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Government Commitment And Regulation Of Prescription Drugs

The U.S. government has legitimate roles to play, but setting prices is not one of them.

by Richard G. Frank

ABSTRACT: Two papers in this volume review efforts worldwide to control the growth of drug spending and discuss the potential role for the U.S. government with respect to rationing of prescription drugs. I put the roles given to government in the two papers in context by focusing on the role of government as a partner with the pharmaceutical industry. I concentrate on the unique features of the prescription drug market, coupled with the fact that government is a payer, regulator, and provider in the health sector. I conclude that the federal government should exercise caution when attempting to regulate prescription drug prices.

Designing health insurance coverage and payment policy for prescription drugs is difficult and contentious. The stakes are very high. One hears daily accounts of the awful choices facing numerous elderly citizens with no prescription drug coverage that challenge our self-image as a decent and generous nation. The idea of elderly Americans stinting on care of chronic illnesses in order to pay the rent is vexing. In addressing a Medicare drug benefit as well as other policies aimed at pharmaceuticals, we are challenged to balance expansion of coverage, the costs of insurance, and the preservation of incentives for pharmaceutical manufacturers to innovate. Drug innovations have brought great health benefits to Americans during the past thirty years.

In the language of economics, prescription drug policy is so difficult because it is an industry with low marginal cost and high fixed cost. Tablets can be produced and distributed for pennies, while development of new drugs costs hundreds of millions of dollars. Thus, high gross margins on brand-name drugs offer large and tempting targets for policies attempting to control costs. Such cost-control solutions need to be balanced against our society’s appetite for new treatments that will benefit us as well as our grandchildren.

Two papers in this volume address issues related to the regulation of the pharmaceutical industry in the context of health insurance and payment schemes. Government plays an important role in markets for prescription drugs in all countries. All Western countries have created institutions that establish standards for safety, efficacy, and quality in manufacturing, but governments’ roles differ when it comes to rationing the use of drugs that meet safety and efficacy standards. The papers offer some views on the potential role for the U.S. government with respect to rationing of prescription drugs.

Richard Frank is the Margaret T. Morris Professor of Health Economics in the Department of Health Care Policy, Harvard Medical School, in Boston. Health Affairs invited his response to several papers on drug spending, which precede this Perspective.
In this commentary I put government roles in context by focusing on its role as a partner with the pharmaceutical industry. I concentrate on the unique features of the prescription drug market, coupled with the fact that government is a payer, regulator, and provider in the health sector.

**The Prescription Drug Market**

The U.S. prescription drug market is a $140 billion dollar industry. Spending on prescription drugs has been growing at a rate of 15–18 percent per year over the past few years. The industry spent about $30 billion in 2001 on research and development (R&D), producing products that have fundamentally altered the process and outcomes of treatment for major diseases. Drug manufacturers spent nearly $16 billion in 2000 on promotion of drugs, $2.5 billion of which was spent on direct-to-consumer advertising. Accounting profits as a percentage of revenues have averaged approximately 18 percent in recent years. (Rates of return when properly adjusted to account for the asset value of R&D are much closer to normal rates of profit.)

The industry is appreciated for its benefits, but there is suspicion that similar levels of innovation might be obtained for less. Glossy advertising campaigns and reports of exorbitant entertaining of physicians fuel such suspicions. That people least able to afford drugs pay the highest price raises concerns about fairness. Some drug firms have engaged in practices that run against the spirit of the law, even if not illegal, by exploiting regulatory rules and patent litigation to keep generic competitors off the market. Nonprice competition has long been active, price competition has until very recently been relatively modest. It is public suspicion in part that drives the impulse to regulate the rationing of prescription drugs. Alan Maynard and Karen Bloor argue for a strong set of regulations that override consumer choice and other market mechanisms. Panos Kanavos and Uwe Reinhardt, in contrast, focus on regulations that aim to create market-like incentives to promote greater price competition.

**Government And Drug Regulation In The United States**

The U.S. government is a major purchaser of prescription drugs. While playing a more limited role than most European governments do, it purchases drugs primarily on behalf of Medicaid, the Department of Veterans Affairs, and the Department of Defense. In 2000 government paid for nearly 22 percent of all spending on prescription drugs in this country. Adding a Medicare drug benefit would involve government in paying for an estimated additional 30 percent of drug spending. That government could regulate prices and possibly quantities for more than half the market frightens the industry and leaves many others uneasy. Some of this discomfort can be attributed to an unsettled U.S. debate about the role of government in general.

Moving away from the larger ideological argument, it is important to consider whether there are special issues involved with assigning a large regulatory role to government when it comes to prescription drugs. The industry argues vehemently against government involvement in pricing and other aspects of rationing. One source of this opposition is that government is likely to be an unreliable partner even if the industry were to agree to price controls and other regulations. Similar observations have been made regarding the government’s ability to keep long-term commitments. This inability is posited to stem from the fact that policy making is dynamic and that there are typically no institutions that can enforce the agreements government makes when it initially establishes a policy. In the prescription drug market, when government is both purchaser and regulator in an industry with high fixed costs and low marginal costs, the commitment problem may be especially important to take into account.

When budget pressures become intense and policymakers are regulating an industry with gross margins (price minus production and distribution costs) of 75–80 percent, the temptation to reduce the margin becomes irresistible. The high rates of accounting profit offer a justification to reduce revenues to the in-
Industry. Even when the incentives for R&D are recognized, it will likely be argued that a 60 percent gross margin is probably good enough. It may be so. However, the costs of being wrong are enormous.

Government must be involved in bringing prescription drugs to all Medicare beneficiaries. Providing an indemnity-like benefit for Medicare while preserving R&D incentives will not be financially sustainable. What, then, should the guiding principles be in designing the government role? Unlike Maynard and Bloor, I do not have great confidence that public budgets and prices will be consistently set at reasonable levels over time. Nor do I believe that consumers’ preferences should commonly be overridden by cost-effectiveness judgments. The heterogeneity in consumers and their responses to treatment makes it unlikely that consumers are always wrong. Setting budgets and prices in favor of today’s fiscal pressures can do a great deal of damage. The consequences may be a threat to a major source of technical advance that has improved the well-being of our citizens.

This does not mean that the government should do nothing. A Medicare drug benefit is long overdue. Here I sympathize with the tack taken by Kanavos and Reinhardt. In the specific case they analyze, reference pricing, they recognize the damage that can be done by using strong, centrally administered financial incentives. Acknowledging the commitment problem and the technical uncertainties involved in implementing new regulations, I believe that government should design insurance, promote institutions that buy drugs effectively, facilitate reliable information on medical treatments, and set the rules for the decentralized drug purchasing on behalf of people with public insurance coverage. By not having government directly involved in setting prices for prescription drugs, I believe that we have the best chance for improved efficiency and fairness in procurement of drugs in a manner that would minimize the deleterious effects of the commitment problems of government in an industry with high fixed costs and low marginal costs.

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