

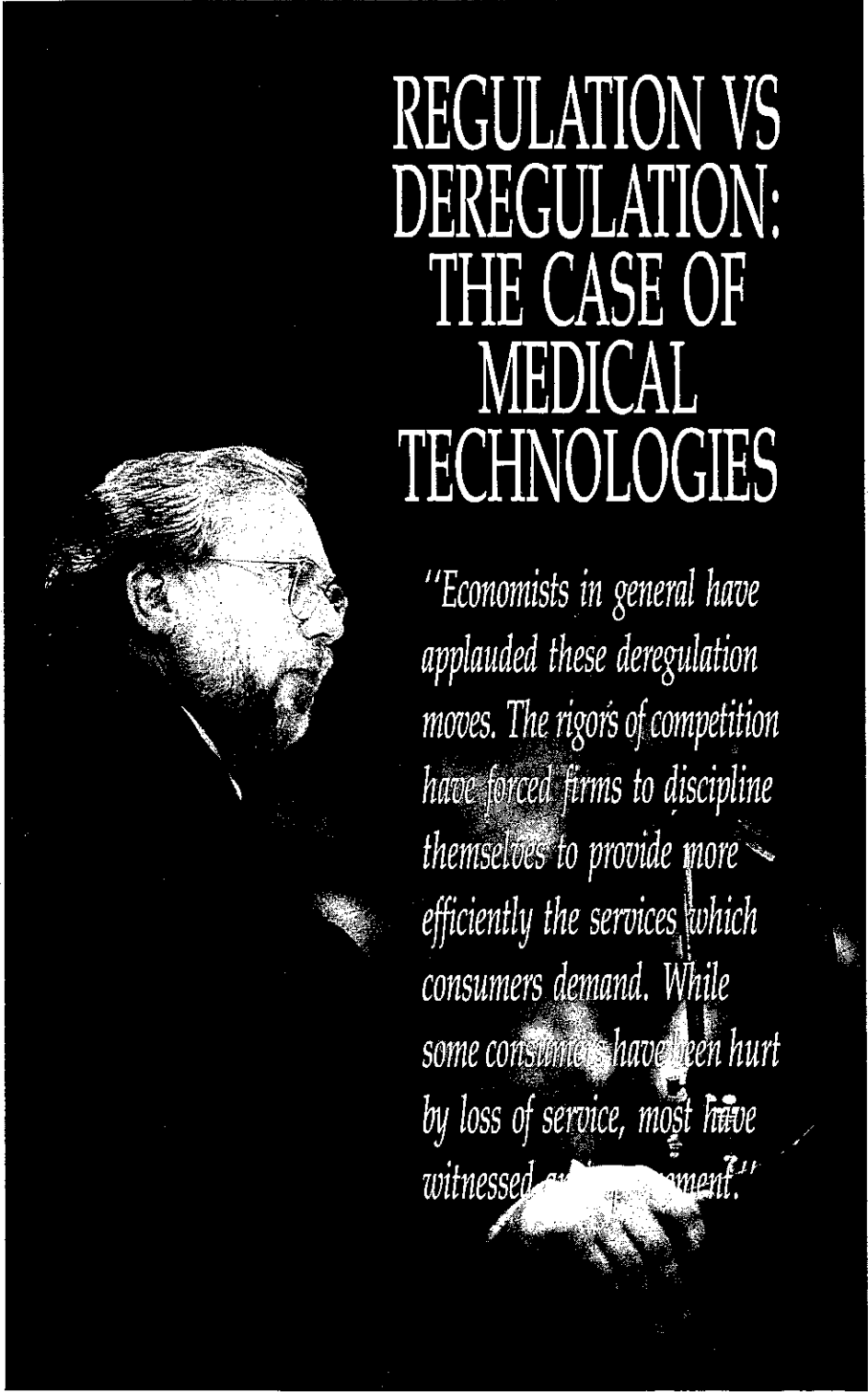
ECONOMIC DIRECTIONS

A Publication of Saint Vincent College's Alex G. McKenna Economic Education Series

Saint Vincent College, Center for Economic Policy Education, Latrobe, Pennsylvania

Volume 2 Number 2 February 1992

REGULATION VS DEREGULATION: THE CASE OF MEDICAL TECHNOLOGIES



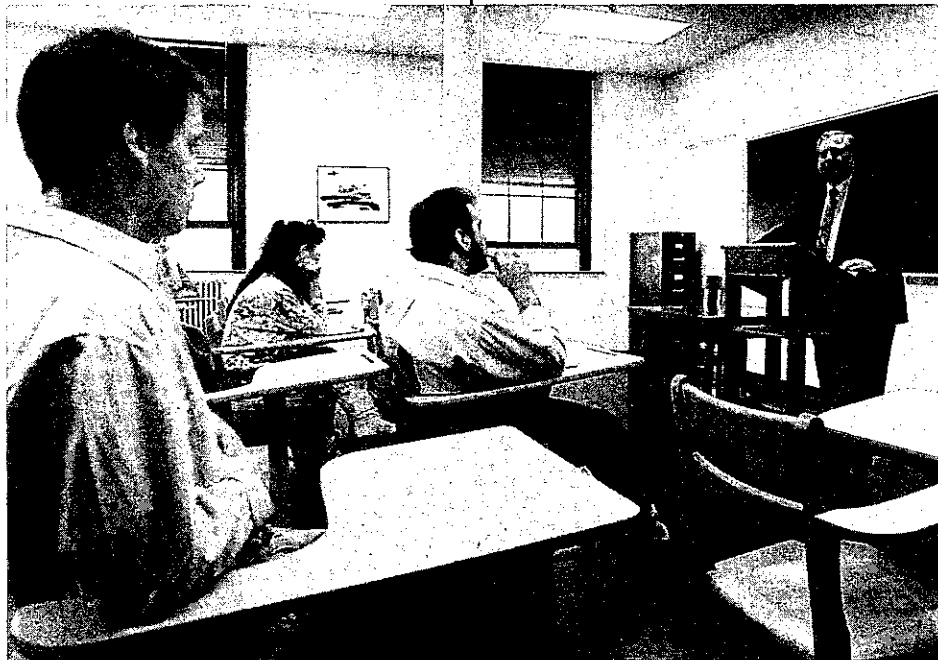
"Economists in general have applauded these deregulation moves. The rigors of competition have forced firms to discipline themselves to provide more efficiently the services which consumers demand. While some consumers have been hurt by loss of service, most have witnessed improvement."

(The following is a transcript of a lecture delivered by Dr. Ronald W. Hansen, Associate Dean for Academic Affairs at the William E. Simon Graduate School of Business Administration of the University of Rochester, at Saint Vincent College, Latrobe, Pennsylvania, on November 20, 1991. The lecture was the second presentation in the 1991-1992 Alex G. McKenna Economic Education Series of lectures on privatization, taxation, and government deregulation.)

© 1992

During the past 15 to 20 years there has been a lot written about the deregulation of the American economy. Major sectors of the American economy which have been subject to entry and price regulation have been systematically deregulated. For example, the transportation industry, including trucking, railroads, and airlines, had been one of the most heavily regulated industries. Firms were not free to expand their service areas, set their own prices or even abandon unprofitable routes. Many managers of transportation firms were frustrated by requirements which resulted in return trips absent cargo or the inability to seize on a profitable new route. But there also was a certain complacency generated by the regulated environment. His competitors, should the regulator allow any, had to play by the same rules. And there was an implicit understanding, if not a legal obligation, that the losses on unprofitable services would be offset by higher than normal profits on other sectors of the business. So passengers or freight shippers on high density routes or long hauls often subsidized users of the marginal routes through the regulated rate structure.

As deregulation progressed, the environment for firms in the transportation industry, as well as in telecommunications, has changed substantially. There is more freedom to set prices, enter new markets, or abandon unprofitable lines. But along with these new freedoms, firms face a new challenge -- competition. Competition may come from older firms exercising their new freedoms, or from young upstarts who see what they think are profit opportunities. The old order is gone and there is a new set of winners and losers. Customers and competitors, not regulators, determine the profitability of the firms. Some firms have



Dr. Hansen talks with some students about their career plans.

prospered immensely while established grand names have become footnotes in the history books. Many consumers find better and cheaper service while others have bid farewell to scheduled train and airline service.

Economists in general have applauded these deregulation moves. The rigors of competition have forced firms to discipline themselves to provide more efficiently the services which consumers demand. While some consumers have been hurt by loss of service, most have witnessed an improvement.

As an aside, I should note that banking remains an exception. There has been some deregulation of banks, though many strictures still apply.

And the federally controlled insurance funds did not adjust their rates or policies to reflect the changing environment. While some of the current problems of the banking industry were an inevitable result of having long-term assets and short-term liabilities at a time when interest rates were changing drastically, the removal of some regulations without adjustments in the deposit insurance policies undoubtedly played a role. Banks were free to acquire riskier assets without incurring any change in their deposit insurance coverage or rates. It is interesting to note that to solve the problem some individuals advocate removing more layers of regulation whereas others want to return to tighter regulations.

Whether they like the results or not, most individuals view the past two decades as a period of substantial deregulation of American industry. Contrary to this popular view, I would argue that this has not been a period of deregulation. Rather this has been a period in which the focus of regulation has changed. Those regulations that have been reduced or eliminated are those affecting price, quantity, and entry. In these industries, regulators controlled who could enter which segments of the market, the price that could be charged and the quantity and quality of service to be provided. Many of these barriers have been removed and indeed greater competition has resulted in significant changes in these markets.

In contrast, during the past two decades, there has been a growth in health, safety, and environmental regulation. The EPA was established in the early 1970s and OSHA was established in 1970. In addition to the rule-making done at these agencies, Congress has passed a variety of related legislation. State and local governments have joined in with their own regulations. The authority granted to the Food and Drug Administration in the

1962 amendments to the Food, Drug, and Cosmetics Act has been used subsequently to significantly increase the requirements for new drug approval. In 1976, the FDA was granted authority to regulate medical devices. Recently the FDA, in cooperation with the Department of Agriculture, has announced new standards for labeling foods, particularly with respect to health claims. The list could go on and on.

Whether one views the growth in health, safety, and environmental regulation as a net good or bad, the point which I wish to emphasize here is that we have not been living in a period of deregulation. Rather we have experienced a shift in the nature of regulation of industry. We have shifted from regulation of markets to regulating products and workplaces. Whether it is causal or coincidental, the deregulation has occurred in those areas which are most easily analyzed by basic economics. Demand and supply functions are well suited for analyses of entry limitations or price regulations. The growth area in regulation presents greater analytical problems. Placing values on health and environment is much harder for economists and we have not been particularly successful in selling our measures to a wider audience.

It would be presumptuous to conclude that rigorous economic analyses published in scholarly journals led to the demise of many of the regulations governing price and entry

"It is the physician who must understand the safety and effectiveness of alternative treatments in order to convey the relevant information to the patient."

into industries. These articles, and the more popular press pieces based on this scholarly research, undoubtedly have had considerable impact in the demise of these regulations. Technology has also played a role. Satellites and other advances in telecommunications technology made it harder for AT&T to fend off potential competitors. The greater the substitutes for the regulated services, the harder it was to preserve the entry restrictions and prices.

At the same time, there was a growth in scientific studies relating diseases to environmental and workplace conditions. Many individuals dismissed rat and mouse studies which, when extrapolated, required humans to consume unbelievably high amounts of a substance to have the same concentrations as the rodents. As Edith Efron has so well



ECONOMIC DIRECTIONS

A Publication of Saint Vincent College's
Alex G. McKenna Economic Education Series.

CO-EDITORS

Dr. Gary M. Quinlivan
Associate Professor of Economics

Mr. Lee J. Weissert
Instructor in Economics

ASSISTANTS TO THE EDITORS

Mr. Robert C. Baldini, C '93
Mr. Christopher M. Berdnik, C '93

STAFF

Mr. Dennis J. Yanan, C '92
Mr. Michael J. Kozy, C '92
Ms. Linda Wirfel, C '92
Mr. Raymond M. Hrin, C '93
Ms. Jennifer J. DeHosse, C '93
Mr. James E. McBride, C '92



WELCOME — Greeting Dr. Hansen (center) to Saint Vincent College were Mr. Alex G. McKenna (left) of the Philip M. McKenna Foundation, Dr. Gary M. Quinlivan (right), director of the series.



GETTING DIRECTIONS — Dr. Hansen gets a copy of *Economic Directions* from Saint Vincent College students Linda Wirfel, C'92 (right) and Jennifer J. DeHosse, C'93 (left).

documented in her book *The Apocalyptics*, the studies concentrated on industrial carcinogens even though the same animal tests resulted in conclusions that many naturally occurring substances such as oxygen were carcinogenic. However, many of the suspect substances were basic to industrial processes and epidemiologic evidence supported the claims of carcinogenicity, leading to further concern about the safety of the workplace. Faced with a bewildering array of claims about potentially harmful effects of substances which were not immediately obvious to the average citizen, it is not surprising that there was a clamor for greater government regulation.

The growth in regulation of medical technologies is in part a testament to the success of medical researchers. The pharmaceutical cupboard consisted primarily of natural compounds prior to the development of the sulfa drugs in the 1930s and the post-war development of "wonder drugs." Drugs now treat many conditions which were previously untreatable or which required invasive surgical procedures. Genetic engineering and other products of the growing biotechnology industry will result in further additions to the impressive array of pharmaceutical treatments. Although pharmaceuticals are designed to provide beneficial therapies, they also have the potential for serious harm, particularly if used in unintended ways.

Medical devices which formerly consisted primarily of prostheses and relatively simple diagnostic equipment have been joined by implantable pacemakers, artificial hips and valves, lithotripters, lasers, and MRIs, to name but a few of the growing list. Surgical procedures, in part aided by new drugs and devices, now include transplantation, new cardiovascular techniques and laser surgery. Technological advances have moved many surgical procedures to an outpatient basis.

Most but not all new medical technologies are subject to regulation. All new pharmaceuticals must be approved by the FDA prior to marketing. Firms are required to conduct at their own expense extensive clinical trials to demonstrate a drug's safety and effectiveness. Based on its review of the data submitted by the firm, the FDA approves the product for specific uses and determines what claims the firm can make about the product. If the firm wishes to make other claims about the product it must conduct additional clinical trials and submit evidence for further review by the FDA. Firms must maintain records on and report any adverse drug reactions which occur after marketing a drug. In addition, a firm may be required to conduct specific post-marketing tests.

For medical devices, the procedure is somewhat different. The majority of devices are covered by class approvals and the firm need only comply with the established standards for the product. For devices which are invasive or life-supporting, clinical trial evidence must be supplied and pre-marketing approval obtained. Surgical procedures are basically unregulated except insofar as they involve a new drug or device. Surgical procedures are monitored by institutional review committees, peer groups, or insurance carriers.

The case for increased regulation of medical technologies lies in the difficulty for individuals to assess their safety and effectiveness coupled with the realization that mistakes can result in severe disability or death. In many situations one does not have the luxury of trying out several competing therapies to see which works best. It is important that consumers have reliable information before experiencing the medical technology.

The consumer's desire for reliable information need not result in increased regulation. However it can be argued that a completely

unregulated marketplace might open the door to opportunistic behavior on the part of unscrupulous individuals. Images jump to mind of snakeoil salesmen peddling dangerous medical technologies and preying on the dreams of the incurably ill. How large this problem would be, absent any regulation, is debatable but there are a variety of safeguards which we could expect.

In the absence of regulatory authorities, patients and physicians would still demand information about medical technologies. Would the private marketplace provide reliable information? One could imagine a variety of information intermediaries which would develop. First, one should recognize that almost all new medical technologies involve the use of a physician who acts as an informed intermediary for the patient. It is the physician who must understand the safety and effectiveness of alternative treatments in order to convey the relevant information to the patient. The physician in turn has a variety of information sources. In addition to the advertising by the suppliers of medical technologies, the physician has available a vast medical literature and seminars as well as information from peers. Some technologies may receive an endorsement or prohibition from specialty medical groups. But who would develop reliable information for the physician?

Medical technology suppliers would find it difficult to market their products unless they were able to convince physicians and patients that their claims were true. Company X claiming that their product is the best thing since sliced bread may garner a few buyers, but for substantial sales the claims would need to be backed up by some solid evidence. Certification of claims of safety and effectiveness could be accomplished through well established brand names. Even in the absence of other guarantees, a company with deep assets puts its reputation on line in backing its claims. Failure to live up to adver-

tised claims would result in either civil damages, loss of sales on other product lines, or more likely both. In a world where one's name is one's bond, it would pay to build and maintain an established name.

Absent regulation another phenomena which would emerge would be independent testing laboratories (The "Good House-keeping Seal for Medical Technologies"). These laboratories would be particularly important for smaller firms whose reputation or asset base is not sufficient to provide a significant quality guarantee. Liability laws may further eliminate marketing of unsafe products or temper exaggerated claims of effectiveness.

Given current trends in health and safety regulation, it is perhaps a flight of fancy to consider a completely unregulated marketplace. Even though Americans have long prided themselves on rugged individualism, there is a strong streak of demanding government protection from certain perceived ills. The demand for health and safety regulation is fed by the clamor for government protection. Thus rather than dwelling on a regulation versus no regulation environment, one should look at the pluses and minuses within a regulated medical technology sector.

The current pharmaceutical and medical device regulations extend beyond providing the marketplace with information on the product's safety and effectiveness. The FDA decides to either approve the marketing of a product for a specified set of indications and uses or to prohibit the marketing of the product. This involves the agency in making risk assessments for the whole population. It must decide whether in aggregate it is better to allow a technology to be marketed to any potential users or to be denied to all users. While technically it can approve products for specific uses, it also must recognize that once marketed, doctors are free to utilize the technology for whatever purposes they deem appropriate, subject to possible legal liability.

Risk assessments by the FDA are inevitable since the conditions for which most medical technologies are intended are themselves injurious to the patient. The patient may face pain, immobility, or death as a result of his illness, even when treated with existing therapies. The prospective new therapy may reduce these effects of the illness but at the cost of potential other side effects. One should look not only at the risk added by the new therapy but also at its effects on the other risks which the patient faces. Even though the technology may not be completely safe, and few are, it may reduce the overall risk faced by the patient. While we often talk about a technology as being "safe," we should focus on safe relative to the alternative. It would be a mistake to prohibit use of a technology which, while risky per se, reduces overall risk. Whether a medical technology is risk reducing or risk increasing may depend on the conditions surrounding its application. Yet unless we are able to minutely specify the conditions under which



GUESTS AT LECTURE — Dr. Hansen (right) greets Mr. Douglas Clark (left), executive director of Latrobe Area Hospital, and Rev. John F. Murtha, O.S.B. (center), president of Saint Vincent College.

a technology is to be applied, we may not be able to refer to the technology as being safe or harmful.

Risk assessment is further complicated by the fact that the conditions at risk are not one dimensional. The threats to one's health are often multidimensional. The pain and suffering caused by the disease may be quite different from the therapeutic effects or potential adverse effects of the technology. For example, the debilitating effects of arthritis may be reduced by a drug which causes periodic nausea and in some patients may lead to severe stomach ulcers. It is a matter of personal preference whether we view the nausea to be better or worse than the arthritic pain. The choice is complicated further when we add the possible development of severe stomach ulcers. Because we all differ with respect to our preferences and willingness to take risks, even if we were fully informed about all the potential consequences and their probabilities, we could honestly disagree about whether to accept the new technology. We should not be surprised to find fully informed patients selecting different therapies for the same condition. Since individuals may differ in their starting conditions, the range of differences in willingness to accept therapies is even greater.

If regulatory authorities were to make the marketable/nonmarketable decisions based on the preferences of the "average" patient, there would be technologies which would be prohibited even though there may be a substantial number of individuals who would prefer it. There would also be technologies which were approved which some individuals would not be willing to try. These individuals have the option of not using the new technology. However, the current system of prohibiting unapproved technologies has the inherent problem of denying access to technologies which some patients would consider to be useful.

Our regulatory system coupled with our own perceptions of risk make it more likely that products will be prohibited. As several critics have noted, there is little reward to the FDA from a speedy approval of a beneficial new technology. However should the agency approve a technology which later is shown to have significant adverse effects, we the public blame them and FDA officials find themselves in a hot seat on Capitol Hill.

The second guessing of FDA decisions is made more probable by our own perceptions of risk. Observed consequences overshadow the unobserved. A drug which reduces death from a disease from 30% to 20% but brings immediate death to 2% of the patients is likely to be perceived as very risky even though on net the death rate is reduced. However, the two patients in a hundred who die from the drug are easily identifiable, whereas it may not be possible to determine which 10 patients lived who would not have survived with the alternative therapy. There is a myopia that Aunt Sally would have lived anyway but anger that the drug killed Uncle Fred. It is hard for statistical

About the Series

The Alex G. McKenna Economic Education Series is presented by the Saint Vincent College Center for Economic Policy Education at Saint Vincent College. These periodic lectures are open to the general public and their purpose is to explore the role of free markets in solving many of the social problems confronting the United States and the world today. Dr. Gary M. Quinlivan, associate professor of economics at Saint Vincent, directs the series.

The Alex G. McKenna Economic Education Series is made possible by a grant from the Philip M. McKenna Foundation Inc. of Latrobe, Pennsylvania.



FULL HOUSE — A large crowd gathered in the Science Center Amphitheatre for Dr. Hansen's lecture.

superiority to overcome an identified loss. Since most of us have a tendency to let the identifiable overshadow the statistical, we should not be surprised that Congress does the same and that the FDA faces pressure to be extremely cautious in approving new medical technologies.

Another source of cost in the regulatory process is the time delays in approving new technologies. For many of the same reasons noted above, the FDA has an incentive to be cautious in its decision process. This is manifest not only in the ultimate decision but also the time required to obtain a decision. Delays may result in the accumulation of more data or a closer look at existing data which may change the decision. However delays in the approval effectively denies the therapy to some patients. If the proposed therapy represents a major improvement over existing therapies, the cost could be high. But this cost is largely hidden. Few of us are aware of what is in the FDA pipeline and what potential improvement we may forego. If Aunt Sally had died as a result of the new therapy not being available, it is unlikely that we would be able to link her death to the delays at the FDA in approving a drug which was unknown to us.

Traditionally the FDA has borne little cost to a cautious, go-slow approach. For example, one of the major revolutions in treating cardiovascular disease is a class of drugs referred to as beta blockers. These compounds were available in the United Kingdom for about ten years before the FDA approved one for the U.S. market. When the first beta blocker was approved, it was announced that the drug could prevent 10,000 deaths a year. But looked at another way, had the drug been approved ten years earlier, 100,000 deaths would have been prevented. Despite the enormous numbers of individuals who died earlier than they would have had the drug been available, there was little reaction from the public. *The Wall Street Journal* ran a very negative editorial, but the public did not storm the Park Lawn building. In fact, during the 10 years that the drug was available abroad, there was virtually no

public knowledge that this class of drugs existed. Even for such an important therapeutic advance, delays in approval created little stir. Imagine how much pressure is generated for lesser therapeutic advances. For the most part only the sponsoring firms and a few specialists are even aware of items in the pipeline.

Another difficulty in assessing medical technologies is the determination of what constitutes evidence of effectiveness. Some common measures such as a reduction in blood pressure or a lowering of the cholesterol levels may not signal an improvement in the patient's health. Even though considerable research has shown a linkage between high cholesterol and heart disease, there are some researchers who question whether lowering cholesterol levels in a patient will reduce his risk of heart disease. Should the developer of a new technology to reduce cholesterol be required to demonstrate not only the cholesterol-reducing properties of the therapy but also demonstrate that the reduction in cholesterol reduces heart disease? From a scientific point of view the latter is more appealing, but it would significantly lengthen the time and cost required to demonstrate effectiveness. At what point is it sufficient to rely on markers of health as opposed to long-term studies?

For pharmaceuticals the development times are very long and the costs high. In a study which I helped author under the auspices of the Center for the Study of Drug Development at Tufts University, we estimated that the time from first clinical trial to FDA approval was 98 months and a typical lead time prior to clinical trials was on the order of 4 years. If one factors in the cost of drug candidates which do not reach approval and recognize that the funds tied up in drug development could have been earning returns in other investments, we estimate the average pretax cost of developing a new pharmaceutical to be \$231 million in 1987 dollars. This is for a group of drugs first tested in humans by U.S. owned companies between 1970 and 1982. By comparison, in

an earlier study which I conducted using a similar methodology, the average cost for drugs first tested in humans between 1963 and 1975 was \$54 million in 1976 dollars or roughly \$100 million in 1987 dollars. The real costs have more than doubled during this period. Moreover we did some within-sample analysis for our recent study and noted a near doubling from the first part of our period to the second. We did not attempt to analyze this increase in terms of regulatory costs versus other sources of cost increase. We did note that the FDA review process itself is about 30 months and reducing this by one year would save nearly \$20 million in interest cost alone. These higher costs must get passed on to consumers or the level of drug research will have to decline.

Recently the pressures facing the FDA have changed, largely as a consequence of the AIDS crisis. The disease is severely debilitating, eventually fatal and has no known cure. In part because of its high incidence among homosexuals, there were readily identifiable and organized groups to lead a campaign for better treatments. The various AIDS groups have identified therapies in development and have organized pressure on the FDA for faster approval. I know of no other disease related groups that have been as effective at drawing public attention to the potential therapeutic benefits of drugs in the FDA pipeline. The AIDS related organizations have drawn attention to



the consequences of slow decision-making at the FDA, and have expressed a desire to have the FDA release experimental drugs for treatment. Even though AIDS drugs have been fast-tracked by the FDA, the pressure from these organizations has helped to focus attention on the length of time it takes other drugs to obtain marketing approval. Some other disease related organizations have followed the lead of the AIDS organizations in calling attention to the consequences of delays in approving promising drugs in their disease area.

One of the themes which reoccurs in the discussions of early releases of AIDS drugs is the right of the patient to be more involved in selecting his/her therapy, including having the right to choose the risks which they are willing to take. This does not require abolishing the FDA. But it would mean that

the FDA role would move in the direction of collecting and certifying information about a new medical technology, leaving more of the utilization decisions to the patients and their physicians. It is after all the patients, not the officials at the FDA, who most directly bear the potential gains and losses from the new medical technologies. In my opinion, this would be a great step forward in the regulation of medical technologies. Although the current AIDS crisis has built momentum in this direction, I consider it unlikely that there will be a major reorientation of the role of the FDA in regulating medical technologies.

In November 1991, the Vice President's Council on Competitiveness and the FDA did announce a major change in the method of reviewing drug applications. In headline form they announced that they would reduce the average clinical and preclinical testing phase for drugs to treat life threatening diseases from the current 9.75 years to 5.5 years and for all other drugs to 7 years. In the press release they cited our cost of drug development study and stated that these reforms would reduce the average cost of \$231 million by \$60 million for accelerated approvals and by \$28 million for the rest. Part of the time and cost savings would be accomplished by using more external reviewers rather than processing everything in house. For drugs targeted for accelerated approval, there would be an elimination of many of the requirements currently in late clinical trials. One of the trade-offs would be a greater use of post-marketing studies and an easier mechanism for withdrawing a drug from the market should the evidence warrant.

The goals of the Council's plan are laudable. Most of the reform measures are ones which those of us who are critical of the FDA processes can endorse. The one area in which I part company with many other critics is on the desirability of harmonizing the regulatory process with other developed

"We must be willing to accept some errors of inappropriate approvals."

nations. In Europe this is occurring as part of the 1992 harmonization of economic policies. It is very appealing to have only one set of regulators to deal with. Many in industry complain that they must deal with multiple regulatory authorities each of whom have different formats and standards.

I agree that this duplication carries a cost and that harmonization on the surface makes a lot of sense. But a movement toward one decision making authority is entirely different. One of the measures which we have of the FDA's performance is the approval times in other countries. In fact the Quayle Council on Competitiveness used the comparison with the UK to make their case for faster approval. If we move in the direction of one super agency, this standard of comparison will be lost. My prediction is that if the regulatory process moves toward one authority, the whole process will be slower rather than faster.

This is not the first time that streamlining of the FDA process has been announced, although the current targets are much more ambitious than earlier plans. Whether this plan is fully implemented and achieves its targets remains to be seen. If it does, it will be a major reversal of the trends I noted earlier. My own prediction is that little will ultimately change. The first time there is a failure to detect a severe adverse effect of a newly approved drug, there will be pressure to return to something resembling the old system.

Although the plan calls for an internal tracking system to follow the progress of each product application, there was no mention of what form accountability would take or whether there would be penalties for failure to meet the target times. One should note that the statutory review time for an NDA application is now 180 days even though the average is 30 months.

My skepticism of the efforts to deregulate medical technologies has nothing to do with any thought that the regulatory authorities are not competent or that the proposed reforms are not sincere. My skepticism is based on my view of the public perception of risk taking. The trade-off for faster and cheaper approval processes is the increased possibility of approving a technology which later turns out to be unacceptable. We must be willing to accept some errors of inappropriate approvals. Even in determining what is acceptable, we must be more able to evenhandedly balance the visible and the invisible risks of a disease and the technology. The AIDS crisis has helped focus attention on the cost of delaying the introduction of new technologies, but for many people this is probably viewed as a special case. Unless the public fundamentally changes its perceptions of risk, I fear that we will continue down the road to ever greater regulation of medical technology. Unfortunately we may never be aware of the cost we impose on ourselves.

On Our Mailing List?

If you would like your name to be added to the mailing list for either the Alex G. McKenna Economic Education Series Lecture or the Economic Directions newsletter, please indicate your preference and send your name and address to:

Dr. Gary M. Quinlivan, Economics Department, Saint Vincent College, Latrobe, Pennsylvania 15650-2690.



ECONOMIC DIRECTIONS

Saint Vincent College
Latrobe, Pennsylvania 15650-2690

Non Profit Organization
U.S. POSTAGE PAID
Latrobe, PA 15650-2690
Permit No. 110