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Restraining Medicine Prices: Controls vs. Competition

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***Restraining Medicine Prices:
Controls vs. Competition***

by Murray Weidenbaum

Policy Study
Number 116

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Executive Summary

The American pharmaceutical industry — one of the few high-tech sectors of the U.S. economy that still leads the world marketplace — is under unparalleled assault from its own government which threatens price controls and other restrictions. Public policymakers need to consider carefully the consequences of their actions before rushing headlong into the controls morass. This report provides some needed perspective.

Critics of pharmaceutical companies complain that prices and profits are very high. They are not satisfied with the industry's responses: prescription medicines are a small part of health care costs; drug prices are now slowing down substantially; generous earnings are needed to invest in the expensive process of developing new drugs; medicines are often far more cost-effective than alternatives such as surgery.

Key Findings and Conclusions

This study of pharmaceutical prices reaches several major conclusions:

1. As a result of the monopoly rights granted by the Food and Drug Administration for specified periods of time, successful new drugs are often very profitable. However, the odds of coming in with a financial blockbuster are low; most new drugs do not cover the company's investment in research and development.
2. The extended regulatory procedures of the Food and Drug Administration raise the time and cost of developing new medicines. Government and private researchers estimate the total before-tax cost in the range of \$231-359 million per successful "new chemical entity" (and in the neighborhood of \$194 million after taxes).
3. Increasing domestic and foreign competition is slowing down price increases of prescription medicines. Patients' costs for the eight most widely used chemical compounds grew at an average annual rate of 1.6 percent from 1985 to 1992, less than half of the rate of increase in the consumer price index.

Murray Weidenbaum is Mallinckrodt Distinguished University Professor and Director of the Center for the Study of American Business at Washington University in St. Louis.

Introduction

4. Outpatient prescription drugs are less than 5 percent of U.S. health care expenditures. Nevertheless, the public concern arises primarily from the fact that medicare and other health insurance and benefit programs cover little or no medicine costs.
5. Price controls, as urged by many critics, have an unrelieved history of failure in the United States. They divert resources from the sectors of the economy whose prices are controlled and result in shortages, qualitative or quantitative, on the part of the consuming public.
6. Nevertheless, price controls are politically popular. Politicians are applauded when they institute these controls and they are also lauded when they eliminate the controls after they become discredited.
7. There is a better alternative to price controls in responding to consumer concerns about high prices — more competition. Unfortunately, federal and state laws and regulations limit the role of price competition for prescription medicines.
8. These anti-consumer restrictions should be lifted. States should eliminate the prohibitions against advertising the price of prescription drugs. Such restrictions make it hard for consumers to shop for the best price.
9. The FDA should reduce its barriers to advertising prescription medicines. The record shows that, by promoting competition, advertising reduces the prices that consumers pay.

The best protection for the consumer is not governmental price controls, but a strong and competitive private sector. Reforming the costly and elaborate regulation of pharmaceuticals will do far more for the consumer than a new round of government controls. Such action would also speed up the introduction of new and better medicines.

The American pharmaceutical industry is experiencing an unparalleled assault. Patients are upset about the high and rising prices for the medicines that they need. Congressional committees and consumer groups are aroused by the high profits that are reported.¹ And the president of the United States has repeatedly promised to "crack down" on the pharmaceutical companies and seems to be advocating some form of price controls.

In turn, the industry has responded with several counter-arguments:

- Prescription medicines are a small portion of health-care costs.
- Prescription prices in recent years have been rising no faster than other health-care costs and are now slowing down substantially.
- The public concern seems to arise primarily from an artifact of the way that health care costs are financed: many insurance and benefit programs, notably medicare, cover little or no medicine costs.
- As a result, this relatively small part of the total health care system frequently represents a large share of the patient's personal cash outlay. It is estimated that prescription costs represent the highest out-of-pocket medical expense for three out of four elderly Americans.²

These counter-arguments are not satisfying the public or their governmental representatives. The pressure to regulate drug prices is escalating. In the memorable words of one senator, "It is hard to believe that a company could charge so much for such a tiny pill."³ Given the frequent tendency of Congress to legislate first and investigate afterwards, there is an urgent need to examine the issue of pharmaceutical prices more closely. This report attempts to do just that by probing below the surface of the current debate.

The Nature of the Prescription Medicine Business

Three key characteristics describe the U.S. pharmaceutical industry today:

1. It is truly a high-tech industry, one of the very few in which the United States still leads the world.
2. It is an extremely high-risk industry, but one which rewards generously those who succeed in developing new and better medicines needed by the public.
3. It is facing a two-front threat — one in the form of growing pressures from foreign competition and the other from hostile public policy.

Let us examine each of these three points in detail and see how closely they relate to each other.

The High-Tech Pharmaceutical Industry

Most people think of the electronics and computer companies when they talk about high-tech. Some add the aerospace industry. Of course, all three are key elements of this country's advanced technological base. However, by any objective measure, the pharmaceutical companies merit inclusion in that category.

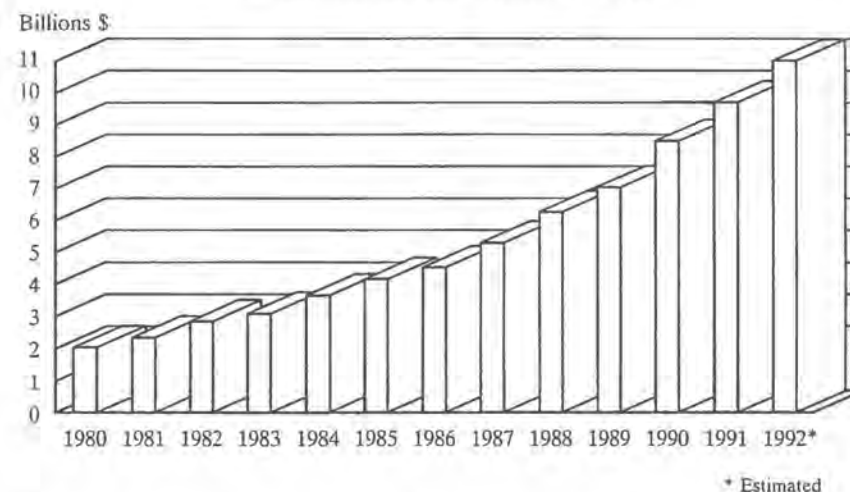
According to the National Science Foundation, in 1990 the average manufacturing company devoted an amount equal to 3 percent of its sales to research and development (the R&D/sales ratio is a standard measure of the technological intensity of an industry or firm). Several major industries did far better than that. Electronics reported a 5.5 percent ratio and computers an 8 percent ratio. However, this is dwarfed by the 16 percent experienced by the members of the Pharmaceutical Manufacturers Association.

Moreover, the major pharmaceutical companies report a steady and rapid increase in their funding of R&D. As shown in Figure 1, their outlays for R&D rose from \$2 billion in 1980 to \$10.9 billion in 1992, a more than five-fold increase.⁴ Because of the special nature of the product, the R&D is uniquely intensive. The U.S. Office of Technology Assessment has identified twelve different phases of the pharmaceutical R&D process as described on page 6.

Of course, expenditures on R&D are at best an input. What is desired is the output in the form of a greater flow of new and better medicines. The public has not been disappointed on that score. While many Americans bemoan the inroads that foreign companies are making in our domestic markets, the United States can properly boast of a world class pharmaceutical industry, one which is clearly the international leader. An analysis of 97 new drugs introduced in world markets between 1975 and

Figure 1

Pharmaceutical Industry R&D



Source: Pharmaceutical Manufacturers Association.

1989 reported that the United States was the source of 47 — almost one-half.⁵ An analysis of 196 "consensus new drugs" (those sold in a majority of major markets worldwide) reported a similar conclusion for the period 1970-85. During that longer period, the pharmaceutical companies of the United States accounted for 85, or 43 percent, of the total.⁶

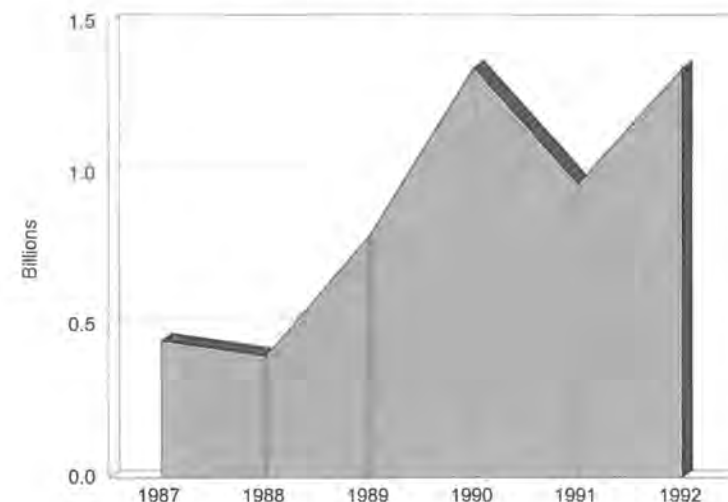
It is also instructive to examine the March 9, 1992 issue of *Fortune* magazine which contains a scorecard on international competitiveness. *Fortune* gives the pharmaceutical industry one of only two As. In comparison, electronics received a dismal D. A somewhat similar result was reported by the General Accounting Office (GAO). In a November 1992 report, the GAO stated that, with one exception, all eleven high-technology industries "exhibited some decline in the U.S. leadership position over the 1980s." The exception was the pharmaceutical industry.⁷ While so many other industries complain about rising import penetration of our domestic markets, the U.S. pharmaceutical companies generate a substantial excess of exports over imports, year after year — with Japan, as well as with many other nations (see Figure 2).

The Pharmaceutical R&D Process

1. *Synthesis and extraction* — identifying new molecules with the potential to produce a desired change in the biological system (e.g., to inhibit or stimulate an important enzyme, to alter a metabolic pathway, or to change cellular structures).
2. *Biological screening and pharmacological testing* — exploring the pharmacological activity and therapeutic potential of compounds.
3. *Pharmaceutical dosage formulation and stability testing* — turning an active compound into a form and strength suitable for human use.
4. *Toxicology and safety testing* — determining the potential risk a compound poses to humans and to the environment.
5. *Application for review* — to give the U.S. Food and Drug Administration (FDA) the opportunity to prevent testing of the compound on humans.
6. *Phase I evaluation* — the first testing of a new compound on human subjects in order to establish tolerance, absorption rates, etc.
7. *Phase II evaluation* — controlled clinical trials on a relatively small number of patients.
8. *Phase III evaluation* — clinical trials of a drug's safety and effectiveness in hospitals and outpatient settings.
9. *Process development for manufacturing and quality control* — establishing a company's capacity to produce a product in large volume and at high quality.
10. *Bioavailability studies* — using healthy volunteers to document the rate of absorption and excretion from the body of a compound's active ingredients.
11. *New drug application* — applying to the FDA for approval to market a new drug, providing all the information gathered during the drug discovery and development process.
12. *Post-approval research* — undertaking experimental studies and surveillance activities after a drug is approved for marketing.⁸

Figure 2

Pharmaceutical Trade Balance



Source: U.S. Department of Commerce.

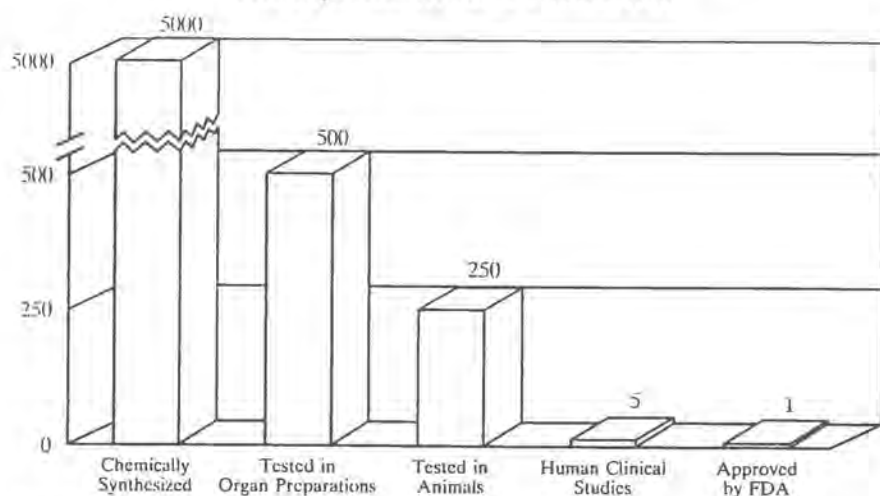
The High Risks Faced by the Industry

There is no doubt about it. Successful new drugs are often very profitable. The Food and Drug Administration does grant monopoly rights, albeit for limited periods of time for any one medicine. But the other side of the coin is that the odds of coming in with a financial blockbuster are low. A study at Duke University of 100 drugs revealed that a majority did not even cover the company's investment in R&D.⁹

Why are the odds of attaining real profitability so low? For insight into that question, we must examine in more detail the nature of the extended processes by which new pharmaceuticals are developed by the companies and approved by the FDA. First of all, thousands of promising new chemical compounds are subjected to intensive laboratory and animal testing before being tested in clinical studies in humans. On average, 5000 different compounds must be tested in order to come up with one new drug approved by the FDA. Usually, 50 compounds are tested on animals before one is tested on humans and only one out of five of those gains FDA approval (see Figure 3). In plain English, that means that most proposed medicines don't make the grade. Even when they do, they take a long time to pay off.

Figure 3

The Pipeline of New Medicines



Sources: National Cancer Institute, Food and Drug Administration, and Pharmaceutical Manufacturers Association.

Delays. The FDA has been repeatedly criticized for delays in approving new drugs.¹⁰ It takes the FDA typically 2-1/2 years to review a proposed new pharmaceutical product. However, that is only a fraction of the total time involved from the viewpoint of a pharmaceutical firm. A study at Tufts University reported that it takes an average of 12 years to get from initial research through final review for approval of a new medicine.¹¹ (See Figure 4 for the steps in the procedure.) Nobody wants unsafe pharmaceuticals on the market, but the tendency of the regulators has been to be so cautious as to delay the approval of new and better medicines.

A study of new drugs that were introduced in both the United States and the United Kingdom in the period 1977 to 1987 reported that far more — 114 — were first available in Great Britain, compared to only 41 that were first available in the United States. The average delay time behind the British ranged from five years for respiratory medicines to three years for cardiovascular medicines to one year for endocrine medicines.¹² We should acknowledge, however, that the British put more emphasis on costly post-marketing surveillance than does the regulatory regime of the United States.

Figure 4

The Steps Toward Drug Approval



Source: Joseph DiMasi, "The Cost of Innovation in the Pharmaceutical Industry" *Journal of Health Economics*.

These delays, however, are not surprising, given the cardinal rule for bureaucratic survival: Do not stick your neck out. If you were an FDA reviewer and you were to approve a new prescription medicine, you would be taking a substantial career risk. If anybody should suffer any severe adverse reaction, you would be exposed to tremendous public criticism. On the other hand, if you do not approve the drug, the potential users are unlikely to complain, since they do not know about it and they will soon pass from the scene. With the recent exception of drugs for AIDS patients, little congressional attention has been devoted to the failure to approve a new medicine.

As a result, the FDA reviewers faced with a difficult decision often ask for more studies, and delay the introduction of new pharmaceuticals. Consider the results bluntly: if 16 people are harmed by side-effects of a drug in use, that becomes front-page news. If 10,000 people die prematurely because approval of a new drug has been delayed, the public is unaware. By the way, that figure of 10,000 is not plucked out of the air. It was the estimate of how many people died needlessly each year during the period 1967-1976 when the FDA was slow in approving beta blockers for reducing the risk of heart attack. The United Kingdom had given the go ahead earlier.¹³

In 1992, Congress did enact a law designed to speed up the FDA approval process with funds from a new set of user fees. Although the Prescription Drug User Fee Act is now in force, the Clinton Administration has indicated that it intends to use the revenues to reduce the overall budget deficit.

The average cost of developing a new drug rose to \$231 million in 1990.

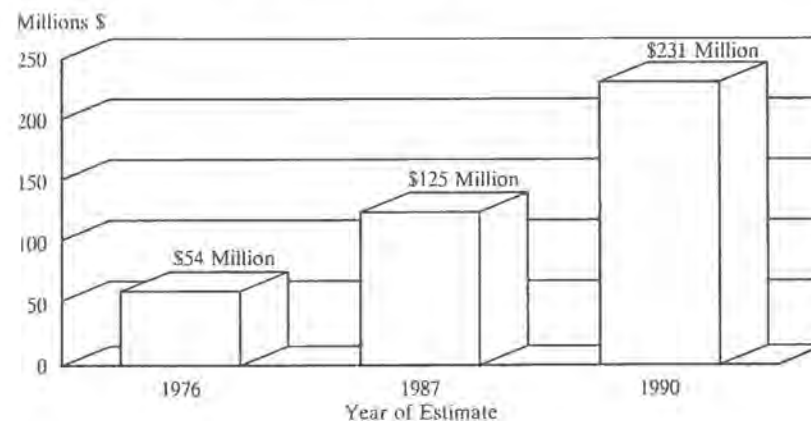
Expense. The entire drug review sequence is not only very time consuming, it is also very expensive. As would be expected, specific estimates of cost vary considerably. Studies at the University of Rochester, Texas A & M, and Tufts University show that the average cost of developing a new drug rose from \$54 million in the 1970s to \$125 million in the 1980s, and to \$231 million in 1990.¹⁴ (See Figure 5.)

An early 1993 study by Congress' Office of Technology Assessment (OTA) reports that "a reasonable upper bound" on the fully capitalized cost of R&D per successful NCE ("new chemical entity," the technical term for a pharmaceutical) at the time of market approval is \$359 million. This figure is comparable to the earlier private studies, but that is not the way that the OTA study has been reported.¹⁵ The newspaper accounts have instead compared the OTA's estimated *after-tax* cost per NCE of \$194 million with earlier studies of *pre-tax* costs.¹⁶ That biased comparison leads the reader to the erroneous conclusion that the private figures are too high. As the OTA report warned, because of the rapid changes in science and technology, it is impossible to predict the cost of bringing a new drug to market today from estimated costs for drugs whose development began more than a decade ago.¹⁷

Of course, any of these estimates — \$194 million, \$231 million, or \$359 million — represents a very substantial commitment of corporate funds. The basic incentive to make these large investments is the possibility of achieving high profits. As economist Sam Peltzman has pointed out: "Drug companies undertake these massive searches knowing there will be a big payoff if they hit a winner. We can have lower drug prices if we accept less of that searching [for new chemical compounds]. That's the choice we face."¹⁸ The OTA study concluded that the profits of drug companies are higher by 2 to 3 percentage points

Figure 5

Rising Cost of Drug Development



Sources: R. Hansen, University of Rochester; S. N. Wiggins, Texas A&M University; J. A. DiMasi, Tufts University.

a year than other high-technology, high-risk industries that are dependent on scientific research.

The Two-Front Threat

The expansion of overseas economies as other nations also achieve advanced industrialization constitutes a two-edged sword for the American pharmaceutical industry. On the one hand, that development means additional markets for the products of the U.S. industry. As we have seen, exports of American-made medicines constitute a positive factor in this nation's balance of trade and, hence, balance of payments.

However, on the other hand, the increased sophistication of industries in other nations enables them to compete more effectively with their American counterparts. As we can also recall from Figure 2, the U.S. pharmaceutical trade surplus in the last few years has not exceeded the 1990 level. Moreover, while the U.S. industry still maintains a lead in the introduction of new medicines, other nations are reducing that gap. Japan and Western Europe all have strong and active pharmaceutical firms. Of the top 36 NCEs approved and marketed in the United States in the 1980s, U.S.-based companies received a significantly

smaller market share than they did for the NCEs approved in the 1970s (62 percent versus 82 percent). During the same period, foreign-based companies more than doubled their share of NCEs in this critical portion of the U.S. market (from 18 percent to 38 percent).¹⁹

Overseas locations also exercise an attractive force on American companies that are considering the optimum location of new facilities in the increasingly global economy. This issue is becoming especially relevant in view of the possible withdrawal of tax benefits for manufacturing investments in Puerto Rico as discussed below.

The major threat to American pharmaceutical firms arises from its own government.

Thus, the major threat to American pharmaceutical firms arises from its own government. Repeated statements by the president of the United States that he intends to "crack down" on the domestic industry are not to be taken lightly. Top Clinton adviser James Carville was recently quoted by the *Wall Street Journal* as saying, "We'll be trying to change the health-care system. Those who get in your way, you try to run over by saying they are putting their self-interest against the national interest."²⁰ That approach surely loads the deck against private enterprise in any public policy debate.

At this point formal price controls have not been proposed by the Clinton Administration, but early moves in that direction are already visible. For example, the tax system has attracted attention as a way of enforcing government "guidelines" on increases in the price of medicines. Specifically, the White House and its congressional supporters have focused considerable attention on Section 936 of the Internal Revenue Code, the provision that exempts from federal taxation the income that is earned through manufacturing operations in Puerto Rico and other U.S. territories. Although the tax benefit is available to American businesses generally, drug companies have been among the major beneficiaries of Section 936, as has the economy of Puerto Rico. Much of the profits (about \$15 billion) has been deposited in Puerto Rico banks. One British observer, Canute James of the *Financial Times*, describes these deposits as "a pillar of the island's financial stability." He reports that the

tax incentives are seen as the main fuel for the rapid expansion of the Puerto Rico economy.²¹

U.S. legislators have proposed several key changes to Section 936. Some would limit it to firms that raise their prices no faster than the consumer price index — which amounts to a form of price control. One senator has suggested replacing Section 936 with a partial credit for wages paid.

Meanwhile, the House of Representatives has been holding hearings on legislation increasing the enforcement authority of the Food and Drug Administration. The proposed Food, Drug, Cosmetic and Device Safety Amendments would give the FDA very broad and vaguely defined powers. For example, the FDA could issue subpoenas requiring the attendance of any witness and the production of any document that relates to any matters within that federal agency's vast jurisdiction.²²

This would, of course, be in addition to the agency's substantial existing enforcement power, which includes inspecting pharmaceutical factories without warrant, seizing batches of a product if the batch is adulterated or mislabeled, and carrying out multiple seizures, effectively eliminating a product from the market. The danger in giving bureaucratic officials sweeping powers was underscored, perhaps inadvertently, in a recent statement by the head of FDA's Drug Surveillance Branch:

We used to say that if a company made certain changes, then we would probably not take any action. Now, we won't. Now, even if they make the changes, they might end up in court. We want to say to these companies that you don't know when or how we'll strike. We want to eliminate predictability.²³

To a substantial extent, the FDA itself is the victim of the tendency of the Congress to enact many new laws with statutory deadlines which are impractical to meet. For example, the prestigious Advisory Committee on the Food and Drug Administration, in its final report in May 1991, concluded that it "will probably be impossible to meet" the deadlines set in the Safe Medical Devices Act. It reached a similar conclusion on the Nutrition Labeling and Education Act, stating that "the law sets out objectives that cannot be achieved within the statutory timetable." The Committee added, presciently, "The whirlwind of new legislative demands will not soon abate."²⁴

It is intriguing to note that the timing of governmental decisionmakers may be less than optimum. These legislative demands were less intense during the 1980s when the U.S. phar-

maceutical industry was one of the few sectors of manufacturing to report increases in employment. Currently, the rising interest in restrictive legislation coincides with the announcement of restructuring and layoffs by several large pharmaceutical companies.

Moreover, some Washington cynics maintain that congressional action on controversial issues usually occurs after the intensity of the problem has abated. This surely has been the case in much legislation designed to cure temporarily high unemployment.

In the U.S. pharmaceutical industry, payer pressure — plus increasing domestic and foreign competition — is curbing price rises. Recent data on retail prescription prices show that patients' costs for the eight most widely used chemical compounds grew at an average annual rate of 1.6 percent from 1985 to 1992, less than half of the rate of increase in the consumer price index. According to medical industry consultants L. John Wilkerson and Robert Easton, because of increased innovation and competition, the exclusivity periods in which companies enjoy price protection for new high-value medicines have dropped from ten years in the 1960s to three to four years in the early 1990s.²⁵

According to economist Burton Weisbrod, only 25 percent of the 200 largest-selling drugs remain in that group 15 years later and about 10 percent of the 200 are new each year.²⁶ As the patents of these brand-name drugs expire, generic versions become available and begin to erode the market share of the existing brand-name pharmaceuticals. This is particularly true since the passage of the Drug Price Competition and Patent Restoration Act of 1984, which facilitated the entry of generic producers after patent expiration.²⁷

The Consumer Interest in the Pharmaceutical Industry

Consumers have a very ambivalent attitude toward the companies that make pharmaceutical products. On the one hand, patients appreciate the ability of these firms to develop new and better medicines. But, on the other hand, they resent what they see as greedy corporations taking advantage of the situation to raise prices inordinately and to make excessive profits. This latter attitude is encouraged by governmental attacks on the industry's pricing practices.

A recent report by the General Accounting Office (GAO) provided added fuel to the fire. The GAO reported that, because of government price controls in Canada, the prices of many medicines are substantially lower there than in the United States — on average, about 25 percent at wholesale.²⁸ As in so many issues of public policy, the facts of the matter are too complicated to fit on the proverbial bumper sticker. The Pharmaceutical Manufacturers Association countered by noting that discounts and rebates by U.S. manufacturers were ignored in the study. Ernst Berndt of MIT called the GAO study procedures not meeting "basic professional standards of integrity and reliability."²⁹

New and Better Medicines

There is little, if any, argument that the U.S. pharmaceutical industry produces a constant flow of new and improved products. In striking contrast, virtually no innovative pharmaceutical products have been developed in Canada since the advent of stringent price controls in that nation in 1969. Lacy Glenn Thomas of Emory University has shown that countries like France and Austria, which have the toughest price restrictions on pharmaceuticals, also do the least research.³⁰

Moreover, many of the innovative medicines developed in this country — while very expensive — enable the patient to avoid painful and even more costly surgery. For example, the cost of treating ulcers with H-2 antagonist drug therapy runs about \$900 a year, a very considerable sum of money for the typical patient. But, according to data from the U.S. Health Care Financing Administration, the cost of ulcer surgery, in contrast, averages \$28,900.³¹ (See Figure 6.)

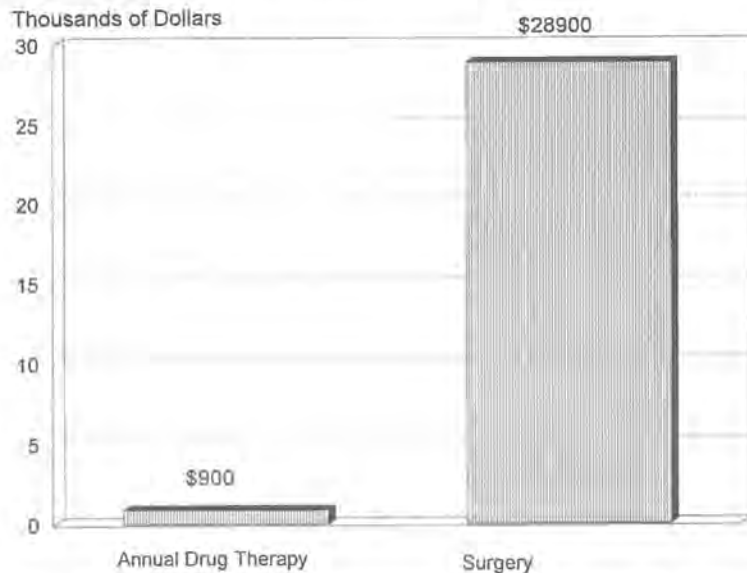
It is useful to consider the somewhat analogous case of treating drinking water with fluoride in order to reduce dental bills. Consumers rarely if ever complain about the expense of this cost-effective alternative to medical treatment because the cost is buried in their tax bills or water bills. In any event, let us turn to the subject of high prices for medicines.

High and Rising Medicine Prices

On the surface, the facts are clear: the prices of many pharmaceutical products are high and rising. In the aggregate, outlays for pharmaceuticals in the United States rose from \$20 billion in 1985 to \$32 billion in 1990. Back in 1985, the expense for medicines came to 4.8 percent of total medical expenditures. According to the Health Care Financing Administration (a part of

Figure 6

Ulcer Treatment Cost Comparison



Source: Pharmaceutical Manufacturers Association and U.S. Health Care Financing Administration.

the U.S. Department of Health and Human Services), despite the large absolute rise since then, pharmaceuticals accounted for the same 4.8 cents of the average health care dollar in 1990-1992. That is, costs of prescription medicine have risen at about the same rate as other health-care costs. However, we should note that overall health-care cost increases have clearly outpaced the general inflation rate in recent years.

Thus, there are several ways of presenting the facts, some favorable to the industry and others unfavorable. For example, it is common to ignore the close relationship between medical and pharmaceutical costs and merely state that the prices of medicines have gone up faster than the consumer price index — at least until very recently. Such a statement may be technically true (this point is covered a little later), but it is far from the whole story. In contrast, reporting that the prices charged for medicine have been going up at the same rate as hospital and doctor bills — and no faster — is also accurate, but provides a very different perspective.

Looking at the price record prior to 1980 is also revealing. Between 1966 and 1982, outpatient drugs were a steadily declining share of U.S. health care expenditures — from a high point of 8.8 percent in 1966 to a low of 4.7 percent in 1982 (see Figure 7). We can only speculate as to why the improvement in the relative cost of drugs stabilized in the early 1980s and has not declined further since. Perhaps the rapid rise in the cost of developing new drugs since then has played a part in that change. Surely, we would expect that scientists first discover and companies market the medicines that are easier and hence less costly to develop. Over time, the more difficult and expensive medical applications are developed.

Costs of prescription medicine have risen at about the same rate as other health-care costs.

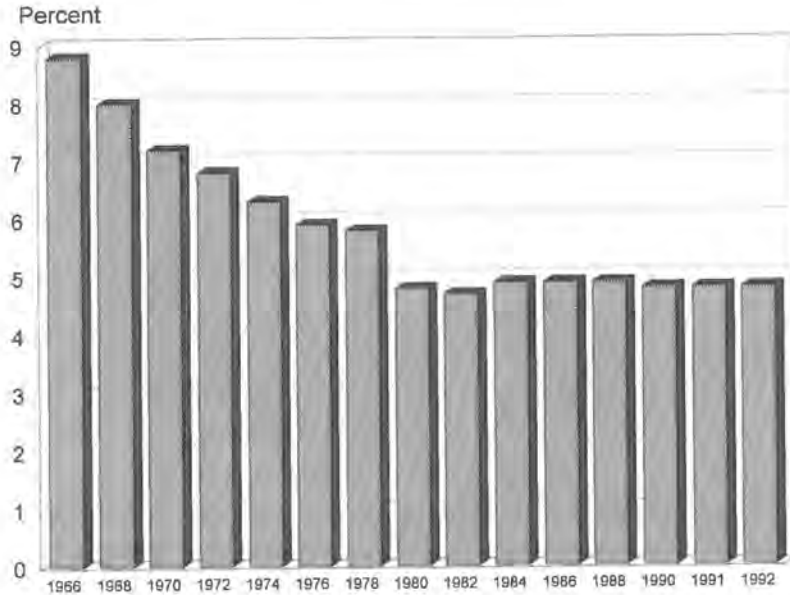
Pharmaceutical researchers have attributed much of the rise in the cost of developing new medicines to the use of more patients in clinical trials, increasingly complex testing, and growing interest in developing treatments for chronic and degenerative diseases like cancer and Alzheimer's.³²

We must also be aware of the fact that knowledgeable researchers question very seriously the validity of the numbers on pharmaceutical prices issued by the U.S. Bureau of Labor Statistics (BLS).³³ The point here is well known to economists and statisticians but usually ignored in discussions of public policy. That is, the official price indices do not take into account the fact that the quality of the products that consumers buy often changes over time. To the extent that is the case, some portion of the reported increase in drug prices is due to the fact that Americans are buying newer and better, albeit more costly, prescription medicines.

In the case of automobiles, in contrast, BLS takes into account the extent to which new cars are safer and pollute less. If the price of an otherwise similar car rises only by the cost of new safety and anti-pollution equipment, BLS would not report that the price of automobiles is going up. The agency deducts the safety and environmental costs on the assumption that the new model car is different — and better in that regard — than the previous model.

Figure 7

Outpatient Prescription Drug Share of U.S. Health Care Expenditures



Source: U.S. Health Care Financing Administration.

The advances in new prescription medicine are often dramatic, yet BLS does not treat them in a similar way. In a 1992 study performed at the Massachusetts Institute of Technology, an effort was made to do just that in the case of medicine used to control high blood pressure. The MIT researchers found that, for the six-year period January 1986 to December 1991, more than one-half of the reported price increases (53.6 percent) was accounted for by quality improvement.³⁴ A comparable study of anti-ulcer drugs at the University of Michigan came up with similar conclusions.³⁵

In a far more substantive response to the concern over high prices for drugs in August 1992, pharmaceutical companies set up a toll-free 800-number so that physicians could call to get free pharmaceuticals for indigent patients. Approximately 2,500 calls are currently received each month.³⁶

Two Responses: Price Controls or Competition

Many people's instinctive response to high or rising prices is to call for government price controls. In fact, in an effort to reduce public concern and to head off formal controls, some of the major pharmaceutical firms have promised to keep their price increases within the overall rate of inflation. Some disagreement has occurred about the extent to which the companies have achieved the price target.³⁷

Perhaps the more binding approach is the growing likelihood that Medicare coverage will be expanded to include pharmaceutical products. In such event, some limited form of price regulation on prescriptions paid by Medicare would be quite likely.

Medicare coverage will likely be expanded to include pharmaceutical products.

Reimbursing medicare patients for drug purchases could become a two-edged sword. Initially, such a change would ease the financial burden on the elderly — and thus reduce the political pressures on health-care policymakers. But these reimbursements could also become the vehicle for giving the federal government more opportunity to control drug prices.

Experience With Price Controls. Of course, the United States has a great deal of experience with controlling prices. These episodes have ranged from general price controls during World War II, the Korean War, and the 1971-73 period, to controls on rent by many municipalities which continue to this day. The experience is uniformly adverse. Investors shift their funds to sectors of the American economy without price controls. The deteriorating housing stock in New York City is a constant reminder of the failure of selective price controls. Moreover, in the case of more mobile resources than land and buildings, investors increasingly have attractive alternatives overseas.

But, most important, consumers suffer from the shortages that result. These shortages may be quantitative, as occurred in many markets during 1971-73 or qualitative, as Canada is experiencing right now. In the case of Canada, the ready availability of new medicines developed in the United States has alleviated the problem of lack of innovation by the Canadian pharmaceutical industry.

Evaluations of the 1971-73 experience with price controls are uniformly negative. A "temporary" 90-day freeze was quickly transformed into formal controls that lasted for nearly three years. Evasions and distortions became widespread. Because foreign trade was exempt, rapid increases in exports produced spot shortages. Some of these items were imported back into the United States merely to avoid the price controls. Product quality deteriorated as producers attempted to maintain profit margins in the face of the government's price ceilings ("caps" is the current euphemism).³⁸

According to Dr. Marvin Kosters, a senior official in the Nixon Administration during the 1971-73 wage and price controls, "It would be a mistake to underestimate the ingenuity of people in the private sector to take advantage of discrepancies in a system of price controls." A similar conclusion was reached by Dr. Barry Bosworth, a senior official in the Carter Administration's efforts to enforce voluntary wage and price guidelines, who noted: "... you just never would have believed so many things could go wrong."³⁹

These are not isolated judgments. A recent *Washington Post* roundup of expert opinion on price controls in health-care reported variations on the same negative theme:

The reaction of price controls now, as in the past, is likely to be evasion, inflation, and confusion, experts say. The resulting distortions could include everything from unnecessary surgery to longer waiting lines, from poorer quality care to strikes over the wages of nurses, technicians, and other health care workers.⁴⁰

The Alternative of Competition. There is an alternative to price controls in responding to consumer and public concerns over pharmaceuticals. That alternative is more competition. Again, some careful consideration is necessary. Simply eliminating the patent protection enjoyed by developers of new medicines would not work. The absence of patent protection would take away the incentive to undertake the large investments necessary to develop new pharmaceutical products.

The basic alternative to price controls is to broaden the role of price competition. At the present time, many states prohibit advertising the price of prescription drugs. Such restrictions make it difficult for consumers to shop for the best price.⁴¹ Every state legislature which has enacted such anti-consumer legislation should promptly repeal it. Even industry critic Senator David Pryor has urged that the market for medicine be made more

price-sensitive. He specifically states, "Any reform effort should make sure that both doctors and patients are more aware of prices."⁴²

At the federal level, the Food and Drug Administration should reduce the barriers it has set up which inhibit advertising prescription medicines.⁴³ Because consumers must obtain a prescription from a physician in order to acquire prescription drugs, there is less reason to fear deception in advertising in this market than in any other. On the positive side, experience shows that direct advertising can reduce the prices that consumers pay.⁴⁴ Such evidence was cited by the Supreme Court in the decision overturning state bans on advertising of eyeglasses.

The current FDA rules on advertising appear to be needlessly bureaucratic. Specifically, the agency should reconsider the requirement for the misnamed "brief summary" which must accompany any ad that both mentions a health condition and indicates the name of a drug which can be used for the condition. The notorious "brief summary" is actually a lengthy statement in small print listing side effects and contraindications associated with a prescription drug. Of course, such information is essential for physicians, for whom the brief summaries were originally designed, but the technical language borders on the incomprehensible for the average patient.

The FDA regulations also discourage prescription drug ads from being shown on television, a major source of information for many consumers. The high cost of ads in the print media — resulting from the FDA requirements — also reduces their use. Like so much government regulation, the result is just the opposite of what the FDA wants to achieve. Due to the restraint on advertising, consumers may not be aware that a treatment exists for a certain condition and so they will not consult a physician. In other circumstances, consumers may suffer some symptoms (e.g., thirst) without realizing that these are symptoms of a treatable disease (e.g., diabetes). Alternatively, a new remedy with reduced side effects may become available, but patients are not aware of it and do not visit their physicians to obtain a prescription.

As has been demonstrated in many other areas of the economy, the best protection for the consumer is not governmental price controls, but a strong and competitive private sector. Reforming the costly and elaborate drug regulation process will do more for the consumer than a new round of government controls. Simultaneously, such action would speed up the introduction of new and better medicines. Increasing the scope for com-

panies to compete for the consumer's dollars is demonstrably the best way for government to "protect" the public.

Conclusion

There are a few basic lessons that public policy makers need to learn.

First of all, deal with a broad issue such as health care in a comprehensive manner. Do not look at doctor bills or hospital bills or medicine costs in isolation. Otherwise, there is great danger of squeezing (or "cracking down on," to use the prevailing political term) the most cost-effective part of health care.

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Secondly, realize that regulation is a powerful medicine. Government regulation is not as costless as it may seem. It generates lots of costs as well as benefits. Some of the most important costs may be hidden, in the form of unexpected and unwanted side-effects, such as reduced innovation of new and better products and processes.

Third, price controls are an act of frustration. Sadly, they are doubly popular. Politicians are applauded when they institute these controls and once again when they eliminate the controls after they become discredited.

Fourth, expand the role of competition. Warts and all, the competitive marketplace is the most effective protector of the consumer.

Notes

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4. See Gerald T. Mossinghoff, "Economics of the Pharmaceutical Industry," in *America's Pharmaceutical Research Industry* (Washington, D.C.: Pharmaceutical Manufacturers Association, 1992), pp. 25-64.
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17. Office of Technology Assessment, *Pharmaceutical R&D*, p. 1.
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