1. The net impact of environmental regulation on productivity and economic growth in the industrial sector is economically adverse, though whether the public benefits of health and welfare are worth the cost is a different question not addressed in this report.

2. The adverse effect is concentrated in that category of industry concerned with conversion of natural products into intermediate forms for further processing or manufacture. The most heavily affected industries are electric utilities, pulp and paper, steel, chemical processing, oil refineries, and the base metals, copper, lead, and zinc. Although data are lacking, the effects identified in these six large basic industries probably also apply to industry in general and small businesses and entrepreneurial ventures possessing similar characteristics.

3. The principal effects of regulation are not direct and are caused by the need to allocate resources to meeting mandated environmental requirements which otherwise would be used for replacing and modernizing plants and the creation of new business enterprises.

4. National environmental policy as reflected in current laws and regulations tends to lead to regulatory overkill. Some of the sources for this over-reaction are: (a) use of statistical and epidemiological data to derive environmental standards, (b) reliance on emission reduction rather than ambient concentrations as the primary route to achieving environmental quality standards, (c) setting standards based on a worst case basis instead of on the basis of the average or typical situation, and (d) basing standards on detailed operating requirements in addition to performance requirements.

The environmental panel believes that the adverse effects of regulation on the innovative process can be substantially alleviated without significant compromise of the progress toward a cleaner environment in which to live. Policy options which should be considered are listed on the next page. The list is a broad outline of types of policy options rather than a detailed list of possible actions.

Policy Options Recommended for Further Consideration

- Develop more innovators by support of education and research in universities and educational institutions.
- Increase the knowledge base by encouraging existing national laboratories and agencies to:
  - study the dynamics of transformation and ultimate fate of pollutants in the environment
  - study the relationships between pollutants and public health
  - develop and disseminate methodologies for risk/benefit analysis.
- Increase availability of discretionary funds to the most severely impacted segments of industry by:
  - permitting intercompany development of pollution abatement technology
  - granting tax credits, subsidies and incentives
  - direct providing of Federal funds.
- Improve the risk/reward ratio for innovators/sponsors by:
  - reducing uncertainty of content and timing in regulations
  - increasing the timetables for compliance.
- Decrease the regulatory inhibition to the innovative process by:
  - providing protection of proprietary information
  - establishing priorities for enforcement action.
- Separate the functions and powers in the regulatory system by:
  - separating standard-setting from enforcement
  - providing appeal mechanisms outside the agency
  - setting up special courts with the expertise to understand the issues.
- Improve the process of regulation by:
  - developing standards based on consensus among knowledgeable and interested parties
  - increasing public participation early in the process to reduce the need for disruptive intervention and litigation
  - permitting arbitration in enforcement actions
  - emphasizing results rather than methods.

ANALYSIS AND DISCUSSION

According to Schumpeter, technological innovation is the principal and, perhaps, only source of economic growth in the advanced industrial societies. A considerable body of economic literature has appeared in support of this hypothesis. No other credible theory has been advanced that successfully accounts for the increases in productivity that have been experienced in the western industrial countries.

At least three requirements must be met if innovation is to operate successfully:

1. There must be an adequate supply of innovators (i.e., people who have the requisite capability to generate and synthesize information relating to needs, opportunities, and knowledge in a form that can be empirically demonstrated).

2. Adequate resources must be provided—the principal ones being money and the availability of time and other resources not purchasable for money.

3. The ratio of reward to risk must be perceived as adequate by the individuals and institutions involved both directly and indirectly in supporting the innovative process.

terials, the effects could be devastating to the packaging industry and the food industry.

Requiring stricter standards than are necessary to protect the public will result in discontinuance of research on products subject to these regulations. We recommend that regulations of this nature be based on the judgment of the appropriate members of the scientific community as to the significance of the migrating material to public health with appropriate risk/benefit judgments resolved by the agency involved.

V. FDA Approval of Ingredients and New Processes

FDA considers Freedom of Information as its number one priority and petitions for approval of new ingredients and processes as one of its lowest priorities. This has resulted in two major problems. Whereas it is generally agreed that a "low risk" ingredient should take no more than 6 months to process by FDA, it averages more than 18 months currently. During this process, trade secret information on new ingredients and processing techniques rapidly becomes public through FOI and through the publication of the information in the *Federal Register*. This length of time does inhibit the willingness of industry to invest in new products for fear of preemption. Thus, many processes in the food industry will remain pre-1958 vintage. Foreign competitors will have an advantage and will be able to outperform U.S. industry since they are not subject to the same requirements. The solution is to reorder priorities and develop a mechanism for adequate protection of trade secrets and other confidential data.

VI. Intent To Regulate

Because of legal restrictions on premature disclosure of potential contents of a new generic regulation (such as for sanitary practices), FDA, USDA, and other agencies must develop regulations without external communications. This can create problems in that Industry and consumer input can only come after a proposed regulation is published in the *Federal Register*. The regulations promulgated in this fashion may not reflect up-to-date industry practices or the feasibility of implementing the regulation. This would stifle innovation since new, more efficient practices would be outside the regulations. We feel a notice of intent to regulate should be published and comments and proposals solicited before the proposed regulation is published. We believe regulations will be more sound, feasible and acceptable under this practice.

VII. Arms Length Attitude of an Agency From Industry

FDA has been considering restricting communications between agency personnel and Industry personnel, [11] but not with others. We believe this will operate to the detriment of the industry, the consumer and the Government. It is essentially impossible for agency personnel to be up-to-date with industry practices and processes under such a policy. Action of this nature would almost ensure regulations based on obsolete data to the further detriment of innovation in the food industry. Further, this would result in defensive research by industry to defend current practices.

VIII. Diversion of Management Time

FDA law is unique among agencies in that it allows for absolute criminal liability on the part of senior management. [12] The effect of this law is that senior management, for their own protection, must involve themselves in many details of company operation that do not add to productivity. This absolute liability causes a great deal of research time to be diverted to defensive protective efforts rather than innovative research. The solution is to prosecute for negligence only those who are negligent.

IX. Rigid Regulations That Control Products and Processes

Some regulations can be written so detailed that they can forestall the development of new products. The low acid canned food regulation recently published by FDA [13] is an example. Processed cheeses, which are widely accepted and safe, could not have been developed under current FDA regulations. The solution to this is the development of open-ended regulations which provide for innovative development.

X. Agency Policies

Any agency policies that decrease the amount of basic research funding (i.e., in-house funding of research) to universities has an effect on innovation by the industry since new basic technology, especially in the food industry, is becoming scarce. Grant policies do not foster exploratory research.

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THE EFFECT OF FEDERAL POLICY AND REGULATIONS ON INNOVATION IN THE FOOD INDUSTRY

PREAMBLE

There are many effects of regulations on innovation. One is the direct effect on the diversion of scarce resources from the innovative process to one of maintenance, product cost cutting, filling out of government paperwork, and attempting to comply with the seemingly innumerable regulations of many agencies, occasionally at cross purposes with each other. It is true that many of the regulations, by themselves, may require only a small amount of time and effort by research personnel, but the additive effect can and has become substantial. Therefore, we believe that not only should the drain on research resources of a specific regulation be analyzed, but it must be done on the basis of the additive or cumulative effect of previous regulations.

Our technical resources in many disciplines in the United States are scarce. For example, the recent rise of interest in nutrition has caused a need for nutritionists that exceeds the supply. Diversion of these resources into analytical effort for nutritional labeling is a waste, especially when alternate data sources already exist. This is similarly true for superficial regulations that divert toxicologists, pathologists, food and packaging engineers, and others.

It is impossible within the time frame of this report to delineate all or even most of the effects of government regulations in the food industry, therefore, some examples have been selected to illustrate the problem. We hope that an opportunity will exist for additional compilation of information. Hopefully, this will become an ongoing, continuous process over the years.

I. Decrease in Innovative Research Effort in the Food Industry

One of the greatest effects of regulation of the Food Industry has been the diversion of scarce technical personnel from innovative research to that of compliance and other defensive efforts. A survey was made in 1974 of the "Changing Roles of Industry Research Groups" in 38 companies representing 60 percent of the food manufacturing industry and representing annual gross revenues of more than $50 billion. [1]

Adequate scientific standards for safety and efficacy should not, of course, be abandoned. No drug should be approved unless it works and its therapeutic efficacy outweighs the risk to the patient receiving it. However, that scientific judgment can best be made by focusing the review on what the total body of scientific evidence shows about the effect of the drug on patients for whom it is indicated. The decision should not hinge on whether one study or another has been conducted in accordance with some particular scientific orthodoxy that the FDA elects to endorse.

RECOMMENDATION NO. 6

The certified summary should be adopted as the primary document for regulatory review.

A major cause of delay and frustration for the pharmaceutical industry is the demand for excessive and often duplicative work. As the cost of developing new products increases, fewer research projects can be maintained at any given time. Much has been written and said about the staggering increase in the past 15 years in the paperwork necessary to document a new drug's safety and effectiveness. It is estimated that the FDA today must review an average of 120,000 pages of complex data for each new drug application. One company recently submitted 428 volumes of research results, totaling 664,000 pages, as part of its application.

Such voluminous raw data is not the norm for scientific communication. It amounts to regulatory overkill on a grand scale. It is recommended that FDA adopt new policies that will expedite the approval process without abdicating its responsibilities or sacrificing the scientific quality of its reviews.

We submit that the most practical vehicle would be the certified summary. A properly prepared summary—endorsed by a panel of experts—could provide all essential information in systematic form and reduce the need to review all raw data and thus expedite the decisionmaking process. FDA could verify the summaries by spot checking the raw data, but, meanwhile, the application could be managed more efficiently. A company, along with its certifying responsible officer, that knowingly distorted or falsified a certified summary in order to get marketing approval, would be subject to meaningful penalties.

RECOMMENDATION NO. 7

To broaden its regulatory perspective, FDA should expand its use of Advisory Committees in helping resolve complex and difficult scientific questions.

Expanded use of Drug Advisory Committees could resolve problems that otherwise might stagnate for long periods. By tackling tough scientific questions, properly constituted and well used, Committees can share responsibility with FDA personnel and speed decisionmaking at relatively modest cost—without new regulation.

The composition of the Advisory Committees is a matter that requires careful consideration. In addition to inclusion of academic and consumer representatives, representation should come as well from such voluntary agencies as the American Cancer Society, American Heart Association, American Diabetes Association, etc., since these groups are particularly qualified to give informed advice involving benefits and risks in major disease categories.

On matters requiring technical expertise, experienced clinical and pharmaceutical researchers are needed. Consequently, industry scientists must be included, for to do otherwise would deny the contribution that can be made by those who know the most about the specific problems to be solved.

RECOMMENDATION NO. 8

The law regulating the issuance of patents should be changed so that the effective date of United States patent issuance coincides with the FDA's approval to market a new drug.

Patents obviously play a key role in stimulating innovation by providing some measure of economic protection to individuals and firms that discover and develop new products. They are normally applied for early in the research and development process. However, the time necessary to develop and gain regulatory approval for a new drug today is much longer than that for obtaining patent approval. As a result the average effective patent life for a new drug has shrunk to between 10 and 12 years (some recent studies indicate it is now as low as 8.8 years). [8] The patent life should be restored to the 17 years typical of most other products by making drug patents effective at the time of marketing approval by the FDA.

RECOMMENDATION NO. 9

A program of postmarketing surveillance and continuing investigation of newly approved drugs could help shorten the premarket testing period if combined with a common sense set of guidelines for such studies. Preclinical investigations ought to be appropriately curtailed or expedited in a way that realizes the social and economic benefits of the surveillance concept.

Without compromising the requirement that new drug approval be based on demonstration of safety and effectiveness, a system which would allow the FDA and the new drug applicants greater flexibility seems eminently desirable. It is recommended that the law be amended to allow the FDA Commissioner to approve a new drug or issue a premarket approval application on the condition that the sponsor undertake suitable additional investigations or generate more scientific information where necessary. This concept would allow the FDA to approve a therapeutic compound when the material submitted to the Agency is judged inadequate under current law to permit unconditional approval, yet public health needs require the early availability of the drug. It is important to stress, however, that this authority should be limited only to those situations when it will expedite the approval of the drug. Otherwise, it

tion, rather than facilitate it. In effect, the bill perpetuates the things most seriously wrong with the present system. Instead of resolving problems, it creates new ones by giving the force of law to the very tendencies that are at the root of our current difficulties in U.S. drug regulation. Thus, while promising efficiency and a speedup in the approval process, it gives greatly increased discretion and control to the regulator. The end result is a proposed law that is more complex, that provides for more adversarial proceedings, and far more formalistic standards and criteria.

What can and should be done? There are a number of positive steps that could be taken to facilitate pharmaceutical innovation which have emerged from the testimony, published literature and policy papers on this subject. The reforms have the support of many if not most people knowledgeable about drug assessment. We believe these steps could do much to foster U.S. drug innovation and enable the American pharmaceutical industry to retain and strengthen its competitive position vis-a-vis foreign firms (only two of the world's top five companies are U.S.-based), while at the same time maintaining safeguards needed for the protection of patients.

RECOMMENDATIONS

RECOMMENDATION NO. 1

The President should issue an Executive Order instructing the FDA to make encouragement of therapeutic research and innovation a coequal responsibility with that of ensuring new drug safety and effectiveness.

The FDA's current mandate charges it only with protection of the consumer—in the narrow sense of avoiding health hazards of unsafe or ineffective drugs—and not with fostering the interests of the consumer in making new therapies available. In view of this fact it is not surprising that the Agency's actions, on balance, have tended to impede rather than facilitate research progress.

A number of observers have pointed out that a major contributing factor to the slowdown in the introduction of new drugs in the United States is the fact that there is no incentive among FDA regulators to approve important new therapies, only fear of reprisals for approving a drug which may prove harmful. Former FDA Commission Alexander Schmidt described the problem this way:

> In all our FDA history, we are unable to find a single instance where a Congressional Committee investigated the failure of FDA to approve a new drug. But, the times when hearings have been held to criticize our approval of a new drug have been so frequent that we have not been able to count them. The message to FDA staff could not be clearer. Whenever a controversy over a new drug is resolved by approval of the drug, the Agency and the individuals involved likely will be investigated. Whenever such a drug is disapproved, no inquiry will be made. The Congressional pressure for *negative* action is, therefore, intense. And it seems to be ever increasing.

Dr. Schmidt went on to say, "Congress should be as willing to investigate charges that FDA is not approving important new therapeutic advances as it is to hear charges that we resolve close issues in favor of approval. Until perspective is brought to the legislative oversight function, the pressure for FDA to disapprove new drugs will continue to be felt, and could be a negative influence on health care in this country." [7]

There must be assurance of course that the testing of drugs in man will be conducted in as safe a manner as is reasonably possible. However, a preoccupation with safety has led to an imbalance in regulatory perspective and an adversarial attitude that serves the public interest poorly. In making decisions guided only by a negative mandate, insufficient heed has been paid to the great importance of facilitating the development of new and improved medications for the American people.

The time has come for a major new mandate to be added to the FDA's mission—a mandate to encourage innovation. Without the expressed interest of the President in the progress of drug therapy, the Agency cannot be expected to fully serve that interest.

RECOMMENDATION NO. 2

The Department of Health, Education, and Welfare should issue an Annual Drug Innovation Report to analyze and evaluate the effects of FDA regulatory policies and actions on drug innovation and safety in terms of the overall social and economic objectives of U.S. health care. Additionally, whenever new regulations are proposed, HEW should be required to issue "Research Impact Statements" assessing their impact on drug innovation.

As a further incentive for the FDA to adopt a positive mandate as part of its mission, HEW should be required to regularly assess the impact of Agency regulatory practices on U.S. drug research and to issue an annual report on the subject. This continuing assessment would enable FDA to develop policies and programs which have minimum adverse impact on innovation. The requirement to include an "Impact Statement" in all proposed regulation relevant to drug research would help ensure that the regulations reflect a balanced perspective with respect to protection of the consumer, on the one hand, and encouragement of innovative drug research on the other.

It would be appropriate for the Annual Drug Innovation Report to include an up-to-date assessment of the economic impact of regulation on U.S. drug research. Both the cost and time required to complete the development of a new drug have increased dramatically over the past decade. In some therapeutic categories, this has become a major deterrent to further research and development.

Both the Drug Innovation Report and the Research Impact Statement are entirely consistent with President Carter's avowed interest in reforming the process by which agencies develop their regulations including the preparation of economic impact studies of any new regulatory proposals. The measures are also consistent with and supportive of Mr. Carter's recently announced intention to help fight inflation by reducing the cost of

tional parts per *billion* and hormone residues in parts per *trillion,* the problems of cost and benefit determination resurface. This particular manifestation of the general problem has been debated in the context of the proposed sensitivity of method (SOM) regulations [38 *F.R.* 19226 (19JUL73)].

Unfortunately, regulatory impacts on AH innovation do not end even with direct product approval regulation. An especially sensitive example of this has been the FDA's implementation of the Freedom of Information Act (FoIA) (see F.R. 24 Dec. 74). Linderman [8] documents the FDA's assignment, or withholding, of trade secret exemption from FoIA disclosure largely on the basis of the agency's administrative convenience rather than on the merits of the data. Given his opening, it is scarcely surprising that 86 percent of the FoIA requests in the first 2 years of the procedure's operation can be classified by Linderman as "industrial espionage." He further cites National Agricultural Chemicals Association figures documenting withdrawal of 18 firms from pesticide research under the pressure of similar regulation at EPA and FDA does not even follow EPA's practice of giving a sponsor advance notice of FoIA disclosure.

Another trend present in AH product regulation, as well as other product groups, is the practice of mandating not only *ends* but *means.* FDA's proposed Good Manufacturing Practices (GMP's), Good Laboratory Practices (GLP's), and BVM Stability Standards are mentioned by Mongiardo [3] as illustrations of the "cookbook" mentality. Clearly these regulatory requirements add cost, essentially all of which must be passed on in the form of higher prices, but they also do something more demoralizing: by mandating both methods *and* results (rather than just results), they deny a producer even the chance to outthink his competitors and develop a cheaper "way." Obviously, the public would have benefited from this "compliance competition," had it been allowed to flourish.

CONCLUSION

Boyd [1] concludes that the forces and trends described above will indeed have a "chilling" effect on innovation in AH products:

> The various factors involved have created a prohibitive expense in keeping products on the market or clearing new products for the market. As a result, there now appears to be every reason to believe drug industry interests will logically be limited to drugs applicable to major health problems in major species. If it is a relatively minor health problem, or if the specie involved is not a major market, there simply may not be financial incentive to do the necessary work. This trend has and apparently will continue to create a bigger void in the protection of AH and promotion of economical production.

Mongiardo [3] foresees consequences for the very structure of the AH product industry:

> A natural adjunct but unintended consequence of this (regulation) has been a pattern which is becoming more and more anticompetitive.
>
> The more detailed the regulations, the higher the standards created, the more difficult it is for the small manufacturer to stay in business. Regulation has a cost which must be absorbed in the price of the product. The greater the volume, the less impact regulations have upon the profitability of a manufacturer. Unfortunately, the converse is also true.
>
> The FDA's efforts with GMP's, GLP's and Stability Guidelines will have one major unintended consequence. These efforts will substantially increase the cost of doing business and force marginal manufacturers out of the new animal drug business. Even financially healthy small animal drug manufacturers will find it more difficult to compete. Unless this trend toward increasingly more detailed regulation with ever higher minimal standards is reversed, the number of manufacturers will decrease until only a few major companies remain.

In sum then, the net effects of the explicit and implicit regulatory forces we have discussed will be measured first and foremost in needed therapy being delayed or even precluded, research projects not undertaken, and species not treated. Costs, and therefore prices, will be increased further. Research and development activity will continue to be concentrated in fewer and larger firms. Lastly, but not of least importance to those who appreciate the considerable, unseen power of the marketplace, competition will be reduced.

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passed on in the form of higher prices, but they also

recently estimated that the full economic cost per new drug entity in 1976 is over $50 million.[5]

Another manifestation of the regulation contained in these 1962 Drug Amendments is the international impact. It has been shown that the U.S. regulatory system has generated a "drug lag." This is a lag where new drugs become first available in foreign markets to a significantly greater extent than in the United States.[6]

Another important indicator of the effect of increased regulation on pharmaceutical innovation is the impact on the economic return to R. & D. and the movement of R. & D. resources that this implies. Schwartzman has estimated the return to drug R. & D. investment for a relatively recent period and found it to be significantly below the return that could be gotten from any widely available alternative investment.[7] This should cause a reduction in the amount of real resources devoted to drug R. & D. and this is consistent with the preliminary findings of Schnee and Caglarcan.[8]

Finally, although the preceding examples of the impact of increasing regulation in the pharmaceutical industry are indicative of its social impact, there has been a direct assessment of this social impact via the effect that the 1962 Drug Amendments had on drug consumers. Peltzman has estimated that the 1962 Drug Amendments resulted in a social loss of over $300 million to the consumers of new drugs. The major portion of this loss was from the lack of the availability of new therapeutic agents but it was also reflected in higher drug prices.[9]

The preceding studies have been summarized to indicate the significant negative social impact that increased drug regulation has had on innovation in the pharmaceutical industry.

IMPACT ON MEDICAL DEVICE INNOVATION OF INCREASED REGULATION

Because of the similarity between the forms and institutions of drug and medical device regulation it is very likely that the history of drug regulation serves as a predictor of the impact of regulation on medical device innovation.

Before an attempt is made to identify the specific aspects that will be affected by medical device regulation, it is necessary to identify the source of the negative impact that comes through FDA-type regulation. This can be illustrated by resorting to the use of statistical inference methodology. It is stated that when drawing inferences concerning a particular hypothesis, an analyst is subject to two types of error. What is referred to as a type I error is where the researcher rejects a particular hypothesis when it is in fact true. Type II error is when the analyst accepts a hypothesis when indeed it is false. Another way of looking at these is that when the analyst makes a type I error he is crying wolf when nothing is wrong. On the other hand the type II error is not crying wolf when something is wrong.

It appears the FDA regulators and the regulations they devise make them inherently subject to type I errors. This means that they must be overly cautious in their approval of new drugs and devices because the political consequences will be much more severe when they approve a drug or device that subsequently is harmful than when they do not approve, or they delay approval, of a drug or device that is beneficial. In the former case the harmed and their constituents will be very visible and vocal. In the latter case the harmed and their constituents will be difficult to identify and therefore they will not be represented.

Thus it is the attitudes of regulators and the environment in which they operate which are crucial. If these attitudes and this environment for the medical device regulators are the same as that for drug regulators then the same negative results will occur for device innovation.

The primary effect that results from the greater regulation that is represented by the 1976 Medical Device Amendments is the greater economic costs associated with the regulation. This cost involves the direct costs that occur due to the greater number of resources that must be applied to satisfy regulatory requirements. In addition there are the economic costs associated with the time requirements that result from the regulatory process. At the same time regulation of this nature generates an added dimension of uncertainty. Thus, not only is there the uncertainty of the scientific-technical variety, there is the uncertainty of complying with relatively rigid regulatory requirements.

Another effect that will result from the increased regulation of medical device innovation is the structural change that will occur in the industry. Grabowski has analyzed the industry structural change that occurred in the pharmaceutical industry that can be attributed to the regulation embodied in the 1962 Drug Amendments. This is a structural change where innovation is more highly concentrated in larger firms.[10] An important part of the advantage of larger sized firms centers around the economies of scale that are associated with the regulation itself. Through the use of computers and sophisticated equipment, larger firms are able to comply with the FDA's regulatory requirements at lower cost.

It can be expected that the structural change that will occur in the device industry will be of a significantly different nature than the structural change that occurred in the pharmaceutical industry. The distinction centers around the fact that the Pharmaceutical industry had reached a level of "technological maturity." This maturity is characterized by a relatively large number

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[8] J. Schnee and E. Caglarcan, "The Changing Pharmaceutical R. & D. Environment," *Business Economics,* 11 (May 1976).

[9] S. Peltzman, *Regulation of Pharmaceutical Innovation: The 1962 Amendments* (Washington, D.C.: American Enterprise Institute, 1974).

[10] H. G. Grabowski, *Drug Regulation and Innovation* (Washington, D.C.: American Enterprise Institute, 1976).

RECOMMENDATION

The FDA should be required to reassess the list of material to be disclosed. If the FDA has, in fact, appraised the safety and effectiveness of the device, including all its components, even a qualitative disclosure of ingredients would appear to add little to the protection of the public.

COST/BENEFIT AND RISK/BENEFIT ANALYSIS

While the fundamental problem of regulations and their effects lies in our inability to evaluate these ratios, there are some aspects of the issue that apply particularly to the medical devices field. While it may seem justifiable to require proof that an artificial sweetener or other substances "will not cause cancer," the proof of zero tolerance or zero risk enormously increases the cost to society. An article in the October 6, 1978 issue of *Science* quotes an ad hoc committee commissioned by the Surgeon General as reporting: "The principle of zero tolerance for carcinogenic exposures should be retained in all areas of legislation presently covered by (the Delaney clause) and should be extended to cover most (other) exposures as well. Exceptions should be made only after the extraordinary justification."

Thus, we may be faced with proof of negatives that can only be met by costs approaching infinity or by removing the material from our environment entirely. Zero tolerance and zero risk can not be required of medical devices manufacturers and still expect new product development to continue at an acceptable pace. Such an approach is out of proportion to the return on investment necessary for the medical devices industry.

The problem is compounded by another issue. Much regulation is based on standards that set degrees of toxicity, of corrosiveness, of purity, etc. If variable standards are used by different regulatory agencies, medical devices manufacturers can find themselves caught between the rules of two agencies, causing greatly increased cost.

RECOMMENDATION

We would strongly agree with a recommendation of the "Government Involvement in the Innovation Process." Issue 9 of that report calls for support of hazards analysis to identify hazards earlier, to analyze hazards, and to educate workers and consumers on hazards. The Round Table and Pharmaceutical Manufacturers' Association have major programs on methods to identify costs of regulations. A similar program in industry or Government should be started to measure benefits on even a semiquantitative basis.

RECOMMENDATION

In 1976 an economic impact evaluation was made by FDA of the IDE regulations. Their analysis was based on an estimate of 10 to 20 new devices per year that would fall under the regulations. Most other estimates (PMA, HIMA, OSMA) are that hundreds, if not thousands, of medical devices will be subject to clinical testing each year, in part because any modification of a device that may affect its safety and effectiveness must be the subject of another application to FDA and a clinical investigation initiated to prove the value of the modification. For example, there have been frequent modifications of most radioimmunoassay diagnostic kits in order to improve performance.

We would recommend that FDA be required to do an updated economic impact study based on the "tentative final" IDE regulations as published on May 12, 1978.

RECOMMENDATION

As of October, 1978, the FDA has in the proposal stage six new parts to its regulations.

Part 50—Protection of Human Subjects
Part 52—Obligations of Sponsors and Monitors of Clinical Investigations
Part 54—Clinical Investigations
Part 56—Institutional Review Boards
Part 57—Clinical Laboratories
Part 58—Good Laboratory Practices for Nonclinical Laboratory Studies.

All investigational activities of all drug and medical devices manufacturers will be affected by the final rules of these six parts. We recommend that an economic impact study of these six parts should be immediately done—not part by part but evaluating the interactions and effects of all six parts.

RECOMMENDATION

Although neither the drug nor medical devices statutes empower FDA to inspect financial data nor address the issue of cost recovery, the FDA has in its recent IDE regulations proposed for the first time that FDA will establish the reasonableness of cost recovery levels during the investigational phase. Paragraph 812.50(c) says "sponsor shall not commercialize the device by charging . . . investigators for an investigational device if the FDA finds the compensation to be unreasonable in view of the manufacturing and other costs of the device, and has notified the sponsor of this finding." We recommend that the FDA adopt the language of paragraph 312.1 of the drug regulations. In that language the FDA says: "If the drug (device) is to be sold, a full explanation of why the sale is required and should not be regarded as commercialization of a new drug (device) . . .".

The reason for this recommendation is found in the small firm/small market aspect of much of the medical device industry. In the OSMA testimony, a device was described that sold only 2 or 3 units per year. Even a cost of $60,000 (a minimal figure) for a clinical investigation would raise the cost of the unit from $300 to $7,800. The cost might well be larger than even that figure when final procedures are established in the six new parts to FDA rules on investigations.

Tax credits can provide stimulation of innovation in areas deemed important to society on a priority basis. Categories should be established—on the basis of national interest—to receive commensurate tax consideration. For instance, money spent on research and development of medicine in general might be deducted from income at the rate of cost plus 60 percent, on cancer at cost plus 75 percent, on diseases of the underdeveloped countries at cost plus 100 percent, etc. This would (1) allow industry to respond immediately to congressional or presidential determinations on the needs of the United States, (2) increase the number of jobs, (3) decrease transference of innovation to foreign countries, and (4) obviate the need for Government to set up expensive and permanent bureaucracies. The industry supervisors of such programs would have greater incentives than government employees to develop useful drugs because most of the money being spent would be derived from company resources—not taxes.

D. Double taxation by taxing corporate profits and dividends is a disincentive to invest in industrial innovation. Taxation on corporate profits should be discontinued.

E. Research and development expenditures are such that they should be considered capital expenses.

II. Regulatory Requirements and Attitudes

Innovation in the pharmaceutical industry is inhibited by regulatory requirements and attitudes.

Government regulation dates, at the Federal level, from the creation of the Interstate Commerce Commission almost 100 years ago. Originally, regulation was primarily directed at the economic practices and conditions of public utilities. In recent years, it has invaded every aspect of innovation. The prolific discoveries of the 1950's and early 1960's have sharply decreased, the costs have escalated, delays in approval of drugs have increased, and innovation is stagnating. There was considerable controversy about the "drug lag." It is now clear that the United States does lag behind Europe in drug development, but that comparison in itself is not important. It is important to determine the impediments that prevent us from achieving the goals of which we are capable—and to take action to remove such impediments.

The traditional role of regulatory agencies has been the prevention of activities that might be injurious to society. While this is highly desirable, positive programs to help society have largely been ignored. Rewards and accolades have been bestowed on government employees who carried out their role of stopping or prevention, but there has been no such recognition for those individuals who have worked hard to expedite the approval process. Consequently, a negative attitude has developed. This negative attitude has been reinforced by public criticism from politicians, consumer groups, and the press, of employees of FDA who have aided the innovation process.

At this time most members of Government feel that they have only a negative role—that they are not allowed to help or encourage innovation. There are personal risks if they encourage innovation; there are no benefits. Help and encouragement from Government comes only when public or political pressure is applied.

This should not be taken as a castigation of the diligent workers in FDA nor is it intended to minimize the difficulties under which they work. It is their responsibility to assess the risks and benefits of making a new drug available to the public. The evaluation of the benefits of a new drug is usually relatively straightforward; however, there are some drugs that are much more beneficial than was suspected when development started. We can predict the risks; however, the risk of *not* providing the drug expeditiously is just as important. The latter assessment is seldom made.

The development and review process by FDA is difficult and time consuming. Industry does not object to reasonable requirements nor delays that are necessary for adequate review. However, excessive requirements are common and much of the time of reviewers is spent in endlessly documenting their diligence in order to avoid possible criticism in the future.

It is inevitable that disagreements will develop between scientists in Government and industry. There is no adequate mechanism at the present time for settling such problems. It is suggested that a Science Court system be established. The presiding officer and operating staff of the court should be appointed by the Justice Department. The voting members of the court should be experts appointed by the Academy of Sciences. Any possible conflicts of interests of the experts should be divulged to the Academy of Sciences and the public. Such conflicts should not be a bar to service on the court unless the individual is challenged before the court proceedings start.

The idea that the zenith in the drug treatment of disease has been reached appears to be one of the underlying principles of individuals involved in consumerist activities and in FDA. It has been mentioned in several forums that the limited number of drugs now currently available is adequate for the treatment of disease. The FDA itself has inadvertently supported this philosophy with the development of its New Drug Evaluation Rating List. It lists which drugs represent major therapeutic advances and which do not. This type of categorization and philosophy implies that a Federal agency can with a stroke of a pen assess the technological advances in a given therapeutic area before the drug is adequately tested and used. The true therapeutic advantage of an agent cannot be assessed until it has been used for some time. The negative view on innovation of drugs is analogous to a proposal that once arose within the Federal Government to eliminate the patent system since discovery was complete.

This negative attitude concerning innovations and technology must be discouraged within the Federal Government if discovery is to progress. The "penicillin" for cancer, multiple sclerosis, and degenerative cardiovascular diseases for example, may be just around the corner if development is encouraged.

In recent years innovation has flourished in Japan. The balance of payments has favored Japan, and the value of the dollar, in relation to the yen, has fallen.

2. The emergence of postmarketing side effects which may curtail or eliminate the product's commercial value.

3. A postmarketing risk that the product, even if safe and effective in man, may not generate revenue sufficient to recover the original investment and provide an adequate return.

An indication of technical risk is a statement by the Pharmaceutical Manufacturers Association that its members, in 1970, tested 704,000 compounds for pharmacological activity of which only 1,013 proved promising and safe enough after testing in animals to move into clinical tests. Since fewer than 20 new compounds reach the market in a typical year, this means that the investment in research and development produces an enormous number of "dry holes" for every successful compound. For example, Merck & Co. in the period 1966-76 reportedly introduced only one commercially important drug in the U.S. market after investing almost $800,000 in research.[2] Further evidence of technical risk is supplied by Hansen who states, "only about 12 percent of the drugs which enter the human testing process will reach the market." [3]

It is also very difficult to predict in advance the commercial potential of any new pharmaceutical product. It is not until most of the research and development funds are committed that a picture emerges as to the range of efficacy, size of market, approved promotional claims and other major factors which determine commercial potential. In addition, competitors may introduce products before or after marketing of a compound which may drastically alter the commercial potential.

Since the variability of each human being and the individual's reaction to a potent pharmaceutical is virtually infinite, the postmarket risk of unexpected side effects is also very considerable. Despite extensive clinical trials over long periods of time, it is only after marketing a pharmaceutical product to a wide audience of patients around the world that the overall safety can be demonstrated conclusively.

A. Potential Scope of Pharmaceutical Markets.—Unlike other markets which have virtually unlimited demand (for example, recreation, housing, automobiles), pharmaceutical markets are limited as follows:

- Incidence of disease
- Number of days of therapy required per disease
- Total potential days of therapy.

Hence, the scope of pharmaceutical markets is limited by the ability of the industry to discover and develop new products and to convey the utility of these products to the medical profession. The final demand for these products will be limited by the incidence of disease for which the products are effective and determination by the physician as to the frequency and duration of usage.

[2] *Fortune*, March 1976, P. 135

[3] Ronald W. Hansen
The Pharmaceutical Development Process: Estimates of Current Development Costs and Times and the Effects of Regulatory Changes. 8/77

B. Profitability.—The research and development investment necessary to produce a new pharmaceutical product has been rising steadily for several reasons:

- Increasing technical complexity
- Rising regulatory requirements
- Inflation.

In addition, the number of significant new products introduced has been declining. It is appropriate to use the number of new chemical entities introduced as the best estimate of significant new products. Since the cost of shepherding a duplicate or "me too" product through the regulatory process is essentially as costly and time consuming as with a research breakthrough, it is not likely that many firms in the future will devote any significant portion of scarce R. & D. resources toward imitative products. Also, given the rising costs of research, only a few new products offer the opportunity for recovery of R. & D. and an adequate return on investment.

With the R. & D. cost rising and the number of new chemical entities declining, the cost per new chemical entity has gone up steeply:

R. & D. Cost Per New Chemical Entity
(in millions)

R. & D. investment		New chemical entities		Cost per new chemical entity
1957–61	$917	1962–66	78	$11.8
1962–66	1,486	1967–71	63	23.6
1967–71	2,562	1972–76	67	38.2

Assumptions:

1. R. & D. investment per P.M.A. survey
2. Number of new chemical entities developed from DeHaen reports.
3. Five-year lag "from R. & D. investment to new product introduction"

C. Return on Investment.—The return on investment in the pharmaceutical industry has decreased sharply from the 1950's. In that period and the early 1960's there was a prolific era of new product introductions, and drug stocks generated a greater return to shareholders than stocks in general from 1950 to 1970; however, the return for drug stocks is far below stocks in general for 1971 to 1977.

Return to shareholder
(percentages)

	1950—60	1960—70	1971—77
S&P 400	17.2	7.2	4.0
S&P Drug	20.5	11.6	—.1

D. International Competition.—It is important to view the U.S.-owned pharmaceutical industry within the perspective of worldwide competition from foreign-owned companies. For example, of the top 5 pharmaceutical companies in the world, only 2 are U.S. firms. Of the top 10, 5 are U.S. firms versus 6 in 1972.

Since the variability of each human being and the

properties. Clearly, advanced analytical methods have outdistanced the goals sought when the original regulatory statutes were designed. Yet the statutes are rigorously applied, to the detriment of product innovation.

The most vivid examples of this are in the field of carcinogenicity. Once a particular trace chemical presence has been identified, the regulatory bodies place a scientifically unjustified degree of faith in controversial screening techniques (such as the Ames test) and, on the basis of "guilty-until-proven innocent," disapprove or ban a product. The sponsor of such a product can sometimes reverse such a decision, but not without lengthy and costly additional research. Faced with these hurdles, firms are less inclined to invest in innovation.

RECOMMENDATIONS

- Rules leaving no room for interpretation in light of recent evidence and scientific judgment (e.g. the Delaney Clause) should be dropped.
- Application of appropriately flexible rules should benefit from more, and more effective, use of "outside" expert guidance—provided through duly constituted advisory committees.

Theme No. 3.—Innovation is being slowed by the erosion of financial incentives, growing out of regulatory approval delays, complete with excessive requirements for disclosure of information and inadequate protection of trade secrets.

For innovation to occur in a competitive economy such as ours, there must be the prospect of financial reward to the innovator. Such reward is heavily dependent upon the prospect of exclusivity. This was recognized by the founders in the Patent Clause of the Constitution. In our modern economy, it has been reiterated by the findings of Federal agencies and Congressional committees.

Innovative products and techniques must usually be patented prior to submission for regulatory approval. To the extent that the regulatory process is delayed, as is increasingly the case, it means the effective commercial life of the patent is reduced. Present regulations also require exhaustive submissions of information as part of the product approval process. When regulatory agencies interpret the Freedom of Information Act to require public disclosure of this data to competitors, the competitor has an opportunity to copy the innovator at little cost. Thus, overbroad disclosure combined with regulatory delays means that competitors, using the fruits of the innovator's research, can enter the market with their version of the product shortly after the initial approval. (Such disclosure can also imperil the patentability of some products in foreign markets.) There is no more serious disincentive to innovation than this sequence.

A common rationale for full disclosure is that, by enhancing competition, it will reduce prices to the consumer. But the long-term loss to society of taking the profit motive out of research is far greater than any short-run benefit such as this. A cheaper pesticide, for example, reduces food prices less than a new product that works better and increases crop yields more than enough to justify its higher cost.

RECOMMENDATIONS

- "Innovation Impact" analyses should be required of all proposed regulations or legislation that could have a negative influence on innovation.
- A continuing Presidential Commission should review both the Innovation Impact statements and the overall performance of Federal agencies in nurturing innovation.
- Effective patent protection should be lengthened for products which require complicated, time-consuming premarket approvals by government agencies.
- A system for disciplining government agencies to adhere to premarket product approval/disapproval time limits should be instituted.
- A "Cost of Regulation" study, similar to the six-agency study designed by Arthur Andersen and Company and implemented under the aegis of the Business Roundtable, should be commissioned for the Food and Drug Administration—both because of the costs this agency generates and because of its position as an early health and safety regulatory model.

Theme No. 4.—Innovation is being slowed by the growing diversion of researchers and resources from innovative work to technical compliance and defensive research.

When food companies must concentrate their scientists and funds on nutrition labeling instead of nutrition research, and drug companies must continue to test a new product indefinitely, even after FDA approval; when scientific personnel must spend an increasingly large part of their time in Washington instead of in the laboratory; and when most companies report they are shifting research toward more short-term, less risky projects—then a distortion in the utilization of research capability is occurring which is a serious threat to needed innovation.

RECOMMENDATIONS

- Please note the suggestions under risk/benefit (No. 1 above) and delays/disclosure (No. 2 above).

Theme No. 5.—Innovation is being slowed by the decline in the role of recognized experts in advising regulators on technical issues.

The ultimate forum in which disagreements between the regulator and the regulated are resolved is the courts. But because courts rely on agency expertise when it comes to technical issues, the agencies themselves have very often invited the participation of impartial, objective and appropriately skilled advisory committees to provide the expertise they may themselves lack. Today, however, effective formation and functioning of advisory committees is in doubt because of the overapplication of "conflict of interest" rules in ways that go far beyond their intent. In some cases, agency regulations seem to us to say those who know the most about the subject are disqualified to advise on it because they work in the private sector or in many sections of academia. The result is their governmental

[13] S. Mayers and E. E. Sweezy, "Federal Incentives for Innovations—Why Innovations Falter and Fail—A Study of 200 Cases," PB–259 208 NTIS (January, 1976) pp. 41ff.

[14] Charleswater Associates, Inc., "The Impact on Small Business Concerns of Government Regulations that Force Technological Change," PB–282 706 NTIS (Sept. 1975) pp. 147ff.

[15] W. Tucker, "Of Mites and Men" *Harper* (August 1978) pp. 43–58.

[16] For a survey of capital budgeting practices in selected industries see J. M. Fregmen, "Capital Budgeting Practices: A Survey" *Management Accounting* (May, 1973) pp. 19–25, and J. W. Petty et al, "The Capital Expenditure—Making Process of Large Corporations" *The Engineering Economist* (Spring 1975) pp. 159–172.

[17] W. Y. Oi, "On Evaluating the Effectiveness of OSHA Inspection Program," PB–254 U.S. Dept. of Commerce, National Technical Information Service (May 1975).

[18] "Small Firms and Federal R. & D.," William K. Scheirer, Consultant, Office of Federal Procurement Policy, Office of Management and Budget, Executive Office of the President.

[19] Tri-Level Survey of Traffic Accidents done by Indiana University, DOT–HS–034–3–535 (July 1974).

[20] H. G. Grabowski and J. M. Vernon, "Innovation and Invention—Consumer Protection Regulation in Ethical Drugs" *American Economic Review* (Feb. 1977) pp. 359–364.

[21] Anon., "Truck Brake Standard Debated" *Automotive News* (March 28, 1978) p. 30.

[22] C. T. Sheehan and A. K. Mann, "Statement of the Cast Metal Federation on Occupational Safety and Health Programs before the Subcommittee of the Senate Human Resources Committee" (Oct. 4, 1978)

[23] P. H. Abelson, "Regulating Exposure to Carcinogens" *Science* (Oct. 13, 1978) p. 139.

[24] Anon., "Firestone Recall on Its '500' Tires Will Begin Soon" Wall Street Journal (Oct. 23, 1978) p. 8.

[25] *"Grimshaw* v. *Ford Motor Co."* Case No. 197–761 (Feb., 1978).

[26] Interagency Task Force on Product Liability—Final Report, U.S. Dept. of Commerce.

[27] Paper by Paul M. Storm, 1976 Product Liability Prevention Conference.

[28] Product Liability in Europe, Edited by Paul M. Storm. Fred B. Rothman & Co., So. Hackensack, N.J. 07606, $17.95.

[29] Proposed Uniform State Product Liability Act, National Product Liability Council, August 1978.

[30] J. C. Boland, "Total Recall? Federal Product Safety Moves Cost Industry a Bundle" *Barrons* (Aug. 7, 1978) pp. 9ff.

[31] D. V. DeSimone, "Technical Innovation: Its Environment and Management" U.S. Gov. Print. Office (Jan. 1967) pp. 17ff.

[32] Senate Hearings, Nov. 21, 1978, Senate Commerce Consumer Subcommittee on Costs and Benefits of Federal Regulations.

[33] Anon., "Ford Pulls Out of $160 Million Project with U.S. to Develop Stirling Car Engine" *Wall Street Journal* (Oct. 19, 1978).

[34] J. Shaw, "EPA and OSHA: Gearing for Change" *Chemical Engineering* (Oct. 9, 1978) pp. 70–72.

• Out of 61 important inventions and innovations of the 20th century selected for analysis, over half of them stemmed from independent inventors or small firms.

• Major inventions made during the decade 1946–56 were studied and it was found that over two-thirds of them resulted from the work of independent inventors and small companies.

• One hundred and forty-nine inventions in aluminum welding, fabricating techniques, and aluminum finishing were studied. Major producers accounted for only one of seven important inventions.

• Of 13 major innovations in the American steel industry, four came from inventions in European companies, seven from independent inventors, and none from inventions by the American steel companies.

• Of seven major inventions in the refining and cracking of petroleum, all seven were made by independent inventors. The contributions of large companies were largely in the area of improvement inventions.

Further, it was pointed out that in the 20th century such products as penicillin, shrink proof knit wear, and cellophane came from independent inventors or small firms.

The United States has thus obtained benefits from small firms. Yet recent studies of the failure of 92 innovations indicated that regulation problems were held responsible in 25 percent of the cases. [31]

As much as 50 percent of a small business manager's time can be spent dealing with regulation. This time represents a diversion of crucial skills at a critical stage in development. [12, 14]

These two factors cannot be held solely responsible for the decline in venture businesses in this country. These are, however, factors that make venturing unattractive and thus are contributing to the decline of this historically potent source of innovation. Special treatment is thus suggested in this area to redevelop a climate for new venture development.

In assessing the desirability of addressing preferential treatment, consideration must be given to the fact that changes here may have a large and fairly immediate impact on growth. Funding of R. & D. takes time to be felt through the innovation cycle and changes in work rules may increase productivity on present products. Ventures, however, can take the form of commercializing existing ideas in lucrative areas. Thus, this area can produce rapid response in high impact areas.

A package is suggested that would provide:

- Workplace relief from inspections that would be based on an inspection scheme that emphasized self-development of safe practices. Once an emerging business category was fixed, it would be excluded from usual treatment until a significant deviation from interindustry norms developed or probable cause had been observed. Size would be fixed by firm demographics in the industry, but critical size would be larger than the 10-person level presently allowed. Note that this recommendation does not mandate exceptions but does require a show-cause approach.

- means for providing funds for compliance tests and liability insurance, if required. If regulatory practice, in effect, established barriers to entry as occurred in the Nutrilite case, then some remedy should be available. [15] Small business loans or outright grants are possibilities.

- the opportunity to expense venture expenditures in the year they occur. An established company can expense its expenditures against sales. A venture will frequently go through a stage where expenditures exceed sales and must therefore be supported out of capital. To encourage venture investments, it is suggested that the residual owners' shares of these expenditures be made allowable tax deductions.

- a requirement that a small business impact statement accompany new regulation. Undoubtedly, the regulatory impact on small businesses was accidental and unintentional. Such being the case, it is suggested that attention be given to this area by study *before* regulation and not after.

Recommendation 4—Indirect Factors.—

- Legislation should be proposed to enable the various regulatory review committees to exert check and balance control over regulatory agencies. The Regulatory Council and Regulatory Analysis Review Group should be given particular consideration for this role with input and participation required by CEA, CWPS, and OMB.

- Full allowance for research and experimental costs should be permitted, either as current expense or amortized over five years.

In the long run, the country must rely on established procedures in affecting agency activities. There presently are several committees in existence that serve this purpose. [32] * One committee is newly created and in the executive branch, i.e. the Regulatory Council. Another, the Oversight Committee, exists in the congressional branch. Outside of judicial action, these groups are depended upon almost solely to impact regulatory practice, which, undoubtedly, is guided by attitude.

An oversight group, i.e. the Regulatory Analysis Review Group, would appear most effective in providing uniform approaches to regulation, e.g., in the areas of goal setting, communication, and reasonable risk criteria. With the multiplicity of regulatory studies presently being conducted, there must be some internal feeling among agencies that such an approach is in the common good. Although agencies are accountable to Congress and the President, and although public notice is given on rulemaking, much agency activity is conducted under the auspices of enabling legislation. Prac-

* [32] This reference contains testimony which presents an excellent picture of the current role and activity of the various overview committees.

ment awarded the Plaintiff $128 million * for a single event. [25] One might consider the potential for recalls, at best, and personal injuries, at worst, which may well emerge with the new fleets of downsized automobiles required to meet the fuel efficiency standards.

Thus, the risks associated with product recall and product liability suits are such that product liability insurance rates with established carriers have increased dramatically in the last 10 years. Moreover, the available insurance may stipulate very high deductibles.

The major reason for this has been the growing number of lawsuits involving product liability. [26] Many legal authorities point out that the major differences between product liability lawsuits in the United States, Europe, and Australia is the system of contingent fees which is normal in the United States, in all personal injury cases, but which is considered unethical and outright forbidden in virtually every country in Europe and Australia. [27, 28] The enormous rewards the plaintiff may get if the U.S. court finds in his favor make it difficult for the small innovator and entrepreneur to afford insurance.

To overcome this, we propose Federal legislation to establish a sliding fee scale that will permit a judge to establish the attorney's fees at a separate hearing following the completion of the product liability trial. At this hearing, the attorney would present evidence of the work involved and the judge would establish the fee within the constraints of the sliding fee scale legislation. We also recommend the establishment of a model statute that would include similar lawyer's fee control to be adopted by the States.

Apart from the lack of any limitations of magnitude or risk, there are also no temporal limitations. In general, the risk of having to make a product recall extends throughout the service life of the article, and the risk of a product liability loss extends beyond that by the appropriate statute of limitations. Moreover, there is a strong tendency to regard product failures in obsolescent products (but still in service) as defects in the light of present day technology and standards. Thus, liability should be limited to a specific number of years after the product is introduced in the marketplace, and liability should be limited to a specific number of years from discovery of damage. [29]

Finally, we note the peculiar proliferation of risk in a product recall situation arising when a small number of known defective specimens contaminate a much larger population of normal products. All members of the total population are subject to the recall, whatever the cost, and in the event that defective units are not readily and unambiguously distinguishable from the nondefective specimens, all of them must be destroyed.

The underlying intent of recall practice and the tort system associated with product liability is public protection. A secondary consequence is the possibility of driving firms from the marketplace by bankruptcy. Firm withdrawal has been forced with certain consumer products, for example King Candy Co. of Fort Worth, Texas [30], so producer or consumer durable goods manufacturers appear as possibilities. The penalty and/or stigma merely has to be great enough. Of course, it may be desirable to eliminate these companies from society, but if that is the case, is bankruptcy the proper approach?

Obviously some means must be found to define, regularize, limit, and/or alleviate the risk of loss of invested capital as a result of recalls and product liability, or investment capital will not be forthcoming to pursue such risky businesses. Moreover, it is recommended that public protection and punishment of the firm be considered as two separate items. It is suggested that a mechanism be set up which will monitor the availability of insurance at a reasonable cost and make recommendations for corrective action as required. It should be noted that the intent of this recommendation is not to provide a windfall to firms or industries, nor allow unsafe products to pervade the marketplace. Rather, an attempt is being made to suggest a means for auditing the costs of product recalls or liability and thus reduce the uncertainty of doing business for those firms that are responsive to the public desire for product safety.

With regard to performance options in product safety, we have the following anecdote. Briefly, this was the situation: the staff of the Consumer Product Safety Commission sent to the Commission (in mid-October) a series of options, among which the Commission was to choose, in order to reduce or eliminate injuries from contacting the moving mower blade. *The goal is a good one, one which the Outdoor Power Equipment Institute urged the CPSC to address when it petitioned the agency for a mandatory standard in 1973.*

The problem, then, was not with Federal regulation. It was with the particular options which reached the Commission for decision. All three options studied by the staff were "design" options, i.e. the specific means by which mower blade protection would be achieved. All of them proceed on the assumption that, to accomplish a worthwhile goal, there is only one method: stopping the blade's movements within a short period of time. The OPEI position was that there were other ways, in addition to "blade stop", which can achieve the goal just as effectively and probably for a much lower cost. Two companies in the industry had developed a "monofilament line" mower, while another firm had marketed (for several years) a mower with a nonmetallic blade. These are examples of "less harmful" blades, because amputation of fingers, hands, or toes is less likely than with a metal blade. A third concept is to limit or prevent access to the blade through shielding.

Under the CPSC staff options, however, none of these methods met the standard, because none of them would have a "deadman control" which would stop the blade upon release. The staff response has been that a manufacturer who has developed technological alternatives must come to the CPSC and seek an "exemption" from the requirements of the standard. Such an approach would mean that only those firms with the time, money, and other resources necessary to fight their way through the agency's decisionmaking procedures would be able

*Subsequently reduced on Appeal to $6.6 million.

Responsible people do not take issue with the objectives of regulatory safety and health programs and, in large part, employers do not object to them. Numerous business have had successful voluntary programs for years. OSHA, in retrospect, has been costly with a questionable impact on safety and has elected to take an adversary position in enforcement. Thus, an effort that was initiated to improve safety has contributed instead to inflation and a skepticism in industry toward Government. If there is one agency that might be reevaluated, it is OSHA, and a business-labor coalition might review this topic.

It is recommended that the efforts of OSHA be redirected toward a spirit of compliance. A suggested program has already been directed to the Subcommittee on Labor of the Senate Human Resources Committee by the Cast Metals Federation and is included here: [13]

(1) Each employer would be required within a reasonable period to establish a current and specific risk analysis of his workplace and all jobs involved in his operation. He would accomplish this by means of injury and illness investigations and analyses designed to show the specific causes of each incident. The employer's knowledge then would enable him to set up specific countermeasures to eliminate or reduce these risks. He would define needed safeguards and train his employees to avoid unsafe actions and thus work safely within the risk.

(2) Each employer would then develop an occupational safety and health program tailored to the specific needs of his operation. This would be expressed in terms of objective criteria such as specific injury or illness reductions to be achieved in a stated time period and with specific programs to be implemented. The safety and health program would be submitted to a regional OSHA office for review, comment, and approval.

The employer's program might or might not reference standards which, if used, could be selected from consensus, professional society or trade associations, or requirements such as threshold limit values of toxic substances where health-related environments were involved. Essentially, each program submitted would be the best possible program each employer could prepare, related to the risks of his specific workplace. Professional safety and health consultation would be available to any employer who desired such assistance and would be provided by OSHA or, if a private consultant were retained, through tax credit. Participation of employers and employee representatives in preparation of the program would follow along agreed contractual labor relations practices.

(3) The employer would submit the occupational safety and health program to OSHA for acceptance. A Review Board composed of safety and health professionals, industry, and labor representatives would be empowered to adjudicate any conflicts. Once accepted, the program would be reviewed on a biennial, triennial, or other reasonable period for updating and determination of effectiveness as evidenced by bottom-line results; that is, the trend or level of occupational safety and health incidence rates reported annually or semiannually.

(4) The occupational safety and health program, as an essential part, would contain a comprehensive training program for hourly and supervisory personnel involving job safety analyses, stipulating standard job procedures, and specifying potential health and safety hazards to be avoided. The program would also be required to provide for investigations to determine specific causes of injuries and illnesses, reporting and recordkeeping, and implementation procedures (all internal) to assure that corrective measures are instituted.

(5) Once an employer's occupational safety and health plan was accepted, and if semiannual or annual reports to OSHA demonstrated satisfactory performance, the continued acceptance of the plan would follow without need for compliance inspections. This situation would prevail so long as the employer showed an annually improving trend, or remained in the upper one-fourth with respect to incidence rates for his industry and size of business.

Failure to improve within a reasonable period would require a review of the plan to determine what was lacking and revision to implement corrective actions. This means of achievement would permit the most flexibility and the most cost-effective solution that an employer and his employees could devise. It would put a strong element of cost competition and profit incentive into compliance. It would not require application of standards which were not relevant, nor expenditures lacking merit to improve safety and health.

(6) Employers whose safety and health records were poor—in the lowest (worst) quarter or bottom half compared with similar organizations in their industry—would receive OSHA inspections and consultation (not citations or fines) and would be required to amend their occupational safety and health program where analysis of specific causes or poor implementation showed a need for improvement. Fatalities, hospitalization of five or more employees, or employee complaints would require a visit by an OSHA compliance official as is now the case. Willful failure to perform in accordance with the accepted occupational safety and health program would result in fines or appropriate legal action to cause compliance.

There would be some reluctance to totally endorse this approach because to be applied generally, it requires study and approval by Government, business, and labor. For example, job safety analysis within the firm would have to be handled in a fashion to reduce what would otherwise represent a monumental amount of paperwork. Nevertheless, the spirit of improving safety by program institution instead of enforcement of standards is appealing, and this program might be the cornerstone of future practice.

One other topic that deserves discussion is new regulation. In new regulations, cost-benefit consideration must be the mode of operation. If, indeed, the underlying force for regulation is safety then it is difficult to understand why cost of regulation is not weighed in decisions on approach. Surely it is apparent that flex-

- Fewer patents being issued to U.S. companies
- More patents being issued to foreign companies (particularly the Japanese.) [11]

There is increasing evidence that many of the governmental policies are a significant factor in the decline in overall industrial innovation and, more important, are having a disproportionately adverse impact upon small innovative enterprises. [12–15]

B. Some Reasons for the Decline in Innovation

From our analysis of the impact of safety regulations stemming from the concurrent demands of the American legislative, administrative, and judicial branches of Government for increased protection from industrial products and workplace accidents, three major areas of negative impact on corporate decisionmaking emerge.

- The direct and indirect cost of compliance with safety regulation for new products and new projects resulting in lower anticipated returns on investment capital.
- For many new manufactured products, the possibility of recall creates uncertainties in financial analyses and unpredictable possible future costs.
- The probability of product liability suits resulting in increasing damage claims for new products is disproportionately large in contrast with existing products and partly uncontrollable by the manufacturer.

When considering the direct and indirect costs of safety upon new product decisionmaking, most modern industrial firms are concerned with the time adjusted value of money since they usually have options for applying their limited capital to a number of alternatives. In many corporations, capital allocation decisions are made using rate of return on investment formulas, and new product development projects are considered relative to investments in plant modernization, plant expansions for existing products, and even the purchase of existing products and businesses possessed by other firms. [16] The competition for capital is often so intense that a new project promising an 18 percent rate of return, for example, may be funded while one providing only a 12 percent rate may not get funded. (As an aside, a zero, or even negative, return project must be accepted if it is regulation related.)

Many projects, if they could exist without regulatory impact, would provide rates of return at the high end, but are not funded because of the depressing effect of regulatory costs in the rate of return calculations. Additional scientific and engineering costs to develop the product to meet government standards and safety regulations, delays in obtaining necessary governmental approvals, larger plant and equipment costs for its manufacturer due to workplace safety, and larger product manufacturing costs due to workplace and consumer safety factors, all enter into the rate of return calculations and can substantially depress the ability of the new product to compete favorably with other investment opportunities. This is particularly true since investments in plant and equipment for existing products receive direct tax credits and accelerated depreciation. Rewards for innovation are not exceeding the rewards for other options.

The recall and product liability impact is less quantitative but possibly more deleterious in corporate decisionmaking. Manufacturers (particularly of new products) are open to unpredictable liabilities stemming from circumstances which cannot always be controlled and are often unlimited in severity. In many cases the introduction of something new simply does not appear worth such additional risks.

The impact of safety regulation and liability impacts disproportionately upon small innovative businesses. For instance, the rate of OSHA safety inspections per employee workplace in a small firm is four times as great as for a large firm. [17] Yet, the innovative entrepreneur is considerably less equipped to deal with such inspections because he does not possess staff safety engineers and attorneys familiar with OSHA's many regulations and procedures. This presents a substantial drain on the creative energies of the small company, yet firms with less than 100 employees have been responsible for 24 percent of the major inventions since 1953, and firms with less than 1,000 employees, for approximately one-half. [18]

C. Some results of the new governmental environment

From our analysis, it appears that the present attitudes within the executive, legislative, and judicial branches of Government, particularly in the area of workplace and product safety, are contributing to:

- Lower industrial R. & D. spending
- The diversion of critical scientific and engineering talents into defensive projects away from creative projects
- The freezing of the status quo
- The construction of absolute barriers of entry into existing markets by rigid government standards
- A distorted product mix in the U.S. economy away from areas of intense regulation
- The elimination of much small business innovation.

D. Some Causes of This New Environment

In reviewing the effectiveness of the various agencies involved with safety regulation and the enormous associated cost, the following scenario can be proposed as a typical industry *perception.*

The American public is demanding more and more protection from the acts and products of others. While the public continues to incur the large scale risks of smoking and driving when drinking, they are demanding to be protected from others (83–97 percent of automobile accidents are related to human factors and only 4–14 percent, to vehicle defects). [19] Then, our

(b) To be responsible for eliminating duplication and inconsistency in both substantive and procedural aspects of regulations.

(c) To maintain a docket of pending regulations.

(d) To maintain on a monthly basis an annotated code of current U.S. regulations.

(e) To develop manuals of style, form, and terminology to be used in drafting regulations.

(f) To enforce policies restricting the promulgation of regulation.

(g) To enforce the application of sunset laws to regulatory programs.

(h) To represent the Government's position in matters of interest to the Government before Courts of Standards and Appeals.

percent is wasteful and likely unjustified, based on an evaluation of needs. Such excesses also escalate premature obsolesence of existing control technology. Economic impact statements, cost/benefit analysis of alternates, and R. & D. to determine effectiveness of controls are among the measures specified by Congress and the executive branch to avoid these excesses, but they do not appear to be applied.

9. *Especially affect small businesses.*—The complex body of law and procedure stemming from government regulations presents a formidable threshold cost and manpower burden on all affected businesses regardless of size. Particularly significant are the multiplicity of regulatory reviews, their sequential pattern of approvals and the costs of developing methods to achieve compliance in technologies outside the small venture's expertise. The consequence is to make it virtually impossible for small business to emerge in regulated products or processes. This seriously constrains the spirit of free enterprise and handicaps small businesses that are significant contributors to the industrial innovative process and provide over half of U.S. employment.

OTHER FINDINGS

1. There is no doubt in impacted industries that regulations have a serious negative effect on industrial innovation and on productivity and contribute to inflation.

2. The requirement and methodology for making rigorous cost/risk/benefit analysis is inadequate. Consequently, the economic impact as well as the anticipated benefits become apparent only after some period of implementation—a costly process. Estimates are often opposed on the basis that bodily harm cannot be evaluated. Little use has been made, however, of cost/benefit analysis of alternates where probability of harm can separate alternatives without assessment of the cost of suffering.

3. Responsible business has recognized the hazards of technology since the inception of industrialization. It has responded to that threat of its own accord by structuring internal safeguards in the form of:

(a) Extensive product testing before and after market release, and

(b) Extensive and sophisticated measures for ever improving quality control of the manufactured product and the manufacturing process.

Externally, business has collectively developed organizations to set quality- and safety-related standards and utilizes a variety of independent laboratories either to underwrite their product or augment internal testing.

Contrary to what seems to be popular belief, business is interested in more than making a profit. Among these concerns is that of staying in business. The public in aggregate is a most discerning buyer, and businesses do not long survive in a free enterprise system by selling inferior products.

These positive factors in the system of controlling the impact of products and processes should not be lost in a national quest for ways to further improve the environment, health and safety of the public.

4. It is recognized that society has the right to determine the priority it wishes to give to the improvement of its environment, and to the protection of its health and safety—that is not an issue. However, in order to arrive at an effective and intelligent decision on those matters, society is entitled to know the alternatives of choice as well as the cost it will have to pay and the risks it must take, for the benefits desired. Zero risk is not humanly obtainable. The reasonable task of Government is the collection and dissemination of that pertinent information for the optimum short- and long-term balance of cost (risk, and benefits and the means of regulation. Society, working through the Congress, can then determine the level of resources it can allocate and the pace of environmental improvement and health and safety protection it can afford in balance with other national goals.

RECOMMENDATIONS

1. We endorse the President's objectives for improving the regulatory process as stated in Executive Order 12044 and urge that it:

(a) Establish national priorities for regulations and coordinate agencies' activities.

(b) Tighten procedural requirements for analyzing and evaluating the risk/cost/benefits and alternative choices for proposed regulations before their enactment.

(c) Systematically reevaluate existing regulations to determine their risk/cost/benefits as well as the alternative choices for effecting their objectives.

(d) Develop a better means for evaluating risk/cost/benefits and alternative choices.

(e) Get early public involvement in the regulation evaluation process before enactment.

(f) Find ways to include some members well qualified as participants in the process of innovation from the academic and/or industrial community.

2. Because regulations are proving to have serious and far-reaching effects on our economy and hence on society, it is encumbent on Congress to be more diligent in its role as overseer of the regulatory agencies. To this end:

(a) The administrator of a regulatory program should inform Congress, on a regular basis, regarding those issues formulated by the procedures of his agency which involve matters of substantial public interest which in his judgment cannot be resolved on a scientific basis alone.

(b) Administrators should examine existing regulations periodically to determine the continued need for their use in the situations covered, and to determine the possibility of replacing centralized controls with decentralized and/or voluntary controls.

(c) Regulatory agencies should be required to determine the effect of their regulations on the incentive and motivation of individuals and corporations to engage in pioneering research and new product development.

GOVERNMENTAL CONCERNS

The Subcommittee commends the President for initiating a comprehensive and intensive effort to curb excessive regulation and to clarify and simplify Federal regulatory programs. We note that strong voices in the Congress are supporting this effort. We find particularly pertinent both Senator Edward Kennedy's call for "a new pragmatism" in economic regulation and his criticism of the ". . . government mentality that sees regulation as the natural order of the universe, that equates the *Federal Register* with Holy Writ, and that believes that anything the marketplace can do, Government can do better."

Congress gives evidence of recognizing that its laws must be more definitive in its prescriptions, more careful in mandates and timetables assigned to administrative agencies, and more discerning in avoiding structural overlap. Recent Congressional debates have addressed means of controlling and perhaps recalling power that has been delegated to administrative agencies. There appears to be recognition that Congress has failed effectively to oversee the regulatory programs it has spawned —that it has tolerated a regulation process that is often ineffective in meeting the intent of its delegated power. In the absence of effective oversight by Congress, the regulatory agencies have by mandate or by interpretation immersed the country in a relatively impenetrable, incomprehensible, and unmanageable morass of regulations. Under pressure to show results, agency administrators have made administrative rules that appear to go beyond the intent of the legislation, and they have employed interpretive rules on substantive matters. Due process is not truly available in the rulemaking process. Industry and intervenors have refused to accept administrative decisions that they consider contrary to Congressional intent and have sought judicial relief with the result that many important programs have been paralyzed by litigation. In many areas, the conditions which the regulatory programs were designed to improve and correct have not been improved, and in some cases have worsened. The expectations of the public have been disappointed, and Government and industry alike have been discredited. These conditions make it imperative that Congress devote more time to effective oversight of regulatory programs which it has set in motion and which now need effective monitoring. In short, the unnecessary costs of regulation and the uncertainties it has produced are not all agency ineffectiveness—they result in many instances from the pattern of legislation itself.

It is encouraging that the executive branch appears to be keenly aware of the threat that imprudent and excessive reliance on regulation poses to the efficiency and credibility of our Government and the threat it poses to the development of a dynamic economy capable of reestablishing American preeminence in technology and trade, domestic and international. The issuance of Executive Order 12044, the establishment of a Regulatory Calendar and the creation of the Regulatory Council and of the Regulatory Analysis Review Group are all manifestations of this awareness and of the need for regulatory reform.

We believe the objectives set forth in the President's Executive Order 12044 of March 1978, calling for simplification and a study of alternative approaches to regulation, and the objectives of the Regulatory Analysis Review Group and the Regulatory Council can best be accomplished by creating a U.S. Office of Administrative Law as proposed in our Recommendation No. 6.

ROLE OF THE INNOVATION PROCESS

Industrial innovation is the primary if not the only means of improving productivity. For the past decade, United States productivity improvement has lagged other industrialized nations, and poses a growing threat to U.S. exports to balance trade for our growing appetite for imports of energy, materials, tools and consumer goods. Productivity is also essential to domestic wealth in providing more goods and services than the public can afford.

Industrial innovation is also the means of developing new businesses that are the primary source of economic growth to provide employment for a growing work force and upward mobility for the disadvantaged.

When industrial innovation is impeded by unnecessary regulatory rules and procedures, investment is stifled in innovation to improve productivity and provide new business. Rules that specify how to achieve performance goals also limit innovation in methods of providing improvement in environmental control, health and safety.

CHARACTERISTIC OF INNOVATION PROCESS

The innovation process is generally defined as progressing through several distinct steps of evolution starting with the accumulation of specialized scientific knowledge and proceeding to the production and distribution of products based on the application of that scientific knowledge. While innovation is generally associated with new products or processes, it also plays a major role in developing less costly ways for making existing products or processes; thus directly and indirectly, it is the keystone for productivity improvement.

The industrial innovative process depends on the services of skilled technologists. To the extent that this resource is eroded through diversion, redundancy, or inefficiency, the capacity for innovation is diminished.

The rate of investment in a venture based on innovation generally increases substantially as the project moves progressively from inception to implementation, so the crucial innovation decision is often made close to the point of implementation. Conversely, subsidizing research and development is an essential step, but by itself does not assure commercialization and consequent social benefits.

Ventures based on innovation are generally characterized by high risk. Inherently they deal with the future and with new knowledge. Few projects survive from technical concept to commercial implementation. Thus innovation-based ventures must hold promise of high returns. This need was recognized in the protective rights granted through patents. It is also for this reason

Due process is not truly available in the rulemaking

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This seems solid to us. But the Public Interest Subcommittee would like to inquire into whether this write-off can be structured to prevent its becoming just another tax shelter.

Recommendation No. 11.—"Create a sliding tax rate for longer term investments in small businesses, properly defined, which spend more than a given percentage of revenues on research and development."

This seems reasonable in principle, but we do object to the reduction in tax rates being set as extremely low as proposed. Reduction is one thing. Reduction to zero is something else. Similarly, 5 years is an awfully short time period.

Recommendation No. 12.—"Permit patents to be written off over a period somewhat shorter than their legal life."

We recommend against allowing patents to be written off over a period shorter than their life, because it increases the incentive to large firms to buy patents either for the purpose of suppressing competitive ones or of absorbing potential new competitors. Other arguments relevant here are the same as those presented in response to the recommendation for immediate writeoff of plant and equipment.

Recommendation No. 13.—"Modify the concept of the 'prudent man' that has been embodied in government regulations so as to allow institutions to hold a certain percentage of their investment portfolios in venture capital."

The "prudent man" provisions of ERISA were set up to prevent fraud and excess. Whether that was wise or whether it has been effective is uncertain. It may have been both. But the Public Interest Subcommittee does support the proposal that a percentage—say up to 5 percent—of the portfolio be freed up for venture capital investments as proposed, or the definitional amendment allowing the "prudent man" rate to apply to the portfolio as a whole rather than to each investment individually. This measure alone might well have a substantial favorable impact on the venture capital market with only slight increase in risk for the institution's beneficiaries and at virtually no cost to taxpayers.

Recommendation No. 14.—"Encourage States to liberalize the investment restrictions on State regulated pools of capital so as to allow investment of some portion of these funds in equity positions in small businesses or venture capital firms."

Our comments on recommendation No. 13 apply here as well. In sum, the Public Interest Subcommittee endorses the recommendations within reason, i.e., without entirely relieving managers of institutional funds from all reasonable and wise, prudent restrictions. We urge further inquiry into what would be reasonable and wise strictures, but approach the question conservatively, bearing in mind that an investment approach that has been highly successful over one 5- or 10-year timespan may well prove disastrous financial management in another economic or investment environment.

Recommendation No. 15.—"Simplify the regulations regarding the private placement of small investments."

Regulations regarding the private placement of small investments have very recently been revised to simplify them and reduce the cost of compliance. If the Industry Subcommittee believes this simplification does not go far eough, relevant analysis and evidence should be introduced. Otherwise, recommendation No. 15 is no longer necessary.

Recommendation No. 16.—"Increase the SEC's Regulation A limits on the size of investment offerings."

The SEC's Regulation A limits have recently been raised from $500,000 to $1.5 million. That seems sufficient.

Recommendation No. 17.—"Successfully conclude the current round of international trade negotiations."

Of course we support successful and timely conclusion of the current round of international trade negotiations.

Recommendation No. 18.—"Review, on a more timely and aggressive basis, those items which government policy prohibits from being exported."

The Public Interest Subcommittee is delighted with this recommendation and supports it strongly. Many of us are deeply disturbed by the aggressive overseas marketing of products banned or otherwise restricted in the United States. We urge that current policy prohibiting certain exports (currently applied to products the Department of Defense restricts for security reasons) be broadened to include banned pesticides, foods and drugs not approved by the Food and Drug Administration, and highly dangerous substances such as enriched plutonium. And we urge that this be done on a "timely and aggressive basis." We view all of these as among "the most sensitive of items."

Recommendation No. 19.—"Minimize the application of U.S. laws to extraterritorial business ventures."

We recommend just the opposite. The Public Interest Subcommittee questions the assertion that "attempting to apply [meritorious law] to individuals and corporations outside the jurisdiction of the United States has only resulted in unnecessary loss of business for many American firms." Where is the documentation of the cause of "business lost?" Such assertions in specific cases are often just sour grapes; an excuse by sales personnel and companies which failed to make a sale. Determining the reason for a sale not made is not always easy. Furthermore, something important is lost by exempting overseas activities from meritorious laws that apply domestically.

Recommendation No. 20.—"Establish a Federal Governmentwide regulatory budget, subject to review by the Executive Branch and by Congress, that would set overall limits to the economic effect to be allowed to result from government regulations."

This recommendation is virtually unworkable. The limits of an economic effect must be set relative to the benefits of the regulation or to the cost of *not* regulating. Economic effect is so complex as to virtually preclude prediction. What about netting out economic benefits? Besides, some regulations relate to values that are so basic to our culture and to ethics worldwide that

Society or by the American Patent Law Association. These registers should be updated periodically and copies should be distributed to manufacturing and engineering executives and to patent attorneys.

The Proposal—4.—Exempt from income tax the first $25,000 of income received by a manufacturer from exclusively licensing in-house developed but unused patents and technology for any type of product or process, on an arms-length basis, to an individual or small company, provided that the licensee will have shown reasonable diligence to exploit the license. In addition, allow a tax credit of up to $25,000, to be applied on the basis of license income in excess of the first tax-free $25,000, to match out-of-pocket costs for furnishing specific engineering services to facilitate the use of the licensed technology by the licensee.

The Proposal—5.—As an optional alternative to Proposal—4, a licensor should have the right to treat all income up to $500,000 received from a manufacturing license as capital gain income.

The Proposal—6.—A manufacturer who establishes a spinoff venture or joint venture to exploit new or unused technology with an employee or group of employees in which the employees would own not less than two-thirds of the equity, could for each such venture take a tax credit of up to $50,000 for losses of cash (as distinguished from investments in kind) invested to help finance the enterprise. As a condition of this credit, the manufacturer would give up the right to acquire or take control of the spinoff venture.

2. **The Problem.**—There are large numbers of U.S. patents owned by American and foreign citizens and companies which are not utilized. In some cases, the patents are of minimal or questionable value or cover inventions that are not considered "commercial." Other patents may be defensive in purpose or have the effect of preventing competitors from bringing better products on the market. Some large corporations have accumulated massive banks of patents which may immobilize or neutralize individual patents of others.

The Proposal—Any U.S. patent owned by any party which is not being or in the process of being commercially or operationally utilized for a consecutive period of 3 years should thereafter be subject to compulsory license to any party that is prepared to utilize the patent. Proof of use or nonuse must be factual and involve regular as distinct from pro forma working—burden of proof to be on the patent owner. Terms of a compulsory license could be freely negotiated between the interested party and the patent owner but there must be an equitable code to fix maximum financial terms that a patent owner can require. This code should differentiate limitations on the basis of company size, the nature and subject of the patent, and fields involved. The parties to a compulsory license must be arms length. Except if government funding were involved in the development work upon which the patent is based, the licensor should not be obliged to provide know-how.

B. Inventors: Individuals and Small Business Principals

Relatively few inventions or inventive concepts of individual inventors are commercialized. Indeed, most inventions and patents are probably not worth developing. However, many are or would be if (a) the inventor had or could obtain development capital; or (b) if his abilities were reinforced with other technical capabilities and research facilities; or (c) if companies with business of a nature that should make the invention of same interest, were prepared to give it proper consideration; or (d) if there were places the inventor could go with confidence for responsible guidance. Unless we find ways of giving new ideas a better opportunity to develop on their merits, our economy will continue to lose the special vitality of creative and entrepreneurial individuals. In a society with increasing numbers of better educated young people and a larger proportion of older people with the creative potential of experience and more leisure time, the loss would seem to be growing.

1. **The Problem.**—It is excessively difficult for individuals, who cannot on their own exploit their inventions, to find companies willing to evaluate these inventions seriously. Small companies may not have the time or money. Large companies, with forbidding "confidential disclosure" proceedings, are difficult to approach. Many, with in-house patent departments display a "macho" in relation to company patent and know-how positions that in effect (a) denies outside inventors fair and objective consideration or (b) serves to chill efforts to license these inventions to others or (c) makes it impractical if not economically impossible for the inventors to assert their patent claims.

The Proposal—1.—There is no general solution to the problem of culling valuable concepts from the vast stream of ideas that individuals generate. It is up to individuals to propel their concepts to a point where their innovative merits can be established and protected. However, within a business, there should be an identifiable procedure or function of encouraging, evaluating, and rewarding employee ideas—and for perhaps patenting and exploiting the good ones. In any event, ideas and the capacity to generate ideas are a national asset. Government and business should cooperate in a national campaign to encourage creative thinking and to inform individuals of the basic steps that should be taken to prove and protect their ideas. Simple pamphlets—"Your Idea—How to Protect It"—could be widely distributed. This could also include references to government agencies which solicit ideas that relate to national-interest objectives—environment, energy, health, and defense.

The Proposal—2.—Top management of companies —particularly large corporations—should examine the procedures with which new ideas and inventions are received and the "hospitality" accorded them by responsible executives. Attitudes of excessive defensiveness or N.I.H. should be changed. The notion that most good ideas either originate or are nourished by

licenses under the patents and know-how developed by the TDC.

The Proposal—3.—Every manufacturing company should have the right to a tax credit of up to $25,000 each year, to a cumulative ceiling total of $100,000, to match out-of-pocket expenses assigned to specifically designated new product development projects. This incentive cannot be applied to costs of upgrading existing products. The $100,000 ceiling can be augmented at the rate of 2 percent of the net f.o.b. sales value of new products developed by the company for a period of 3 years from the date of first sale of any such new product.

The Proposal—5.—Losses of manufacturers attributable, by accepted accounting practices, to the manufacture and sale of new products may be carried forward against profits for 10 years.

C. Government: Technology, Patents and Procurement

The Government is the largest single participant and sponsor in basic research and development that serve to broaden the potential for product and process innovation. Government R. & D. is conducted in its own laboratories and, under grants and contracts, by private industry, research agencies, and universities. Much of this work is defined as "basic research" or is related to specific public-interest purposes and end uses. Apart from this, the Government, through various agencies, spends at least $60 billion for goods and services required for its operations.

1. **The Problem.**—Relatively few government patents have been exploited except within narrow fields or for particular end uses of original government interest. The under exploitation of government patents and technology is caused by the fact that (a) many patents require extensive further development in order to define possible end uses and their viability; and (b) because the Government has been inconsistent and uncertain in its patent licensing policy; and (c) limited ability to accompany patent licenses with know-how developed during previous development activities, particularly if conducted under private auspices; and (d) the details of patents and know-how available for government license are not widely known to industry, especially to small companies.

The Proposal—1.—All information concerning government patents and know-how that is available to industry should be part of the computerized bank referred to in Proposal A1–2.

The Proposal—2.—The Government should be willing to grant exclusive licenses under patents to small companies or individuals who are willing to commit themselves to minimum conditions of patent development and utilization within prescribed periods of time. It would be acceptable to grant such exclusive licenses to PDC's and TDC's contemplated by Proposals B 2–1 and 2. A TDC would also receive sublicensing rights. The Government should also have a qualified policy of granting exclusive licenses for government patents to large companies which would be committed to minimum levels of exploitation, including sublicensing obligations.

The Proposal—3.—R. & D. contracts granted by the Government should require that government patent rights also include the rights to acquire and to have communicated at government instruction and reasonable expense all know-how, developed under the contract, to third parties to whom the Government may grant exclusive licenses under patents acquired pursuant to the contracted R. & D. This would include exclusive licenses under a patent for specific fields of application.

The Proposal—4.—Authorize the Government to enter into agreements with properly accredited licensing organizations so that the latter, on a contingency basis, will undertake to license or make acceptable (determined by parameters of Government policy) arrangements for exploiting or developing individual Government patents. These agreements can cover groups of patents in particular fields, on an exclusive or nonexclusive basis, for specified periods of time. They can provide for periodic payment of nominal fees or prescribed minimum conditions of performance by the licensing organizations as a condition for retaining exploitation rights with respect to specific patents.

The Proposal—5.—Government agencies should extensively contract with small business and technically qualified entrepreneurs to develop specific end products which are related to specific public-interest objectives. These contracts can be associated with patents owned and licensed by the Government to the other contracting party or with patents owned or acquired by the contracting party. The ultimate purpose of the contracting party would be the manufacture and sale of the developed end product commercially—not merely to the Government. The Government should recover the original value of the contract plus interest as a royalty on commercial sales of the end product.

2. **The Problem.**—The standards and specifications by which government purchases are controlled fail to provide adequate opportunity for product innovations that can permit lower costs and improved product performance. This makes it particularly difficult for a small business which is not an established supplier to the Government and which cannot afford to simultaneously produce products that must compete in the commercial market and products made to government specifications. Moreover, it is often impractical for the individual entrepreneur or for the small business to seek and obtain revisions of government standards and specification.

The Proposal—1.—Establish "ombudsman" departments in major government purchasing centers to deal specifically with revisions in standards and specifications proposed by small business. The "ombudsman" departments should have access to the technical judgments and facilities that can enable prompt action on proposed specification changes that are deemed advantageous to

under $5 million, with annual revenues during the latest 3 years averaging less than $10 million. The terms "export" and "export expansion" are deemed to include all business activities that come within the interests and objectives of U.S. manufacturers in foreign markets.

2. The program must attract the entrepreneurial motivations of businessmen as its primary dynamics.

3. Economic proposals should be available without discrimination to all U.S. companies regardless of size. However, they must have particular relevance to the needs, interests and motivations of small business.

4. The statistics for measuring the success of the program are the number of additional companies brought into export. Increased revenues from foreign transactions, while important, are secondary except as they may reflect a broader base of U.S. participants.

5. Tax-related incentives must project as self-financing through anticipated business growth. They should not permit redirection of established export relationships for tax-saving purposes.

6. It recognizes that technology and specialized know-how, whether or not associated with patents and trademarks, is a primary tool of trade development for many manufacturers whose existing products cannot compete in foreign markets, or who place access to overseas technology and technological feedback as primary business objectives.

THE PROGRAM COMPONENTS

The program has three basic components:

1. Government policies and services.
2. A structure of program incentives.
3. Vehicle for program implementation: the Small Business Export Trade Corporation.

I. Government Policies and Services

The Federal Government can initiate policies; target objectives; promote legislation; and focus incentives, facilities, and services for fostering international business. Historically, small business has derived relatively little benefit from such government actions because they have essentially dealt with business as a monolithic estate. Government actions have not been devised to function in terms that are meaningful to small business. (For example: DISC, Export-Import Bank financing, etc. back to Webb-Pomerene.)

On the other hand, some policies that could appropriately assist small business are repressed because they give undue benefits to big business. (For example: while technology transfer by big business can mean "export of jobs", to small business, it can only add markets and resources to help growth.)

A. **The Problem.**—Small business has no effective agency for presenting its views and interests at top national levels concerning foreign trade policy and programs. The President's Export Council as now constituted represents big business. Its membership is unqualified to speak for small business—indeed, some have questioned the validity of small business' concern with foreign markets. Small business clearly must be in a position to speak up and promote policy and program in its own behalf.

The Proposal.—Either within the existing PEC or as a separate peer group, create a facility through which small companies can provide knowledgeable, creative and effective "export expansion" input and initiatives at top executive and legislative levels in Washington. A President's Small Business Export Council must be carefully constituted and its functions adequately defined. It should have staff facilities appropriate to its purposes situated within a suitable executive branch of Government.

B. **The Problem.**—Government international services to business do not adequately serve small business. They fail to identify and qualify trade and technology opportunities in good time. Input is often dubious and followup unreliable. They fail to deal effectively with the barriers that have insulated small business from foreign markets and from timely access to overseas technology and innovations.

The Proposal—1.—Improve government (Department of Commerce in particular) techniques for defining, developing and disseminating trade opportunities to the business community. Computerized input should be more comprehensive, and regional (field office) information terminals should be established.

The Proposal—2.—Overseas government commercial facilities should be more uniformly staffed with qualified commercial officers. Staffs should be amplified and administratively separated from embassy functions, preferably under the separate authority of Trade Commissioners. A corps of "transaction service" officers could be constituted specifically to assist small companies in business development projects.

The Proposal—3.—Organize low-cost overseas business seminar and factory visit tours and "make-a-deal" missions. Government and business executives should cooperate in creating, guiding, and implementing this program, perhaps in association with overseas trade fairs.

The Proposal—4.—Organize small business missions in cooperation with Governments of LDC's with a view to creating manufacturing joint ventures geared to LDC industrial infrastructure needs. This could be combined with a program of bringing individuals with suitably qualified potential from LDC's to the United States for intensive project training. This could be further associated with an administrative liaison facility, perhaps under Government auspices, in the LDC.

The Proposal—5.—Libraries of the regional field offices of the Department of Commerce should have copies of major trade and business publications available. Also, subjects of scientific articles published abroad should be appropriately indexed on a central computer with digests selectively prepared.

The Proposal—1.—Shares providing a minority equity and having a par value of up to $50,000, which are received as consideration for know-how or for intangible property rights in a foreign manufacturing joint venture are to be deemed a tax-free exchange, and subject to tax as a capital gain only when liquidated on the basis of money constructively received. If the joint venture is established in LDC's, the tax-free exchange ceiling would be increased to $100,000. Each manufacturer would have an overall cumulative "tax-free exchange" ceiling of $250,000.

The Proposal—2.—With respect to investments-in-kind (such as used machinery, special tools, etc.) in foreign manufacturing joint ventures, the excess between the par value of minority equity and the book value of the investment-in-kind, up to a maximum amount of $50,000 in each venture, would be deemed a tax-free exchange. For investments-in-kind in joint ventures in LDC's, the ceiling would be $100,000. Equities covered by this provision would be subject to tax as a capital gain and only when liquidated and money received.

The Proposal—3.—Dividends received or equity in earnings of foreign joint ventures would be subject to U.S. tax (with foreign tax credits) only if the dividends or earnings are received in or can legally and without penalty be converted into U.S. dollars. If dividends on earnings are reinvested in a foreign joint venture to maintain a constant equity position, they would not be subject to current U.S. tax, although the use of foreign tax credits would be correspondingly deferred.

G. **The Problem.**—U.S. antitrust regulations operate to restrict unfairly the access of small companies to overseas technology. Large corporations can readily capture the technology, know-how, R. & D., and grant-back values of patents from foreign subsidiaries. They can often acquire foreign companies having patents, technology, and products that are desired.

Small companies cannot operate in this fashion. They must rely heavily on technology transfer arrangements with independent companies. However, the productivity of these arrangements—particularly the technological feedback and grant-back values they can generate—is inhibited by antitrust provisions. Thus, small companies are disadvantaged in competing with large companies, particularly in fields which are most subject to evolutionary and innovative changes.

The disparity is further accentuated by the ability of large corporations, who cover world markets through foreign subsidiaries, to defer U.S. taxes and to control their markets: the *de facto* ability to protect sources of supply, pricing and profits. Antitrust regulations deny equivalent opportunities to small companies who operate through technology transfer. Moreover, they compound a fear of many small manufacturers: That export development through technology transfer works to set up foreign ventures, benefiting from U.S. know-how and lower overseas costs, as domestic competitors.

The Proposal—1.—Permit small manufacturers to acquire exclusive grant-back rights to patentable developments of foreign licensees or joint ventures in which they have minority interests. Grant-backs should include the right to extend, through sublicenses, grant-back rights to other licensees and joint venture associates in other countries.

The Proposal—2.—Small manufacturers may legally exclude foreign licensees and joint ventures from competing in the U.S. market with respect to products covered by technology transfer agreements.

The Proposal—3.—Small manufacturers can set themselves up as exclusive sources of supply for additives or specific components required by foreign licensees and joint ventures in connection with the fabrication of products under technology transfer agreements.

NOTE: Antitrust concessions to U.S. companies in connection with international technology transfer agreements must be subject to foreign laws that govern foreign parties to such agreements.

H. **The Problem.**—Small manufacturers do not regard the benefits to be anticipated from export markets as commensurate with the risks and problems involed.

The Proposal.—The first $100,000 of profits on export sales and from technology transfer relationships shall be subject to tax at 50 percent of the regular U.S. income tax rate. The determination of such profits should be permitted by following prescribed procedures within the accounting operation of each manufacturer and need not require the formation of a separate DISC or export corporation.

III. Small Business Export Trade Corporation

Experience indicates that, for economic and psychological reasons, most small manufacturers do not respond to "naked" export incentives. There must be a mechanism for putting incentives to work—to neutralize the small manufacturer's concerns and inertia. To fill this need, legislation should be enacted to create a new kind of enterprise: a Small Business Export Trade Corporation (SBETC). The SBETC is conceived as an entrepreneurial facility that has the competence and motivation to assume the full burden of finding export markets for client manufacturers and for developing and servicing these markets.

The essential elements of SBETC, as a business for bringing small American manufacturers into world markets, are set forth as follows:

1. **SBETC Functions.**—Acting essentially as the "foreign department" of its clients, the SBETC would coordinate overseas market conditions and opportunities with client capabilities, potential and objectives, by variously performing the following services:

(a) Export sales, directly to major end users or through qualified distributors or sales representatives. The SBETC would normally purchase client products on standard client terms for resale and assume all responsibilities and risks, other than client product warranty, which export transactions may involve.

(c) The SBETC would be permitted to take "double deduction" of expenses specified in II-A with respect to each QC. However, the QC would have prior right to utilize this incentive in connection with proper expense items as it may prefer to undertake directly.

(d) Incentives relative to equities and investments in kind in overseas joint venture as set forth above in II-F shall apply to the SBETC.

(e) Utilization of incentives by the SBETC shall not be cumulative from year to year. Nor can they be transferred or improperly allocated among QC's.

(f) The following program incentives would be available only to QC's and not to SBETC's: II-E, II-C2, II-G. As to II-G, instead of the QC, the SBETC will pay 50 percent of the regular U.S. income tax on the first $100,000 of the SBETC profits each year from export activities for each QC, up to an annual ceiling of $500,000 of SBETC profits for all QC's.

8. **SBETC Qualification.**—In order to gain and retain the advantages of SBETC incentives each year, the SBETC must fulfill various qualifying conditions:

(a) Each year during the first 3 years, the SBETC must serve at least three QC's. Thereafter each year, it must serve at least five QC's.

(b) A QC will not qualify as such for SBETC "incentive" purposes if in any year after 4 years from the start of a QC relationship, the combined total of QC export sales plus other QC foreign income received by the SBETC shall be less than 10 percent of gross SBETC revenues or $100,000, whichever is less, unless, for the year in question, the SBETC shall have at least 5 other QC's whose sales-income total shall meet the "10 percent or $100,000" test.

(c) After 5 years, 75 percent of gross SBETC revenues must be generated by products of at least five QC's and the revenues attributable to each QC must be at least 10 percent of such revenues; provided, if exports of U.S.-made products of any QC in any year shall exceed an f.o.b. value of $100,000, or if technology transfer relationships shall generate taxable U.S. income of at least $25,000, such client shall automatically be deemed qualified as a QC for SBETC incentive purposes.

(d) Exclusive of income derived from technology imports, no more than 5 percent of gross SBETC revenues may relate to product imports, and in no event may import activity be conducted except to the orders of QC's.

(e) SBETC accounts must be set up so that the sales and income associated with each client shall be clearly and properly distinguishable for purposes of administration and for determination of profits and compliance generally.

(f) With respect to each QC, the SBETC shall be obliged to show each year that it shall have exercised due diligence in seeking to develop overseas business. Yardsticks of due diligence shall be administratively established.

9. **SBETC Administration.**—Although other government agencies can be considered, the U.S. Department of Commerce seems best organized and prepared to administer the SBETC program. In any event, administrative responsibility and parameters for establishing regulations and controls must be clear and definite. Certification procedures for an SBETC would have to be fixed and compliance overseen.

comment

OF THE PUBLIC INTEREST SUBCOMMITTEE ON ECONOMIC AND TRADE POLICY

industrial innovation

Comment of the Public Interest Subcommittee on the Industry Report on Economic and Trade Policy

This paper presents the reactions of the Public Interest Subcommittee to the specific recommendations of the Industry Subcommittee on Economic and Trade Policy. These reactions and comments are presented in the overall framework on innovation with which the members of our subcommittee would view any recommendations for improving innovation.

Evidence available has not convinced the Public Interest Subcommittee that there is a problem with the rate of innovation sufficiently serious to merit expensive government intervention. The measurements cited to substantiate the alleged problem are indirect and insufficient. Some persons point to the relative decline in the U.S. portion of patents internationally as evidence of a problem with the rate of innovation in this country. The decline may primarily reflect the transfer of technology or the innovative activities of U.S. corporations abroad and that of their subsidiaries and licensees. Regrettably, statistics are too sparse to test this hypothesis. Other measures which are considered surrogates for declines in innovation—such as declines in percent of GNP spent on R. & D., declines in government spending for R. & D. in industry, declines in the formation of small technology-intensive companies, declines in the rate of U.S. labor productivity growth—all rest on uncertain assumptions about relationships between innovation, on the one hand, and R. & D., technology or productivity, on the other.

From the public interest perspective, the rate of innovation is subservient to the question of the direction of innovation. We see the critical issue to be the direction of innovation in our society. While there may or may not be a problem with the rate at which society is innovating, we do detect distinct problems with the social and economic significance of present innovations. Therefore, the Public Interest Subcommittee proposes an overall framework within which any recommendations for improving innovation can be considered. It is a framework for formulating public policy, a way to assess a government role, if there is to be any, in promoting or inhibiting innovation. It is this framework within which the Public Interest Subcommittee presents its reactions to the recommendations of the Industry Subcommittee on Economic and Trade Policy.

EVALUATION OF RECOMMENDATIONS

The discussions of the Public Interest Subcommittee reflected five criteria for, or questions asked about, each recommendation made by the Industry Subcommittee. The five criteria, or questions, are:

1. Toward what goal?
2. How effective?
3. At what cost?
4. Who pays?
5. Is it targeted at small, new businesses?

THE AIMS OF INNOVATION

If the Government is to take any role in promoting innovation in society, it is proper for it to do so only after first answering the questions: Innovation to what end? How does the type of innovation which is being promoted relate to various government objectives? Does the innovation being promoted improve the quality of life? How is that improvement distributed among the various groups in society?

These questions can best be addressed by defining the basic goals of our society; for it is these goals which define the directions that government efforts for innovation should take. They can be called social goals or ethical goals. Many are also legal goals in the United States, affirmed by the Clear Air Act, the Water Pollution Control Act, the Consumer Product Safety Act, the Occupational Safety and Health Act, the Full Employment and Balanced Growth Act, the Civil Rights Act, etc.

Another approach to identifying shared goals would be to take the results of a poll or referendum. A Gallup opinion poll in 1976 asked the question: If and when more Federal funds from Washington become available, which of the following areas should be given first consideration, second consideration, third consideration? All three responses were totaled. The response was as follows:

	Percentage
Health	53
Education	48
Law enforcement	41
Welfare	32
Housing	26
Pollution and conservation	24
Mass transit	19
Military defense	16

Yet all too often we find that the preferred goals are slighted or the priorities are reversed. For example, military research and development takes the lion's share of Federal research and development expenditures. We

declines in percent of GNP spent on R. & D., declines

for a more thoughtful piece, looking beyond new ways to make a buck off the taxpayer.

The Industry Subcommittee's remarks that "any system that rewards savings is inevitably going to have some disproportionate benefit for the relatively wealthier; but the Subcommittee has avoided recommending any scheme which would be an extreme example of this problem." The Subcommittee should be commended for forthrightly identifying this effect and for considering it a problem. However, the Subcommittee's recommendations do not reflect this concern. What is needed is more serious and imaginative inquiry into alternative approaches that would avoid the predicted result. In the view of the Public Interest Subcommittee, such a result is not inevitable at all. For example, research and development incentives could be targeted at those innovations which best serve the real interests of those at or below the median income by improving the quality and decreasing the cost of basic necessities like food, medical care, and shelter. Or, given sufficient lead time to allow for research and development, Government could work from the consumer end by providing or increasing direct subsidies to consumers for purchase of certain goods, as it has for solar energy devices and improved insulation. Such subsidies to consumers would serve as an effective incentive for innovation. And small business has a real crack at this market.

EXTERNALITIES OR GOVERNMENT REGULATIONS

The Industry Subcommittee on Trade and Economics bemoans the assertion that "government regulations designed to incorporate what had previously been externalities—the cost of pollution, for example—has resulted in greatly restricted profitability." The Subcommittee does not state the obvious—that incorporating externalities removes the burden of payment borne by such groups as the general public or neighbors of the firm those on whom these costs had been imposed in the past and who reap no related profit. Now some of these costs have, by law, been shifted back to those who produce the externalities and enjoy the profits of such production, as part of the normal cost of running a business. We find no injustice in that.

The Industry Subcommittee even bemoans the inability of firms to "completely recover" the costs associated with these new requirements. It points out only indirectly that there has been partial or even substantial recovery of such expenditures, through offsetting revenues and more efficient production, plus economic benefits like job gains in other sectors, e.g., pollution control industry. The real question is not whether the cost of pollution control is zero to a firm, but (1) whether it exceeds or is less than the cost of pollution, and (2) perhaps more important, what is the just incidence of that cost. Those who profit from producing the goods and services and those who choose to purchase the goods and services are appropriate recipients of the bill.

TAX PROPOSALS

In the paper prepared by the Industry Subcommittee on Economic and Trade Policy, there is a variety of tax proposals aimed at increasing profitability or cash flow. These tax proposals are based on the theory that business is eager to innovate, but simply does not have sufficient funds. This is a myth. An article in *Business Week* (September 18, 1978) pointed out that between 1970 and 1977 cash in the hands of the 545 biggest industries, transport companies and utilities grew from $40 billion to $75 billion—more than enough cash to finance a capital spending boom. The magazine reported that "top corporate executives and a good many economists concede that tax measures aimed at generating more cash as a way to stimulate investment probably would not do the trick." In a recent Senate antitrust hearing, Senator Edward Kennedy pointed out that Exxon today could acquire J. C. Penney, DuPont, and Anheuser-Busch using only its accumulated cash and liquid assets.

Under present conditions, the only purpose to be served by creating additional tax loopholes in the name of investment incentives will be to enlarge further the corporate share of the national income. Any investment stimulus that might result would be temporary at best, because it is futile to stimulate investment if there is insufficient purchasing power available to absorb the output from that new investment. And the country has indeed been experiencing a shortfall in purchasing power, as is evident from (1) the way in which real hourly compensation of the Nation's employees has been lagging behind growth in the Nation's output per hour; (2) the high rate of unemployment; and (3) the low rate of capacity utilization.

The Trade and Economic Subcommittee asserts that, despite President Carter's prime goal of simplifying the tax structure, "Inevitably, tax policy is truly the best single tool available to economic policymakers in addressing" the structural economic problems cited by the Subcommittee. Others would argue that it is the worst, because tax expenditures do not even appear in the budget, except as reduced revenues. Tax reductions and exemptions therefore avoid the scrutiny given to line items in the budget by Congress, the Administration, the press and the public. In the legislative process, they are only considered by the House Ways and Means and Senate Finance Committees. Unlike appropriations, they are not reviewed by the congressional committee dealing with the substantive issues. In 1975, $78 billion of government spending was run through the tax system and therefore was not seen in the budget. In a 1980 budget appendix the Government estimates tax expenditures will rise to $227 billion by 1980, of which $49 billion will be for corporations. Spending ceilings and expenditure controls do not apply to tax expenditures. And under tax expenditure benefits, the more profit you make, the more benefits you get.

As a result of increasing tax expenditures, the effective income tax rate for corporations (as measured in the National Income Accounts), declined from 47.5 percent of profits before taxes in 1969, to 41.3 percent

The Industry Subcommittee on Trade and Economics ... (2) the high rate of unemployment; and (3) the

have become ineffective, inoperative or counterproductive for encouraging our growth as a free-enterprise economy.

The potential for greater innovation input into our economy must be developed from the following primary sources:

1. Unexploited and underexploited patents and developments of industry.
2. Inventors: individuals and small business principals.
3. Government patents and technology.
4. University and laboratory research developments.
5. Foreign technology and product developments.

A program to energize these innovation input sources must harness the following kinetic elements of our economy:

1. Competition between industries and among companies within industries to come up with or improved products at lower cost.
2. Entrepreneurial motivations that foster development and the projection of new products and ideas into the marketplace.
3. Forces for public interest and industrial change, stemming from considerations such as environment, demography, consumerism, productivity, health.
4. Government spending for (a) research and development and for (b) a wide range of products.
5. Government regulations that mandate private investment and development to meet new standards and requirements prompted by public interest and considerations.
6. Tax policies that can influence the flow of private-sector capital and capital allocations.
7. Availability of venture capital which can govern research and development initiative.

The input potential of each primary innovation source has been restricted by a variety of influences, some of which must be dealt with as problems. The principal problems are described below—in association with proposals for reducing their negative impact. They are presented as recommendations in principle—detail, where given, is intended to indicate thrust and not finality.

A. Unexploited and Underexploited Patents and Developments of Industry

Many manufacturers, and certainly most large companies, now have and continue to develop fully or partially completed products or technology projects which are abandoned for a variety of reasons. Similarly, many companies devise techniques, components and special purpose equipment that are specifically designed for their own uses but which, in suitably adapted form, have a broader commercial potential. Such abandoned and peripheral developments, if selectively but aggressively promoted with a new entrepreneurial perspective, might be salvaged and commercialized.

Some large corporations have established licensing departments to exploit these developments, but with limited success. Most have not. However, by adding this reservoir of potential to the mainstream of innovation, not only do we add to the vigor of our economy but also (as is accomplished with all energizers of innovation) to the growth and productivity of America's pool of engineering and entrepreneurial talent.

1. **The Problem.**—Most large companies do not attempt to license or otherwise exploit abandoned or peripheral projects variously because (a) it may help competitors; (b) it is too costly to maintain a licensing program based on internally generated technology; (c) potential of individual projects is too small to justify an effort; (d) further technical work and adaptations may be required to establish commercial possibilities; (e) antitrust regulations may make licensing inadvisable; (f) ignorance and underappraisal of technological assets that have licensing potential; and (g) company policy. Ways must be found to overcome or bypass these difficulties so that developments that have become sterile can have an opportunity for commercialization.

The Proposal—1.—A promotional effort should be made by Government in cooperation with business, industrial and professional organizations to encourage industry to inventory its unexploited technologies and, as they stand, to make them available for exploitation by others to mutual advantage. Such technologies can also include older and less advanced manufacturing methods and product designs, suited for employment in LDC economies. Promotion should feature opportunities for profit combined with serving the national interest.

The Proposal—2.—The Department of Commerce should establish a computerized bank into which companies—and indeed, all domestic and foreign owners of patents and technology "packages"—can register their available products and process technologies. To qualify for listing, a prescribed form containing essential information would have to be acceptably prepared. Appropriately indexed by subjects and markets, the computerized data could be fed out through regional terminals for consultation by those seeking new product and technology opportunities. Specific company contacts, negotiations and agreements would be private. The desirability of charging registration and/or terminal access fees can be considered.

The Proposal—3.—Independent licensing and technology transfer organizations can be useful for encouraging manufacturers to exploit unused and peripheral technology. Most companies either do not know that specialized professional services of this type are available or do not know where to find those best qualified to handle contemplated licensing projects. Accordingly, the Government should prepare a register of licensing and technology transfer organizations, noting services and facilities each offers and the basis upon which services are compensated. As a condition of listing, each registrant could be required to furnish certification to prescribed standards of professional qualifications and ethics by the Licensing Executives

savings and loans, State credit unions, and State retirement systems all tend to restrict rather than enhance the availability of venture capital. Action by the Federal Government that would encourage a reversal of this tendency would be as welcome a measure as relaxation of comparable Federal regulations.

Recommendation No. 15.—Simplify the regulations regarding the private placement of small investments.

Commentary.—In April 1974 the Securities and Exchange Commission adopted rule 146 under the Securities Act of 1933, in an effort to reduce and clarify the nature of the requirements for the private placement of small investments of the kind that are typical of venture capital opportunities. For a variety of reasons, that rule has not achieved the goals intended, and in some cases has even complicated the picture further. Without descending into the kind of detail that is necessary in order to specify exactly how the rule should be further modified, the Subcommittee wishes to go on record in support of further modification of the rule so that it will more nearly achieve its original purpose.

Recommendation No. 16.—Increase the SEC's regulation A limits on the size of investment offerings.

Commentary.—Currently, regulation A imposes a flat dollar limit on the amount of money that can be involved in an offering without becoming subject to all of the limitations imposed by the regulation. This limit is in need to further upward adjustment in order to take into account the effects of inflation over time. Doing so would facilitate the raising of capital for new ventures needing relatively small amounts of capital, many of which now find the burdens imposed by the fact that their capital needs exceed the limits of regulation A to be excessive, if not preclusive of successful placement.

Trade Policy Recommendations

The Subcommittee is convinced that a revived policy of protectionism for domestic industries does not represent a solution to the problem of faltering innovation and investment. While an increase in foreign competition has had unpleasant consequences for some sectors of the American economy, the Subcommittee believes that relief from unfair trade practices such as dumping and subsidized imports, rather than protection from vigorous but fair competition, is the proper policy to adopt in those instances. It would diminish American industry's incentive to innovate and compete if there were not tough competition from abroad to act as a spur. Conversely, unfair competition can have precisely the opposite effect.

A trade environment in which U.S. manufacturers have worldwide marketing opportunities enables a company to sustain production runs, amortize development costs, and fund research and development for products that might not be profitable in a market restricted solely to the United States. Conversely, government policies which restrain the ability of American industry to develop and maintain world markets increase unit costs, thereby adding to inflation, and increase the risks of development sufficiently to preclude some products from being developed at all. The recommendations that follow address both these points.

Recommendation No. 17.—Successfully conclude the current round of international trade negotiations.

Commentary.—It is critical that the current round of trade negotiations end with an agreement that further reduces tariff and nontariff barriers to international trade. Failure to sign a treaty could lead to a disastrous new round of protectionist measures around the world, because of a loss of momentum toward increasing freedom in trade policy that has been importantly responsible for the worldwide prosperity of recent decades. The Subcommittee feels that it is important that it be on record in support of a treaty, because the benefits of world markets as a stimulus to innovation in this country are real and important.

Recommendation No. 18.—Review, on a more timely and aggressive basis, those items which government policy prohibits from being exported.

Commentary.—There are often legitimate reasons of national security which prevent the free export of American-manufactured goods. The likelihood that a high-technology product will not be available for export overseas has an inhibiting effect on its development in some cases. If there were more assurance that a product could be sold on the world market, there would be more products of this kind under development. A continuous review of the list of products embargoed, with a bias in favor of allowing the export of all but the most sensitive of items, would be helpful in this regard. At the present, reviews are often infrequent and unnecessarily strict, resulting in the embargo of products which are available commercially overseas from foreign manufacturers.

Recommendation No. 19.—Minimize the application of U.S. laws to extraterritorial business ventures.

Commentary.—Many important and useful domestic laws become difficult and unnecessary impediments to international commerce when attempts are made to apply them to situations in which jurisdiction is murky. Complications with the U.S. antitrust laws in this regard have been recently recognized by the Administration, which has promised clarification of their applicability to joint ventures with overseas companies. But there are other examples of laws that have been passed in the United States which have resulted in unjustified and useless complications in international business arrangements, particularly when regulations or the language of the statute have tried to affect the behavior of overseas corporations involved in a business venture with an American partner. However meritorious the intent of these laws, attempting to apply them to individuals and corporations outside the jurisdiction of the United States has only resulted in unnecessary loss of business for many American firms.

annual budget, and would thereby provide the largest portion of its benefits to firms engaged in disproportionately large amounts of innovation. A "windfall" tax benefit effect can be avoided by excluding some portion of expenditures on the basis of a base period, thereby providing benefits only for additional innovative activity.

Recommendation No. 5.—A substantial increase in the investment tax credit for those capital expenditures that are research related, making it refundable for this purpose.

Commentary.—This recommendation would channel a large portion of the corporate investment dollar into R. & D. capital equipment by creating a greater incentive in that area. Since many corporations that would react to this incentive are now already getting the maximum tax advantage that can be derived from the investment tax credit, it would be desirable to make the effects of this new incentive refundable, or payable to those corporations. The cost of this program should be relatively modest because of the limited amount of R. & D.-related capital expenditures that would be eligible.

Recommendation No. 6.—Permit income tax credits for individuals and corporations for a substantial proportion of contributions to research oriented, non profit institutions, including universities, for the conduct of basic research, as long as the results of that research are available to the public.

Commentary.—One of the side effects of the pressure on corporate profits during the last decade has been a decline in the amount of basic research conducted by corporations. Increasingly, this kind of research is conducted almost exclusively either through government procurement or at independent research facilities. The latter institutions' largest problem is securing a continuous source of funding to assure scholars that their work can continue without interruption long enough to succeed. Allowing a tax credit, as opposed to the current deductibility, for contributions made to institutions of this nature specifically for basic research, would increase the incentive to support such work and thereby make funding for such activity relatively easier to secure.

Recommendation No. 7.—Permit research and development expenditures incurred in the United States to be allocated solely to the U.S. income of the taxpayer.

Commentary.—Treasury regulations recently issued to implement Sec 1.861–8 of the Internal Revenue Code required that R. & D. expenditures had to be apportioned to both foreign source and domestic income, in an effort to recognize the fact that innovations in the United States often result in licensing and other revenue from foreign sources. However, the effects of the regulations are: To apportion expenses to foreign source income even when that income is incidental to the innovation; to result in double taxation, because foreign governments do not allow this allocation to be taken into account when figuring taxes due them; to encourage the location of R. & D. facilities abroad instead of at home so as to escape the effects of the regulations, thereby diminishing both the amount of R. & D. conducted in the United States and, in the long term, the tax revenue generated from its conduct. The Subcommittee believes these effects are clearly at variance with the desired effect of encouraging U. S. R. & D. activity in order to help improve the competitiveness of the U.S. economy, and strongly urges liberalization of the regulation at issue, or repeal of the law which required it.

Recommendation No. 8.—For small businesses, properly defined, which spend more than a given percentage of revenues on research and development, allow more favorable stock option incentives to founders and key personnel by (a) increasing the qualified options time from the current 5 to 10 years and (b) postponing the tax on income derived from the exercise of nonqualified options until the shares have been sold rather than paying the tax at the time the option is exercised.

Commentary.—For small, technically oriented businesses, the struggle to retain key personnel is often difficult. Other recommendations deal with the difficulties of such businesses in attracting investment capital, but this recommendation addresses what is likely to become an increasing problem as the American economy enters a period of scarcity in trained and competent engineers. The only material incentive that a small business can offer to the would-be inventor or entrepreneur, either to the founder or a key member of the team, is the promise of wealth through a substantial multiplication in value of the stock of the company. This recommendation would enhance the flexibility of that inducement in ways that the Subcommittee, particularly members who have had experiences with such situations, judges to be extremely useful.

Recommendation No. 9.—Allow tax-free rollover of equity investments, or—alternatively—immediate or accelerated deductibility of initial investments, in small businesses, properly defined, which spend more than a given percentage of revenues on research and development.

Commentary.—The provision would free capital from an artificial nonmarket constraint created by government tax policy. The tax consequences of withdrawing capital from a successful small business investment are now so severe that many potential investors stay away from investing in the first place, feeling that the risks of such investment are not justified by the potential aftertax reward. The net effect is, of course, to discourage the number of investors interested in such high risk investments. Allowing a tax free rollover provision would eliminate this difficulty, permitting capital to move from one small business, as it matures, to another without adverse tax consequences. The Subcommittee is confident the net effect would be a substantial increase in the amount of capital available for investment in this sector of the economy.

an important consideration in tax and macroeconomic policy.

But the tax code is the best available means for addressing what has become the central problem in United States economic policy today, the failure of productivity to grow fast enough to offset inflation, and the failure to create sufficient, new self-sustaining jobs, caused by inadequate investment. Restructuring the tax code can correct this fundamental deficiency by eliminating disincentives to savings and investment. The balance of this paper presents the Subcommittee's thoughts on how this can be achieved, with special emphasis on policies to stimulate innovative activity.

What the Subcommittee would like to emphasize is that the specifics are almost less important than the general notion of increasing the profitability and the cash flow of American industry by such measures as reducing the capital recovery period for investment in plant and equipment, eliminating the double taxation of corporate dividends, and broadly speaking, moving toward a tax system that encourages savings instead of consumption. Specific programs that are more narrowly focused on providing incentives for business to direct a greater portion of the current, inadequate supply of investment dollars into innovation are in the end just so much tinkering at the margin.

Only a reversal of the figures cited earlier regarding the decline of aftertax returns on investment at a time of rising capital costs can have the profound impact that is necessary to truly spark a substantial increase in the kind of innovative activity that ultimately pays off in increased productivity growth rates and increased job creation. Accomplishing such a reversal will require acceptance by economic policymakers of a redefinition of the fundamental economic problem that we confront as a nation. If there can be widespread acceptance and understanding of the interrelation of innovation, investment, productivity and job creation, and the primacy of this problem in deciding how to structure the Federal tax system, then it is possible to reasonably anticipate a solution to the difficulties of lagging innovation that spurred the domestic policy review of which this Subcommittee's work is a part.

Particularly with respect to the recommendations that follow regarding tax policy, the Subcommittee recognizes that the appearance of the proposals is that of a list of benefits which it is suggesting the Government confer. Two points need to be made in that regard. First of all, there is a matter of perception involved, in that each of the recommendations should instead be legitimately regarded as the removal of a legislated disincentive, rather than the suggestion of a new incentive, to innovative activity. The effect of our tax system has been to encourage spending at the expense of savings—it is now necessary to tilt the balance, and remove some of the disincentives to saving that have been established, if innovative activity and productivity are to grow.

The second point is that the Subcommittee has adopted a "cafeteria-style" approach to these recommendations, suggesting those that it thinks would be effective in achieving the desired goals. But the Subcommittee has not tried to do the work of the Congress for it, and devise a complete and internally consistent set of recommendations on a single menu. Instead, it has arrayed the options that it believes merit serious consideration by the policymakers.

The Subcommittee has rejected the idea of recommending a program of government-directed innovation altogether. The Subcommittee strongly believes that the market is the best allocator of resources among various innovative ideas. The experience with solar energy research, the Subcommittee suspects, may prove to be an important demonstration that it is quite possible to devote more resources to a particular field of research than the sensible possibilities can absorb. The Subcommittee's recommendations are therefore an effort to correct insufficient investment brought on by environmental and historical developments, rather than a means to involve the Government in allocating or priority setting among various innovative ideas. While there are areas, such as national defense, where government procurement of R. & D. and related activities has a natural and important place, the Subcommittee is convinced that the marketplace will do the best job of allocating the increased investment dollars that would result from implementation of the recommendations that follow.

Principles Guiding Tax Policy Recommendations

While the Subcommittee is convinced of the need to fundamentally refocus the emphasis of economic policymakers in evaluating the Federal tax system, it also recognizes that the tax system has another basic duty to perform, raising the revenue necessary for public purposes. In light of that other imperative, the Subcommittee has tried to follow several guidelines in recommending which changes in tax policy should be given priority as specific measures to stimulate innovative activity. These guidelines are as follows:

1. Recommendations should not result in so drastic a reduction in revenue as to be infeasible; at the same time, any loss of revenue that is involved should be cost effective. In short, proposed changes in the tax laws should result in relatively high benefits in the form of increased R. & D. and other innovative and investment activity in relation to their tax cost.

2. Recommendations should not include totally novel theories of taxation that raise substantial new difficulties in understanding, interpretation, or compliance. Some tax policy changes that logically belong in any list of tax policies designed to induce additional investment and savings would raise so many questions with regard to their fairness that they would lead to substantial increases in tax avoidance by taxpayers convinced that the resulting system was unfair. To some extent, any system that rewards savings is inevitably going to have some disproportionate benefits for the relatively wealthier; but the Subcommittee has avoided recommending any scheme which would be an extreme example of this problem.

3. The recommendations should not introduce additional, unnecessary complication into the tax code or

EXECUTIVE SUMMARY

The Subcommittee on Economic and Trade Policy has concluded that the primary issues with regard to the impact on innovation of policies under its purview are as follows:

- For established corporations, tax disincentives to overall investment and to R. & D. need substantial revision, in recognition of changed economic circumstances.

- Venture capital is in short supply for new, innovative businesses trying to establish themselves, and legislated disincentives to savings should be lessened, while certain regulatory policies are also changed, in order to alleviate this shortage.

- Foreign competition, conducted legally within the United States, is a spur to innovation that must continue to be allowed, while certain government policies that restrict U.S. businesses' ability to compete abroad should be changed.

- The drag on the economy created by regulatory activity must be recognized for what it is, and consciously reviewed and budgeted for by the Federal Government.

- While a new, large scale program of basic research directly funded by the Government is not desirable, the Government should encourage the conduct of basic research at universities and should also simplify its procurement policies to make it more feasible for small businesses to compete successfully for government contracts.

ECONOMIC POLICY AND INNOVATION

Public opinion in the United States now generally accepts the proposition that inflation fighting should be the top priority of government economic policy, a view which the Subcommittee shares. A reversal of the decline in the rate of productivity is an important part of the solution, along with monetary and fiscal policy. And, in the terms of the economics profession, the importance of innovation is its role in increasing productivity and rates of economic growth. Economic literature pinpoints capital formation as an important mechanism by which this interconnection operates. These same studies have unanimously concluded that all available evidence points to a significant, positive relationship between the amount of innovative activity in an economy (such as company sponsored R. & D.) and economic growth and productivity. Some of the research has indicated that the magnitude of the impact of this kind of innovative activity can be enormous.

The inflation-fighting benefits aside, it does not take an expert in economics to recognize the more difficult to measure differences in the quality of life that result from significant innovations. Among other problems, there is no real agreement as to the significance of the differences in life that result from new products. But it goes uncontested even by the most determined of Luddites that the innovation that has characterized Western society for the past century has profoundly transformed the nature of the life led by its citizens. The argument is only over whether that transformation has been for the better.

In today's society, innovation's impact is in the economic marketplace. It is not enough for the inventor to invent; he must also bring his idea for a new product or process to market. Therefore, the study of ways to stimulate innovation inevitably becomes a study of how the environment for businesses, large and small, influences the probability of an invention or innovation successfully going from idea to marketplace.

The concern of this particular Subcommittee is the effect of economic and trade policy upon this critical probability. The recommendations that follow are the Subcommittee's best judgment as to how the environment can be favorably altered in such a way as to result in more innovation. A brief review of the main features of the current economic environment for business must be the starting place.

For established corporations, the past years have seen a decline in profitability and a decline in overall cash flow relative to reinvestment. According to W. Michael Blumenthal, Secretary of the Treasury, aftertax rates of return on investment have declined from around 8 percent during the mid-1960's to around 4 percent during recent years. While it is by no means the only cause, in some industries the cost of government regulations designed to incorporate what has previously been externalities—the cost of pollution, for example—has resulted in greatly restricted profitability, as profits have been squeezed by an inability to completely recover the costs associated with these new requirements.

And no study of innovation can be complete without a discussion of the special needs of small and venture capital enterprises, which historically have played such a key role in the process of innovation in the United States. Almost of necessity, the basic strategy of a small company requires innovation; i.e., the avoidance of direct competition with large established firms with high capitalization. As a result, small companies have contributed importantly to the emergence of new technologies in America and have pioneered new and more efficient methods of distribution and merchandising products and services. Not the least of the contributions of small companies to the American business environment is their function in prodding older, established companies to develop new technologies, products and services.

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FOREWORD

A domestic policy review of industrial innovation is being conducted as a result of President Carter's concern for the status of industrial innovation in the United States. This review is being directed by the Industrial Innovation Coordinating Committee, chaired by Secretary of Commerce Juanita M. Kreps.

An Advisory Committee on Industrial Innovation has been established that will bring to bear the views of business and industry, organized labor, the public interest, and the academic community expert on the subject. The subcomittees created under this Advisory Committee are examining a wide array of Federal programs and policies that impact upon industrial innovation.

This Report on Economic and Trade Policy was prepared by the Advisory Subcommittee on Economic and Trade Policy under the chairmanship of William M. Agee, Chairman, President, and Chief Executive Officer of the Bendix Corporation. This Subcommittee, composed of representatives of the business and industrial community, has focused on economic and trade issues and their impact on industrial innovation.

Following is the membership of the Subcomittee on Economic and Trade Policy.

safety of the country's workers, and the health of its population. In addition, the Committee was asked to provide full documentation for its positions and recommendations.

The public portion of the domestic policy review culminated in a series of seven public symposia held in January 1979. Representatives of the industrial, labor, public interest, and academic subcomittees participated in these symposia, along with senior policy representatives from concerned government agencies.

The final reports of the Advisory Committee on Industrial Innovation contained in this volume were made part of the body of material under consideration by the Cabinet-level Coordinating Committee. The involvement of the members of the Advisory Committee and the recommendations contained in their reports have been a vital part of the Administration's domestic policy review.

Acknowledgement

The names of the members of the various subcommittees of the Advisory Committee on Industrial Innovation appear at the beginning of each report. Staff liaison to the Advisory Committee was provided by the following members of the Department of Commerce.

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Notice: This series of reports represent the views of the Advisory Committee on Industrial Innovation, an advisory committee convened by and reporting to the Secretary of Commerce. The views of the Committee do not necessarily represent those of the Department of Commerce or any other agency of the Federal Government.

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UNITED STATES DEPARTMENT OF COMMERCE

Juanita M. Kreps, Secretary
Chairperson, Coordinating Committee
Domestic Policy Review of Industrial Innovation

Jordan J. Baruch, Assistant Secretary for Science and Technology

September 1979

ADVISORY COMMITTEE ON industrial innovation

FINAL REPORT

ADVISORY COMMITTEE ON INDUSTRIAL INNOVATION

FINAL REPORTS

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PREFACE

DOMESTIC POLICY REVIEW OF INDUSTRIAL INNOVATION

An increase in industrial innovation will contribute significantly to the reduction of inflation, the creation of jobs, the improvement of the country's balance of trade position, and the ability of the nation to conserve natural resources and reduce reliance on non-renewable energy resources.

In recognition of these facts, in May of 1978 President Carter called for a domestic policy review of industrial innovation. This effort, designed to afford the issue of industrial innovation the highest level of policy attention by the executive branch, was conducted by a Cabinet-level Coordinating Committee chaired by Secretary of Commerce Juanita M. Kreps. Functional management of the policy review was directed by Jordan J. Baruch, Assistant Secretary of Commerce for Science and Technology.

Advisory Committee on Industrial Innovation

More than 150 senior representatives from the industrial, public interest, labor, scientific, and academic communities participated in the policy review through membership on the Advisory Committee on Industrial Innovation. Subcommittees of this Advisory Committee met during the fall and winter of 1978 to deliberate the effect of the Federal Government on industrial innovation. These deliberations encompassed the following areas:

- Economic and trade policy
- Environmental, health, and safety regulations
- Regulation of industry structure and competition
- Federal patent and information policy
- Federal procurement policy and direct Federal support of research and development.

The industrial members of the Advisory Committee produced 10 reports, one addressing each of the substantive areas, and one integrating across the areas from the point of view of small business. The Labor Subcommittee and the Public Interest Subcommittee each produced an independent report which also cut across all of the issues.

The members of the Advisory Committee were asked to consider, in preparation of the reports:

- The effect of Federal policies and programs upon industrial innovation, and,
- Specific recommendations for changing existing policies and programs or initiating new ones in order to enhance the state of industrial innovation in the United States.

In addressing these issues, the Committee was cautioned to be cognizant of the deep commitment of the Administration to other social goals such as a clean environment, the

INDUSTRIAL ADVISORY SUBCOMMITTEE REPORT ON ECONOMIC AND TRADE POLICY

industrial innovation

Advisory Committee on Industrial Innovation

Report of the Industrial Advisory Subcommittee on Economic and Trade Policy

A Report of the Industrial Advisory Subcommittee on Economic and Trade Policy of the Advisory Committee on Industrial Innovation established as part of the Domestic Policy Review

February 15, 1979

ADVISORY COMMITTEE ON INDUSTRIAL INNOVATION

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Yet, capital has become significantly less readily available for new businesses. A recent survey by the American Electronics Association (AEA) documents the increasing difficulty that new, small companies are having in gaining access to capital markets. Of the firms they studied:

- Companies founded between 1971 and 1975 were able to raise only half as much equity capital, on the average, as firms founded between 1966 and 1970; and
- Firms founded in the more recent period had an average debt to equity ratio of more than 2:1, compared to the more secure 1:1 ratio that had prevailed for the previous 15 years.

There has been a long decline in new public equity offerings by small companies in the U.S. from the levels prevailing through the 1960's. The figures cited by the AEA study are symptomatic of this problem.

For these businesses, the kind of tax incentives that can improve the rate of innovation in a large or medium-sized corporation are often irrelevant. The small businessman is less likely to be sophisticated enough to take full advantage of the incentives offered, and he is often not in a position to do so. For example, one must first be making a profit before a lowering of Federal corporate income tax rates benefits cash flow, and many small businesses are unprofitable for long periods of time before achieving success. For the small businessman, the availability of capital has become the greatest unaddressed problem.

At the same time, U.S. companies have become subject to increasingly sharp competition from abroad, even in the arena of technologically sophisticated products such as automobiles and electronics. Among the reactions to this development has been a revival of public pressures for increased protectionism that would have been unthinkable a decade ago.

Again, for the small company the problem of increased competition from abroad also wears another face, the difficulty of successfully entering new markets abroad. As business becomes increasingly international in scope, the importance of the opportunity for increased export potential offered by small business increases. While the Subcommittee has no specific recommendations to offer on this point, short of increased or more effective programs of the kind the U. S. Department of Commerce has run for many years, the opportunity to help alleviate America's trade imbalance that is offered by this kind of entrepreneurial activity abroad is important and cannot be overlooked.

Small and large businesses alike have felt the impact of a recent spurt of regulatory activity by the Federal Government. The rapid falloff in productivity growth since 1967 roughly corresponds with a rapid increase in environmental and safety regulations. Though the Subcommittee does not believe that all these regulations are necessarily unjustified, there is no doubt that their impact constitutes a new drag on the U. S. economy that was not previously present, one which decreases the relative competitiveness of U. S. products abroad while requiring large amounts of corporate financial and other resources at home.

And importantly, an inflationary environment has drastically altered the rates of return for new investments that businesses can accept. Faster recovery of capital costs has become a watchword in investment decisions by business, with an eye on the importance of profitability over the short term as a means of continuing to be an attractive investment for anyone whose alternative is an instrument with a fixed rate of return enhanced by inflation. Inflation has also meant that the cost of capital has reached all time highs, acting as a deterrent to capital spending by all corporations, large and small. This condition contrasts with the lower costs of capital available in both Japan and Germany.

All of these environmental considerations can be thought of as alterations in the risk-reward ratio for business investment. In essence, risks have gone up and rewards have come down at a time when the cost of capital for American business is at an all time high. In such a situation, what one would expect would be absolute declines in the rates of investment by industry for capital expenditures. And in fact, that is exactly what has been the case. Capital expenditures by American businesses expanded by an average of 3.8 percent per year in real terms during the first quarter century following World War II, but by only 0.9 percent per year since then.

The Subcommittee believes that the relationship between innovation and productivity and growth is an interdependent one. Ninety percent of the investment necessary to bring an innovation successfully to market comes after the invention process is complete; and innovation without success in the marketplace is devoid of the economic benefits that make it worthy of attention from government policymakers. Changes in policy designed to encourage innovation therefore have to do more than just encourage brilliant thinking, so to speak. They must also work to alter the environment in which new ideas are considered, so as to increase the chances that the full potential of the idea will be realized. Doing so requires increasing the cash flow of established businesses, creating incentives or removing barriers to business investment in productivity, and increasing the availability and lowering the cost of capital for those with a useful innovation who wish to develop it by creation of a new business.

Inevitably, tax policy is the best single tool available to economic policymakers in addressing such a structural economic problem. The Subcommittee believes that it is time to change the major economic purpose served by the U. S. tax system. It is necessary to recognize that the problems that confront today's economy are primarily problems of an inadequate or structurally constrained supply of investment or savings. This situation is different from the economic environment that has been the setting for most economic policy making since the 1930's depression, during which the primary concern has been a macroeconomic use of tax policy to increase consumption and limit savings in the economy. That situation is no longer the central difficulty for economic policy in the United States, though the overall level of demand of course must also remain

its administration. The Subcommittee recognizes that, to some extent, a complex tax code is nothing more than a reflection of the complexity of the economy that is being taxed. But it has tried to avoid recommendations whose implementation would require the introduction of new accounting concepts or novel tax treatments that would be significantly different than parallel treatments already in use in the tax code. The Subcommittee has thus acted on the premise that existing complexities are inherently superior to new complexities unless a convincing case can be made to the contrary, at least in part, because a common understanding of the existing complexities has already evolved under the pressures of day-to-day administration. Hopefully, the result of this conservative attitude is that the Subcommittee's recommendations would not involve substantial additional complexities if adopted, either for taxpayers or the Internal Revenue Service.

Tax Policy Recommendations

The Subcommittee recognizes that its charter is to recommend measures to encourage innovative activity *per se,* and that there is no shortage of specific measures, including specific tax policy options, that will accomplish that goal. Most of this section is devoted to a description of the specific tax policy ideas that appeal to the Subcommittee within the parameters of the guidelines just enumerated.

But the Subcommittee feels that it would be remiss if its first and primary tax policy recommendation were not of a more general and sweeping nature, because the Subcommittee believes that only a significant overall change in the thinking of the shapers of tax policy in this country can ultimately have the effect that is desired. The Subcommittee believes that the removal of disincentives to savings and investment should be the primary purpose of tax policy designed to encourage innovation. Tax policy is the only tool at the disposal of the Government that can have anywhere near the required impact. It should be emphasized that the Subcommittee believes this first recommendation to be of more potential significance than all of the other, more specific measures which follow it.

Recommendation No. 1.—Move to increase overall incentives for savings by individuals and investment by established corporations through use of the tax code.

Commentary.—In the process of debating the last Federal tax reform bill, the Congress and the Executive Branch considered several different policies, each of which would have this effect. Among them were allowing for more rapid recovery of capital through depreciation, eliminating the double taxation of corporate dividends, lowering corporate income tax rates, enhancing the investment tax credit in numerous ways, and lowering rates of taxation on capital gains. The Subcommittee believes that measures like these should be at the top of the priority list when evaluating tax policies that will ameliorate the lag in U.S. innovation. It is the general belief of the Subcommittee that more rapid recovery of capital through depreciation would be the most cost-effective way of encouraging innovation and its application by established industries. Such measures as elimination of the double taxation of corporate dividends and lower taxes on capital gains would provide more incentive to savings by individuals.

Recommendation No. 2.—Review the economic assumptions used by the Government in evaluating the revenue impact of tax proposals.

Commentary.—Clearly implicit in the Subcommittee's first recommendation is a belief that economic circumstances have changed, and that removal of disincentives to savings and investment will result in increased economic activity over time. If the premise is correct, then the Federal Government can certainly expect that adoption of the Subcommittee's first recommendation will result in increased, rather than lost, government revenues over time. In evaluating the various alternatives encompassed in these tax recommendations and others, the Subcommittee strongly urges the Executive Branch and the Congress to review the economic assumptions now used in the models that calculate the revenue impact of changes in tax policy, in order to eliminate those assumptions which unrealistically minimize the likely impact on economic activity of policies designed to spur savings and investment.

Recommendation No. 3.—Allow the immediate writeoff of all R. & D. expenditures, properly defined, including those for facilities and equipment. Failing that, allow a 3- or a 5-year writeoff for facilities and equipment, comparable to the special depreciation rules now being applied to capital expenditures for pollution control facilities.

Commentary.—Present law permits salaries, wages, materials supplies and other expenditures in R. & D. to be deducted as incurred, even though the benefit of such expenditures may only be realized at some time in the future. Other Western countries, including Canada and West Germany, currently allow expenditures for the equipment and facilities used by these workers to be immediately written off as well. Allowing this practice in the United States would not only increase corporate cash flow and improve the incentive to make such expenditures, but it would also make R. & D. capital expenditures relatively more attractive than other capital expenditures, thereby providing an incentive for corporations to channel a larger proportion of their investment dollar into R. & D. activities.

Recommendation No. 4—Allow a research tax credit for those research-related expenditures not now eligible for the investment tax credit, allowing for appropriate carryback and carryforward provisions. This might be limited to those expeditures in excess of those made in some previous period.

Commentary.—A "research tax credit" has a clear precedent in the existing investment tax credit, which was enacted in an effort to encourage one particular kind of corporate activity. It would be particularly helpful to small or growing businesses for which research expenditures form a substantial portion of the

Another high-powered method of attracting new capital to investments in small or new venture companies would be to allow immediate writeoffs of initial capital investments in such small businesses—or alternatively, accelerated writeoffs over a short period of years. Such writeoffs, of course, would reduce the cost basis of the investments to zero and would result in a large capital gains tax eventually. The appeal of such immediate "tax shelter" to individual investors has been well demonstrated in the marketplace—in real estate, oil, etc.

As between the alternatives of tax-free rollovers versus immediate deductibility of investments in new ventures, the Subcommittee prefers the former. On a very short-term basis immediate writeoffs would probably attract the most capital to this area—so much that we are concerned that there might be excess capital generated in ill-conceived ventures, resulting in greater "waste" than would the tax-free rollover proposal which has a long term reward. In venture capital, time horizons should be long term.

Recommendation No. 10.—Allow startup operating losses to flow through to founding investors in small businesses, properly defined, which spend more than a certain percentage of revenues on research and development.

Commentary.—New small businesses typically are characterized by substantial losses in their early years of operation, followed only then—if ever—by profitable operations. Sec. 1244 of the Internal Revenue Code and subchapter S laws allow losses in businesses covered by these laws to be passed through to investors, thereby making these businesses more attractive to those investors who are in a position to sustain losses on their investments as an offset to other income. The qualifications for subchapter S treatment, however, are such that few new ventures qualify. We believe the treatment afforded under these provisions of the tax law should be more generally available.

In the same context, the Subcommittee wishes to note that any measures that would make it easier to buy and sell corporate tax losses would achieve much the same effect. In recent years, IRS rulings have made it increasingly difficult for tax losses resulting from an unsuccessful venture to be used by a more profitable acquiring company. The effect is to deprive the investors in the unsuccessful venture of their right to recoup some of their losses through sale to a more profitable company. The IRS "hard line" on transferring tax losses is simply one more deterrent to investment in high risk new ventures.

Recommendation No. 11.—Create a sliding scale tax rate for longer term investments in small businesses, properly defined, which spend more than a given percentage of revenues on research and development.

Commentary.—If the tax-free rollover provisions or the exemption of small business investments from capital gains taxes cannot be achieved, the Subcommittee believes considerations should be given to reduced or zero tax rates for investors who invest in small or venture capital businesses over long periods of time. Under such a plan capital gains taxes on sales of small business investments would gradually decrease to zero over a period of time, perhaps 5 years.

While the effect would be somewhat diminished by the disincentive of requiring the capital to be invested over an extended period of time, the Subcommittee still believes that the advantage that would be created for investors would add significantly to the general availability of capital for such businesses. Such an incentive to long-term investing is especially desirable in financing new ventures which require long time horizons to reach fruition.

Recommendation No. 12.—Permit patents to be written off over a period somewhat shorter than their legal life.

Commentary.—At present, patents have a legal life of 17 years and must be written off over that period even if their economic life is shorter than this because of rapid technological evolution in the field. Permitting a shorter period in which to recover patent costs would minimize the resultant disincentive to obtaining a patent that now exists because of the effects of inflation—at present, taxpayers are required to expend current dollars, getting them back only in later years when they are worth a fraction of their original value.

Regulatory Policies Affecting the Availability of Capital for New Business

Recommendation No. 13.—Modify the concept of the "prudent man" that has been embodied in government regulations so as to allow institutions to hold a certain percentage of their investment portfolios in venture capital.

Commentary.—ERISA and other legislation have had the broad effect of making institutional managers of fiduciary capital even more conservative—by requiring that prudent man concepts guide each individual investment decision. The Subcommittee believes that it is well within reason for a "prudent man" to invest a small but meaningful portion of his investment portfolio in venture capital enterprises. Amending the definitions of "prudent man" embodied in various regulations in such a way as to allow institutions to apply it to their *overall* portfolio, instead of to each investment, would encourage investment in small growth companies and venture capital. Alternatively, exempting a certain percentage of assets—up to 5 percent of total portfolio values—from the "prudent man" rule would yield similar results.

Recommendation No. 14.—Encourage States to liberalize the investment restrictions on State regulated pools of capital so as to allow investment of some portion of these funds in equity positions in small businesses or venture capital firms.

Commentary.—States as well as the Federal Government restrict the availability of various pools of capital for venture and small business purposes. Regulations and legislation affecting banks, insurance companies,

Overall Regulatory Policy

While the Subcommittee recognizes that other Subcommittees are at work on the overall question of government regulation, the regulatory activities of Washington have become an issue in economic policy. The burden of regulation upon the U.S. economy is the subject of intense debate. The Subcommittee did not try to quantify the economic consequences of regulation, nor to resolve the debate among those who have tried. But the Subcommittee did want to take note of the Administration's expressed intent to create a coordinating committee in an effort to establish a regulatory agenda for the country and to prevent contradictory or unforeseen problems caused by multiple regulations, each affecting a single sector of the economy. The Subcommittee wishes to suggest one further step along the same line, while expressing its sincere enthusiasm for what has been done so far.

Recommendation No. 20.—Establish a Federal Governmentwide regulatory budget, subject to review by the Executive Branch and by Congress, that would set overall limits to the economic effect to be allowed to result from government regulation.

Commentary.—In recent years, the new Congressional Budget Committees, and the procedure for setting budgetary ceilings by Congress, have had the beneficial effect of establishing a relationship between individual bills considered by Congress and the overall resources of the Federal Government, as well as considering the fiscal policy effects of various overall levels of government activity. An analogous need exists in the arena of government regulation, in which government action can often have an impact as great as the Federal budget. Some recognition of the economic costs—and benefits—that will result from regulatory action has begun to be recognized as important. But it is necessary to move beyond the mere recognition of the importance of these factors, gratifying though that recognition may be. It is necessary to budget for their effect on the economy, so that the lack of an overall perspective, akin to the myopia of the old Congressional budget process, does not produce unexpected or unintended economic consequences. While there are numerous difficulties involved in such a proposal, including the evaluation of the economic consequences of regulatory actions, the existence of laws that currently leave regulators with inadequate flexibility to recognize cost-effectiveness arguments in considering their actions, and the absence of a preexisting organizational structure for implementation, the Subcommittee believes the importance of this recommendation is great enough so that these obstacles should not prevent its being pursued.

Research and Development Policies

The Subcommittee recognizes that the government policies regarding the subsidy and encouragement of research and development of direct interest to the Government are of greater concern to large than to small businesses. The Subcommittee also believes that the role played by large businesses in innovation is significant. Indeed, many small companies have been founded by entrepreneurs who gained their experience and training in larger companies. However, certain changes in government policies in this area could have a beneficial impact on innovation, in both the large and small company environments.

Recommendation No. 21.—Increase the support of basic research conducted at universities and other educational institutions.

Commentary.—Universities are one of the best institutions for the conduct of basic research. The increasing pressures on the profitability of American business have reduced their effort in the area of basic research, which is characterized by long lead times and problematic payoffs. Nevertheless, the importance of basic research to the quality of innovation is extremely important. Without a flow of new basic research, ideas are not present to be explored for commercial application. Therefore, the Subcommittee strongly recommends Federal Government support to universities and other educational institutions for basic research as a high priority item in evaluation of the Federal budget.

Recommendation No. 22.—Review government procurement policies in order to make it less difficult for small and venture companies to successfully compete for projects and contracts.

Commentary.—The burden of current government procurement policies, particularly at large contracting agencies like the Department of Defense, makes it virtually impossible for any organization not already of considerable size to handle the administrative and reporting requirements associated with execution of contracts. While the Subcommittee does not feel that it can identify in detail how these policies should be amended so as to minimize these difficulties, it urges a review of both existing legislation and regulation in an effort to do so.

A PROGRAM FOR INCREASING THE NATIONAL INNOVATION DIVIDEND*

A program for enlarging the national innovation dividend through promoting research and development and improving the climate for innovation should:

- Redefine the role and responsibilities of Government and business in relating and using their research and development capacities more effectively toward economic and social objectives;
- recognize that there are no issues of innovation that are absolute and that uniformly affect all segments of our economy—so that, in judging problems and solutions, we must guard against allowing statistics to dominate philosophic values;
- have a strong bias toward developing the role of creative individuals, entrepreneurs and small business—in net effect and not merely expressed intent;
- dare to introduce new policies and concepts, and to modify or replace institutions and mechanisms that

* Eugene M. Lang

in 1977. Many huge firms pay less. For example, Allied Chemical, with pretax earnings of over $240 million, and a statutory tax rate of 48 percent, paid a worldwide rate of −2.3 percent on worldwide income, a U.S. rate of −21.2 percent on worldwide income and a U.S. rate of −24.4 percent on U.S. income

As Donald Lubick, acting Assistant Secretary for Tax Policy at the Department of Treasury, pointed out at the Commerce Department symposium on this subject, one-half of U.S. corporations paid no Federal income tax last year. A more then generous tax structure for business and recent tax reductions have presumably increased cash flow, but we certainly don't see greater innovation as a result.

One wonders about the urgency of the alleged need for better profits or cash flow when the *Wall Street Journal* quotes an executive of a cosmetic firm that is planning to spend $18 million in one year to sell a deodorant: "The wetness-stopping properties in Dry Idea aren't any better than competing products," the executive is quoted as saying, "But the consumer thinks it is. It seems to the consumer that it goes on drier. So she thinks it keeps her drier." An innovation such as this indicated no lack of cash flow and could be said to contribute to a diversion of scarce resources from far more critical and productive ends.

If, in looking at what our foregone tax dollars might buy, we ask "innovation to what end?" and "how well?" and "for whom?" we can easily see that subsidizing the case cited above would be a highly questionable investment of public money.

THE RECOMMENDATIONS

We find that roughly half the Industry Subcommittee's recommendations—Numbers 6, 8, 10, 11, 13, 14, 17, 18, 21 and 22—have some merit when evaluated according to the Public Interest Subcommittee's objectives. For most of these, however, we recommend significant modifications.

The other recommendations are remarkably self-serving for a group of people working under the auspices of the U.S. Department of Commerce. Many of the recommendations constitute a thinly veiled appeal for a wide variety of subsides without a shred of assurance that the dollar benefits would be directed to innovation. Far less do they address the basic question of innovation for what? Furthermore, despite the rallying call for venture capital and small businesses, we are convinced that most of the dollar benefits would accrue to very large well-established firms—by no means in the market for venture capital.

The following are the Public Interest Subcommittee's comments regarding the specific recommendations of the Industry Subcommittee. (The Industry recommendations appear in quotes.)

Recommendation No. 1.—"Move to increase overall incentives for savings by individuals and investment by established corporations through the use of the tax code." The Industry Subcommittee cites the following as examples of how to achieve this end: Allowing more rapid recovery of capital through depreciation, eliminating the double taxation of corporation dividends, enhancing the investment tax credit, lowering the rate of taxation on capital gains.

No hard evidence is presented to demonstrate the unfounded assertion that such policies would ameliorate the alleged lag in either investment or innovation. There is no assurance that the funds gained from such policies would be directed to research and development, just as there was no assurance that funds Mobil pled for, on the basis of the urgency of exploring new energy sources, would be used for that, rather than to purchase Montgomery Ward. More important still, especially in the light of the Industry Subcommittee's own introductory assertion underlining the importance of reducing inflation, there is not a shred of evidence that such an approach would be cost effective. Rather, the suspicion is that it would be very expensive indeed.

The Public Interest Subcommittee has suggested an alternative. We propose the establishment of an Investment Development Bank, at both the national and State levels to promote and support research and development. Such a bank could be modeled on the Connecticut Product Development Bank, which specifically addresses and is targeted to the needs of venture capital. The development bank would also fund nonprofit research and development centers.

Recommendation No. 2.—"Review the economic assumptions used by the Government in evaluating the revenue impact of tax proposals."

The recommendation to review economic assumptions used in evaluating the revenue impact of tax proposals is perfectly reasonable, at face value. The associated commentary presented by the Industry Subcommittee, however, is not reasonable. The Subcommittee asserts that the "Federal Government can certainly expect that adoption of the Subcommittee's first recommendation will result in increased, rather than lost, government revenues over time." This is utter nonsense. Whether or not it would result in a loss or a gain in revenues depends on the cost of the tax changes on the amount of resulting economic growth, the distribution of the income generated by that growth, and the tax structure that will prevail in the future—to suggest a few of the relevant variables. It should be noted that the Subcommittee has not attempted to project in its report the cost of such tax changes.

Recommendation No. 3.—"Allow the immediate writeoff of all R. & D. expenditures, properly defined, including those for facilities and equipment, comparable to the special depreciation rules now being applied to capital expenditures for pollution control facilities."

This plea for immediate writeoffs of all R. & D. expenditures, including facilities and equipment, offers no guarantee that the equipment and facilities, once written off, would not be merely resold or converted to other uses. After immediate writeoff, how would we be asked to respond to the cry for cash flow the next year? There are numerous good reasons for depreciation to coincide with the real economic life of plant and equipment. This recommendation ignores them. It is a sort-sighted proposal indeed.

commentary presented by the Industry Subcommittee

would insist that in evaluating the effectiveness of government efforts to enhance innovation, the purpose is equally, if not more, important than the quantity.

PUBLIC SOCIAL ACCOUNTING

How should progress toward these ethical/legal goals be measured? Admittedly, measuring progress toward the achievement of stated social goals is more difficult than defining the goals in the first place. But it is also true that a lot less effort has gone into trying to measure such progress than should be the case. The Public Interest Subcommittee is fully aware of the reality of decisionmaking today. If you cannot count it, as the saying goes, it does not count. While this may be the reality, it is not the necessity. We who would promote innovation should ourselves be willing to innovate in developing new and useful measures.

We therefore call for the development and use of "public social accounting" measures. Public policy initiatives to promote innovation should be subject to such a "public accounting" particularly when those policies involve subsidy or aid of any kind.

It is often also necessary to account for that which cannot be counted. It would be premature and irresponsible to put dollar figures on all important factors. So, qualitative and descriptive information can play an equal role in pubic decisionmaking, just as a securities analyst's or portfolio manager's qualitative assessment of management plays a key role in investment decisionmaking.

The following is an example of how such a public social accounting might be used, and how it differs from a more traditional approach. The public commitment expressed by the Occupational Safety and Health Act, to a workplace in which a worker need not fear disability or death as a result of his or her occupation, typically receives only one kind of measurement—the cost of implementing conditions that might provide such a safe workplace.

A full public accounting would measure these costs, but it would also measure the costs of not providing a healthy workplace. It would assess the costs of increases in worker's compensation and unemployment insurance, disability and survivors payments, labor turnover, absenteeism, and reduced morale and labor productivity.

The public accounting would also consider the cost of disease and health problems whose causes can be linked to the workplace. For example, the Government Accounting Office has estimated that cancer alone costs 15 billion annually—($3 to $5 billion for direct care and $10 to $12 billion due to lost earning power and productivity)—and 40 percent of cancer cases can be traced back to causal factors in the workplace. Public accounting would also try to consider the often ignored costs of not providing a healthy workplace which are imposed on future generations.

HOW EFFECTIVE?

The second line of questioning, after that of goals, is whether or not a proposed public policy is targeted to offer any assurance that each dollar of the subsidy or tax break advocated would flow into additional research and development or innovation. Disappointingly few of the Industry Subcommittee's recommendations offer any such assurance.

On page 8 of the Industry Draft Report on Economic and Trade Policy, the Industry Subcommittee asserts that solar energy may demonstrate "that it is quite possible to devote more resources to a particular field of research than the sensible possibilities can aborb." We are convinced that it is not solar research and development but the heavy, long-term subsidy for the development of nuclear power that is the prime example of devoting "more resources to a particular field of research than the sensible possibilities can absorb." According to Battelle Laboratories, since 1950, $12.4 to $14.2 billion has been spent on research and development for nuclear power. Despite the size of this investment, and in the face of fearsome and still unresolved potential short- and long-term health and safety threats of the technology, nuclear power can compete in the marketplace only with further expensive direct subsidies, heavy lobbying for its support, and substantial public relations expenditures. Even with that type of support, the industry magazine *Electrical World* reports that the market for new nuclear power plants has dried up in the United States. Yet the proposed Energy Research and Development Administration budget for 1978 included $1.75 billion for nuclear fission, nearly $400 million for fusion, and only $250 million for solar. Nuclear fission absorbed an estimated 40 percent of the ERDA's budget increase.

Besides, it is still early to tell what will come of substantial research and development expenditures for solar energy since the Federal Government did not even begin to put research and development dollars into solar until 1970.

AT WHAT COST? WHO PAYS?

Despite the report's introductory comments that inflation fighting should be the top priority of government economic policy, the report makes not the slightest attempt to put cost figures on the broad benefits which Government is expected to confer. Cost is a third criterion which must be considered—how much and who pays? Furthermore, the argument that the benefits would accrue primarily to small businesses appears frequently to be a sop. Many of the benefits would flow to big business. The report itself states, on page 7, "For (small new) businesses, the kind of tax incentives that can improve the rate of innovation in a large or medium-sized corporation are often irrelevant."

The Industry Draft Report contains a key statement with which the Public Interest Subcommittee is in full accord. The report states: "The Subcommittee recognizes that the appearance of the proposals is that of a list of benefits which it is suggesting the Government confer." These proposals bear more than the appearance of a list of benefits to industry. They are transparently self-serving. One would have hoped

(b) Bulk export shipments with overseas repackaging.

(c) Overseas product assembly using U.S.-made components, wholly or in part.

(d) Technology transfer relationships; overseas manufacturing licenses and joint ventures.

(e) Development of technological exchange and acquisition opportunities specifically oriented to client interests and objectives.

(f) Consulting services or execution of specific technology and export development assignments.

2. **SBETC Organizational Requirements.—**

(a) Must have minimum paid-in capital of $100,000.

(b) Must initially represent not less than three qualified U.S. manufacturers (see below) for noncompeting product lines for specified export territories.

(c) Must establish a bona fide business operating unit with essential facilities and staff.

(d) One or more U.S. resident persons or corporations can own an SBETC but no SBETC client can own more than 20 percent of the SBETC.

3. **SBETC Clients.**—There would be two categories of SBETC client: qualified and unqualified. Income from services to qualified clients (QC) would be covered by tax incentives. Income from unqualified clients (UNC) would not.

(a) A qualified client (QC) would be any of the following:

(i) Any small U.S. manufacturer whose exports during the three years before becoming an SBETC client shall not have exceeded 2 percent of gross revenues. A small manufacturer which operates under its own identity would be deemed a qualified client even if it were a subsidiary of a larger company.

(ii) Any U.S. party with an undeveloped product or invention that is not in production and which is to be offered for overseas development and licensed production.

(iii) Any U.S. manufacturer, regardless of size or general export sales, whose products are not being made or sold in any LDC markets and which are offered to an SBETC for promotion specifically with respect to such markets.

(iv) A party can have QC status with respect to only one SBETC relationship.

(b) An unqualified client (UNC) would be any client who does not fall within a QC definition.

(c) An SBETC client shall be deemed to retain its QC status, regardless of its growth, so long as it shall remain a client and the substance of its SBETC relationship shall not be diminished.

4. **SBETC-Client Relationship.**—Each SBETC would contractually establish the conditions of its client relationships. The contract should provide the SBETC with the necessary authority, responsibility, and security to justify a long-range market development effort. The following principles are recommended as bases for the formulation of contract provisions:

(a) Establish policies and business objectives which are to govern an SBETC-client relationship and actions of the parties thereunder.

(b) SBETC activities in behalf of a QC should be entirely at SBETC risk and expense. The client should be only obliged—but not limited—to supply or sell products as regularly manufactured, property rights as established, and know-how as conveniently available.

(c) Encourage close SBETC-client working contact that can foster overseas sales, promote technology transfer relationships, stimulate the feedback to client of product, production, and application R. & D. of foreign customers, sales agencies, licensees and joint ventures.

(d) Technology transfer arrangements negotiated by the SBETC should be subject to client approval.

(e) Specify the basis upon which program incentives are to be utilized and shared.

(f) Termination of the SBETC-client relationships should be possible if income and other objectives, contractually agreed upon, are not fulfilled within a reasonable time.

5. **SBETC Sources of Income.—**

(a) Profits on the resale of exported products.

(b) Share of royalties and service fees from overseas licenses and joint ventures.

(c) Share of equities in overseas joint ventures and dividends therefrom.

(d) Royalties on products obtained for clients from foreign sources.

(e) Fees from consulting or for carrying out specific overseas projects.

6. **Client Sources of Income.—**

(a) Profits on products sold to the SBETC for export.

(b) Share of royalty income and service fees from overseas licenses and joint ventures.

(c) Share of equities in overseas joint ventures and dividends therefrom.

(d) Feedback values of commercial and technical data generated by overseas relationships, including grant-back rights to patentable product, and process developments and improvements.

(e) Profits on new products obtained from foreign sources through SBETC efforts.

7. **SBETC Incentives.**—Except as otherwise indicated or qualified, SBETC incentives would include all of the program incentives listed above in *loco clientis.* However, except for II-G, the QC should have the right to take advantage of program incentives to the extent that they are not utilized by the SBETC. Taking the foregoing into account, the following would apply as or with respect to SBETC incentives:

(a) Losses of the original SBETC paid-in capital investment should be deductible from ordinary income by SBETC investors.

(b) The SBETC could set up a bad debt reserve for each QC export account as provided in IID1, but with an overall reserve ceiling for all QC's of $250,000.

The Proposal—6.—Schedules of charges for government services should be revised to encourage use by smaller companies. A formula for funding services based on a nominal percentage of trade volume resulting therefrom should yield greater income to the Government and justify costs of broader service facilities.

II. Program Incentives

Most small U.S. manufacturers make no effort to export or to maintain overseas technology contracts. Many do not believe that their products can be sold abroad. They are intimidated by real or fancied problems of foreign trade. Language barriers restrict technological communication. They do not know the techniques of international business and are unable or unwilling to risk the costs of learning. Conventional export agencies such as EMC's are reluctant to represent the average small manufacturer, preferring easier selling for the technological elite.

In shutting off potential profits of foreign markets, small manufacturers also substantially deny themselves access to overseas technology and innovation that can be meaningful to their competitive positions and growth. Government services, while important, cannot be expected to solve this general problem or to do for business what business should properly do for itself. Therefore, it is essential to establish an array of incentives that, in the face of all problems and risks, are compellingly motivating to small manufacturers or to their export-development surrogates. The following incentives are addressed to these problems:

A. **The Problem.**—Small manufacturers are reluctant to risk the cost of finding, developing and servicing foreign markets and customers.

The Proposal.—During the first year of a programmed export effort, a manufacturer could deduct twice the amount of out-of-pocket costs, up to a $10,000 total, incurred specifically to develop export sales. Such costs would exclude travel but would include items such as preparation of foreign language literature, overseas advertising, trade fair participation, supply of samples. It would also include the cost of subscribing to foreign trade and technical publications. In each succeeding year, the "double deduction" ceiling would be $5,000, but could be increased up to $20,000 by adding the amount by which 3 percent of total exports of the preceding year shall have exceeded $5,000. For calculating such additional deductions, foreign business travel expenses could be included.

B. **The Problem.**—It is too expensive to engineer or adapt U.S. products to the standards, specifications, and preferences of foreign industries and consumers.

The Proposal.—Permit "double deduction" of out-of-pocket engineering and tooling costs specifically incurred for adapting products to foreign market requirements, to a cumulative maximum of $50,000. This would include expenses such as conversion to metric dimensions.

C. **The Problem.**—It is often difficult and disproportionately costly to finance small export transactions.

The Proposal—1.—Establish a nonprofit facility, under direct or indirect government auspices, to provide a properly qualified exporting manufacturer with a revolving credit of up to $100,000 to cover the financing of bona fide export orders, having up to $10,000 f.o.b. value.

The Proposal—2.—Permit accelerated 5-year depreciation and a 20 percent investment tax credit based on the cost of U.S.-made capital equipment, specifically or to the extent specifically used for making products for export, to a cumulative total of $100,000.

D. **The Problem.**—The small company is often unable or unwilling to assume credit and other risks of selling to overseas customers. The tendency to insist on letter of credit dealing inhibits foreign sales relationships.

The Proposal—1.—Each manufacturer may set up at the end of each fiscal year a reserve for bad debts equal to 50 percent of outstanding export receivables not covered by letter of credit to a maximum of $50,000.

The Proposal—2.—Establish a nonprofit "minimum red tape" facility under direct or government auspices to provide low-cost insurance for specified risks. This possibly could be accomplished through modified FCIA and OPIC procedures and charges. Risks specified could include reasonable protection against cost increases in relation to quotation and supply commitments.

E. **The Problem.**—Many small manufacturers are unwilling or unable to risk the cost of protecting their products and processes abroad by patents and trademarks especially if there is little prospect of exploiting them. By the same token, failure to obtain patents and trademarks may foreclose opportunities for product export or for establishing technology transfer relationships.

The Proposal.—To a cumulative maximum total of $15,000, permit manufacturers to take a double deduction of out-of-pocket disbursements incurred in applying for and maintaining overseas patents and trademarks.

F. **The Problem.**—The exploitation of small business know-how, as an avenue for penetrating foreign markets, poses some special problems. For example, equity in a foreign joint venture received as a consideration for know-how supplied under a license or technology transfer agreement is subject to tax as ordinary income in the United States, even though cash income is not received. Few companies are willing to pay out U.S. taxes in order to receive speculative "paper values" of a foreign venture. This and other obstacles to technology transfer relationships are dealt with in the following incentive proposals.

the Government and that establish opportunities for small business to sell its innovated products.

The Proposal—2.—Government agencies should make a greater effort to identify areas of improvement that are desired with respect to specific products. Such identified areas shall be widely published and made known to industries involved. Within stipulated ground rules, government agencies should be able to commit themselves to purchase minimum quantities of particular products with specified improvements if the supplying manufacturer, at his own cost, will carry out the development work necessary to accomplish the improvements.

D. University and Laboratory R. & D.

Universities and private laboratories are extensively involved in conducting basic research from which new and improved products and processes may be innovated. Much of this work is done under government contract and grant. Private industry also supports a substantial share of such research.

1. **The Problem.**—Much research conducted by universities results in developments which are interesting, significant but far removed from useful and productive product and process embodiments. Likewise, limited budgets prevent universities from adequately patenting their developments and from carrying researches to a point where commercial possibilities are defined.

The Proposal—1.—The Government should provide opportunities for limited funding of patent applications by universities to cover important research developments. Likewise, individuals and corporations should have the right to contribute funds to universities for covering patent expenditures under an arrangement that would provide for participation in any eventual royalty income and with the further proviso that such income would be regarded as capital gain. The reimbursement of government funding would have prior claim on income received by universities from patent licenses.

The Proposal—2.—The Government in cooperation with professional organizations such as the Licensing Executives Society and the American Patent Law Association, should develop a program for educating university administrations and faculty on the issues and procedures for protecting inventions derived from research activities and for resolving related issues of rights and ownership and methods of exploitation.

The Proposal—3.—Include university inventions within the computerized bank as per Proposal A 1–2.

The Proposal—4.—Utilize university inventions and research as "case study" projects for MBA students to define and work out prospectively viable product development and marketing programs. A formal MBA program to require or permit students to address their knowledge and ingenuity to setting up proposals based on completed research and/or issued patents could be very rewarding to the universities and to the economy—and in creating entrepreneurial attitudes and objectives within the next generation of business leaders. It is also proposed that any patent owner could submit his patent to a business school as a possible "case study" for student analysis. In fact, MBA facilities could become a useful facility for giving individual inventors an opportunity to have their inventions practicably evaluated.

E. Foreign Technology and Product Developments

A major part of research developments and innovative product developments, covering virtually every field of activity, originates abroad. In some industries and lines of research, foreign R. & D. has become more prolific and advanced in relation to U.S. "output." This reality is associated with another fact: The value and productivity of in-house R. & D. is directly related to its capacity and willingness to absorb and be influenced by exposure to external—foreign—R. & D.

The problems and proposals related to this category of consideration are presented in a separate program.

A PROGRAM: SMALL BUSINESS GROWTH THROUGH OVERSEAS MARKET DEVELOPMENT

Below is outlined a program designed to bring small American manufacturers into the mainstream of world trade. In part, the mainstream relates to the development of export markets. No less important, it relates to the stimulation of product innovation with access to and utilization of new technology. These elements profoundly influence the role of small business in America's economic growth and the health of our competitive environment.

The primary objectives, export markets and opportunity to acquire new technology and to stimulate product innovation, are intertwined. They are relevant in an era characterized by rapid technological change and increasingly integrated world markets. They should help counter trends that are eroding the structure of our economy: (a) the increasing concentration of world trade and technological relationships in the hands of the largest companies, (b) the declining proportion of total U.S. product innovation generated by small business and, (c) the declining position of U.S. industry vis-a-vis other industrial nations in creating new and better products for world markets.

THE PRINCIPLES

The following principles have been considered in selecting and shaping program concepts and proposals:

1. For purposes of this presentation, "small business" is defined as an independent company with fewer than 250 employees, assets under $7.5 million, net worth

input from external sources must be instilled. Unduly repressive features of "confidential disclosure" agreements, that inhibit consideration of outside ideas, should be modified. Management should insist that ideas and inventions which are accepted for consideration be reviewed with reasonable dispatch, that the inventor be kept informed and ultimate decision communicated—if negative, preferably accompanied by reasonable comment.

The Proposal—3.—Large corporations must be deemed to have a "public interest" responsibility with respect to monopoly positions conferred by their patents. Accordingly, an individual inventor or small business having a patent, the use of which infringes on claims of patents owned by a large corporation or by the Government, should have the right to demand a compulsory license on reasonable terms (this can be established by code—note Proposal A 2–1). However, a consideration of such compulsory license could be a nonexclusive cross-license of the subordinate patent.

The Proposal—4.—Establish an administrative tribunal system to provide binding judgments within specified limits for controversial situations where, based on expert professional judgment, an inventor claims his patent is being infringed by a large corporation and the latter refuses to recognize any such bona fide claim unless an infringement suit is processed and the validity of the patent defended. While any business, large or small, has the right to refuse to pay for values that it does not recognize as valid, large corporations should not be permitted to utilize the costs of litigation in effect to prevent individuals and small companies from seeking reasonable compensation for their inventions. Administrative tribunals, to be legislatively constituted with prescribed authority, can be set up under the Department of Justice or U.S. Patent Office, perhaps drawing help from professional organizations such as the Licensing Executives Society and the American Bar Association. Appeal from a tribunal decision could be made only in terms of reasonableness of an award and not on the basis of patent validity.

2. **The Problem.**—Frequently, a development project is blocked by some difficulty that requires help beyond technical facilities available or known to the inventor. Similarly, development work may depend on a team effort involving a variety of technical disciplines.

The Proposal—1.—The Government, perhaps in cooperation with industry, should create regional panels of expert technical consultants who, on a scheduled basis, can assist individuals and small companies in overcoming technical problems that block product development effort. Consultants should be in a position to listen learnedly and to advise on courses of action that the inventor may pursue to solve the problem or where he may go for proper expertise. The procedures and agenda of consultation must be administratively worked out and the parameters of services available determined. The facilities of government agencies and information sources, with which the inventor may not be familiar or find accessible, can be drawn upon.

3. **The Problem.**—Many inventors with potentially valuable patents require capital for product development. Sources of venture capital for individuals have diminished while the costs of development work have increased. Shortage of development capital has been a factor in decreasing the proportion of innovative product input by individuals and small business. This condition must be ameliorated.

The Proposal—1.—A new business concept called Product Development Corporation should be created. For the purpose of developing and eventually setting up to produce his product, an inventor with a patented concept would have the right to form a PDC, to which his patent or patent application would be assigned. The inventor would prepare a development prospectus which, among essential data, would indicate capital requirements. For incentive purposes contemplated by this proposal, there would be a $250,000 ceiling PDC capital. Part of this capital might be supplied by the inventor but the major funding would come from outside individuals and corporations. It is proposed that an individual be able to invest in a PDC and receive a full tax credit for such investment to the extent of 20 percent of his Federal income tax with an annual $50,000 ceiling and a personal lifetime cumulative maximum of $250,000—which maximum could be increased by the amount of 20 percent of income which the investor might receive from the PDC. The investor could sell his equity in the PDC for capital gain, with the inventor having right of first refusal. The investor would not be permitted to assign income from the PDC except to an eleemosynary institution. Any number of individuals could invest in a PDC on whatever terms and conditions were established by the prospectus or by agreement with the inventor.

Corporations could become investors in a PDC but would be limited, altogether, to a minority interest. Moreover, any corporation could not be manufacturing products similar to that of a PDC in which it would invest. A corporation would have the right to receive a tax credit on its investment up to 10 percent of the first $250,000 of its taxable income and 5 percent of taxable income above that amount. There would be a maximum cumulative tax credit of $1 million which can be increased by 10 percent of taxable income received by the corporation from its PDC investments.

The Proposal—2.—A new business concept called Technology Development Corporation can be formed by an entrepreneur for purposes of conducting research and developing specific technology packages for exploitation by industry. A TDC could acquire patents and know-how from outside inventors who need not be participants in the venture. Investors in a TDC would have the option of considering their cash investment as a currently deductible expense in determining income tax liability and would be entitled to receive income from the TDC as capital gain. Individual and corporate investors in a TDC would be treated alike for tax purposes but no simple corporate investor could own more than a 20 percent equity in a TDC. All investors in a TDC would have the right to acquire

Recommendation No. 4.—"Allow a research tax credit for those research-related expenditures not now eligible for the investment tax credit, allowing for appropriate carryback and carryforward provisions. This might be limited to those expenditures in excess of those made in some previous period."

This recommendation is slightly better. It is better targeted at innovation and does not seek a greater benefit than for other investments. Limiting the tax credit to R. & D. expenditure increases would strengthen it.

Recommendation No. 5.—"A substantial increase in the investment tax credit for those capital expenditures that are research related, making it refundable for this purpose."

This is a plea for further incentives from those who have already taken such full advantage of existing tax breaks that no tax remains to be paid. The Public Interest Subcommittee maintains that most very large corporations pay little enough of the tax bill as it is, without further reducing their share. The proposal for a negative income tax certainly met plenty of opposition when it was proposed for the poor. How then can we, in good conscience, propose it for the rich? There is, however, a narrow area in which such a proposal might be supported—for small, independent, new companies still in the startup phase, which cannot yet generate much sales revenue.

Recommendation No. 6.—"Permit income tax credits for individuals and corporations for a substantial proportion of contributions to research oriented, nonprofit institutions, including universities, for the conduct of basic research, as long as the results of that research are available to the public."

This recommendation met with a varied reaction from the members of the Public Interest Subcommittee. It is a proposal for a tax credit which is carefully targeted for basic research and could not easily be used for marketing alone or for areas of business unrelated to innovation. It would go to institutions which have established goals and objectives for research other than projected profitability alone. The Public Interest Subcommittee supports that.

Our reservation is whether it is the most effective way to spend Federal money; for a credit is roughly as expensive as a direct grant or expenditure. Perhaps the democratic process should be involved in choosing the recipients and deciding upon possible restrictions on grants. Yet, often private philanthropy is more open to good new ideas than is government, and more willing to assess and take risks. On this issue, we reserve judgment.

Recommendation No. 7.—"Permit research and development expenditures incurred in the United States to be allocated solely to the U.S. income of the taxpayer."

Here is another case of business seeking most favorable tax treatment everywhere at once. Needless to say, we are opposed.

There is a thread of contradictions throughout the Industry Subcommittee's commentary on this recommendation with regard to comparisons between conditions and regulations in the United States and abroad. On the one hand, the Subcommittee argues the case for U.S. support of industry's innovation, basing its claim largely on the allegation that the United States is hampered in international competition by regulations for health and safety which are stricter than abroad, and that other leading industrial countries subsidize their industry's R. & D. more heavily than this country does, offer them greater tax advantages, etc. On the other hand, U.S. industry complains about R. & D. expenses which are treated less favorably by the tax laws of other countries, and thus argues for benefits from the United States to compensate for that treatment.

Recommendation No. 8.—"For small businesses, properly defined, which spend more than a given percentage of revenues on research and development, allow more favorable stock option incentives to founders and key personnel by (a) increasing the qualified options time from the current 5 to 10 years and (b) postponing the tax on income derived from the exercise of nonqualified options until the shares have been sold rather than paying the tax at the time the option is exercised."

If implemented, this recommendation would allow more favorable stock option incentives for small businesses that spend a lot on R. & D. We find this reasonable with two modifications. First, this is a venture capital argument and should be applied only to new businesses, properly defined. Second, we recommend broadening the stock option privileges to all personnel for the reason that many workers, including hourly workers, work at greater risk and frequently for smaller return and slimmer benefits when they work for small, new firms. This broadened approach would lessen the degree to which this recommendation disproportionately benefits the relatively wealthy.

Recommendation No. 9.—"Allow tax-free rollover of equity investments, or, alternatively, immediate or accelerated deductibility of initial investments, in small businesses, properly defined, which spend more than a given percentage of revenues on research and development."

This raises several problems. First, the latest tax revision bill has already considerably reduced the tax on capital gains. Second, this is a tax advantage which is heavily skewed to benefit the relatively wealthy. Third, the Public Interest Subcommittee finds the recommendation surprising inasmuch as the benefits intended for new firms in the recommendation are possibly outweighted by the problems it would create. New firms need stability, so it would seem that any change that would make venture capital investment more liquid, would lead to less stability in this capital base, and might render such new firms more vulnerable to takeovers.

Recommendation No. 10.—"Allow startup operating losses to flow through to founding investors in small businesses, properly defined, which spend more than a certain percentage of revenues on research and development."

it would be ludicrous to consider abandoning them because they are costly. What is the economic effect, for example, of outlawing murder? This proposal is no more easily implemented than would be a law setting overall limits on the externalities a business (or business cumulatively) may impose on the public. Yet the latter would confer greater benefits.

Recommendation No. 21.—"Increase the support of basic research conducted at universities and other educational institutions."

Certainly we support increasing the funding of basic research conducted at universities and other educational institutions. The interesting question, then, is which research projects shall get what share of the funds? How shall they be selected? Which institutions should they be directed to? Who should make these decisions? Is there any role for the public? To what extent could these funds be directed to research calculated to serve basic need of the public, or key goals identified by the public, e.g., the previously cited Gallup poll?

Recommendation No. 22.—"Review government procurement policies in order to make it less difficult for small and venture companies to successfully compete for projects and contracts."

We agree with the objective stated here. Unfortunately, over 75 percent of Defense Department contracts are negotiated, not competitively bid. We urge that a greater portion of them be awarded on a competitive basis.

Small business does get in on subcontracting, but the Defense Department and the Office of Management and Budget report that prime contractors have increasingly taken on the subcontracting market as well. We urge that the business community itself consider the impact of this trend on new firm formation, competition and innovation, and consider altering it.

INDUSTRIAL ADVISORY SUBCOMMITTEE REPORT ON ENVIRONMENTAL, HEALTH, AND SAFETY REGULATIONS

industrial innovation

Industrial Innovation Advisory Committee Report of Industrial Advisory Subcommmittee on Environmental, Health, and Safety Regulations

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Industrial Innovation Advisory Committee

Report of Industrial Advisory Subcommittee on Environmental, Health and Safety Regulations

D. N. Frey, *Chairman*

In response to an invitation by the Department of Commerce, representatives of business from companies covering a range of industries and sizes met in a series of meetings:

1. To present their views on the matter of how government regulations relating to environmental control, health, and safety affected the process of industrial innovation; and
2. To recommend constructive ways to stimulate innovation and to reduce the adverse effects of the subject regulations on the process of innovation without violating the public mandate for a clean environment and assurance of adequate protection from hazards to health and safety arising from products or the work place.

The Subcommittee noted at the outset that regulation is required to set standards for essential public purposes and social goals. Regulation has had a long, constructive history in food, drug, and health fields. In the newer area of environmental, health, and safety controls, regulations serve to apply standards earlier and more uniformly. This makes it possible for a concerned business to undertake major control programs, knowing they will not lose competitiveness to others who, without regulation, would not undertake comparable programs. The Subcommittee emphasized that the need or presence of regulation is not in contest—improvement in the environment and protection of health and safety are a national priority and a part of overall national goals to which all members of society are expected to respond.

The deliberations of the Subcommittee, therefore, concentrated on the regulatory procedures, rulemaking, and rule promulgation that represent unworkable and unnecessary burdens on industrial innovation. Two broad categories of these burdens were recognized. One is the unnecessary costs of compliance review and reporting that withdraw resources that could be used for innovation. The second is regulatory procedures, overlaps, overspecification, and delays that produce uncertainty and thereby limit innovative decisionmaking. Both add unnecessarily to inflation. All business and its public share owners are currently affected and concerned by both categories, but small business and its share owners face a proportionately larger burden.

The overall magnitude of these unnecessary burdens of governmental regulation on industrial innovation has not been well documented. However, the Business Roundtable is completing a broad survey of unnecessary compliance costs. And there are some other specific examples. It should be noted that if compliance procedures run only 1 percent of sales, this amounts to 40 percent of the average national R. & D. On the investment side, McGraw-Hill reports average environmental controls run 7 percent of all manufacturing investment, and the industries that convert natural products to intermediate form (electric utilities, pulp and paper, steel, chemical processing, oil refining and basic metals like copper, lead, and zinc) often spend 50 percent or more of their investment for environmental purposes. Beyond these expenditures, of course, is the continuingly increasing cost of operating such investment without an increase in output. As for delay, perhaps more notable is the increased interest cost for nuclear plant construction—total plant costs have increased 50 percent and more because of licensing delays. There has been a near collapse of small venture business starts, and introduction of new chemical entities in the Drug Industry has dropped by 60 percent in the last 15 years. The delay in licensing tends to limit innovative choices to those few health improvement drugs that have superior leverage. While these examples clearly indicate that regulations have detracted from industrial innovation by withdrawing resources and posing uncertainty, the Subcommittee was not charged with further comprehensive documentation of the magnitude of these effects.

The following report notes the governmental concerns for regulatory effects on industrial innovation, the role and nature of the innovation process, views of specific effects of regulation on that process, additional findings and recommendations.

that the investor is sensitive about the confidentiality and proprietary rights of all venture know-how and inventions.

The innovation process is characterized by a long time span from conceptualization to implementation. Time has a bearing on cost, because of the time value of money. Time also has a bearing on risk, because the accuracy of critical projections diminishes rapidly as the length of projected time increases.

In summary, then, a business venture based on innovation operates on a delicate balance of its own internal economics. Any outside force which upsets this balance by increasing cost, delaying time of commercialization, increasing risk of failure, diverting resources, or reducing proprietary protection, has a high leverage for discouraging or making impossible investment in this process.

HOW REGULATIONS AFFECT INDUSTRIAL INNOVATION

The Subcommittee members note, from their own experience and observations, the following aspects of regulations that deter the industrial innovation process. All aspects listed refer specifically to environmental, health and safety control regulations that:

1. *Divert capital investments to nonproductive areas.*—Prime or basic industries are especially impacted by high capital requirements to meet environmental regulations. Investments for productivity improvement must often be indefinitely deferred, thereby impairing the competitive stature of affected industries versus their foreign competitors. In industries like electroplating and foundry work, small firms are exiting their business, causing concentration. In basic businesses like lead, zinc, and copper smelting, firms are exiting or transferring overseas. All business faces reduced resources for innovation that will improve productivity and add to economic growth.

2. *Increase costs of product development.*—The use of complex procedures for market entry and the excessive costs of regulatory compliance serve to increase costs without apparent commensurate benefit to the public. Such costs, and the regulation of prices, affect the free market mechanisms and add uncertainty to innovation.

3. *Lengthen the product development cycle.*—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 new innovation developments.

Other effects of this delay are to increase project cost, lower the efficiency and hence the availability of technical manpower resources, increase the risk of investment recovery because of larger entry costs and less foreseeable market conditions, and reduce the period of investment recovery by effectively reducing the period of patent protection.

There is growing evidence that the United States is falling behind the world in the availability of desirable products. This is of particular concern with respect to beneficial drugs and pesticides. Availability should not be argued as adequate compensation for safety, but safety should delay availability only when delays are really necessary and the risk/cost/benefit decision is a balanced evaluation made with the people affected.

4. *Add uncertainty to decisionmaking.*—A number of regulatory standards have been promulgated only to have the standards changed at a later date. A number of regulatory objectives have been announced and later abandoned. Such changes have occurred on relatively short notice compared to time required for investment recovery. This uncertainty increases investment risks in innovative ventures and consequently reduces their attractiveness and initiation.

5. *Add excessive assimilation and reporting requirements.*—The sheer mass of regulations that were issued last year has been almost impossible to assimilate in many industries. Separate industrial organizations have often been needed just to read the regulations and to prepare the multiplicity of near-duplicate reports specified. In effect, a bureaucracy is needed in industry just to cope with paper work without any measurable benefit—adding costs that reduce resources for innovation.

6. *Provide inadequate protection of trade secret information.*—Regulatory agencies frequently are not prepared, nor required, to provide adequate security for proprietary information submitted by industry in response to permit requirements, compliance reports, etc. In addition, some agencies are refusing 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 widely disseminate trade secret information for the public good, it should not be at the expense of the share owners whose investment created it. When this occurs, further innovation decisions are stifled.

7. *Specify means rather than performance goals.*—Specification of means or methods prevents innovation in the manner of meeting performance goals for environmental, health and safety control. Methods should be given for reference only to show one way to meet the performance goal, to show a method used for economic impact analysis, and to provide a method for small businesses who may be unable to divert their R. & D. resources away from their business objectives.

8. *Waste capital by setting standards on capability rather than need.*—A broad range of regulations are established on what can be achieved, not on what is needed for protection of the public. Advancing capability, like our increasing ability to measure, thus results in advancing requirements but, paradoxically, new science does not seem to be introduced in reestablishing the original base for a standard. This approach limits innovation of alternate technology for the purpose. It also results in standards requiring excessive capital expenditures for the benefits obtained, i.e., the standards often exceed the law of diminishing returns. In some estimates, 80 percent of the benefit is obtained with 20 percent of the expenditure. Much of the remaining 80

(d) Regulatory agencies should be required to determine the effect of their regulations on the facility with which new products can be introduced into the market. Specifically, they should determine the effect of the regulations on the cost of qualifying for market entry and on the cost of securing market entry in terms of both time and money.

(e) Regulatory agencies, taxing bodies and revenue agencies should be charged with the responsibility for minimizing any adverse effects of proposed regulations, practices, and policies upon investment in research and upon investment in new products and new processes.

(f) Agencies should be held accountable for their claimed results of risks/cost/benefit related to regulation. Their performance should be reviewed regularly, and failure to achieve results should be cause for invoking sunset legislation to deregulate or to find a better alternative.

3. Government should recognize that, where regulation is necessary, the need for effective regulation is so great that every effort should be made to assure a high level of competence in the regulatory agency. It should be recognized that an important element of competence is the development of experience with the actual effect of regulatory measures on suppliers and users of products and services being regulated.

Government should also sponsor research to develop a better knowledge base of the "cause and effect" aspects of the health and safety hazards to be regulated, so that more meaningful regulations can be written. When there is need for intermediate regulations, the regulatory agencies should confine the scope of regulation, both with respect to objectives and means of achievement, within the bounds of existing knowledge.

4. New legislation and new regulations should seek approaches that encourage industrial innovation while serving public purposes. Examples are:

(a) Reduce uncertainty of content and timing of regulations.

(b) Adjust the timetable for compliance to take into account the state of the art for effecting a correction, local conditions, and the availability of capital.

(c) Because the inventor of a new product which cannot be marketed without government concurrence receives no benefit from his invention until government action permits the product to be marketed, the life of the patent of such products should run from the date when sale of the product is permitted.

(d) Recognize that safety, health and environmental impact data may be proprietary information and provide effective protection of the rights of owners of such data, or provide full acquisition compensation where such information is needed for public purposes.

5. In all areas of government control there should be a presumption against the use of mandatory regulatory controls. Alternative means of developing acceptable standards and practices should be fully explored before mandatory controls are determined to be required and are imposed. Examples of alternatives are:

(a) Improvements in our educational curriculum to prepare our citizens to live in a high-technology environment.

(b) Education of workers, management and the public with regard to the risks and benefits incident to innovation, e.g., exploitation of chemical synthesis.

(c) The use wherever feasible of market and tax incentives, e.g., favorable tax treatment for the cost of pioneering research.

(d) The fullest possible utilization of the American voluntary standards procedures with representatives of government agencies at all levels of Government participating in developing standards of interest to them. In nonfood or nondrug product safety, it should be possible to utilize the excellent resources of existing standards associations and independent private laboratories to further the regulatory objectives. Similarly, in workplace safety, private industry and insurance companies have already done much to contain risk for both humanitarian and economic reasons, and it should be possible to harness this resource.

(e) The establishment of a system of "Courts of Standards and Appeals," including a court of final appeal.

(f) Use of cooperative programs involving joint effort by industry, labor, technical societies, and associations of consumers and environmentalists to develop safety, health, and conservation codes.

(g) Use of performance specifications, not methods specifications. The latter prevent innovation and should be used for reference only to show how a performance goal can be achieved, to show the basis for economic impact statements, and for use of small businesses.

(h) Seek ways to equalize regulatory burdens placed on U.S. suppliers and the lesser burdens on foreign suppliers, so the latter will not have special competitive advantage over domestic suppliers in the United States or abroad.

6. It is a basic tenet of our law that those who are subject to it should have ready access to the text of the law, that the law should be comprehensible, that its intention should be clear and that the history of its evolution should be available in order that its intent may be discerned and elucidated. The mass of regulations that has evolved does not meet this basic standard of due process of law. Therefore, government policy should be to reduce absolutely the volume of regulatory law by the dissolution of regulatory agencies which are not needed and by providing for the engrossing, codifying, and annotating of the remaining body of administrative law. To facilitate this work, we recommend the creation of a U.S. Office of Administrative Law to perform the following functions:

(a) To advise and assist regulatory agencies in the drafting of regulations.

agencies should confine the scope of regulation, both (g) Use of performance specifications, not methods

SAFETY SECTION REPORT

I. BACKGROUND FOR THE ANALYSIS

Safety regulations affect both the workplace and the end product. Thus, the impact on a firm's business is all encompassing and touches virtually every portion of the innovation process. In addressing the potential importance of these regulations on innovation, we have first attempted to establish a framework of the innovation process from an industrial viewpoint. Broad issues are then set forth, and subsequently, some examples of reaction are developed. Finally, recommendations are made that we believe should enhance innovation.

In going through this process, it becomes clear that there is a hazy distinction between safety and health/environmental regulation. Thus, examples are sometimes cited that cross these lines. This haziness is understandable because the underlying purpose in regulating health and the environment is, of course, individual safety.

It likewise becomes evident that there is not a clear consensus of the impact of regulation, safety in particular, in innovation. To a certain extent this difficulty stems from measurement problems. In only a few cases have attempts been made to even quantify costs, and these examples have been challenged. [1–6] Our concern is with trends. Increased resources appear headed for compliance and less for innovation. A number of examples are drawn from the drug industry which has the longest general experience in dealing with an agency. By comparison, experience with NHTSA, CPSC, EPA, ond OSHA is relatively sparse.

Evidence is largely anecdotal. In a strictly scientific sense this is less than desirable, but in this assignment there is little else that can be done. If we wait for overwhelmingly clear trends to develop, it may be too late to structure solutions. As it is, because of lags inherent at stages in the innovation cycle, the policy recommendations instituted immediately may not have measurable impacts until the 1980's.

II. THE INNOVATION CYCLE

The innovation cycle includes:

1. Basic knowledge development
2. Product/process development
3. Manufacturing development
4. Diffusion to the marketplace.

Safety regulations affect all these items. The need to identify both toxicity levels and carcinogens are included in basic knowledge development. Likewise, the recent campaign of OSHA on laboratory safety is likely to impact this area, particularly in our schools and universities. This area is of particular concern as the methodology applied to industrial research would have an immediate and direct negative affect. [7] Product development certainly is affected by the product tests that are required to establish compliance, and process development is impacted by the emphasis on engineering versus behavioral solutions to regulations. Manufacturing development, which can be taken as a step beyond process development, is impacted. Likewise, diffusion in the marketplace, which is really a time of acceptance, is impacted by the positive or negative effects imposed by regulation.

Firms attempt to control this cycle. Therefore, in reacting to regulation, the firm responds in allocation of resources. It is difficult to make general statements on how firms are impacted because it can be expected that the impact will vary by industry and firm demographics within the industry. Nevertheless, we believe that a statement of general issues is relevant and important since the decisionmaking attitude responds to general as well as specific firm issues.

III. GENERAL OVERVIEW

It is obvious to even the most casual observer of American life that government regulation of private sector industrial activities has increased greatly in recent years. What may be less obvious is that the new regulatory environment is having an adverse impact on industrial innovation that is the process whereby new products and services are generated and diffused into the American economy. It was the purpose of the Safety Subcommittee to analyze and report the effects of safety related legislative and regulatory actions upon private sector decisionmaking relative to advancing technological innovation.

By innovations we do not mean the products developed as substitutes or the appendages hung onto a product or process, but we mean the developments that have led to market expansion and real GNP growth.

A. Observed Trends

Some effects of the present environment upon innovation decisions in industrial organizations have resulted in shifts in corporate fund allocations:

- Away from basic research into improvements of existing products
- Out of new ventures
- Out on long term projects into projects with shorter term payoffs [8–10].

In addition, the international competitive position of U.S. firms has diminished as can be seen by:

elected representatives in Government pass the problem on to the administrators in Government without specific criteria or guidelines but with the demand that the public be protected. As a result, the administrators adopt zero-risk rules without adequate (or any) fact-finding regarding economics and innovative impacts. The Government therefore puts itself into an adversary position against the business community and enforces the zero-risk regulations. While specific instances support the perception, the scenario, in general, is erroneous. For example, zero-risk rules specifically exist in but two agencies and these are legislated. Nevertheless, industry has responded by taking a safe position in order to reduce exposure to sanctions or large liabilities. This brings with it reduced R. & D. efforts, a trend towards defensive research, and subsequent slower economic growth.

IV. REGULATORY FUNCTION FACTORS

In an analysis of this sort, broader areas of regulations surface. We did not make specific recommendations in these areas because of the incidental association with safety. One difficulty in segmenting a study as has been done in this case is that broader issues may not surface. We would thus be remiss if these concerns were not mentioned.

A. Disclosure of Proprietary Information

Consideration may be given to "Does early disclosure in areas requiring regulatory action affect innovation?" "Do disclosure requirements in safety-related areas reduce the effect of patent life?" And, "Can the process be altered to encourage innovation and be reconciled with factfinding activity?" Specific examples are available in tires, which are subject to DOT performance test, and drugs, which are subject to FDA regulation. In the latter case, a significant departure from the predictions of the product life cycle trade theory proposed by Vernon and others is observed. Not only are new drug innovations being introduced first in foreign countries with much smaller markets than the United States, but they are also produced in their initial stages of product life in foreign plants as well. [20]

B. Timing for Promulgation of Regulation

In general and in specific instances, timing for the introduction of safety regulations has affected the innovation process. For instance, the truck brake anti-skid system has been the topic of much recent discussion. [21] In fact, there is a question as to whether or not the regulation should have been instituted within the original time frame. That is, the failure of the initial systems strongly suggests that inadequate consideration was given to the time and *need* for innovation.

C. Industry/Government Communications

Regulation within the U.S. system of government implies that communication is required. If, indeed, there is a problem in regulation, lack of communication may underlie the situation. The means, quality, participation, and timing of communication are items that are worth study. As indicated in any discussion in this area there are the legislature, oversight committees, and judicial review, but these take the role of being either advocate or adversary hearings. Well run regulation requires calendars of intention and special regard for the entrepreneurial segment of the industry which supplies much of the innovation. In any case, there is a clear need for an approach which engenders a cooperative attitude by all parties in approaching reasonable solutions.

D. SKILL CONSUMPTION

Skills are used in regulatory action. These skills are needed both in the agencies and the firm. In the short term, which happens to overlap the growth in regulation, statistics indicate growing agency budgets which imply greater use of people both in the agency and, as a direct consequence, within the firm. [2] Data on research expenditures, for instance, indicate the need to do greater amounts of defensive or regulatory compliance development. [3–4] The number of scientists and engineers has grown very slowly over the last 5 years; therefore, any deployment into compliance affects output. If, indeed, more research funds are going toward defensive development, then a correlation of reduced innovation and development is inescapable. The underlying hope, of course, is that in the long run the effect will be positive. That is, the demands of regulation will increase the number of scientists on a "market-pull" basis and thus skills will be available for overall benefit. The critical problem is timing and balancing effects.

V. OPTION RECOMMENDATIONS

Recommendation 1—Workplace Safety Regulation.—

- Performance standards should be the mode of operation in the regulation of workplace safety. Incorporated in the operating procedure should be the application of statistical fact finding procedures, utilization of industry data, and allowance for reasonable risk criteria.
- Cost-benefit considerations should be required to support new regulation efforts.

OSHA has demonstrated some curious behavior in its technical, economic and market factfinding. In the cast metal industry, which was the first industry regulated, the agency held hearings and then appeared to ignore industry testimony. [22] This criticism is not confined to industry participants. Presently the agency is establishing regulations for laboratory exposure to carcinogens. In compiling its list, OSHA has declined offers for help from the National Academy of Science. Instead, a private firm was employed in making a survey. The general criticism has been made that the regulations will provide uniform regulations for nonuniform cases and will be largely ineffective in providing time improvements in safety. [23] Present proposals thus invoke little enthusiasm.

ibility in obtaining performance allows for innovative solutions while conserving funds.

A case in point is the textile industry which has relatively low occupational injury and illness rates as reported by the Bureau of Labor Statistics. Yet, it has been singled out by the Occupational Safety and Health Administration for compliance with many regulations which have had little or no influence on reducing injuries and illnesses.

The Cotton Dust Standard is an example of OSHA's lack of communication in the identification of problem areas needing attention. OSHA has identified byssinosis (brown lung) relative to cotton dust control as a major concern, while, in fact, the byssinosis "problem" was out of proportion to the actual situation due to a misunderstanding of the disease, its cause, and effective prevention. In actuality, the textile industry, starting in 1969, was well on the way toward eliminating disabling byssinosis before OSHA proposed its Cotton Dust Standard.

Thus, OSHA's failure to communicate effectively with the industry resulted in issuance of a technically infeasible and inflationary standard on June 23, 1978. This is one of the more comprehensive standards issued by OSHA and covers virtually every aspect of the work environment in the cotton textile industry.

The industry estimates the capital cost alone of compliance with the Cotton Dust Standard—if it were technically feasible—at about $2 billion, in an industry with profits rarely more than 3 percent of sales. More specifically, for the cotton textile industry, $2 billion represents the approximate equivalent of more than 7 years of profit. Seven years when the industry would literally dry up and even greater chunks of its markets would be lost to overseas manufacturers who do not have to meet such a standard.

This is a high price to pay for improper identification of a significant occupational hazard. Careful review of the byssinosis situation by OSHA in an objective manner would have revealed alternative, less costly measures that could have been taken with equal effectiveness.

A second example is available in OSHA's proposed Noise Standard. Administration rulemaking hearings have been held twice by OSHA to promulgate an OSHA Noise Standard. Like cotton dust, OSHA had a meager understanding of available control measures of the noise problem in the textile industry. This lack of knowledge has resulted in lengthy, costly hearings, which possibly could have been avoided if OSHA were more willing to cooperate with involved groups.

The textile industry would be required to spend about $3 billion to meet OSHA's proposed Noise Standard, even if the technology were available, and this expenditure would be on top of the $2 billion for complying with the Cotton Dust Standard.

The industry believes that employees can be and are being effectively protected against hearing loss by hearing conservation programs until machinery can be designed and installed on a normal replacement basis to prevent occupational hearing loss. OSHA continues to cite textile companies for violations, although it must be aware from the record of the hearing that for most textile machines no technology exists for meeting the proposed standard.

Recommendation 2—Product Safety Regulation.—

- In those instances where product safety must be regulated, performance (efficacy) standards should be utilized rather than design (methodology) standards to allow maximum opportunity for innovation within the desired objectives.
- A mechanism should be established with a purpose of reviewing recall and product liability insurance programs. Additionally, model legislation should be proposed to replace the system of contingent fees with a sliding fee scale administered by the courts.

In business and manufacturing areas where use, or even misuse, of the product can produce physical injury or death, the manufacturer is increasingly exposed to the twin threats of product recall and product liability suits.

There can be no quarrel with the contemporary societal view that an injured person has the right to reimbursement for a defective product, or for recovery of damages sustained in the use of that defective product or even in the misuse of a nondefective product if that misuse could reasonably have been foreseen and prevented.

Nonetheless the growing increase in dollar losses occasioned by these two problems serves as a strong deterrent to entrance into such business areas. New product innovation by current producers will be similarly inhibited in some proportion to the degree of novelty of the proposed new product.

The actual numbers of accidents or injuries precipitating recalls and liability suits can be very few in number, vis-a-vis the number of units in service. At that low statistical level, there are few economic techniques of quality control or process control available that can provide management with the necessary reassurance against either recalls or product liability suits. Insofar as misuse of the product is concerned, predictability of exposure is even more difficult considering the vagaries of human behavior and dispositions of the courts as to reasonable behavior. To the extent that the sequence of events leading to product recalls or to legitimate product liability recoveries is unpredictable, it is also uncontrollable.

Not only are recall and liability unpredictable, they are expensive. The virtually unlimited severity of financial loss arising from product recalls and product liability suits is abundantly identified by recent events:

1. The Firestone recall of 10 million tires produced over a period of several years is estimated to cost over $135 million, which is equal to Firestone's earnings for last year, plus various intangible losses. [24] This case is noteworthy in that the circumstances involve a new product in its "first generation within the firm" and even larger expenses may be expected from subsequent liability suits.

2. The Ford Pinto gas tank episode has occasioned many costly liability suits. A recent California judge-

to continue to innovate. For most of the OPEI members, "exemption" means "status quo," since the large majority of member companies are "small" by anyone's definition, including that of the Small Business Administration.

It is particularly frustrating to see an agency developing a "design" standard, when the enabling legislation (section 7 of the Consumer Product Safety Act) explicitly requires "performance" requirements unless such requirements are found to be infeasible. Added to the statutory instructions is the actual existence of alternative designs, showing the desire and the ability of the industry to innovate.

Design standards, however, won't allow innovation. For that reason, we hope that panels involved in upcoming studies will devote sufficient time and resources to an examination of the "design vs. performance" controversy and, in particular, opt for performance standards.

Yet even "performance" standards have their problems. An example of this result is the regulation of children's sleepwear, i.e. pajamas, gowns, sleepers, etc. This story represents one of the conflicts between regulators and industry in recent years, and is sometimes referred to as "the tris affair". While the history of this regulation is a recitation of problems and conflicts, it also illustrates wasted technical effort and frustration which stifles innovation.

The desire for regulation of fabrics used in children's sleeping garments started with the Department of Commerce (the responsible agency prior to the creation of the CPSC) and was initiated by congressional action and pressures from a variety of consumers and other interests. The time frame for study, gathering of sufficient data, and development of the test itself was short. This resulted in a test which, in many respects, was simplistic and unable to truly measure hazard. At the time the test was proposed, suggestions by industry were considered misleading, biased, selfish, or worse.

Rather than determining the technical validity of the test and its relationship to the hazard presented by burning fabrics, test procedures were established to compromise various positions of vested interest. One of the features of the test as it was initially promulgated was the so-called "residual flame time" (RFT). Without going into the technical significance of this aspect of the test, it was this specific requirement which eliminated broad variety of synthetic fabrics from qualifying for the children's sleepwear market. It was also this specific requirement which required use of the chemical flame retardant "tris", subsequently banned by the Consumer Product Safety Commission as a potential carcinogen.

Enormous effort was poured into solving the children's sleepwear flammability problem. Chemical companies, fiber companies, and textile producers devoted major efforts to developing fabrics which met all of the criteria of the promulgated test including "RFT". At the time the test procedures were promulgated, no one knew how important the RFT criteria was nor what added protection it might afford. Yet it was this criteria which necessitated an extraordinary technical effort to develop fabrics which could pass the test. A solution was found by using "tris". However, following the CPSC ban on tris-treated fabrics, the CPSC determined that the flammability phenomenon measured by RFT did not really present sufficient hazard to justify continuing its inclusion as part of the test procedure. The test procedure was accordingly modified.

Such changes in government standards are not unusual and do, and should, occur when needed. Nevertheless, such changes penalize innovators who attempt to develop solutions for the problems created by imposition of test requirements which are subject to change. Implementation of innovative solutions takes time. The desire to innovate was, in this case, prompted by the opportunity for being able to obtain above average returns based on the fact that few firms would be able to develop fabrics which could compete in a market where many could not meet the regulatory standard. In the case of the children's sleepwear regulation, one fiber producer, for example, was able to develop and introduce a special fiber which permitted the manufacture of fabrics and garments to meet the sleepwear flammability standard, including RFT, without chemical treatments. Yet almost as the innovative product was introduced, the CPSC modified the test procedure which in effect, negated the need for the fiber innovation. Now the fiber company is left with a truly innovative product for which no need exists. Research dollars and even greater quantities of investment required to bring this product to market were wasted.

The lessons developed from such tales should not primarily focus on the wasted investment, as bad as that is, but more importantly, on the effect such events have on the willingness of manager to make future investments in R. & D. and other innovation-generating activities. The fiber company which developed the innovative self-extinguishing fiber expected a reasonable return on its research investment. The unpredictable nature of regulatory action destroyed the returns. When the potential returns cannot be increased commensurate with the increasing risk, the investments will diminish and apparently have on a nationwide basis.

Recommendation 3—Safety Regulation in Small Businesses.—Due to the potentially large role that small firms have in innovation, a package should be assembled which permits workplace safety regulation relief, financing for compliance tests and liability protection, specialized tax exemptions, and impact analyses in new regulations.

A previously suggested definition of small business is used in this instance. That is, it is the small *but viable* business with which government agencies must be concerned. The basically sound and well-run enterprise encounters problems when regulations force "nonproductive" expenditures into the process of bringing about technological change. [14]

Specifically, enterprises dealing with introduction of technology are of greatest concern. Clearly these firms cannot be neglected in discussing innovation. As indicated previously in a series of studies:

tices in this area may, pragmatically, be best policed internally. Likewise, an economic growth bias might be expected from those committees which include counsel from the Council of Economic Advisers, Council on Wage and Price Stability, and Office of Management and Budget and informally or formally review proposals and thus have opportunity to influence regulation. The Council of Economic Adviser's impact on cotton dust standards would appear to be a desirable approach.

In a check-and-balance scheme, Congress, specifically the House of Representatives, is set up to oversee regulatory agencies. An *active* role is requested in this area. Such topics as moratorium, sunset, and enabling legislation seem especially appropriate for review at this time. Micro- and macroeconomic studies appear to be indicating the inescapable conclusion that regulation is adversely affecting not only individual firms but the economy as a whole. Perhaps Ford Motor's decision to reduce efforts in Stirling Engine development is symptomatic of the present situation where long term developments are being sacrificed for short term compliance. [33]

It must be realized that a de facto tax has been placed on American Industry, and thus the economy, by requiring accelerated compliance. Capital is diverted and long term strategies are altered. Opinions of the type (Congress) "has already arrived at a judgement concerning the balance of cost and benefit, with the result that work safety and health are to be heavily favored over the economic burdens of compliance"—OSHA, [34] or "We're required to take into account, under the Act, the approximate cost of a standard, but that doesn't mean we have to cost-benefit justify the price of implementing it"—NHTSA, [30] surely are misinterpretations of the original intent. We desire safety, but not at the price of wrecking an industry or the economy as a whole. (Incidentally, it is surprising that an agency with the aforementioned attitude on cost-benefit would be given the additional responsibility of determining interim standards on fuel economy.)

A means of implementing this recommendation is to provide overview groups with the teeth to maintain balance between risk and benefit in Federal regulations. Aside from placing this power in currently constituted groups, one suggestion to consider is a separate office in the Office of the President which could be known as the Office of Regulatory Oversight reporting to the President and to the Congressional Committees having oversight on appropriations and operations of the independent agencies outside of the executive branch. This office could be created by Executive order but the funding would have to be approved by Congress with enabling legislation similar to the way the Office of Special Representative for Trade (STR) was established.

The Office would be operated by a director and a staff charged with examining major regulations (i.e. where significant economic/innovation impact is foreseen) issued by agencies in the Executive Branch as well as independent agencies. Advisory groups representing the private sector, labor, and special interests should meet with the director and staff quarterly to review the findings of the staff prior to reports made to the President and Congress as well as the Director of the OMB and the Chairman of the Council of Economic Advisers. The reports should be made public with attendant publicity.

The second indirect factor we support is tax allowances for research and experimental costs. A tax credit is preferred over an R. & D. subsidy because, frankly, management at the firm level may be in the better interest of the country. Although certain large projects, such as development of alternate energy sources, can only be undertaken at a Federal level, a *turnaround in innovation* may require the incremental investments of individual firms. The difficulty that has been observed in commercializing "commonly held" patents bespeaks the potential difficulty awaiting if the Federal Government biases the decisionmaking process.

Although this option universally affects industry and thus would function as a windfall in some cases, perhaps this effort is most appropriate in structuring a turnaround. Indeed, the option might be imposed specifically as a turnaround device by limiting tax relief to a specific period of time. Moreover, entrepreneural efforts have so markedly declined that it may be necessary to depend on the capital formation ability of larger firms to reverse the present trend.

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HEALTH SECTION REPORT

SUMMARY REPORT: HEALTH AND SAFETY INDUSTRIAL SUBCOMMITTEE, ADVISORY COMMITTEE ON INDUSTRIAL INNOVATION

We are pleased to submit our views on our assigned portion of the industrial innovation and government regulation report. It is our hope this material will be useful in developing the Committee's submission to the Commerce Department for their use in reporting to the President.

Our Committee notes with satisfaction the availability of several excellent and useful reports describing the general interface between Government and the industrial innovation community. The Massachusetts Institute of Technology report for the Office of Technology Assessment (OTA), "Government Involvement in the Innovation Process" (1978) and the Commerce Department study, "U.S. Technology Policy," (Betsy Ancker-Johnson and David B. Chang, March 1977) are especially noteworthy.

Our submission consists of a summary backed up by several reports. The detailed reports represent our own experiences and resulting recommendations on the issue of the effect of government regulation on industrial innovation and a survey of the relevant literature. These reports came from several representatives of diverse industries: pharmaceuticals, foods/nutrients/flavors, animal health products and medical devices. They have, nevertheless, certain common *themes* which it is the purpose of the summary to state.

Themes of the Summary

Industrial innovation is being slowed and restricted by:

1. The growing inability of regulators to make straightforward, scientifically grounded risk/benefit determinations.
2. The inability of the regulatory structure to adjust to advances in analytical techniques and deal with the inevitable ambiguities of product testing methods.
3. The erosion of financial incentives to innovators, growing out of regulatory approval delays, excessive requirements for disclosure of information and inadequate protection of trade secrets.
4. The growing diversion of researchers and resources from innovative research to technical compliance and defensive research.
5. The decline in the role of recognized experts in advising regulators on technical issues.
6. Misleading information on the profitability of research-intensive firms which helps create a public and legislative climate discouraging to innovation.

Theme No. 1.—Innovation is being slowed by a growing inability of regulators to make straightforward, scientifically grounded risk-benefit determinations.

Over the past decade, the procedures by which products are approved for marketing or alternatively taken from market have become increasingly influenced by a view that assigns infinite costs to risk and slight value to benefit. We associate this perspective most frequently with the vocal, committed groups whose declared intent is to protect the environment, the consumer in general, or the consumer's health in particular. Perhaps in an effort to gain public attention and support, these groups seem to be willing to overstate, or "oversell," their case—a case often beginning with reasonable, valid points—and their credibility ends up damaged when their excesses are revealed. The debate over recombinant-DNA research stands as an interesting case study of this phenomenon.

The idea has taken root that to protect the public, Government must oppose new products rather than encourage them. Much recent regulatory legislation, such as the Clean Air and Water Acts, the Toxic Substances Control Act, the Federal Insecticide, Fungicide and Rodenticide Act, the nutrient labeling requirements, the Consumer Products Safety Act, and the proposed Drug Regulation Reform Act of 1978 reflect this view. So do many of the new regulations under which these and other laws are administered. This legislative and regulatory "tilt" creates a climate of excessive, unnecessary and inappropriate caution instead of the climate of prudent risk-taking, based on scientific judgments, in which innovation has always flourished.

RECOMMENDATIONS

- A Presidential proclamation should declare that the fostering of innovation by government agencies is equal in priority to the protection of human health and safety.
- Early, safe phases of new product research and development (for example in drugs) should be deregulated.

Theme No. 2.—Innovation is being slowed by the inability of the regulatory structure to adjust to advances in analytical techniques and to deal with the inevitable ambiguities of product testing methods.

New techniques can now detect impurities in products down to parts per trillion. As a result, regulators are applying far more stringent standards than are necessary to protect the public. Substances that have been safely used for years are being called into question because of the new discovery of minute toxic

reluctance to take prudent risks based on scientific judgments discussed in Theme No. 1.

Generalists and consumer representatives are needed on the committees which advise regulatory agencies. But they should not dominate them, especially where the critical questions are technical and scientific.

RECOMMENDATIONS

- Realistic "conflict-of-interest" guidelines should replace the unnecessarily rigorous rules now in effect.
- Greater use should be made of expert advisory committees to regulatory agencies, including their use as "referees" in disagreements between the agency and product sponsors.

Theme No. 6.—Innovation is being slowed by the dissemination of misleading information on the profitability of research-intensive firms, which helps create a public and legislative climate discouraging to research and development.

The contention that return-on-investment percentages of research-intensive companies are sufficiently higher than the average for all industry as to be "excessive" is frequently advanced by those who justify the need for "more competition" through data disclosure and other techniques, who seek to impose more, expensive regulatory steps, and who seek to standardize all products in order to bring down prices.

In fact, if all industrial accounts were adjusted to capitalize R. & D. expenditures, the return on investment of research-intensive industries would much more closely approximate the return of other industries.

To the extent that regulatory proposals which discourage innovation are justified, then, on the basis of what is largely an artifact of accounting practice, the public is being misled and its interests are ill served.

RECOMMENDATIONS

- Firms should be allowed to report profitability ratios either (or both) way(s): with R. & D. handled as an expense item or as a capital investment.

HEALTH

Introduction

The rapid escalation in the cost of hospitalization has reached such proportions that the Nation now spends an estimated $182.5 billion, or 8.8 percent of the GNP, on health care.[1] This rapid rise in costs has caused the present administration to mount a campaign to contain the costs of hospitalization. This is certainly warranted; however, present costs are small compared to the projected cost of the nation's health bill which will exceed $1 trillion in the year 2000, consuming up to 12 percent of the GNP. Moreover, the total cost of illness will top $2 trillion when such indirect costs as loss of earning power are included. This projection must be categorized as catastrophic in terms of other national goals and our status in world affairs. Every effort should be made to ensure that this dire prediction does not come true.

There are three main approaches that can be undertaken to prevent the rise in cost of health care:

1. prevention of disease,
2. early detection of disease, and
3. improved therapy.

All of these will require innovation to the highest degree possible in order to succeed. Proper incentives must be established and unnecessary regulatory impediments, removed. This is necessary for all innovation; however, it is especially important for the pharmaceutical industry because of the heavy investment that is required in research and development and the high degree of risk involved. Unfortunately, the present climate for innovation in the pharmaceutical industry is bad and getting worse. The problems can be classified as (1) economic and (2) regulatory.

[1] The Bulletin 21 October on a study conducted by Georgetown University's Public Services Laboratory, published in Public Health Reports, the journal of HEW's Public Health Services.

I. Economic

The most significant economic characteristic of the innovative pharmaceutical industry is a strong commitment to new product research and development. Large sums are committed to a new product discovery and development process with the investment and R. & D. effort taking place over a long time period. Indicative of the industry's commitment to research is the fact that, on average, the pharmaceutical industry commits 6 percent of sales to R. & D. compared with 2 percent for all U.S. manufacturing industries. Because of the heavy investment in R. & D., a lengthy period is necessary for recovery of the initial investment and the achievement of a satisfactory rate of return.

Inherent throughout the investment and recovery cycle is a high degree of risk which can be subdivided as follows:

1. The technical risk associated with the attempt to discover a unique compound which is therapeutically useful and safe in man.

*World's 10 Leading Pharmaceutical Companies**

Rank	Company	Sales $M	Rank	Company	Sales $M
1	Hoechst	1,560	1	Hoffman-LaRoche .	1,000
2	Merck & Co.	1,396	2	American Home ..	906
3	American Home ..	1,387	3	Warner-Lambert ..	877
4	Hoffman-LaRoche .	1,148	4	Merck & Co.	821
5	CIBA-Geigy	1,097	5	CIBA-Geigy	637
6	Bristol-Myers	1,063	6	Hoechst	593
7	Pfizer	930	7	Pfizer	559
8	Warner-Lambert ..	916	8	Eli Lilly	516
9	Bayer	890	9	Sandoz	481
10	Sandoz	881	10	Sterling Drug	460

*Ranked by total pharmaceutical sales

Most of the leading industrial countries of the world follow policies which encourage and support high technology industries. Japan, for example, manifests a climate of close cooperation between government and industry which fosters technological advance. Also, many foreign countries offer special tax treatment for research and development investment including accelerated depreciation of research facilities and special grants for the construction of research facilities.

In contrast, the United States has no coordinated national policy with regard to technology and innovation. Rather than offer tax incentives for R. & D., the United States recently enacted a regulation which forces the allocation of a portion of R. & D. expenses incurred in the United States to income earned abroad. This allocation is in addition to research and development expenses already incurred by overseas operations. However, since foreign governments will not permit a tax deduction for the allocated expenditures, the effect is double taxation and an incentive for U.S. firms to conduct a greater share of research and development outside of the United States.

Some consequences of the differences in treatment regarding research activities in the United States versus foreign countries are as follows:

- Because of a decline in total research expenditures in the United States which began in 1969, the U.S. will spend less (adjusted for inflation) on research in 1977 than in 1968, the peak year.

- During the same period, R. & D. investments in Japan, Germany, and the Soviet Union have grown consistently larger.

- About 35 percent of all patents granted in this country currently are being awarded to non-U.S. inventors. In contrast, during 1961, only 17 percent were granted to non-Americans.

- Today, there are 5 percent fewer people engaged in R. & D. in the United States than at the 1969 peak.

- During the same period, professional R. & D. employment increased in nearly all other industrialized nations.

- The rate of new pharmaceutical product introductions in the U.S. is now about 25 percent of the rate of the 1950's and early 1960's. On the average, it now takes about 12 to 15 years to bring a new chemical entity from discovery to marketing compared to 2 years in 1962.

If the United States is to sustain competitiveness on a worldwide basis, it is important that we maintain technologically superior firms. The long-term world economic scenario throughout the rest of this century portends increasingly expensive commodities and raw materials which will also be in relatively short supply. The United States will become more dependent on the importation of key raw materials and must maintain a strong technological position in order to pay for the increasingly expensive commodity imports. Governments of our leading competitors such as Germany and Japan, recognizing the importance of technological superiority, encourage and support their high technology industries. In contrast, recent trends indicate a deterioration of the U.S. technological position.

Recommendations for improving the incentives for innovation on an economic basis:

A. Patents serve as a good incentive for innovation; however, approval by the Food and Drug Administration is equally important and can negate much of the incentive provided by a patent. The development and approval process required by FDA can effectively shorten the useful life of a patent. Drugs that are expected to have a short patent life at the time of approval cannot be developed economically; therefore drugs that would otherwise be useful are not developed. To prevent this inhibition to innovation of drugs, the patent laws should be changed to delay the effective date of approval of a patent until premarket clearance is obtained from FDA.

B. The innovator of drugs must pay great amounts for research and development on compounds that carry a high potential for failure. He runs the risk of civil and criminal penalties in the process of development. And the development and approval process may drag on for many years. After approval, the FDA can allow a competitor to use all of the innovator's data to obtain approval of his product. The copier has minor expenses, little frustration, little delay in approval, and no risks. The competition is thus at a decided advantage —he has no costs to recover—and he can sell his product cheaper than the innovator. In order to survive, the innovator must not test the many old compounds for which he cannot obtain adequate patent life; he cannot attempt to develop drugs for rare diseases, hence, the area of therapeutic orphans; and he must decrease risks. The Government should restore the property rights guaranteed by the American free enterprise system to innovators of drugs.

C. Some types of innovation are more important to society than others. Therefore, priorities should be established and appropriate incentives established to accomplish the objectives. For instance, (1) health is extremely important, (2) costs to government and individuals for health have been rising at an alarming rate, (3) innovation in the pharmaceutical industries as measured by new drugs is decreasing, and (4) innovation in pharmaceuticals is being transferred from the United States to foreign countries.

Much of this is a direct result of cooperation between government and industry. It may not be possible, or even desirable, to set up a Japanese type Government-Industry Council; however, there is no need for an adversarial relationship to exist between the U.S. Government and industry.

The U.S. Agriculture Department is an outstanding example of what can be accomplished when Government develops a positive approach. The results have been truly remarkable and production of food in the United States has become the envy of the rest of the world.

A climate exists, however, in most regulatory agencies that discourages innovation in that the Federal employees know they have a negative role, are not encouraged to develop positive programs, and as a result feel that they are prevented from advising or helping industry. If progress is to be made in the United States to provide improved products and services to Americans and to meet our commitments worldwide, the attitude must be reversed. To this end, the U.S. Congress and the President of the United States should make it unmistakably clear that it is the patriotic duty of all Federal employees to develop positive approaches to encourage innovation in Government, academia, and industry so that safe and effective goods and services can be available without unnecessary added costs. Department Secretaries should be required to make an annual report to Congress and the President indicating the positive action programs initiated on innovation and justification for any negative action (rules, regulations, requirements) that they think are absolutely necessary.

Tremendous progress was made in innovation in the pharmaceutical industry in the 1950's and early 1960's. Patients derived many benefits and the problems encountered were minimal in a relatively unfettered environment. In recent years, improvements have been made in technology, but regulatory restraints have decreased productivity. This has decreased benefits with little or no decrease in risks. We must be prepared to accept reasonable risks in order to develop new drugs—otherwise people are destined to live forever with the diseases that afflict mankind today. It is both inconceivable and uneconomical to accept this premise, especially since the proper regulatory climate and adequate incentives within the free enterprise system will allow us to achieve our goals.

MEDICAL DEVICES

A recent study, "Government Involvement in the Innovation Process" by the Office of Technology Assessment, says: "Of particular concern is the fact that regulation may hurt the competitive position of small firms." The medical devices portion of the health industries is very much dependent upon small firms for innovation. The annual Department of Commerce publication "U.S. Industrial Outlook for 1978" describes the devices market as having more than one-half of its sales coming from eight companies. However, 32 percent of the 1,900 establishments in the industry have less than 20 employees. The Health Industries Manufacturers Association reports that 60 percent of its 267 members have less than $5 million per year in sales. This agrees with another estimate of $8 billion in sales for the industry, with about 2,000 companies to give average sales of $4 million per year.

In addition to the small company aspect of the field, the markets are made up of many product lines of small annual sales. In a recent hearing by the FDA on the proposed Investigational Device Exemptions (IDE's), the Orthopedic Surgical Manufacturers Association (OSMA) described the devices industry as having about 2,000 different companies producing thousands of devices. It is estimated that these companies might produce 2,000 new or modified devices per year for experimental purposes. If the estimate for $8 billion per year for the devices industry is accepted, and a conservative estimate of 5,000 individual product markets is assumed, the average market would be $1.6 million per year. In actual practice, the markets vary from $5,000 per year up to tens of millions of dollars per year. Thus, the effect of regulations on this industry must be measured in terms of its impact on small companies and small markets.

In the past the devices industry has been characterized by its ability to capitalize on these small volume markets with quick development times and quick product revision to meet clinical needs. Small companies could respond to the needs of the medical world for customized products, for products modified for specific prosthetic and diagnostic situations, and for products that could only be developed by "cut and try" development procedures, i.e., modify, test, modify, test until a device could be made that answered the need. With the passage of the Medical Devices Amendment in May 1976, and the regulations that are just now being drafted by the FDA, this type of development company faces an uncertain future.

Our suggestions for maintaining this innovative capacity of the medical devices area are outlined below under the categories described above in the preamble to this section.

PROTECTION OF KNOW-HOW

Medical devices are heavily protected by the manufacturer, by a large degree of secrecy about compositions, and by in-house expertise and know-how. Thus, they are particularly subject to the problems of disclosure of information brought about by disclosure processes of the Freedom of Information Act and the various aspects of the "sunshine" principle. The FDA regulations on confidentiality of information received during the approval processes are given in 21 CFR 314.14. These rules allow qualitative data, including analytical methods, and all correspondence between an applicant and the FDA to be disclosed after approval of the drug or device. It does not allow quantitative data to be given on manufacturing processes, formulas, or sales and distribution. However, qualitative data plus good analytical techniques on the part of a potential or actual competitor may be all that is needed for a competitor to copy a product.

pharmaceutical industry in the 1950's and early 1960's

RECOMMENDATION

The FDA should establish a procedure to reduce the time that an application for approval or an application for clinical investigation will be in the FDA approval mechanism. A reduction in time or a limit in time reduces uncertainty. FDA has set limits of 180 days in one case and 90 days in another for a limit on time for the agency to act. However, both limits can be extended an equal length of time by FDA writing a letter requesting more information. There is no limit to the total number of times that this may be done. In small companies with small markets, such uncertainty in time to obtain approval can totally inhibit innovation.

While no specific recommendation has been developed, we believe a joint approach by FDA and industry might find more satisfactory methods to reduce the cost of development, represented by delays in approval.

IMPACT OF REGULATION ON MEDICAL DEVICE INNOVATION

INTRODUCTION

In recent years there has been a legitimate concern over the rate of innovation in the United States. This concern is raised because innovation affects many aspects of our economic system including growth in productivity, the rate of inflation, and our position in world markets.[1] It is now becoming clear that much of the deterioration in the relative rate of innovation in the United States is directly attributable to regulatory intervention in the activities of firms and individuals engaged in innovative efforts. It is the purpose of this discussion to highlight some of the impacts of a recent increase in regulation on innovation in the medical devices industry. Because the regulation of the device industry is relatively recent it is not possible to directly observe the impact of regulation on innovation. However, as discussed below, there is good reason to use the pharmaceutical industry as an analogy for assessing the impact of medical device regulation. This analogy can then be used to predict the effect of regulation of medical device innovation.

RELATIONSHIP BETWEEN DRUG REGULATION AND DEVICE REGULATION

In 1976 the Medical Device Amendments were added to the Federal Food, Drug and Cosmetic Act. These amendments substantially increased the regulatory controls over medical devices. These controls affect the researching, developing, and marketing of medical devices. The amendments specifically mandated that the Food and Drug Administration is responsible for assuring the safety and efficacy of medical devices. As such the FDA is charged with establishing regulatory procedures to implement this mandate.

In 1962 the Drug Amendments were added to the Federal Food, Drug and Cosmetic Act, and, as with the recent device amendments, the FDA was given the mandate to assure the safety and efficacy of the Nation's drug supply. Since 1962 there have been several economic studies that document the negative impact that regulation has had on drug innovation. There are two main reasons to believe that the 1962 Drug Amendments and the subsequent economic impact assessments of the amendments will serve as a guide to assessing the impact of the 1976 Medical Device Amendments. The first reason is that it appears that for legislative intent purposes, and for establishing FDA procedures, the 1962 Drug Amendments served as a model for the device amendments. Secondly, because the FDA is charged with the responsibility in both areas it is not unreasonable to believe that there will be similarities in both form and effect of regulation. Based on these conditions this discussion will use the 1962 Drug Amendments and their impact on innovation to indicate the impact of regulation on innovation in the medical device industry.

IMPACT OF REGULATION ON PHARMACEUTICAL INNOVATION

The formal studies that have addressed the impact of the regulation embodied in the 1962 Drug Amendments have determined that the impact has occurred in several ways. First of all the increased regulation has shown up as a decline in the absolute amount of innovation taking place in the industry. For the years 1950-61 the annual rate of new drug entities introduced was 56. Since the increase in regulation in 1962 the annual rate has declined to about 17.[2]

The second area that has revealed the impact of regulation on innovation is the productivity of R. & D. There is evidence that the 1962 Drug Amendments caused a significant reduction in R. & D. productivity: i.e., a reduction in the ratio of R. & D. output to R. & D. inputs.[3]

The 1962 Drug Amendments also caused a significant increase in the cost of drug innovation. Although the cost estimates are not completely comparable it is possible to get an order of magnitude assessment of this cost increase from the following studies. Schwartzman has estimated that the average dollar cost of researching and developing a new drug entity in 1960 was around $1.3 million.[4] Hansen has

[1] Edwin Mansfield, "Some Recent Economic Studies Bearing on Public Policy Toward Civilian Technology," (Speech presented to Seminar on the Economics of the Pharmaceutical Industry, Rutgers—The State University of New Jersey, October 12–14, 1978).

[2] H. G. Grabowski, *Drug Regulation and Innovation* (Washington, D.C.: American Enterprise Institute, 1976), p. 18.

[3] D. L. Cocks, "The Impact of the 1962 Drug Amendments on R. & D. Productivity," (unpublished Ph. D. dissertation, Oklahoma State University, 1973).

[4] D. Schartzman, *The Expected Return from Pharmaceutical Research* (Washington, D.C.: American Enterprise Institute, 1975), p. 42.

reason to use the pharmaceutical industry as an anal

of firms with a high degree of technological capability. This precludes any one firm or a small number of firms from dominating the innovative activity of the industry. Thus, the pharmaceutical industry had achieved—structure prior to the significant increase in regulation that naturally assured a high degree of innovative competition. This structure was such that firms were large enough to be able to spread a greater amount of risk over a larger portfolio of R. & D. projects.

This can be contrasted with the medical device industry which has not had the opportunity to reach a significant level of technological maturity. Thus, instead of firms being able to achieve a natural size that includes the normal efficiencies of this size, as well as the efficiencies needed to meet the increased regulation, the medical device firms can only achieve these efficiencies through mergers. There is evidence that this is already occurring.[11] An implication of this is that the plurality and diversity that is often a very important aspect in generating innovation will be diminished.

The final impact of device regulation in the United States will be the comparative disadvantage that the industry will have relative to foreign competitors. This will be especially so relative to Japan which has developed a substantial technological base especially in the area of electronics which forms an important part of medical device innovations.

CONCLUSION

Based on the similarity of the regulatory process for both pharmaceutical and medical devices, and since we have a documented history of the impact of regulation on drug innovation, it is very likely that there will be a significant retardation in innovation in the medical device industry. This is not to suggest that there will not be individual firms who will be successful innovators, but it is clear there will be fewer innovations because of the increase in regulation.

[11] L. A. Couvillion, Jr., "Current Status of Medical Device Regulation," *ADL Impact Services* (December 30, 1977) p. 16.

GENERAL COMMENTS ON THE RELATIONSHIP OF HEALTH AND SAFETY REGULATION TO INNOVATION IN ANIMAL HEALTH AND NUTRITION

The critical and substantial contribution of applied science to the increased productivity of animal husbandry is not serious disputed. As Boyd [1]* has pointed out, the intensive production techniques now employed, including feeding large numbers of animals in confinement, would not even have been possible, or at least economical, without the achievements in animal health science. Indeed, Boyd additionally observed, if the various feed additives and veterinary medicines now widely accepted were not cost-effective, competitive cost pressures on the producers would have eliminated their use quickly and inexorably.

Principal responsibility for safety and efficacy regulation of animal health (AH) products is vested in the Food and Drug Administration (FDA). Basic authority for this regulation was granted in Public Law 90–399, enacted in July, 1968. Very important application detail was provided in implementing regulations promulgated on May 15, 1970 and amended periodically since.

The regulation of AH products is often, and largely rightly, compared to the regulation of human drugs. As Boyd [1] and McKinley [2] have described, the approval process for New Animal Drug Applications (NADA's) has paralleled the growth in complexity and expense, and prolongation in time, widely identified in human New Drug Applications (NDA's). Some observers even contend (Mongiardo [3], for example) that animal drug approvals are even *more* burdensome than human drug approvals, in that many more regulatory decisions in the former system require the intervention of the Office of the General Counsel of FDA.

The apparent view of the Bureau of Veterinary Medicine professionals, as voiced by Kingma, [4] is that Public Law 90–399 and subsequent implementing regulations simply consolidated what had previously been fragmented administration of various products under different sections of the Food, Drug, and Cosmetic Act—biologics, antibiotics, foods, etc.—and did not necessarily enlarge the scope or depth of such regulation. Few in the private sector can be found to agree with this view.

A painfully missing element in the current AH regulatory environment is the mechanism for making truly reasonable judgments of cost and benefit. McKinley [2] cites this as the industry's most pressing regulatory problem. The bureaucratic "incentive" system seems almost to guarantee excessive caution and inaction, providing, as it does, for more extreme penalties for approval of a product that later "fails" than rewards for approving a product that "succeeds."

Although examples abound (and in more agencies than the FDA), the current debate over the use of antibiotics as feed premixes is often cited in this context. [5] The scientific assurance projected by agency spokesmen in pressing for the prohibition of such antibiotic use on the dubious strength of highly controversial research findings contrasts poorly with the documented nonuniformity of European regulation on this same question. [6] In other words, if the "science" is as compelling as FDA spokesmen contend, why is there no consistent regulatory behavior in other advanced countries? We need a less idiosyncratic method to evaluate cost and benefit.

The Delaney Clause applies to AH products to the extent that compounds classified as subject to the Delaney Clause may only be used if their residues are not detectable in food products. But in an era when FDA personnel report techniques [7] capable of detecting antibiotic residues in concentrations of frac-

*See "Bibliography" for references.

FACILITATING INNOVATION IN THE PHARMACEUTICAL INDUSTRY

INTRODUCTION

The research-based pharmaceutical industry makes a major contribution to health research in the United States. In 1977 the industry spent some $1.2 billion on human medicinal research. A total of 24,000 industry scientists and support staff are involved in this effort and the research and development budgets of a number of companies now exceed $100 million annually.

Drugs have become medicine's most important and most cost-effective technology. With our biomedical knowledge accumulating rapidly, the prospects for discovering and developing effective new medications have never looked better. Yet, over the past 15 years, the rate at which new drugs have been developed and approved in this country has declined significantly. A decade and a half ago new chemical entities were introduced at a rate of 42-a-year on average; today the rate is 16, a decrease of 62 percent. Furthermore, studies by Dr. William Wardell of the University of Rochester School of Medicine and other experts have clearly demonstrated that the U.S. is lagging significantly behind Great Britain and other advanced countries in the introduction of new drugs. [1]

Equally disturbing is the trend in U.S. research expenditures. In 1962, the average R. & D. cost per new chemical entity approved was estimated to be about $4 million, today it averages $50 million. Moreover, it now takes 7 to 10 years to bring a new drug to market as contrasted with about 2 years only 15 years ago.

There is a broad consensus in the United States today that regulatory impediments and restrictions have seriously hampered progress in new drug innovation. For example, HEW Secretary Califano has spoken of the need for "cutting out the incredible underbrush of regulation and the hesitation and difficulty in getting a safe drug out to the American people more promptly." [2] J. Richard Crout, Director of the FDA's Bureau of Drugs, has pointed out that "the drug industry is unique among American industries in having both its marketed products and its research on new products under Federal regulation." He concludes that "it is inevitable that such regulation will have an important impact on product innovation and on the economics of the drug industry, although such impact is not the primary intent of the regulatory system." [3]

In a recent paper, Dr. Henry Grabowski, Professor of Economics at Duke University, notes that the notion of a "drug lag" advanced by Wardell and others has been vigorously disputed by some top FDA officials. However, Grabowski reports in the paper that his latest analyses reconfirm that the United States is lagging behind both the United Kingdom and West Germany in new drug introductions; that the lag with Europe includes (on the basis of FDA's own rankings) drugs considered to be significant therapeutic advances; and that regulation has been a major factor contributing to this lag with European countries. [4]

HOW FEDERAL POLICIES AFFECT INNOVATION

The effects of overregulation of pharmaceutical research and innovation are numerous and profound. Escalating regulatory constraints have meant (1) delays for patients and doctors in availability of new drug products (which has tended to force the utilization of more expensive modes of patient care), (2) a profound stifling of the core innovation process, the process of new drug discovery, (3) a shift in research resources from discovery to development, (4) diminished return for industry on R. & D. investment, and (5) movement of American R. & D. to other countries.

Writing in a recent issue of *Modern Medicine,* Dr. Michael Halberstam—a practicing cardiologist in Washington, D.C.—discussed seven specific cardiac drugs not currently available to American physicians even though some are widely used abroad. "The striking thing about the unavailable drugs on this list," wrote Dr. Halberstam, "is the fact that, as presented by experts, they are important drugs, *crucial* drugs, drugs for which we have few, if any, counterparts." He concluded that the list "stands as an indictment of the past policies of the FDA and, possibly, of current policies." [5]

Aside from the human costs to patients in terms of therapy delayed or denied, excessive regulation also has had substantial economic costs. Consider, for example, the recent controversy about the alleged overuse of coronary by-pass surgery for angina pectoris—at an average cost of more than $12,000 per procedure. Some of the surgery could have surely been avoided had modern antianginal drugs been available in the United States as an alternative.

Unrestrained growth in the number and complexity of U.S. drug regulatory requirements has substantially increased the costs associated with research while providing little or no additional protection to patients. "The greatest problem in the regulatory process," says Dr. F. Gilbert McMahon of Tulane University School of Medicine and President of the American Society for Clinical Pharmacology and Therapeutics, "is excessive demands by FDA for more data on efficacy at a time when there is no reasonable doubt that a drug is in fact effective." [6] In addition to the delays caused, and the costs imposed, by the quantitative expansion in regulatory requirements, the increasingly broad regulatory overview of research adopted by the FDA, which extends now to even the earliest stages of the research process, has created difficult problems. At this stage, information is limited, judgments are difficult to make, and delay and wasted effort are extremely disruptive to the momentum of the research process.

In an attempt to streamline and expedite the process, a bill (the Drug Regulation Reform Act of 1978) has been introduced in the Congress that would fundamentally restructure drug regulation in the United States. However, congressional testimony and public discussion regarding the new bill reflect deep concern that it would further encumber and discourage innova-

government regulation and eliminating needless regulation.

Far from being a major contributor to spiraling health care costs, the pharmaceutical industry is in fact an essential factor in control of those costs for two reasons. First, drugs are generally less expensive than other modes of therapy and, secondly, prescription drug prices in this country have risen far less than any other major element of health care. According to the U.S. Bureau of Labor Statistics, prescription drug prices increased by only 22 percent from 1967 to 1977. During the same period, hospital fees rose by 200 percent, doctors fees by 106 percent, food prices by 92 percent, and the overall cost of living increased by 82 percent.

RECOMMENDATION NO. 3

A Presidential Commission, comprised of patient and medical practitioner representatives, should be formed to review HEW's "Annual Drug Innovation Report" and "Research Impact Statements" and to report to the President annually on their findings.

The segments of the public most directly affected by FDA decisions are patients and physicians. However, their views have often been underrepresented in the public discussion of issues regarding pharmaceutical research and innovation. Patients—represented perhaps by the various voluntary organizations dedicated to improving treatment and care for major diseases—have first-hand knowledge of the need for therapeutic progress. Similarly, practicing physicians understand perhaps better than anyone the impact the nonavailability of new therapeutic agents has on treating individual patients.

Patients and doctors are the most obvious voices to speak to the effects of FDA regulatory decisions. The President should weigh their opinions and recommendations in determining whether the American public is being well served by FDA's decisions.

RECOMMENDATION NO. 4

To help deregulate the early phases of clinical research, responsibility for monitoring early studies should be shifted to the research review committee of the medical institutions where clinical pharmacology is practiced.

Overly formal and complex regulation in the early stage of clinical investigation wastes time, money, and scientific resources. Since it is frequently necessary to bring forward a number of prototypes before a developable drug is found, overly cumbersome regulation at this initial stage has powerful negative feedback effects, and can substantially impede the entire discovery process. Moreover, intensive regulatory overview of this stage serves little purpose; FDA's own data establish that these early clinical studies are exceptionally safe. Yet FDA, in making decisions whether to let clinical testing proceed, pays insufficient heed to the negative impact regulation has on the early phase of the innovation process.

Obviously it is appropriate and desirable to have regulatory safeguards for the first tests of a new drug entity in human subjects. However, we believe that unnecessary regulatory delays in the early stages of clinical research could be avoided if the primary responsibility for regulation of the early phases of clinical research were shifted by the FDA to the research review committee at major medical institutions where clinical pharmacology is largely practiced today. Under this approach FDA would retain oversight authority, but relying on these committees would greatly simplify the early stages of the research process while ensuring the scientific merit of the studies and protection of research subjects.

RECOMMENDATION NO. 5

A new drug approval standard should be adopted that mandates consideration of data other than "adequate and well-controlled studies," thereby formally accepting the fact that decisions regarding safey and efficacy of a new drug are ultimately risk/benefit judgments.

Among the principal impediments to drug innovation in the United States is the standard the FDA uses in deciding whether to approve a new drug, and that drug applicants perforce use in planning and conducting research. The 1962 Amendments to the drug law instituted the requirement that an applicant for approval must present "substantial evidence" of a drug's effectiveness, such evidence to consist of "adequate and well-controlled investigations."

The definition of what constitutes "adequate and well controlled" is of course open to scientific, medical, and regulatory interpretation. Over the years since 1962 this standard has been defined and redefined in regulation and actual regulatory practice. In the process it has become tortuously arcane—a standard that well serves the curiosity of scientists but ill serves the real purpose of delivering valuable new drugs to doctors and patients.

It is difficult to reconcile the ever-increasing stringency of regulatory criteria with the simple intent of Congress, as expressed in the 1962 Amendments, that drugs should be shown to be effective. For the simple question: Does the drug work? the regulators have substituted the very different question of whether the drug research measures up to some elegant experimental methodology that the FDA chooses to favor.

A dramatic illustration of this phenomenon is the recent controversy over approval of the antiepileptic drug, sodium valproate. According to an account in the *Washington Post,* the regulator believed the law required him to disapprove this drug simply because there was but one, not two, "adequate and well-controlled" U.S. studies—even though massive European data supported the drug's safety and efficacy (the drug had been used for 10 years in Europe on about 200,000 patients with marked success) and even though he himself considered it to be safe and effective. After a panel of experts assembled by the Epilepsy Foundation of America told the FDA that "further delays . . . would constitute callous negligence," the drug was approved for marketing in the United States.

is conceivable that a large share of industry research expenditures in the future will be spent verifying what in fact is already known and widely accepted by clinical researchers.

RECOMMENDATION NO. 10

New procedures should be adopted that mandate a drug approval or nonapproval decision within prescribed and reasonable statutory deadlines.

The current new drug approval deadline within the FDA is 180 days. This deadline is rarely, if ever, met. Thus, Senator Kennedy in a July 18, 1978 markup session for the 1978 Drug Regulation Reform Act stated, "FDA never meets the 180 days at the present time . . ." [9] The Drug Reform Bill establishes a new and complicated procedure which increases the statutory review period to 360 days—twice as long as specified in the present law.

The drafters of the legislation have indicated that lengthening the time period will somehow expedite FDA review and approval. In light of past experience, however, it would take the strongest kind of faith to believe that this would be the result. Even a call for a show of hands during hearings on the proposed new law at FDA showed overwhelmingly that the Agency's employees believe such a recommendation would serve only to further lengthen the approval time. [10]

We believe that the FDA should be required to make its decisions (and not just defer them, through one expedient or another) within the presently prescribed statutory deadline of 6 months.

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Twenty-eight companies responded and of the 28, usable data were obtained from 24 (63 percent).

Ten companies indicated their R. & D. budgets were increased from 1970 to 1974; 13 indicated decreases; and one indicated its spending stayed the same. The increases averaged 5.7 percent with a range of from 2.0 percent to 6.0 percent. Decreases were greater and averaged 13.5 percent with a range of from 2.6 percent to 40 percent.

"Nonproductive Technical Activity" was defined in this survey questionnaire as including government activity (e.g., nutritional labeling, additives, microbiology, contaminants, complying with EPA, OSHA, FTC, and others). The survey shows that research expenditures have been decreased 15 percent in the innovative areas and increased 40 percent in the nonproductive areas.

Food Processing Magazine conducted an R. & D. survey of the 100 largest food companies (all with sales in excess of $200 million) in the United States in 1977. [2] Seventy-one percent of the respondents reported R. & D. budget increases of 6 percent or more. Fifty-three percent stated they are devoting more time to regulatory activities. Eighty-three percent felt research is shifting toward more short term, less risky projects. The Government was cited as being primarily responsible for this shift.

II. Effect of Rigid Standards (i.e., Standards That Specify Process, Raw Materials, Dimensions, etc.) on Innovation

There are a large number of older food standards (mostly written decades ago) still existing today that forestall innovation, since the mechanisms to cause a change in the standards are often so cumbersome and chancy that most food companies avoid research in these areas. These standards should be written to be open ended. An additional deterrent is the fact that if a new process or new technology is involved, it must be published before it can be practiced and, thus, competitors can be in the market at the same time as the innovator. Some examples are:

(a) Cheddar Cheese [3].—With the current emphasis on nutrition (obesity, cholesterol, etc.), a low fat cheddar cheese would probably find a ready market, however, it is impossible to sell a product of this type under the current standards. Because of the current standard, a low fat cheddar cheese would have to be labeled "imitation cheddar cheese" which has a bad connotation with consumers. Further, many State regulations would prohibit the marketing of this product.

(b) Macaroni and Noodle Products [4]—This standard specifies all ingredients that may be used, as well as specific dimensions of some products. Any deviations from this standard would require a change in the standards—usually a lengthy and costly procedure, especially if challenged. In many cases, new consumer needs cannot be met with products produced under the standards, thus preventing the introduction of these new products. Products that deviate even slightly would have to be labeled "imitation."

(c) Rigid Meat Percentages in USDA Standards [5].—A typical example is beef stew. It must be made with at least 25 percent meat. This forestalls the production of a less expensive, but still nutritious product that could be economically beneficial to the consumer.

There are many other examples in the regulations. We feel the standards should be more open ended to allow innovation. Any differences from the original standardized product could be communicated to the consumer by appropriate descriptive labeling.

III. Nutritional Labeling

Voluntary nutritional labeling regulations have been in existence for some period of time. However, once a manufacturer decides to use nutritional labeling to aid the consumer, he brings the regulation to bear upon himself and opens himself to potential government actions. Many manufacturers cannot afford the resources necessary for compliance and, therefore, do not enter the program. Those that do are faced with high costs of compliance and diversion of resources from innovation. The cost of the numerous analyses, in order not to be in violation of the regulation, is very high. The Grocery Manufacturers of America studied the initial and maintenance costs for nutrient labeling. [6] The initial costs for a small firm were about $18,000 and about $2.5 million for a company with sales above $1 billion. Maintenance programs averaged $4,000 for small firms to $275,000 for large firms. Added to these costs is the fact that new labels cost between $5,000 to $15,000 each for printing plates, depending on the magnitude of the changes necessary. [7, 8]

These costs, which must be passed onto the consumer, could be essentially eliminated if the FDA would accept the data from USDA Handbook No. 8, "Composition of Foods." [9] The food processors who nutritionally label products know from experience that Handbook No. 8 data is remarkably accurate. A program to use this data base, we believe, would be in the best interests of the consumer, the Government, and the industry. Some distinct benefits are that it would allow the small producers to nutritionally label their products which they currently cannot afford to do, and would release scarce resources (i.e., nutritionists, analysts, etc.) for more innovative effort.

IV. Zero Tolerance

Increased sensitivity of analytical instruments to detect materials as low as one part per trillion has caused regulations based on nondetectable levels to have meaning beyond a reasonable intent. In fact, the FDA has taken the position with acrylonitrile bottles that if, in *theory,* any acrylonitrile can migrate from a package into a food product, then it must be banned. This ruling will drastically inhibit innovation in new packaging materials, since it is an impossible condition to meet and is further contrary to good science. This decision, in addition to stifling innovation, eliminated 1,000 jobs and caused a writeoff of $20 million of equipment and facilities. [10] If this interpretation of the law is extended to other packaging ma-

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[11] "Kennedy Plans October Release of FDA-Industry Relationship Policy," *Food Chemical News,* June 19, 1978, pp. 28, 29.
[12] *"United States* vs. *John R. Park,"* Citation Number 421 US658, 1975.
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BIBLIOGRAPHY FOR HEALTH SECTION REPORT

The following pages list an annotated bibliography of literature which substantiates and enlarges upon the points made in the Health Section Report. The articles themselves have not been included here in the interest of saving space. However, copies of any one or all of these articles are available upon request from the Department of Commerce.

SELECTED ITEMS DEALING WITH THE REGULATION OF SCIENTIFIC RESEARCH

1. The Drug Lag: Good or Bad? John P. Morgan, M.D. Concise explanation of why a lag exists, some of the drug categories affected by the lag and recommendations for improving the situation.
2. The Development and Regulation of New Medications, Dr. Louis Lasagna. A rational and flexible approach to drug regulation could ease some of the most worrisome regulatory demands leading to delays in the availability of new drugs. Changes in the national drug regulatory policy and in the performance of the FDA will serve society better than drastic legislative mandates intended either to emasculate the FDA or to grant the agency broad new powers.
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4. Reform in Drug Regulation Overdue, G. Frederick Roll, Connecticut Medicine, January, 1977. Summary of some of the problems that exist in the present drug approval methodology. Makes recommendations based on premise that new drug development is dependent upon an independent, productive research enterprise.
5. Technological Innovation and National Priorities, Dr. N. Bruce Hannay, Vice President for Research and Patents, Bell Laboratories. This article is based on testimony presented at joint hearings of the Senate Subcommittee on Science and Technology and Space and the House Subcommittee on Science, Research and Technology—February 14, 1978. Dr. Hannay discusses how Federal regulation produces less of a willingness to gamble (on new R. & D.) because of the uncertainty of the regulatory climate.
6. A Close Inspection of the "Calm Look," William M. Wardell, MD, Ph.D. Dr. Wardell's rebuttal to Commissioner Kennedy's *Journal of the American Medical Association* article, "A Calm Look at the Drug Lag."
7. Alternative Goals for Public Policy, chapter 15 from *Innovation in the Pharmaceutical Industry.* Professor David Schwartzman demonstrates that current public policy threatens to hinder pharmaceutical R. & D. by:
   (i) diverting limited scientific manpower to academic and other laboratories; (ii) that maximum allowable cost (MAC) regulations will discourage new industrial research and development by reducing the expected rate of return from this type of investment.
8. New Drug Regulation and Its Impact on Innovation, J. Richard Crout. Chapter six from Impact of Public Policy on Drug Innovation and Pricing; Proceedings of the Third Seminar on Pharmaceutical Public Policy Issues. Dr. Crout points out that the drug industry is unique among U.S. industries in that both its marketed products and its research on new products are under federal regulation. He explains the current drug regulatory system and suggested improvement in both law and policy.
9. Socially Optimal Results from Drug Research, Barry M. Bloom. Chapter 10, *ibid.* Points out that although present day results of drug research are not socially optimal, resource allocation decisions made by the research sponsor have little to do with free choice. Instead, social attitudes and government regulatory policies are now the overriding determinants of what kind of new drugs are likely to become available in the future.
10. Protection or Overprotection in Drug Regulation? The Politics of Policy Analysis, David Seidman. Lengthening development times, rising costs and other factors related to regulatory requirements of the Food and Drug Administration are critically influencing R. & D. strategy for the near and distant future.
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16. The New Drug Bill, Edmund W. Kitch.

ENVIRONMENTAL SECTION REPORT

EXECUTIVE SUMMARY

The attached report of the Environmental Panel traces the principal effects of environmental regulatory policy on the industrial sector of the U.S. economy and relates these effects to the functioning of the innovative process. The principal conclusions are shown below, followed by a list of policy options recommended for further study.