What would happen if the United States adopted other countries' drug price regulations?

Drug Research and Price Controls

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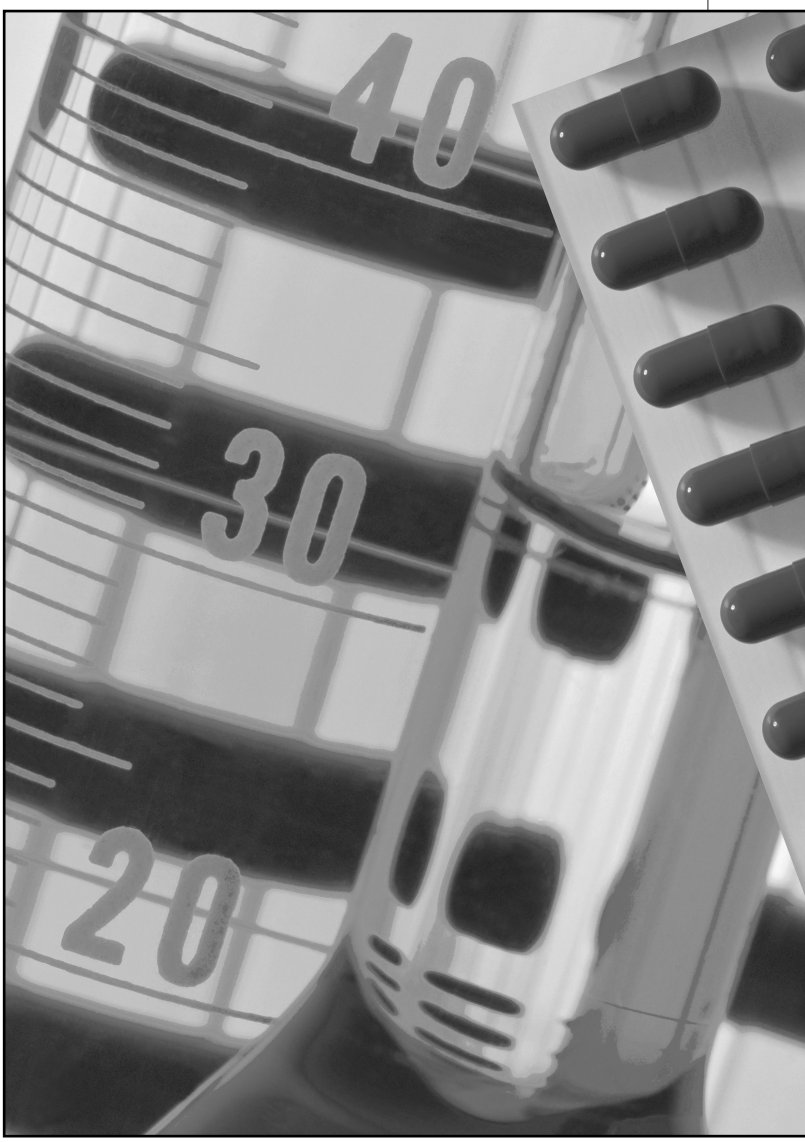
In the United States, prescription drug prices are largely unregulated. That differs from most other countries, where drug prices are regulated either directly through price controls (e.g., France and Italy), indirectly through limits on reimbursement under social insurance schemes (e.g., Germany and Japan), or indirectly through profit controls (e.g., the United Kingdom). For a detailed listing of those controls, see Table 1.

That striking difference has given rise to one of the most contentious public policy issues in recent years: whether or not the U.S. government should join most of the rest of the world in regulating drug prices. In general, supporters of pharmaceutical price controls argue that drug prices in the United States are excessive and that price controls would ensure affordable health care for all Americans. Opponents of price regulation argue that price controls would significantly diminish incentives to invest in pharmaceutical research and development, which would harm medical advances in the future. Are those opponents of regulation correct?



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PHARMACEUTICAL R&D INVESTMENT

Basic economic theory predicts that firms invest in capital up to the point where the expected marginal efficiency of investment (MEI) is equal to the marginal cost of capital (MCC). That equilibrium may be thought of in the classic way as the intersection of a demand (for investment) and supply curve (investment funds). Specifically, the firm's MEI schedule is derived by arranging potential investment projects in a decreasing order with respect to each project's risk-adjusted expected rate of return. Firms will undertake the most profitable projects first

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and will continue to undertake additional projects so long as the expected rate of return from the next project exceeds the firm's marginal cost of capital. The classic supply and demand framework for capital investment may be applied directly to investment in pharmaceutical research and development.

In a neoclassical world, with perfect information and well-functioning capital markets, the MCC schedule would simply be constant at the real market rate of interest. The firm will be indifferent about the source of investment finance. However, recent work — both theoretical and empirical — has demonstrated that the source of finance does matter. Cash flows, because they have a lower cost of capital relative to external debt and equity, exert a positive influence on firm investment spending. That has been particularly true for empirical studies of pharmaceutical R&D investment.

The effect of price controls and other equivalent regulations is to reduce the expected return on investment in R&D (and therefore the demand for R&D). Thus, for firms whose pharmaceutical sales come primarily from markets outside the United States, the expected returns to R&D are likely to be lower (all things considered) than the expected returns to R&D for firms whose market is predominantly the U.S. pharmaceutical market.

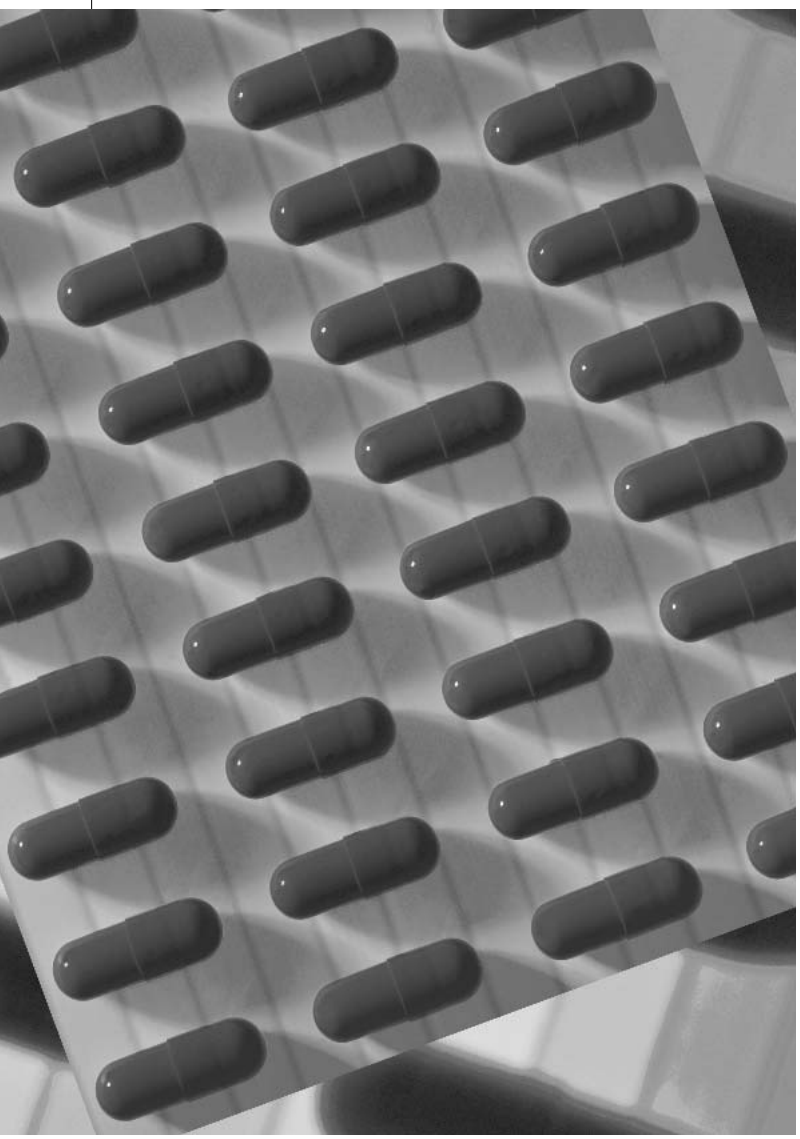

TABLE 1

Regulation Around the World

Various means of regulating prescription drug prices in other countries.

Country	Control Prices at Launch	Control Reimburse-ment Prices	Reference Pricing	Profit Controls	Positive/ Negative Listings	Drug Budgets for Doctors
Austria	✔	✔			✔	
Belgium	✔	✔			✔	
Denmark			✔		✔	
Finland		✔			✔	
France	✔	✔			✔	✔
Germany		✔	✔		✔	✔
Greece	✔	✔			✔	
Ireland	✔	✔			✔	✔
Italy	✔	✔			✔	
Japan		✔		✔	✔	
Netherlands	✔	✔	✔		✔	
Norway		✔	✔		✔	
Portugal	✔	✔			✔	
Spain	✔	✔		✔	✔	
Sweden		✔	✔		✔	
Switzerland		✔			✔	
United Kingdom				✔	✔	✔

Sources: "Pricing and Reimbursement in Western Europe: A Concise Guide," A PhRMA Pricing Review Report (PPR Communications Ltd., 1998); Japanese Information Access Project: "Japanese Regulation: What You Should Know," April 4, 1997 General Proceedings; "Making Sense of Drug Prices," *Regulation*, Vol. 23, No. 1.

Data and model design To begin my research, I collected data for the world's 20 largest pharmaceutical firms (as ranked by 1999 world pharmaceutical sales) for the period from 1988-1999 through IMS America, Standard and Poor's Compustat files, and Scrip Company League Tables. (I ignored firms that ranked between 20 and 50 because many of those are generic drug manufacturers without the same emphasis on R&D as "brand name" drug makers.) Of the top 20 firms for which IMS data were collected, 15 also had data available from both Compustat files and Scrip. Those 15 firms became the sample for my study.

Ranked in order of sales, those firms are: Pfizer, Merck & Co., AstraZeneca, Aventis, Bristol-Myers Squibb, GlaxoWellcome, Pharmacia, Roche, Johnson & Johnson, American Home Products, Eli Lilly, SmithKline Beecham, Abbott Laboratories, Bayer, and Amgen.

I then estimated the following regression model of the determinants of R&D investment intensity:

$$RDS_{it} = f(REG_{it+1}, \text{controls})$$

RDS_{it} = research and development expenditures divided by total firm sales for the *i*th firm in year *t*

REG_{it+1} = percentage of firm pharmaceutical sales outside the United States for the *i*th firm in year *t+1*

In the first equation, the REG variable is intended to serve as a proxy for expected future profitability. (A one-period lead was

employed for theoretical reasons because firm managers respond to expected future returns to R&D, not historical returns. The statistical performance of this rational expectations formulation was similar to other formulations tested, for example contemporaneous values of REG). As part of my previous doctoral dissertation research, I found a high negative correlation (-0.68) between firm pharmaceutical profit margins and the proportion of firm pharmaceutical sales coming from non-U.S. markets. Furthermore, in addition to impinging directly on pharmaceutical profit margins, price regulation diminishes the expected returns to R&D because complex price and reimbursement negotiations delay post-approval product launches. For those reasons, the coefficient on REG was hypothesized to carry a negative sign. An important assumption I made is that the geographical distribution of firm pharmaceutical sales is, to a certain extent, exogenous in the short run. Econometric diagnostics (including Granger-causality tests) and the fact that firm REG values were relatively stable over the sample time period provided evidence suggesting this was indeed a reasonable assumption.

Control variables Both empirical evidence and theory suggest that internally generated funds are an important determinant of firm investment. Models of the determinants of pharmaceutical R&D have consistently demonstrated that to be the case. Thus, I used a lagged cash flow variable in the models as an explanatory variable.

The percentage of a firm's total sales attributable to pharmaceutical sales was also included as an explanatory variable in the models. That variable was designed to control for operations in other industries that are likely to affect a firm's research intensity. Because the pharmaceutical industry is among the most research-intensive sectors of the U.S. economy, diversification into other industries will generally imply a lower overall research intensity.

A European-firm dummy variable and firm fixed effects were also included in several of the regression models to control for systematic differences between U.S. and European firms. Time fixed effects and a time trend variable should capture any industry-wide factors that affect expected profits.

Empirical results Using data from the 15 pharmaceutical firms, several models of the determinants of R&D were estimated over the 1988-to-1998 time period.

The results in Table 2 affirm the central hypothesis that pharmaceutical price regulation diminishes the incentives to invest in R&D. Moreover, the magnitude of the coefficient on the REG variable is quite substantial (-0.07 to -0.20), suggesting that R&D investment may be quite sensitive to the degree of pharmaceutical price regulation.

Impact of a U.S. price control policy To simulate the impact of a U.S. price control policy on R&D investment, I used sample means of RDS and REG in conjunction with the estimated coefficients on REG from the random-effects model specifications (-0.073 and -0.096, respectively). A Hausman test (for fixed effects versus random effects) indicated that was the appropriate model specification. The sample means of the RDS and REG variables for all firms in the sample were 0.116 and 0.426, respectively.

To simulate the effect of a U.S. pharmaceutical price control policy, I increased the value of the REG variable to unity — 100 percent of a firm's pharmaceutical sales are subject to one form of price controls or another — and multiplied that change by the estimated coefficient to predict the effect on industry R&D investment intensity. The results appear in Table 3.

My conclusion that a U.S. price control policy will lead to a decline in R&D investment intensity of between 36.1 and 47.5 percent should be viewed with considerable caution for several reasons. First, the prediction uses a change in the value of REG not observed in the sample — a change from its sample mean of 0.426 to 1.0. The majority of firms in the sample had REG values ranging between 0.3 and 0.8. Such a large perturbation in the value of REG outside its sample range — for predictive purposes — may be inappropriate.

Secondly, my analysis assumes,

TABLE 2

The Effects of Regulation

Regression results from generalized least squares. Dependent variable is R&D-to-sales for 15 of the largest pharmaceutical firms for 1988 to 1998.

Explanatory Variable	Common Intercept	Time Trend	Year Fixed Effects	Firm Fixed Effects	Time Trend Effects Fixed Effects	Year and and Firm Fixed Model	Random Effects without Time Trend	Random Effects with Time Trend
Intercept	0.10 (5.06)	-4.01 (-1.00)	0.09 (2.83)				0.04 (1.32)	-2.01 (-1.38)
$Cashfl_{it-2}$	0.12 (2.07)	0.12 (2.01)	0.12 (1.94)	0.19 (2.34)	0.19 (1.98)	0.18 (1.95)	0.27 (5.88)	0.26 (5.67)
$Pharm_{it}$	0.06 (4.30)	0.07 (4.28)	0.07 (3.91)	0.07 (2.82)	0.06 (2.15)	0.06 (1.82)	0.07 (2.70)	0.07 (2.69)
REG_{it+1}	-0.16 (-4.91)	-0.15 (-3.68)	-0.15 (-3.06)	-0.20 (-2.51)	-0.17 (-1.94)	-0.17 (-1.75)	-0.10 (-2.20)	-0.07 (-1.81)
Euro	0.04 (2.82)	0.04 (2.74)	0.04 (2.89)					
(Year/100)		0.21 (1.03)			0.08 (0.54)			0.10 (1.40)
Adj. R^2	0.74	0.74	0.73	0.76	0.76	0.75	0.76	0.75
N	140	140	140	140	140	140	144	144

t statistics in parentheses

albeit implicitly, that the new U.S. policy would mandate price regulation that is identical to the "average" degree of price regulation present in pharmaceutical markets outside the United States. To be certain, pharmaceutical price regulation is very complex and quite heterogeneous across countries. The fact that my quantification of price regulation is an oversimplification cannot be emphasized enough.

Thirdly, the standard errors of the REG coefficients are quite large relative to the coefficients themselves. The implications are clear: All we can really say is that price regulation in the United States will lead to a decline in R&D intensity ranging from a very small decline to a near complete cessation of all R&D activity; the later is, of course, an absurd conclusion. Finally, it should be expected that any decline in R&D investment intensity resulting from such a policy would occur gradually; pharmaceutical firms do not generally make dramatic adjustments to their R&D investment intensities.

Given those important caveats, it nonetheless seems quite reasonable to expect that a new price control policy on pharmaceuticals in the United States would have a negative (and potentially substantial) effect on firm R&D investment, consistent with economic intuition.

TABLE 3

Price Controls in America

The hypothetical impact of pharmaceutical price regulation in the United States

	REG	RDS
Before U.S. Price Control Policy	0.426	0.116
After U.S. Price Control Policy	1.0	0.074 to 0.061
Percentage Change in RDS		-36.1 to -47.5

CONCLUSION

The past decade has witnessed a dramatic escalation in the political pressures to contain healthcare costs in the United States. A particular focus has been made on the cost of prescription medications. That is not surprising; prescription pharmaceuticals are the least insured element of basic health care in the United States. Furthermore, their prices have been increasing at a rate faster than inflation. Consequently, many efforts have been made to pass into law universal insurance coverage — with price-regulated pharmaceuticals as part of the basic benefit package. Indeed, that was the case under the Health Security Act proposed by the Clinton administration. Despite the fact that Congress failed to pass that legislation, mounting pressures and growing healthcare costs are likely to result in new proposals in the future. From a public policy perspective, it is important to consider both the immediate cost savings associated with price controls and how those controls will affect levels of investment in pharmaceutical R&D — and hence new drug innovation.

My regression results support the hypothesis that pharmaceutical price regulation has a negative effect on firm R&D investment. Using sample means and the estimated coefficients on my REG variable, (from the random-effects model specification), it was projected that pharmaceutical price regulation in the United States would lead to a reduction of between 36.1 and 47.5 percent in industry R&D intensity. New price regulation in the United States could impose a very high cost in terms of foregone medical innovation. R

READINGS

- "The Determinants of Pharmaceutical Research and Development Expenditures," by Henry G. Grabowski and John M. Vernon. *Journal of Evolutionary Economics*, Vol. 10 (2000).
- "Making Sense of Drug Prices," by Patricia Danzon. *Regulation*, Vol. 23, No. 1 (Spring 2000).