Protect Incentives for Pharmaceutical Innovation

In recent years, Congress has faced mounting public pressure to "do something" about the rapidly rising prices of prescription drugs and to rein in what are believed to be excessive industry profits. Although prescription drug spending comprises just 10 percent of overall health care costs, it has been one of the fastest growing components of overall health care spending during the past two decades—rising by an average of 11 percent annually during the 1990s and by 9 percent in 2006, compared to just 6 percent for spending on physician services, according to the Kaiser Family Foundation.

Faced with this public pressure, as well as mounting federal and state government expenditures on drug purchases, members of Congress have proposed a variety of measures to cut the price of prescription drugs. These include reimportation of lower-priced drugs from foreign countries with price controls, direct negotiation of reduced drug prices by the Centers for Medicare and Medicaid Services, and direct restrictions on drug and medical device industry marketing and promotion practices. More recently, would-be health care cost cutters have proposed integrating cost-benefit and comparative-benefit analysis into government-run health programs and in the Food and Drug Administration's (FDA) approval process. For example, the Patient Protection and Affordable Care Act created a new Patient Centered Outcomes Research Institute (PCORI) to study the comparative effectiveness of different treatment options with the expectation that drugs and other treatment options that do not deliver what it considers sufficient "bang for the buck" will cease being prescribed.

Unfortunately, most advocates of such policies have a tunnel-vision dedication to reduce drug costs, with little concern for the effect that forced price reductions would have on industry incentives for innovation. Pharmaceutical prices are high because drug development is expensive, many new drugs treat relatively small patient populations, and most pharmaceuticals fail in laboratory tests or clinical trials before ever making it to market. A 2006 study by U.S. Federal Trade Commission economists concluded that the average cost to develop and test a new drug is between $839 million and $868 million. Thus, policies such as reimportation and comparative-effectiveness analysis would, in the short run, result in lower prices for drugs already on the market, but in the long run reduce both the number of treatment options available and the flow of new drugs entering the marketplace.

The primary argument for incorporating comparative-effectiveness or cost-benefit analysis into government purchasing and ap-

proval decisions is that many expensive new drugs offer little therapeutic advantage over older drugs, but that they cost far more than the closest comparable older drugs. If government health programs paid for only the "best in class" medicine for each therapeutic category, the higher volume of purchases would justify significant price reductions. However, while on average the therapeutic benefit of various drugs in a particular class may be similar, individual patients will often respond quite differently—even to very similar drugs. While it is advisable for public programs to trim excessive costs, implementing cost-benefit or comparative-effectiveness analysis in purchasing or approval decisions would negatively affect patient care.

Although the health care reform legislation stipulates that PCORI recommendations shall not be used as the basis for rationing care, the Act also created a new Independent Payment Advisory Board for the purpose of reducing the growth rate in Medicare spending. That body is expected to rely, in part, on PCORI recommendations to evaluate physician and hospital quality, which means that PCORI recommendations will covertly be used as the basis for restricting available treatment options for patients. Even more pernicious is a proposal by the Centers for Medicare and Medicaid Services and FDA to establish a parallel review process for medical products, which many fear could result in comparative-effectiveness or cost-benefit considerations being improperly introduced into the new drug and medical device approval process.

The argument for reimportation is no more convincing. Although the prices of off-patent and generic drugs—which comprise more than half of all prescriptions filled in the U.S.—are typically higher in other countries, the prices of the latest on-patent drugs is often much lower in countries that impose direct or indirect price controls. Consequently, reimportation advocates promise to relieve high drug costs by allowing American consumers to free-ride on other nations' price controls. But allowing reimportation would effectively import foreign price controls, resulting in less revenue for the industry and a reduction in the capital available to drug companies for continued research and innovation.

Finally, drug industry profits are not "excessive" by any honest measure. Pharmaceutical industry critics like to point out that, in 2005, pharmaceutical firms in the Fortune 500 placed ninth out of the 50 industries ranked by return on assets, 12th in 2004, and second in 2003. However, as the Congressional Budget Office (CBO) notes, "those figures misrepresent the industry's actual profits." Standard accounting measures overstate profitability for R&D-intensive industries by treating most research spending as an expense rather than as a capitalized investment that increases the company's value. "Not accounting for that value overstates a firm's true return on its assets," says the CBO.

Ultimately, high pharmaceutical retail prices reflect the vast expense of developing those products and getting them approved for sale. Without correspondingly high prices, few investors would be willing to take the risks inherent in supplying capital to the pharmaceutical industry. The result would be fewer and fewer lifesaving medicines.

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