulatory impact than direct costs. 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 24 months. On average, more than 7 years elapsed between initial discovery and conditional registration. A 2-year delay in registering the pesticide would reduce the cumulative net income from the product over its total commercial life by more than 50 percent.[28]

In 1982, the EPA announced a more flexible policy toward pesticides that is designed to reduce some of the paperwork, data requirements, and delay involved in registration.[29] It remains to be seen how much these relatively minor changes in FIFRA will improve the conditions for innovation in the pesticide industry. EPA must still work toward a more flexible policy that does not impede the development of new products which deliver improved social benefit in terms of less crop damage and a safer environment.

REGULATION OF PHARMACEUTICALS

Innovation in the pharmaceutical industry also suffers from excessive regulation. The detail and pervasiveness of FDA regulation of drug safety and effectiveness has been called "almost unique, both in comparison with U.S. regulation of other industries, and with foreign regulation of pharmaceutical markets."[30] The innovative R&D process from discovery of a new drug to FDA approval for marketing takes a decade or more. As a result, the cost of discovering and developing a new drug to the stage where it receives FDA approval averaged $70 million in 1980.[31] The current Pharmaceutical Manufacturers Association (PMA) estimate is $84 million. Part of this cost is for basic research, but a significant portion reflects the extensive clinical testing required by the FDA regulations.

It is not surprising then that a number of studies have concluded that FDA regulation has been one of the more important factors underlying the adverse trends in pharmaceutical innovation.[32] A 1979 National Research Council Study concludes that "As regulatory control of this industry has become more stringent since 1962, a number of adverse trends in pharmaceutical innovation have become increasingly apparent."[33] These adverse trends include

- Increased costs of R&D and lower yields on drug R&D investments;
- Declining rates of new drug introductions on the market as reflected by new product innovations;

- A decline in the number of firms introducing innovative new drugs (New Chemical Entities) because, in the view of economists and the industry, the costs of regulation have discouraged innovations by smaller firms;

- Declining growth rates for domestic R&D and shifts in R&D abroad; and

- Earlier availability of new drugs abroad than in the United States.

Last year a study from the National Academy of Engineering (NAE) found that "the data compiled...indicated a clear relative deterioration in the foundation of pharmaceutical competitive position...."[34] Two aspects of the decline in the pharmaceutical industry's competitive position were atypical of the general U.S. industrial experience: (1) the proportion of world drug production located within U.S. boundaries has dropped precipitously; and (2) the steady decline in the American share of world pharmaceutical R&D efforts is markedly more severe than comparable changes in world R&D shares for other U.S. industries. The NAE study found FDA regulations to be a significant factor contributing to this adverse trend. It also found a relatively more favorable environment abroad for pharmaceutical research.

Export controls effectively prevent American manufacturers from producing and exporting drugs approved for sale in other countries unless they are also approved for use in the United States. They must either wait to market their products abroad, license them to other companies, or build manufacturing facilities in other countries. A recent report by the Office of Technology Assessment concludes that export restrictions have a major adverse effect on American competitiveness, resulting in the transfer of technology and the loss of jobs.[35]

Skyrocketing costs and regulatory delays in the approval of new drugs have had a number of negative effects on the industry. There has been a precipitous decline in the number of new drugs approved by the FDA over the last 20 years. The long R&D process required to meet FDA regulations and delays in the FDA approval process substantially reduce the effective length of time during which a drug is protected by patent. The average effective patent term for the new drugs is less than 10 years, little more than half the statutory 17 years.[36] Recent enactment of patent legislation to restore up to 5 years of the patent time lost to meet FDA regulations will ameliorate part of the problem.[37]

The most effective approach to the problems of regulatory cost and delay in the introduction of new, innovative drugs, however, is to streamline the entire FDA regulatory process with the aim of reducing barriers to innovation, commercialization of new products, and international competitiveness of this most important research-intensive industry. An indepth study of the FDA process was conducted by a Congressional Commission on the Federal Drug Approval Process, which in 1982 made extensive recommendations to speed up and improve the process through changes in FDA regulations, operations, and management practices without lowering standards for drug safety and efficacy.[38] Core recommendations regarding FDA regulations included the following:

- To test drugs more expeditiously preliminary requirements for early clinical research in humans should be simplified in a manner consistent with human safety.

- The FDA Commissioner should clarify statutory and regulatory standards with regard to the evidence which must be submitted to establish the effectiveness of a new drug. Two or, when appropriate, one well-designed and controlled study would be sufficient to document such effectiveness.

- New Drug Application (NDA) submissions and review should be streamlined, with summary presentations of data replacing individual case report forms.

- Less restrictive interpretation of conflict of interest statutes should be put into place and experts outside the FDA should be given a more significant role in the Agency's new drug investigation and approval processes.

- Mechanisms should be put in place to ensure equitable resolution of disputes regarding IND's (Investigative New Drugs) and NDA's, with the aim of improving interaction between the FDA and industry.

For several years, the FDA has recognized the need to reform its procedures and initiated a rewrite of the IND and NDA regulations.[39] This process has stalled and should now be reviewed in light of the needs of innovation, research, and development.

LESSONS LEARNED

Regulation adversely affects technological innovation in a variety of ways: it increases costs and business uncertainty, causes delays in research and product approval, slows productivity growth, and diverts research efforts that otherwise could be put to more beneficial uses. The cumulative effects, however, are more severe than the effects on individual companies. Regulation puts our Nation at a competitive disadvantage, adversely affects our quality of life when it costs American workers their jobs, and denies consumers the benefit of safer and better products. Where excessive, regulations should be modified or eliminated.

Evidence clearly supports the proposition that health, safety, and environmental regulation of new products and processes by the Government is a negative factor in the continued vitality of technological innovation. Chemicals, pesticides, and pharmaceuticals are examples where the impact is particularly severe. The medical devices and biotechnology industries appear to be on the threshold of new and stifling regulatory control. We have the opportunity to minimize the harm to these new high-technology industries and help alleviate problems for older industries if policymakers and regulators heed the lessons learned in the years past from excessive health, safety, and environmental regulation.

The problems that regulation poses for innovation are summarized below. They are clearly reflected in the chemical, drug, and pesticide industries,

but studies indicate that they exist in varying degrees in a number of other industries.

1. Lengthened Product Development Cycles. The time span from concept to implementation has increased substantially for regulated products and processes, thereby denying the public rapid access to environmental, health, and safety benefits of innovative developments. These delays increase project costs, lower the efficiency and hence the availability of technical personnel, increase the risk of investment recovery because of large-entry costs and less foreseeable market conditions, and reduce the period of investment recovery by effectively reducing the period of patent protection.

2. Delays in Product Introduction. There is growing evidence that the United States is falling behind the world in the availability of innovative new products. This is of particular concern with respect to beneficial drugs and pesticides. It is a threat for biotechnology and medical devices. Safety should delay product availability only when delays are clearly necessary and the risk/cost/benefit decision is a balanced evaluation made with the people affected.

3. Decline in the Number of New Products. Uncertainties and delays have caused management to become overly cautious in regard to innovation and risk taking, even if the process is likely to succeed.

4. Increased Costs of R&D. Complex procedures for market entry and regulatory compliance produce excessive costs without apparent commensurate benefit to the public. They divert capital and human resources away from innovative R&D, making the process less efficient. Such costs, and the regulation of prices, affect the free market mechanisms and add uncertainty to the innovation process.

5. R&D and Manufacturing Is Moving Abroad. The ever-increasing costs of R&D and product development are compelling many companies to manufacture products abroad. The highly regulated, costly business environment in the United States and the increasing trend toward manufacturing abroad also translate into new products and processes being denied to U.S. consumers. For many products not approved for sale in the United States, export laws and regulations give the manufacturer no choice but to manufacture the product abroad. Differences in international goals and regulations should be considered.

6. Excessive Assimilation and Reporting Requirements. Separate industrial groups have often been needed just to read the mass of regulations and to prepare the multiplicity of near-duplicate records. A separate bureaucracy has been created in industry just to cope with regulatory paperwork without any measurable benefit, adding costs that reduce resources for innovation.

7. Inadequate Provisions for Trade Secret Information. Regulatory agencies frequently are neither prepared nor required to provide adequate security for proprietary information submitted by industry in response to permit requirements, compliance reports, and other documentation. In addition, some agencies are unable to acknowledge the right of industry to place a confidentiality claim on the development of innovative new

manufacturing processes and products. While there may be social needs to disseminate information for the public good, it should not be at the expense of the owners whose investment created it. When this occurs, further innovation decisions are stifled.

8. Effects on Capital. Increased costs, lack of protection, and the trend to conduct R&D and manufacturing abroad contribute to the erosion of U.S.-based, innovation-oriented capital formation. Industry in the United States is hampered through the diversion of capital resources to meet ever-increasing regulatory requirements. Large numbers of U.S. firms rely more on existing technologies and less on new processes for product development. Investment in capital equipment also affects the long-term comparative advantage of a country. One report has stated that "to the extent the U.S. undertakes less real investment...than its major competitors, then the longrun international competition of U.S. industry will be reduced."[40]

In summary, excessive social regulation diverts capital from the construction of new plants and postpones the societal benefits of new technology and products. Ever-increasing regulatory costs drive innovative new firms from the marketplace, creating powerful disincentives to promising enterprise burdened by high startup costs tied to meeting regulatory standards.

WHY THE PROBLEM HAS NOT BEEN SOLVED

Regulations formulated without concern for technological innovation or U.S. competitiveness will have an adverse impact throughout our society. Regulators must, therefore, be sensitive both to those who press for more stringent regulations and to those who support innovation. They should also be required to review regulations as knowledge is gained.

Regulation, by its very nature, is an adversarial process in a largely political arena. Unless the legislative mandates are clear, the pro-innovative voice will not be heard and more stringent regulations than are necessary, based solely on a premise of greater safety, will result. Regulators, of course, must be sensitive to valid safety considerations. However, they should not contribute to the problem through either a concern for an extreme safety imperative,[41] or from an "inability...to make straightforward scientifically grounded risk-benefit determinations."[42] What they clearly need is a better mechanism for sifting through conflicting claims and for distinguishing hypothetical fears from scientifically credible evidence.

In addition, no process exists for a systematic and continuous review of regulations. Such a process is necessary because even the most skillfully drawn regulatory requirements become obsolete over time. Regulatory bureaucracies usually ignore or minimize these problems. Furthermore, revising or eliminating old rules as a result of new information takes time and resources that agencies believe could better be used to promulgate additional rules. Therefore, the Federal regulatory agencies must be required to assess the effects of their rules on a continuous basis and to revise or eliminate them where excessive and/or outdated.

The present Administration has tried to correct some of these problems, but a permanent procedure for review of regulations is needed, with appropriate outside input by industry, scientists, and other experts. A review of existing regulations and initiation of new ones should be made by regulators, Congress, and panels of experts with a view toward protecting innovation and technological progress and ultimately our ability to enhance U.S. industrial competitiveness.

PROPOSALS FOR THE NEXT ADMINISTRATION

A key goal for the new Administration should be to put review of health, safety, and environmental regulations as they impact the innovation, production, or use of new products on the national agenda in 1985. The overall objective should be to implement improved processes for balancing values and pressures in both the review of current regulations and the promulgation of new regulations. We believe that a number of changes can be made to improve Government regulatory policies to lessen the negative effects of current and future regulations on innovation. The President can take one key action without sacrificing the essential goals of health, safety, and environmental regulations:

The President should expand the role of the Office of Science and Technology Policy (and transfer this role to the new Department of Science and Technology when created) to require it to take actions in the regulatory process to balance the needs of science and technology with concerns about health, safety, and the environment. New responsibilities of this office would include

- Assessing the impact that regulations promulgated by Government agencies will have on technological innovation, research, development, product approval, and hence, industrial competitiveness of affected industries;

- Facilitating and initiating actions to encourage the review and promulgation of regulations that can be supported by rigorous scientific evidence; and

- Designating an ombudsman to seek and encourage the participation of qualified outside scientists and technical experts in the process of regulatory review and promulgation.

In implementing this process, several guiding principles should be followed in reforming regulations to enhance innovation and competitiveness:

- No health, safety, or environmental regulation of new products should seek or purport to eliminate every possible risk. Risks below de minimis levels should be left unregulated, except for possible labeling requirements.

- Industry self-regulation should be given an opportunity to develop in new areas as the first alternative to Government regulation.

- When necessary to implement new regulations, it should be done using a more flexible and cooperative approach based on trust and dialogue between industry, academe, Government, workers, and consumers. High-level commissions consisting of representatives of these groups should be established to review present regulations.

- Where Federal safety regulation of new products is necessary, general performance standards should be used wherever possible, rather than specific design standards.

- American producers should be permitted to export a product approved for use abroad even if the product has not yet been approved for use in the United States.

- Protection should be afforded to trade secrets, patents, and the results of R&D, especially when firms must submit confidential data to the Government in order to obtain regulatory approvals.

- The overlapping and often conflicting role of Federal regulatory agencies should be reviewed as to how the regulatory process might be streamlined, especially with regard to emerging high technology industries.

Implementation of these new procedures will be a significant step toward achieving a better balance of regulatory requirements that are less harmful to innovation and industrial competitiveness.