

Comment

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Costly regulations force Upjohn merger

By Donald J. Kochan

Compliance with excessive regulations by the Food and Drug Administration have made it difficult for companies to maintain operations in the U.S. pharmaceutical market. The move by Upjohn Co., Kalamazoo's largest employer with 6,700 employees at its headquarters, to merge with Swedish drugmaker Pharmacia AB is indicative of this fact.

Recent history in the pharmaceutical industry shows a clear trend toward the sale, research and development of more drugs outside the United States. Upjohn itself has been steadily increasing the percentage of its foreign market sales as compared with domestic sales.

Why has there been so much corporate flight in this industry? The answer is simple. The U.S. regulatory climate has made it unprofitable to provide drugs to the U.S. consumer. In an attempt to ensure safety, FDA regulations create nearly insurmountable hurdles that manufacturers must overcome to bring a new drug to the market.

FDA requirements more than double the development costs for a drug and significantly reduce the rate at which new drugs are introduced. A study by Tufts University's Center for the Study of Drug Development showed that 80 percent of drugs approved by the FDA between

1987 and 1989 were available earlier in other countries by an average of six years. Between 1977 and 1987, 114 new drugs were available sooner in the United Kingdom than in the United States.

Overseas operations allow companies to research and develop a drug much more quickly and bring it to market years before they could by operating in the United States. In Europe and elsewhere, the approval process for clinical trials, research and marketing is for now much less bureaucratic and much swifter, while still protecting safety and health.

The FDA also makes it difficult for U.S. companies to continue operating in the United States while taking advantage of the openness of foreign markets. In general, FDA regulations prohibit American products that have not been approved for sale here from being exported to and marketed in countries willing to receive them. In order to sell in any markets, firms unwilling or unable to sink their capital into compliance with U.S. regulations are often compelled to set up operations elsewhere.

In this country, the development of a new drug takes an average of 10 years with costs of \$231 million. These excessive costs make it almost impossible for middle-level companies like Upjohn, let alone small companies trying to enter the market,

to compete with heavyweight pharmaceutical firms that have more capital available to spend on regulatory compliance. Thus, we are seeing increasing consolidation in the field of medical technology, of which the Upjohn-Pharmacia merger is the latest example.

The high costs of FDA regulations have been a major barrier to entry for small businesses in pharmaceuticals. They are more innovative and dynamic than corporate elites and could likely improve the quality of drugs available to consumers. When static FDA regulations protect big business, however, the American consumer cannot reap the benefits of a truly competitive drug industry.

More and more often, companies are abandoning the U.S. market. When FDA actions create disincentives even to attempt providing American consumers with life-enhancing or -sustaining products, and when Americans are barred from taking medicines that have been proven to save lives or promote health in other countries, the regulators should realize they have drastically strayed from their original purpose of protecting consumers.

Pharmaceutical and medical device manufacturers have been moving abroad more frequently, and job growth in the U.S. medical technology industry has been decreasing. As fewer companies retain research and development

projects in this country, as fewer Americans are employed in this field and as fewer innovative products come out of the American pharmaceutical industry, the competitive strength of the industry will diminish.

Just as Kalamazoo's economy is closely linked with the success of Upjohn, the success of the American economy depends highly on a strong domestic drug manufacturing industry. FDA regulations which threaten to destroy this industry, therefore, must be reformed.

As Upjohn merges with Pharmacia AB and moves its headquarters to London, one should be wary of the incentives the FDA creates for Upjohn. Upjohn Chairman John Zabriskie, who will become president and chief executive officer of the new Pharmacia & Upjohn Inc., has already been downsizing and cutting costs during the past two years. The companies have indicated that about 4,000 jobs will be cut during the next two years.

If the FDA continues to make it less profitable for pharmaceutical companies to operate here than in foreign lands, Kalamazoo operations are far more likely to be hit with layoffs than operations abroad.

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