The Impact of Indirect Government Controls on U.S. Drug Prices and R&D

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In this article, we hypothesize that the growth of real drug prices in the United States may have been slowed over time because of indirect government controls taking the form of moral suasion, political threats, and crowding-out. We argue that these indirect control mechanisms are accentuated when government controls a greater share of drug spending. Using national data for the United States, we test this hypothesis and show empirically that an increasing share of government spending on pharmaceuticals was associated with a slowing of the growth of real drug prices during the period from 1962 to 2001. We also show that this reduction in the growth of real drug prices had a meaningful impact on pharmaceutical R&D and number of life years lost. More specifically, we determine that the resulting government-induced loss of capitalized pharmaceutical R&D expenditures was between $251 and 256 billion (in 2000 dollars) from 1962 to 2001 and conclude that the federal government's influence on real drug prices may have cost the U.S. economy between 187 and 191 million life years between 1962 and 2001.

The Legal Setting

Beginning in 2006, the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 will provide about 40 million Medicare recipients with the eligibility to receive prescription drug

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insurance coverage in the United States.[1] Under the MMA, various private health insurance plans are expected to compete among themselves to provide drug coverage to Medicare beneficiaries. Up until now, many of the nation's most elderly and frail Medicare recipients were without prescription drug coverage. Thus, not surprisingly, many look upon the MMA as representing the first major expansion of the Medicare program since 1965 and a milestone in U.S. healthcare policy (Oberlander 2003).

While many Medicare recipients will pay a lower out-of-pocket price for drugs under the act, the MMA is not without its critics. One contentious issue pertains to the manner in which drug prices are determined under the act. Specifically, the MMA, as enacted, contains a noninterference clause: "The Secretary of Health and Human Services (HHS) may not interfere with the price negotiations between drug manufacturers and pharmacies and prescription drug plan (PDP) sponsors. In addition, the Secretary may not require a particular formulary or institute a price structure for the reimbursement of covered Part D drugs" (S1860D-1 as cited in the Republican Policy Committee 2004).

Recently, however, legislation has been introduced to modify various aspects of the MMA, including its noninterference clause (e.g., S. 1992, S. 1950, and S. 2053).[2] The idea behind the removal of the noninterference clause is that the federal government will be able to use its considerable size and buyer clout to "negotiate" even more favorable prices from drug manufacturers and thus save large sums of money for both the elderly and society—money that can be used for other necessities of life such as food, clothing, and shelter.

[1]Financing of the drug insurance program will come from sizable federal subsidies paid to the insurance companies and from annual premium payments of $420 from Medicare recipients (all figures are for the year 2006). Moreover, most Medicare beneficiaries will be required to pay a deductible of $250 and a 25 percent coinsurance rate when purchasing prescription drugs, at least up to a predetermined expenditure level of $2,200. After that amount of drug expenditure, the coinsurance rate will increase to 100 percent until a catastrophic expenditure level of $5,100 sets in, in which case the coinsurance rate will fall to 5 percent. Another feature of the drug bill is that the poorest of the poor will be eligible for varying amounts of premium and cost-sharing assistance from the federal government.

[2]The original 1965 Medicare bill contained a similar clause prohibiting any federal interference. However, the noninterference clause contained in the original Medicare law lasted less than 20 years. In 1983, the federal government introduced the Diagnosis Related Groups (DRG) system, which established prospectively regulated rates to pay for hospital services provided under part A of the Medicare Act. Furthermore, less than 10 years later, the federal government created the Resource Based Relative Value Scale (RBRVS) system. The RBRVS pays physicians under part B of the Medicare Act based on their time and effort in providing services. Both of these payment systems are essentially price controls and conflict with the language in the original Medicare Act.

However, the concern is that the government might simply use its buying clout to "administer" or "control" prices rather than negotiate them. Economic theory suggests that price controls will have a negative impact on drug development for two reasons. First, regulations that suppress drug prices reduce expected revenues relative to costs and thereby make R&D investment less attractive from the firm's (and investors') perspective. This is especially the case with biotechnology firms that are "burning cash" provided by equity investors and that have no current profits or sales to fund R&D spending. Second, suppression of drug prices will also reduce the firm's cash flows, which have been shown to be a particularly important source of financing for pharmaceutical R&D (Grabowski and Vernon 2000; Vernon 2004, 2005). Again, with biotech firms, the expectation that drug prices will be driven down or held flat means that future revenues will be held down as well: the return on investment of existing drugs may fall below the opportunity cost of capital. The capital markets (both debt and equity) will not provide the funds necessary to support future R&D if the government forces rates of return below the opportunity cost of capital. Indeed, we have shown empirically that more than one-third of all new drug launches would have been lost from 1980 to 2001 if the U.S. government had limited pharmaceutical price increases to the same rate of increase as the general consumer price index, thereby reducing pharmaceutical cash flows (Giaccotto, Santerre, and Vernon 2005).

Given the social significance of new drug discovery and development and the anticipated negative impact of pharmaceutical price controls, challenges to the noninterference clause contained in the MMA should be taken seriously. This study empirically investigates how government influence in the past has affected real drug prices in the United States. Evidence on the effect of governmental influence on real drug prices is then used to predict the amount of R&D spending, lives lost, and the corresponding economic costs that may be attributed to this government influence. The empirical findings will serve as a conservative indication of what we might expect with the removal of the noninterference clause from the MMA.

Government's Indirect Influence on Pharmaceutical Pricing

Unlike the governments of many countries in Europe and Canada, the U.S. government has in the past not directly controlled the drug prices paid by private consumers and insurance companies. However,

in the absence of direct private price controls, the different levels of government (e.g., federal and state) in the United States possess various ways to indirectly control private drug prices. Some of these methods of government influence may not be mutually exclusive, and some may be more invasive than others. For discussion purposes, the three mechanisms of government influence are classified as moral suasion, threat, and crowding-out.

Governments, especially the federal government, can sometimes use *moral suasion*, or jawboning, to persuade companies like drug manufacturers to moderate price increases. Moral suasion is particularly effective when company goals otherwise clash with national objectives. The steel industry in the early 1960s provides a prime example of government's use of moral suasion (Scherer and Ross 1990). In 1962, U.S. Steel announced a steel price increase averaging $6 per ton. The price increase drew sharp criticism from President Kennedy, who pointed out that the national economy was experiencing a recession. In response to Kennedy, U.S. Steel eventually rescinded the price increase.

A similar example relating to the drug industry occurred during the 1990s (Pear 1993). In response to the perception of high and rising drug prices, President Clinton's health policy advisers suggested several initiatives, including direct price controls and the reprimanding of companies whose prices were judged to be "excessive." Under heavy lobbying from the drug industry, the government backed away from more direct price controls and leaned toward using "government exhortation" rather than "compulsion" as a means to influence drug prices (Pear 1993). By potentially reducing a company's franchise value through a tarnished national image, the general idea was that adverse publicity would put pressure on the industry to moderate price increases.

The *threat* of more direct price controls in the future provides a second method by which government may influence both the level and rate of increase of drug prices. Threat considers that the actions taken by government today may provide a signal about the invasiveness of actions that the government might take tomorrow. For example, some prominent government representatives might voice the opinion that the government should adopt a more rigid drug-pricing policy unless the industry disciplines itself. Facing the increased prospect of direct controls and lowered expected profits, individual drug companies might moderate their price increases. As another example, state or federal politicians might attempt to initiate new laws to regulate drug prices. Regardless of whether laws actually pass, the drug

industry might perceive that more direct controls are inevitable unless appropriate actions are immediately implemented.

Several proposed laws in the past provide instances where threats of this kind may have worked. As one example, in response to persistently high pharmaceutical profits, Senator Kefauver introduced in 1961 a provision contained in Senate bill 1552 that would have limited pharmaceutical patents to three years of full exclusivity (Comanor 1986). After that period, patent holders would have been required to license their drugs to all approved companies at a prespecified royalty rate. The compulsory licensing provision, however, never passed the parent committee on the judiciary and was not included in the final 1962 drug amendment.[3]

As another example, in 1966, Senator Long introduced a bill stipulating that drugs purchased under federally aided programs should be prescribed under the generic rather than the brand name of the drugs (Schwartzman 1976). While the proposal only applied to individuals covered by public drug insurance programs, it was believed that the approval of the bill would have caused a national trend in private plans as well. Similarly, in 1967, Senator Montoya introduced a bill providing for the reimbursement of the costs of qualified drugs only, which were defined as those drugs acceptable to a formulary committee. Drug reimbursement would have been made on the basis of the lowest drug cost, provided that the drug was of an acceptable quality to the formulary committee. Different aspects of these two bills were merged, modified, and then proposed over the next five years but never progressed beyond the House-Senate Conference Committee. Nevertheless, the threat that these proposed laws generated likely affected the pricing behavior of drug companies at that time.[4]

Crowding-out, the third and final type of indirect control, occurs when public programs expand at the expense of private plans. For instance, the creation and expansion of both the Medicare and Medicaid plans meant less enrollment of the population in private health insurance plans. As another example, government spending on pharmaceuticals amounted to less than 3 percent of total pharmaceutical

[3]Schwartzman (1976) and Comanor (1986) both point out that the pharmaceutical industry has continued to face close scrutiny from the government since the Kefauver hearings in the late 1950s.

[4]Sometimes threats turn into realities. Since 1974, the federal Maximum Allowable Cost (MAC) program has mandated drug substitution in government programs such as Medicare and Medicaid, limiting reimbursement for multiple-source drugs to the lowest cost at which chemically equivalent drugs are generally available, plus a reasonable fee for dispensing a drug (Schwartzman 1976).

spending in 1960 but had risen to nearly 22 percent by 2002.[5] Crowding-out can influence private drug-pricing policies in a number of ways.

First, as the government controls an increasing share of pharmaceutical spending, the moral suasion and threat effects are likely to place increasing downward pressure on drug prices. Simply put, the sincerity behind jawboning and the credibility of threats are much more meaningful when government has more muscle to flex. Second, an increasing share of government spending on pharmaceuticals may reflect a shift of enrollees from private to public health plans. As private plans decline in number, the lower demand for pharmaceutical products results in lower private prices, especially if those moving to the public plans represent the sicker in society and in more need of pharmaceuticals. Third, as the government becomes increasingly responsible for a growing share of spending on pharmaceuticals, the government faces an increasing financial incentive to use its muscle to reduce private drug prices as a means of instituting fiscal restraint given that public prices are typically stated as a fraction of private prices.

From a theoretical perspective, the preceding discussion suggests that the government may wield considerable influence over private drug prices even in the absence of direct price controls. Furthermore, these influences are likely to be more pronounced when the government has greater authority over a relatively high proportion of all pharmaceutical spending. To determine the validity of the theory, we employed annual data for the period 1962–2001 and multiple regression analysis to empirically examine whether the government has historically been capable of exerting an influence over real drug prices in the United States. The multiple regression equation takes the following specific form:

$$(1)\quad \Delta\ln(P) = \beta_0 + \beta_1\Delta\ln(OOP_{t-1}) + \beta_2\Delta\ln(GOV_{t-1}) + \beta_3\Delta\ln(GDP_{t-1}) + \beta_4\Delta\ln(P_{t-1}).$$

Where

$\Delta\ln(P)$ = annual percentage change in the ratio of the pharmaceutical consumer price index to overall consumer price index (i.e., growth of real drug prices from one year to the next);

$\Delta\ln(OOP_{t-1})$ = annual percentage change in the consumers' out-of-pocket fraction of private pharmaceutical spending in the prior year;

[5]Figures come from the Centers for Medicare and Medicaid Services at www.cms.gov.

$\Delta\ln(GOV_{t-1})$ = growth of government's share of spending on pharmaceuticals in the prior year;
$\Delta\ln(GDP_{t-1})$ = growth of real gross domestic product in the prior year;
$\Delta\ln(P_{t-1})$ = growth of real drug prices in the prior year; and
β_i = parameters to be estimated.

Equation (1) represents a first difference equation because the data are first differenced from one year to the next after transforming the variables into logarithms. We examine first differences rather than the level of real drug prices for two reasons. First, the popular press normally draws attention to changes in real drug prices from one year to the next. In fact, it is not uncommon for a newspaper article to point to rising real drug prices as an indication of the excessiveness of drug prices. Second, if unit roots exist in the data, the use of levels can result in spurious correlations over time (Granger and Newbold 1974, Phillips 1986). First differencing serves as a common remedy when unit roots exist in the data. Notice also in equation (1) that all of the independent variables are lagged one year, allowing for the likelihood that drug price decisionmakers look to the previous period for market information when setting current prices.

As noted by researchers, consumer price indexes are not measured without error because substitution effects and quality changes over time are not fully incorporated (Hausmann 2003). Several authors have also pointed out the biases that previously existed in pharmaceutical price indexes because of (1) the undersampling of new drugs, (2) the failure to treat generic drugs as lower-priced substitutes for branded drugs rather than new drugs, and (3) the use of list instead of transaction prices.[6] Nevertheless, the pharmaceutical price index represents the best available time series indicator of drug price swings in the United States. Moreover, since we are examining changes in the ratio of the pharmaceutical and general CPI measures over time, some of the substitution and quality bias in the numerator and denominator may tend to cancel out. In addition, average year-to-year parameter estimates are obtained in the multiple regression analysis below. These short-run estimates may avoid some of the bias because sufficient time does not pass for substitution effects and quality changes to fully work themselves out. It should be kept in mind, however, that any remaining measurement error biases the parameter estimates toward zero if the rest of the model is properly specified.

Our main hypothesis suggests that the sign of the estimated

[6]Beginning in 1995, the Bureau of Labor Statistics has taken steps to correct some of these biases in the pharmaceutical price index.

coefficient on the variable capturing the growth of government's share of spending on pharmaceuticals should be found negative. That is, the moral suasion, threat, and crowding-out effects will be more dominant as government's share of pharmaceutical spending grows, with the effects showing up in a slower growth of real drug prices. The other independent variables control for important changes in the consumer's out-of-pocket fraction of pharmaceutical spending, the past growth of the economy, and past real drug price growth. The empirical results from the basic model are displayed in the second column of Table 1.

TABLE 1
MULTIPLE REGRESSION FINDINGS

Dependent Variable: Annual Growth of Real Drug Prices		
	Model 1	Model 2
Variable	Coefficient (t-statistic)	Coefficient (t-statistic)
Constant	0.018 (3.36)	0.018 (3.53)
Lagged growth of consumer out-of-pocket fraction	0.036 (0.34)	–0.088 (0.73)
Lagged growth of government's share of pharmaceutical spending	–0.122 (2.83)	–0.109 (2.57)
Interaction term between lagged growth of pharmaceutical spending and year dummy between 1992 and 2001		–0.453 (1.87)
Lagged growth of GDP	–0.421 (3.31)	–0.453 (3.65)
Prior year growth of real drug prices	0.790 (11.1)	0.827 (11.6)
Adjusted R-squared	0.833	0.844
Durbin-Watson statistic	1.77	2.01

The multiple regression results account for more than 83 percent of the variation in the growth of real drug prices, which represents a sizable amount for a first difference model to explain. The main hypothesis that increased government spending on pharmaceuticals should be associated with slower real drug price growth is supported by the empirical findings. Since the coefficients can be interpreted as

elasticities because of the first difference in log specification, the empirical results indicate that a 10 percent increase in the share of government spending on pharmaceuticals is typically associated with a 1.2 percent annual reduction in the rate of growth of real drug prices. While a 1.2 percent annual reduction in real drug price growth may not in itself represent sizable savings, total savings can easily amount in the millions of dollars within a few years because of compounding over time.

The third column of Table 1 shows the results for a different model specification where we create an interaction term between the growth of government's share of drug spending and a dummy variable taking on the value of 1 for any year during the period from 1992 to 2001 and zero otherwise. During this period both the Omnibus Budget Reconciliation Act (OBRA) of 1990 and the Veterans Health Care Act of 1992 required rebates or discounts based upon the prices that drug manufacturers charge their most favored customers. In addition, OBRA of 1990 adopted a rebate mechanism that financially penalizes drug companies when they raise their prices for drugs covered by the Medicaid program by more than the general CPI.

From a theoretical perspective, it is unclear how these two public programs might have influenced real drug price growth over time. On the one hand, the financial penalty of raising drug prices beyond the general price level may have moderated drug price increases since the early 1990s (Scott Morton 1997). On the other hand, the most favorite customer clause may have provided an incentive for drug manufacturers to raise private prices even faster than normal over time (Scott Morton 1997, Duggan and Scott Morton 2004). The resulting impact of these two laws on real drug price growth depends on the net effect of these conflicting tendencies as well as on the overall tendency of government to use its moral suasion, threat, and crowding-out abilities as its size grows on the demand side of the pharmaceutical market.

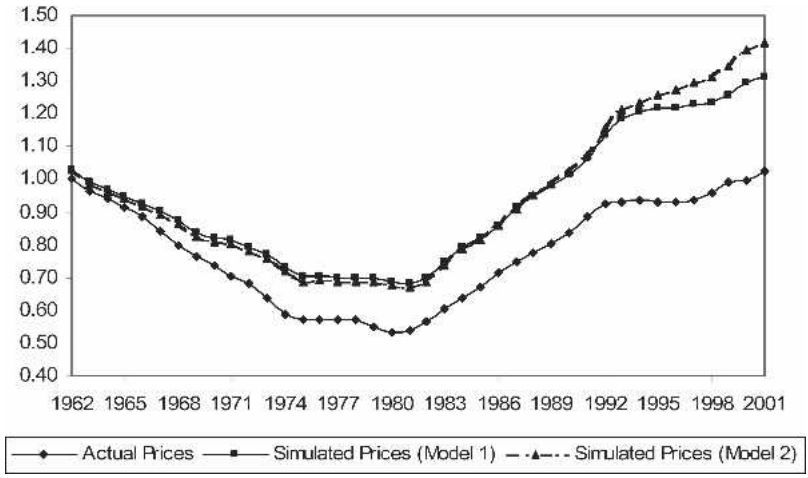
The results in the third column of Table 1 show that government's share of pharmaceutical spending had an even more pronounced effect on real drug price growth beginning in 1992. In fact, the sum of the parameter estimates on government's share and the interaction term suggests that a 10 percent increase in government share on spending was associated with a 5.3 percent drop in real drug price growth after 1992. We are reluctant to attach all of the reduction in real drug price growth to these two laws, however, because many other structural and policy changes took place in the pharmaceutical industry beginning around that time. For instance, the Drug User Fee Act, pharmaceutical benefits management (PBM) companies,

and Clinton's healthcare proposal all evolved during that same period and may have influenced the growth of real drug prices.

In any case, we use both elasticity estimates to simulate the lower and upper bound of real drug prices during the period from 1962 to 2001 in the absence of any indirect government influence. Figure 1 provides a graphical depiction of this simulation. In the figure, the real drug price, as measured by the ratio of the pharmaceutical price index to the general consumer price index, has been set to 1 in 1962 to facilitate the comparison between the periods. Three real drug price series are shown. One series identifies the trend in actual real drug prices over time, whereas the other two series show how drug prices *would* have trended in the absence of any government influence for both the lower and upper bound estimates. Notice that real drug prices actually dropped by roughly 50 percent from 1962 to 1980. Also notice that after 1980, real drug prices continued to increase up to 2001, where they attained approximately the same level observed in 1962.

FIGURE 1

REAL DRUG PRICES FROM 1962–2001: ACTUAL AND SIMULATED



Our simulated drug price series indicates that government policies had a significant impact on these trends. More precisely, had the government's share of spending on pharmaceuticals not grown over the period, pharmaceutical prices would still have declined from 1962 to the early 1980s but not to the degree actually observed. Indeed, the

ratio of pharmaceutical prices to general consumer prices would have stood at approximately 0.68 (0.69 in Model 1) rather than 0.53 in 1980, in the absence of any government influence, thus representing a 27.5 percent differential.

According to the simulations, the effect of government influence on pharmaceutical prices became even more pronounced after OBRA of 1990 and the Veterans Act of 1992 were enacted, and government spending on pharmaceuticals continued to expand. The growing influence can be seen by the widening gap between the simulated and actual drug price series after the early 1990s. In fact, the ratio of pharmaceutical prices to general consumer prices would have equaled between 1.31 and 1.42 (for Models 1 and 2, respectively) instead of 1.02, or at a 28 to 38 percent higher level, in 2001 if not for the new public drug price controls.

Government's Influence on Pharmaceutical R&D and Life Years Lost

How much of a cost did this governmental influence on real drug prices impose on the U.S. economy and on its ability to invest in new medicines? While the federal government's success in exerting downward pressure on real drug prices may have benefited consumers in the short run, because lower drug prices improve access to existing pharmaceuticals, this influence has undoubtedly come at the cost of reduced levels of pharmaceutical innovation.

Before delving into the formal analyses, it is important to emphasize that we will not be undertaking a full cost-benefit analysis; rather, we seek only to estimate the economic costs associated with the government-induced reduction in the rate (and level) of pharmaceutical innovation. Indeed, the issue of whether the government's influence on real drug prices has been, on net, socially beneficial or harmful will not be tackled. However, because the costs associated with forgone innovation are both harder to quantify and to conceptualize than the short-run benefits of increased access (a 40 percent reduction in the price of Lipitor today, for example, is more tangible than the cost associated with a five-year delay in the discovery and development of a new Alzheimer's drug), we have limited our research to estimating these costs.

Furthermore, because most policy debates regarding the containment of pharmaceutical prices seldom give the same consideration to the cost of forgone innovation as they do the potential short-run benefits of expanded access, we hope that our research can serve to

inform this debate and result in more balanced analyses of the public policies affecting the pharmaceutical industry.

We estimate these costs by combining the empirical work presented in the last section with some of our previous research (Giaccotto, Santerre, and Vernon 2005) on the determinants of pharmaceutical R&D growth rates, and specifically our estimate of 0.583 for the elasticity of R&D investment with respect to real drug prices in the United States (which implies that a 10 percent reduction in real drug prices will be accompanied by a 5.83 percent reduction in R&D investment).[7] This elasticity measure allows us to estimate the forgone R&D associated with the government's historical influence on real drug prices over the past 40 years. We then utilize this measure of forgone R&D with the recent research by Lichtenberg (2002) on the productivity of pharmaceutical R&D in the United States over a similar period (1960–97). Combining the empirical findings from these two studies enables us to translate our forgone R&D estimate into forgone U.S. life years. Finally, we employ standard valuations of human life years to generate a dollar cost estimate of the government's influence on real drug prices over the past 40 years.

The first step in our analysis involves measuring the annual reduction in pharmaceutical R&D intensity (i.e., R&D expenditures expressed as a percentage of sales) that has resulted from the government's historical downward pressure on real drug prices in the United States. To measure the annual reduction, we simply compare the observed industry R&D intensity from 1962 to 2001 with the two simulated scenarios in the absence of any government-exerted downward pressure on real drug prices. Within the context of the empirical models presented in the last section, we create this situation by setting the government's share of spending on pharmaceuticals to zero and generating predicted R&D intensities.[8] To obtain estimates of actual forgone R&D dollars, we assumed that real pharmaceutical sales in this counterfactual environment would have remained unchanged. This is a conservative assumption because empirical studies have consistently estimated an inelastic demand for pharmaceuticals. Thus, one would expect higher prices to result in higher total revenues and thus higher R&D expenditures (when measured as a

[7]This elasticity estimate is highly consistent with other study estimates. For example, Scherer (1996) and the DHHS (1994) obtained elasticity estimates of 0.61 and 0.54 to 0.68, respectively.

[8]Because our model is dynamic (in the sense that we are estimating growth rates and not levels), the principal effect of our simulation is achieved by simply constraining to zero the growth rate of government's share.

percentage of sales). Finally, we capitalize forgone R&D dollars to the year 2001 using an 11 percent cost of capital (DiMasi, Hansen, and Grabowski 2003) and sum up these "lost" R&D dollars. Table 2 presents the estimates.

TABLE 2

Estimates of Lost R&D Spending Because of Government Indirect Controls on Drug Prices

Year	Predicted RD-to-Sales (%) (Model 1)	Predicted RD-to-Sales (%) (Model 2)	Actual RD-to-Sales (%)	Cumulative Lost R&D Dollars (Billions of Capitalized 2000US$)
1962	8.72	8.71	8.56	$1.47–$1.55
1965	9.33	9.29	9.14	$5.30–$6.43
1970	9.92	9.84	9.32	$24.53–$29.00
1975	10.15	10.04	9.02	$70.65–$79.85
1980	10.32	10.21	8.86	$118.09–$131.91
1985	14.45	14.43	12.90	$156.09–$172.02
1990	16.14	16.21	14.44	$184.24–$199.74
1995	19.56	19.93	16.70	$213.35–$226.48
2001	19.25	20.14	16.67	$251.00–$256.25

The key estimate from this simulation exercise is, of course, the measure of cumulative forgone R&D investment. We estimate this amount to range between $251.0 and $256.3 billion as of 2001. This figure represents the amount of R&D that the federal government, through its influence and constraint on real drug prices, disincentivized firms to undertake.

A subsequent question is: How much did this "squeezed out" pharmaceutical R&D investment cost U.S. citizens? To answer this question, we rely on the recent econometric work by Lichtenberg (2002). Lichtenberg has estimated that from 1960 to 1997, the expenditures on pharmaceutical R&D needed to gain a single life year were about $1,345. Because his estimate was based on the productivity of pharmaceutical R&D (in terms of its impact on life expectancy in the United States) over virtually the same period as our analysis and simulation exercise, we use his figure to approximate the cost of forgone pharmaceutical innovation. Dividing the aforementioned range of lost R&D investment by $1,345 results in a loss of between

186.6 and 190.5 million life years (lives shortened or crippled by early death or illnesses) due to the absence of new drug development.

Translating this figure into a cost expressed in dollars is straightforward. However, because some controversy exists about the precise value of a human (U.S. citizen, in this case) life year, we present results for a range of estimates ($50,000–$150,000). One might bear in mind, however, that recent research by Murphy and Topel (2003) has estimated that Americans value a human life year at approximately $160,000. As such, it is possible that the high end of our sensitivity analysis is still conservative. These dollar cost estimates are summarized in Table 3. The estimates in Table 3 indicate that the cumulative range of cost associated with forgone pharmaceutical innovation over this 40-year period is $9.3–$28.6 trillion, depending on the assumed value of a life year in the United States and the statistical model used.

TABLE 3

ESTIMATES OF LIFE YEARS LOST AND COST TO THE U.S. ECONOMY BECAUSE OF GOVERNMENT INDIRECT CONTROLS ON DRUG PRICES

Value of 1 Life Year in the U.S.	Forgone Life Years from Government Influence on Real Drug Prices	Cost to U.S. Economy from Government Influence on Real Drug Prices
$50,000	186.6–190.5 million	$9.3–$9.5 trillion
$100,000	186.6–190.5 million	$18.7–$19.1 trillion
$150,000	186.6–190.5 million	$28.0–$28.6 trillion

Conclusion

The MMA currently contains a noninterference clause, but so did the original Medicare Act. With the passage of the MMA, an additional 14 percent of the population—and, more important, an additional 40 percent of drug consumption—comes under the purview of the government in 2006. As drug expenditures rise in the future, fiscal pressure will most likely build for replacing the noninterference clause with some type of direct price control mechanism. Basic economic theory suggests, however, that direct price controls can have disastrous effects on innovation by squeezing out R&D expenditures. Thus, price controls can lead to fewer new pharmaceutical products; products that would have improved, extended, or saved human lives.

In this article, we examined how government's influence in the past affected private drug prices and R&D expenditures. The results from our empirical analysis suggest that government influence in the past has had a sizable impact on real drug prices and thus R&D commitments. Estimates suggest that the government's indirect influence on drug prices has led to a cumulative capitalized loss of roughly $250 billion in pharmaceutical R&D from 1960 to 2001. Because this "lost" R&D means "lost" drugs, we estimate that approximately 188 million life years were never realized because of the indirect influence that the government has had on drug prices. When expressed in dollar terms, these estimates imply that the U.S. government indirectly imposed social cost of $9.3–$28.6 trillion on the U.S. economy.

The impact of price controls on Medicare drug purchases would be significantly greater in a much shorter period of time because they are deeper and because they would affect a larger segment of the pharmaceutical market and would send a negative signal to the hundreds of biotechnology firms that as yet have no revenues and that rely upon venture capital and pharmaceutical firm investment to sustain R&D activities.

The benefits of expanded access to existing medicines must always be weighed carefully against the potential long-run costs associated with reduced levels of innovation. Indeed, a previous study that examined the impact of more rapid access to generic versions of branded pharmaceuticals found that for every dollar in consumer benefit gained by greater access to more immediate access to lower-priced medicines now would cost consumers three dollars in lost future innovation. This was true even though generic competition did not completely eliminate incentives to invest in new medicines (Hughes, Moore, and Snyder 2002). By contrast, price controls, as this study demonstrates, do just that.

It is easy to overlook these long-run costs of drug price controls because they occur many years in the future. But informed and intelligent public policy must carefully consider these costs when conducting policy or proposing new policies. It is the *net* and long-term benefits (or costs) that matter to society, not just the short-term benefits (or costs), which are often much easier to measure and conceptualize.

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