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Pharmaceutical Regulation and Productivity Challenges

by Murray Weidenbaum

Many Americans bemoan the inroads that foreign automotive, steel, electronics, and aerospace companies are making in our traditional markets, often with subsidies from their governments. But there is a shining exception. The United States can properly boast of a world class pharmaceutical industry, which is clearly the international leader.

The High Productivity of the U.S. Pharmaceutical Industry

Of the 97 new drugs that were introduced in world markets between 1975 and 1989, the United States was the source of 47 — almost one-half. We also have more major drugs in the pipeline than any other country in the world. Moreover, it is 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.

The pharmaceutical industry's contribution to the domestic economy likewise is impressive. While manufacturing companies as a whole averaged a 2 percent decline in employment during the decade 1980 to 1990, the drug manufacturers increased their job forces by 24 percent, or approximately 50,000. While so many other industries complain about rising import penetration, this industry generates a substantial excess of exports over imports, year after year — with Japan, as well as with many other nations.

The Congressional Response

So what is the prevailing response in the Congress? The obvious conclusion that you would expect is that the members of both houses would be ecstatic over the industry's stellar

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performance. But that is hardly the case. Senators and representatives alike regularly take the floor to berate the pharmaceutical companies. It seems that the prices they charge and the profits they earn are "too" high.

It is true that the public's outlays for prescription drugs have been rising substantially. As you would expect, different organizations measure the phenomenon differently. Each comes up with slightly different statistics, but each is a variation on the same basic theme: costs of prescription medicine have risen at about the same rate as other health care costs. According to the Health Care Financing Administration (a part of the U.S. Department of Health and Human Services), outlays for pharmaceuticals rose from \$20 billion in 1985 to \$32 billion in 1990. In 1985, the expense for medicines came to 4.8 percent of total medical expenditures. Despite the deceptively large rise since then, pharmaceuticals accounted for the same 4.8 cents of the health care dollar in 1990.

Meanwhile, unfortunately, our distinguished legislators ignore the basic role of economic incentives in a private enterprise system: high profitability is the carrot for superior performance. These members of Congress are also too busy to notice the extent to which those company profits are reinvested in the vital category of research and development.

In any event, those emotional denunciations are quickly followed by onerous proposals to increase the operating costs and reduce the earnings of medicine manufacturers operating in the United States. Perhaps the low-point in a recent floor debate occurred when one Senator exclaimed, "It is hard to believe that a company could charge so much for such a tiny pill." Personally, I find it hard to believe that such a tiny intellect gets elected and reelected to what the members call the world's greatest deliberative body.

Meanwhile, the House of Representatives has been holding hearings on legislation increasing the enforcement authority of the Food and Drug Administration — to enable that already powerful agency to "crack down" on makers of medicines. The proposed Food, Drug, Cosmetic and Device Safety Amendments of 1992 would give the FDA very broad and vaguely defined powers. For example, 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.

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 inadvertently in a recent statement by the head of the 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.

Some members of the Senate are also trying to establish tax-enforced price controls on prescription medicines. In addition, they would like to create a review board to study how other countries control prices of prescription drugs. Of course, those senators are deeply hurt when they are accused of advocating a return to the discredited approach of price controls. They respond that they only want to study the subject and then "only" take away some tax credits if a pharmaceutical company raises its prices above a designated level.

By, in effect, putting a lid on prices, Congress would be reducing the incentive for new investment. As noted in a recent article in *Science*, we are witnessing a dramatic increase in the risks and costs of pharmaceutical R & D. It costs about \$231 million to bring one successful new drug into the U.S. market. Most proposed medicines don't make it. These investments take a long time to pay off, even when they do. A study at Duke University covering a recent decade reported that only 3 out of every 10 drugs introduced ever recovered their research and development costs. A study at Tufts University concluded that, on average, it requires 12 years to bring a new prescription drug to market in the United States. According to the National Cancer Institute and the FDA, it takes about 5,000 compounds synthesized in the laboratories to come up with one marketable medicine. Of the original 5,000 compounds,

only 250 merit testing in animals, five survive to human clinical trials, and one is approved by the FDA.

The irony of the price-control approach was described very accurately by Senator Phil Gramm of Texas, "The fact that we are here on the floor of the United States Senate talking about having the government regulate the price of products when the rest of the world has long ago rejected this foolishness is an absolutely amazing thing."

It is fascinating to consider the implications of the specific price controls proposed by the Senators: to escape the tax penalty for exceeding the arbitrary price ceiling, manufacturers would have an incentive to introduce new products at the highest possible prices. That would enable them subsequently to show price reductions from those high initial bases and thus continue to qualify for standard tax treatment.

Moreover, the proposed Prescription Drug Payment Review Commission being considered in the Senate singles out one successful high-tech American industry for the congressional spotlight. It ignores the fact that prescription medicines are often the low-cost alternative to surgery or intensive hospitalization. It is foolish, under such circumstances, to attempt to hold down the cost of this one highly productive element of medical care. The far more sensible approach is to focus attention on ways of minimizing the total health care package and of maximizing access of patients to cost-effective forms of treatment — which so often include prescription medicine.

A More Positive Approach

There are positive alternatives to Congress merely responding to citizens who understandably are griping because the cost of medicine is rising — and many health care financing plans reimburse little or none of this visible item of cost to the patient. An effort to modernize the drug approach process would help both reduce the cost of developing new medicines and increase the availability of new and better pharmaceuticals.

The Food and Drug Administration (FDA) has been repeatedly criticized for delays in approving new drugs. 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 drug introduction in the United States in the period 1977 to 1987 reported that more than one-half — 114 out of 204 — were first available in Great Britain. The average delay time — behind the British — was five years.

These delays 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 any of these prescription medicines, you would be taking a substantial career risk. If anybody should suffer any adverse reaction, you would be exposed to severe 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. According to a former FDA commissioner, there have been no instances where a congressional hearing was devoted to the failure to approve a new drug.

As a result, the FDA reviewers faced with a difficult decision often ask for more studies, and delay the introduction of new medicines. 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, I did not pluck that figure of 10,000 out of the air. It was the estimate of how many people died needlessly each year during the period 1967-1976 when FDA was slow in approving beta blockers for reducing the risk of heart attack when the United Kingdom had given the go ahead earlier.

The long-term adverse consequences are greater still. The longer it takes for an innovation to be approved by a government agency — and the more costly the approval procedures — the less likely it is that the new product or process will be introduced. On the positive side, it would be far more appropriate for the Congress to study and thus highlight the excellent performance of the U.S. pharmaceutical companies. Maybe they will even be able to come up with lessons from that industry's experience that could be applied to other American industries which are not doing nearly as well in competing with foreign enterprises.

For starters, we can note that the pharmaceutical industry has not grown through highly leveraged acquisitions or issuing large amounts of junk bonds. Rather, it has expanded because the companies invest extraordinary large amounts each year in long-term research and development of new products — about \$11 billion annually or more than the entire federal government spends on all health research. The industry allocates approximately 16 percent of its sales to R & D — four times the average for other manufacturing industries. Not too surprisingly, this industry leads the world in developing new and better products, at least for the time being.

But Congress's approach seems to be, "if it ain't broke, break it."