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Are Drug Price Controls Good for Your Health?

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EXECUTIVE SUMMARY

Now that the Medicare Prescription Drug, Improvement and Modernization Act (MMA) of 2003 provides senior citizens with drug insurance coverage beginning in 2006, several political and special-interest groups have expressed the opinion that the Medicare program should use its immense bargaining power to negotiate prices directly with drug manufacturers. While the MMA, as enacted, forbids such direct negotiation, a modification allowing direct Medicare negotiation is now under consideration. Specifically, proponents such as the American Medical Association and the AARP want the government to reduce drug prices paid by Medicare to those purchased by the Department of Veterans Affairs in the U.S. or set by the Patented Medicines Price Review Board in Canada.

New drugs generate immense social benefits by saving, improving, and extending lives. Economic theory is clear in its prediction that price controls will reduce biotechnology and pharmaceutical research and development (R&D) by lowering expected revenues and through reduced cash flows.

By 2006, the federal government will be purchasing or paying for nearly 60 percent of all prescription drugs in the United States, making it the most important buyer of medicines in America. Hence, we might assume that federal price controls will reduce incentives to invest in new drug development. To determine how direct Medicare negotiation and formulary restrictions might affect pharmaceutical and biotechnology R&D, in this study we examine how government influence has historically affected pharmaceutical prices. Based upon this evidence from the past, we can infer, rather than speculate about, the impact of what happens to pharmaceutical and biotechnology prices and R&D in the future as government exerts more control over prices.

Collecting national data for the U.S. for 1960–2001 and using multiple regression analysis, we find that from 1992 to 2001 a 10 percent increase in the growth of government's share of total spending on pharmaceuticals was associated with a 6.7 percent annual reduction in the growth of pharmaceutical prices. Two new laws, OBRA of 1990 and the Veterans Act of 1992, aimed at controlling drug prices under public programs, account for much of this impact.

Using these regression results, we then simulate how the prices for medicines would have differed throughout the period from 1960 to 2001 in the *absence* of any government influence. The simulation implied that the ratio of the pharmaceutical price index to the general price index would have been 1.27 rather than 0.94 in 2001, suggesting that pharmaceutical prices would have been about 35 percent higher, on average, in the absence of this government influence.

Using the predicted trend in pharmaceutical prices without government influence and an established elasticity of R&D spending with respect to drug prices from prior research, we determined that the resulting government-induced loss of capitalized pharmaceutical R&D expenditures was $188 billion (in 2000 dollars) from 1960 to 2001. This "lost" R&D may be translated into human life years "lost"—literally, increased pain and suffering and shorter lives caused by the absence of new medicines and future research—by using results from recent econometric work on the productivity of pharmaceutical R&D in the U.S. over the same period. We conclude that the federal government's influence on real drug prices cost the U.S. economy approximately 140 million life years between 1960 and 2001.

Applying this same analysis to the future, we predict that the increased government influence on drug purchases under the MMA will dramatically reduce both real drug prices and R&D spending. We estimate that real drug prices will decline by 67.5 percent (or about 49 percent lower than pre-MMA levels) if purchases under the MMA are treated in the same manner as drug purchases under Medicaid and the VA

have been treated historically. We further estimate that this decline will reduce R&D spending by 39.4 percent, or $372 billion over the lifetime of the act. This translates into a reduction of 277 million life years.

With the passing of the MMA, an additional 14 percent of the population and, more important, an additional 40 percent of all drug consumption, will fall under government's purview. Many wish to replace the noninterference clause presently contained in the MMA with some type of direct government price setting mechanism. The results of this study indicate that government's downward pressure on drug prices has historically generated sizable social costs during a forty-year period when only a relatively small percentage of pharmaceutical expenditures were directly controlled by the government.

This suggests that imposing price controls similar to those found in the VA, Canada, or Medicaid for 60 percent of all biotechnology and pharmaceutical use will reduce investment in R&D and lead to a loss of life and life expectancy of a greater magnitude than has been the case for the past half-century for these types of price controls. Consequently, our findings suggest that informed public policy debate should consider the trade-off between lower drug prices now and future health benefits lost because of lower R&D spending.

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BACKGROUND AND PURPOSE OF STUDY

The MMA and the Noninterference Clause

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 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. health-care 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)

This noninterference clause was originally motivated by a belief that competition among private health plans and among pharmacy benefit managers, as well as other market mechanisms, is better designed to keep drug prices at reasonable levels than direct government influence. It was also believed that direct price controls by the federal government, while perhaps well intended, will undermine investment in future drug discovery.

The Original Medicare Act and the Noninterference Clause

Recently, however, legislation has been introduced to modify various aspects of the MMA, including its noninterference clause (e.g., S. 1992; S. 1950; S. 2053). The idea behind this legislation is that the federal government can use its considerable size and buyer clout to secure 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.

While these proposals have not yet passed, they are not without precedent. The original 1965 Medicare bill contained a similar clause prohibiting any federal interference:

> Nothing in this title shall be construed to authorize any federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided, or over the selection, tenure, or compensation of any officer or employee of any institution, agency, or person providing health services; or to exercise any supervision or control over the administration or operation of an such institution, agency, or person. (Oberlander, 2003)

According to Oberlander (2003), the purpose of this statement in the original Medicare bill was to reassure hospitals and doctors that the government had no intentions of regulating their activities as a means of securing their approval for the legislation.

However, the noninterference clause contained in the original Medicare law lasted less than twenty 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 ten 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. The hospital and physician price controls were embraced because of private and fiscal concerns over rising health-care costs and growing deficits. One might argue that these two federal regulations have not been particularly harmful to the respective health-care industries—so why worry about price controls in the drug industry?

Drug Price Controls and Innovation

The main argument against drug price controls is the negative impact that they would have on innovation. Biotechnology and pharmaceutical firms compete to be the first company to bring a new and valuable drug to market and thus receive the potential prize of sizable economic profits. The company expects to use cash flows from current and future profits to support future rounds of research and development (R&D), with the intention of discovering, developing, and marketing newer, and therapeutically more important, drugs in the future.

Because of the time-consuming and highly risky nature of pharmaceutical R&D, the decision-making process tends to unfold sequentially. At several junctures in the R&D process, a company reviews the development status of a drug and makes a decision about whether to continue or to abandon the project. Sometimes projects fail or are rejected unexpectedly because of safety or effectiveness concerns. The decision, of course, rests on the expected profits associated with the developmental drug and thus considers both expected revenues and costs. Expected revenues depend on such factors as the expected price of the drug, its therapeutic novelty, the number of other drugs to treat a given disease, and the potential size of the original market, as well as the potential for establishing new uses through clinical application once the drug is approved by the Food and Drug Administration (FDA).

Projected costs depend on the frequency and severity of anticipated adverse reactions to the drug and the expected development, marketing, distribution, and production costs (DiMasi et al., 1991). FDA drug development costs continue to increase in response to a growing demand for more clinical information and more clinical trial data. These costs influence the number of new projects that can be funded as well as the opportunity costs associated with investing in one project and not another. The most recent estimate of drug development costs published in a leading peer-reviewed economic journal concludes that it costs $802 million to successfully develop a new medicine (DiMasi, Hansen, and Grabowski, 2003).

Price controls will have a negative effect on the development of new drugs 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, 2003, 2004). 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).

Purpose of This Study

Given the social significance of new drug discovery and development and the anticipated negative im-

pact 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.

U.S. GOVERNMENT'S HISTORICAL INFLUENCE ON PHARMACEUTICAL PRICING

Mechanisms of Government Influence

Unlike the governments of many countries in Europe and Canada, the U.S. government has in the past not directly controlled the drug price 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 U.S. 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 four mechanisms of government influence are classified as moral suasion, threat, crowding out, and buyer power.

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 advisors 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.[2]

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.[3]

Crowding out, the third 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 spending in 1960 but had risen to nearly 22 percent by 2002.[4] 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. 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 public drug prices as a means of instituting fiscal restraint. According to dual market theory, lower public prices often result in reduced private prices (Santerre, 2002).

Buyer power, the last mechanism by which the government may indirectly exercise control over drug prices, involves the negotiation of prices that are favorable to the public sector. Like moral suasion and threat, buyer power is accentuated when the government controls a relatively high proportion of pharmaceutical spending. History does suggest that the federal government has incrementally exercised its buying power in pharmaceutical markets. For example, the Medicare program has historically paid 95 percent of the average wholesale prices for certain branded outpatient drugs, mainly for cancer and dialysis patients. Beginning in 1990 with the Omnibus Budget Reconciliation Act (OBRA), the Medicaid program secured even more deeply discounted prices by requiring rebates from drug manufacturers equaling 15.1 percent of the average manufacturer's price (AMP) or the difference between the AMP and the best price, whichever is greater.[5] In 1992, the Department of Veterans Affairs began purchasing drugs for its health-care system directly from manufacturers or wholesalers with discounts of 24 percent or more, depending upon the purchase option selected. It should be noted that the Veterans Health Care Act sets a cap on prices for more than a quarter of the drugs on the schedule. Further, under that act drug companies must sell to the VA or they are barred from doing business with Medicaid or Medicare.[6]

It should also be pointed out that pricing policies might not be separate and apart from government policies designed to shape purchasing patterns. Government health systems establish restrictions such as drug lists, prior authorization, rationing, and delayed access in concert with efforts to reduce drug prices. The aggregate effect shapes the size of the market in the present and potential market opportunities.

Impact of Government Influence on Drug Prices, 1960 to 2001

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 1960–2001 and multiple regression analysis to empirically examine if the government has historically been capable of exerting an influence over real drug prices in the U.S.

In the multiple regression model, the year-to-year change in the ratio of the annual pharmaceutical consumer price index to overall consumer price index (in logarithms) served as the dependent variable. Thus, the variable to be explained by the regression model should be interpreted as the growth of real drug prices from one year to the next. As a first approximation, we anticipated that the yearly growth of real drug prices would be determined by the growth of the overall economy, the growth of government's share of spending on pharmaceuticals, the lagged growth of real drug prices, and the several policy changes affecting the pharmaceutical industry during the period under investigation. We experimented with several specifications for the empirical model. The final, and statistically most robust, model was capable of explaining nearly 85 percent of the variation in the growth of real drug prices over time.

Our main hypothesis was that increased government spending on pharmaceuticals should be associated with slower real drug price growth because of moral suasion, threats, crowding out, and buyer power. This hypothesis was supported by our empirical findings.[7] Specifically, the empirical results indicated that from 1960 to 1992, a 10 percent increase in the share of government spending on pharmaceuticals was associated with a 0.9 percent annual reduction in the rate of growth of real drug prices. During this period, government influence primarily relied on moral suasion, threats, and crowding out and thus had only a very minor effect on private drug prices.

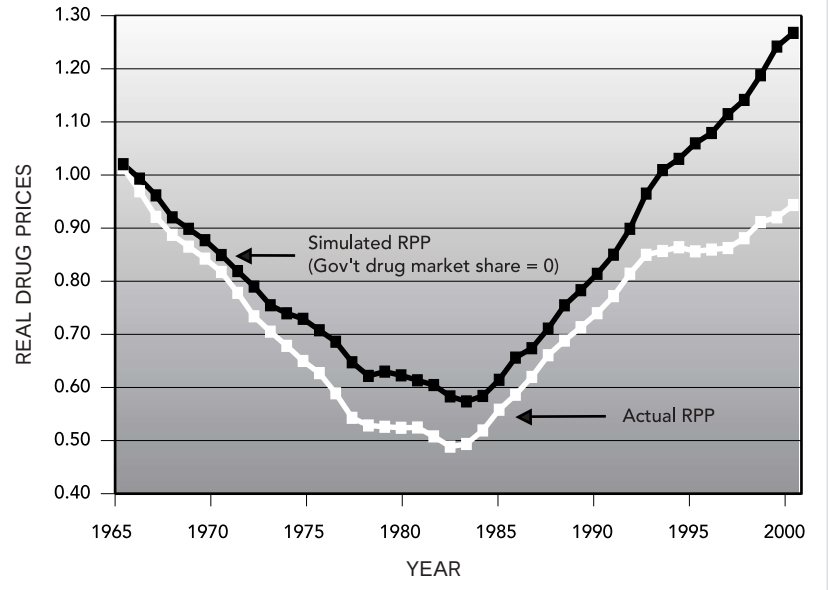
However, the empirical results also suggested that government policies to reduce public drug prices similar to those being proposed for Medicare today had a more profound impact on private drug prices from 1992 to 2001. According to the empirical results, a 10 percent increase in government's share of spending was related to a 6.7 percent annual reduction in the growth of real private sector drug prices. The two major differences during this period—imposition of price controls via the 1990 and 1992 acts and the doubling of government's share of pharmaceutical spending, from 10 to 20 percent—combined to place a distinct downward pressure on private drug prices.

Simulated Real Drug Prices with and without Government Influence, 1960 to 2001

We then used our multiple regression results to simulate what real drug prices would have been from 1960 to 2001 in the absence of any government influence. Figure 1 provides a graphical depiction of this simulation. In the exhibit, 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 1960 to facilitate the comparison between the periods. Two real drug price series are shown. One series identifies the trend in actual real drug prices over time, whereas the other series shows how drug prices *would* have trended in the absence of any government influence. Notice that real drug prices actually dropped by roughly 50 percent from 1960 to 1980. Also notice that after 1980, real drug prices continued to increase but never quite obtained in 2001 the same level observed in 1960.

Our simulated drug price series indicates that government policies had a significant impact on these trends. More precisely, had government's share of spending on pharmaceuticals not grown over the period, pharmaceutical prices would still have

Figure 1: Simulated Impact of Government Influence on Real Drug Prices



declined from 1960 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 0.58 rather than 0.49 in 1980, in the absence of any government influence, thus representing an 18.4 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 1.27 instead of 0.94, or at a 35 percent higher level, in 2001 if not for the new public drug price controls.

GOVERNMENT INFLUENCE ON PHARMACEUTICAL R&D AND LIFE YEARS LOST

How much of a cost has this governmental influence on real drug prices imposed 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 forthcoming 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).[8] 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 forty years. We then utilize this measure of forgone R&D in conjunction with the recent research by Frank Lichtenberg (2002) on the productivity of pharmaceutical R&D in the U.S. 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 forty 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 U.S. To measure the annual reduction, we simply compare the observed industry R&D intensity from 1960 to 2001 with a simulated scenario in the absence of any government-exerted downward pressure on real drug prices. Within the context of the empirical model 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.[9] 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

Figure 2: Estimates of Lost R&D Because of Government Influence on Drug Prices

Year	Predicted R&D as a Percentage of Sales (Government Share = 0)	Actual R&D as a Percentage of Sales	Cumulative Lost R&D Dollars (Millions of Capitalized 2000US$)
1960	8.19%	8.15%	$340
1965	9.36%	9.14%	$9,541
1970	9.80%	9.32%	$27,370
1975	9.91%	9.02%	$68,074
1980	9.82%	8.86%	$107,362
1985	13.54%	12.90%	$127,749
1990	15.27%	14.44%	$140,161
1995	18.91%	16.70%	$157,534
2001	19.79%	16.67%	$188,310

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 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. Figure 2 presents the estimates.

The key estimate from this simulation exercise is, of course, the measure of cumulative forgone R&D investment. We estimate this amount to be $188 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 U.S.) over virtually the same period as our analysis and simulation exercise, we use his figure to approximate the cost of forgone pharmaceutical innovation. Dividing $188 billion by $1,345 results in approximately 140 million forgone 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 below in Figure 3.

The estimates in Figure 3 indicate that the cumulative range of cost associated with forgone pharmaceutical innovation over this forty-one-year period is $7–21 trillion, depending on the assumed value of a life year in the U.S.

Figure 3: Effect of Lost Life Years on U.S. Economy

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	140.0 million	$7.0 trillion
$100,000	140.0 million	$14.0 trillion
$150,000	140.0 million	$21.0 trillion

The Potential Future Costs of the MMA

As a final, if somewhat more speculative, analysis, we also can generate a first-order approximation of the prospective costs associated with the expected increase in government influence on pharmaceutical prices under the MMA. Following the approach of Golec and Vernon (2004), we develop an infinite-time-horizon R&D investment model. Using our previously discussed results on the influence of government purchases on real drug prices in the U.S. and our empirical findings from an earlier study on how prices affect R&D investment (Giaccotto, Santerre, and Vernon, 2005), we calculate the present value of "lost" R&D that will occur under the MMA, when the government's purview over total drug purchases is expected to climb to 60 percent.[10] Given the inherent difficulty in forecasting future events, we will keep our analysis simple and adopt the following assumptions:

1. R&D investment will grow at a constant rate in perpetuity after 2006.
2. The industry cost of capital for financing R&D also will be constant after 2006.
3. From 2006 on, government purchases (or the purchases that the government will have purview over) will become 60 percent of all drug purchases.[11]

To quantify how extending past policies and price controls to a larger market share will affect this present value stock of R&D, we model how an increase in the government's share of drug purchases to 60 percent (the expected share of total drug purchases that the government will oversee under the MMA) will affect real drug prices and then how this change in real drug prices will affect R&D investment in 2008. Based upon our regression model of the determinants of real drug prices, an increase in that share from 21.8 (the percent of drug sales bought by the government in 2001, the last year in our sample) to 60 percent is a 101 percent increase.[12] Using the estimated elasticity from our regression model, this implies that real drug prices will decline by 67.5 percent (0.667*1.01), all else held constant.[13] From our earlier research on the relationship between R&D investment and real drug prices, and specifically our R&D-price elasticity estimate of 0.583, we predict that this will lead to a 39.4 percent decline in R&D expenditures (0.583*0.675). Thus, because of the passage of the MMA in 2006 and the significant increase in the government's purview over the share of all drug purchases, our empirical models suggest that if past policies regarding price controls are applied to drugs purchased under the MMA, in 2008 total R&D expenditures will be approximately $30.0 billion, or about $17.7 billion less because of a sizable increase in government purchases (from $47.7 to 30.0).

Therefore, over an infinite time horizon, the present value of the stock of "lost" R&D, in 2007, will be about $508 billion. In 2004 dollars, this is approximately $372 billion. Adopting the same methodology used in our retrospective analyses, this translates into 277 million life years and, depending on the presumed value of a life year, the following dollar costs.

Figure 4: 2004 Estimated Present Value Cost of the MMA's Negative Impact on Pharmaceutical Innovation

Value of a Human Life Year	Long-Run Economic Cost
$50,000	$13.8 trillion
$100,000	$27.7 trillion
$150,000	$41.5 trillion

These predicted long-run costs associated with the government's expanded influence under the MMA appear to be quite high. These costs reflect the increasing productivity of people around the world as a result of new medicines as well as the claim that many illnesses can have on well-being in the absence of new drugs. Hence, these long-run costs, which are easily forgotten in immediate concerns about the affordability of medicines or short-term budget constraints, should not be ignored in policy debates.

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 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.

CONCLUSIONS

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 paper, we examined how government 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 $188 billion in pharmaceutical R&D from 1960 to 2001. Because this "lost" R&D means "lost" drugs, we estimate that 140 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 $7–21 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. In fact, our prospective analyses, while necessarily more speculative than our retrospective analyses, suggest that applying current price controls to MMA purchases would reduce present value R&D spending by a further $372 billion, costing 277 million life years in the United States because of forgone discovery of new drugs.

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Appendix
Multiple Regression Findings

Dependent Variable: D (LRPP)
Method: Least Squares
Date: 05/25/04 Time: 10:57
Sample: 1960–2001
Included observations: 42

Variable	Coefficient	Standard Error	t-Statistic	P-Value
D(LGDP(-1))	-0.389742	0.104793	-3.719164	0.0007
D(LPUB(-1))	-0.086158	0.036614	-2.353126	0.0242
D(LPUB(-1))*D92	-0.579867	0.223008	-2.600213	0.0134
D(LRPP(-1))	0.854943	0.131145	6.519069	0.0000
D(LRPP(-2))	-0.375947	0.127824	-2.941118	0.0057
WH	0.035633	0.007753	4.596012	0.0001

R-squared	0.865946	Mean dependent variable	-0.002188
Adjusted R-squared	0.847327	S.D. dependent variable	0.039870
S.E. of regression	0.015578	Akaike info criterion	-5.354293
Sum squared residuals	0.008737	Schwarz criterion	-5.106055
Log likelihood	118.4402	Durbin-Watson statistic	1.950186

Definitions of the Variables:

D(LRPP) = change from one year to the next of the logarithm of the real drug price, defined as the ratio of the pharmaceutical price index to general consumer price index.

D(LGDP(-1)) = lagged value of the change from one year to the next of the logarithm of real gross domestic product per capita (measure of the growth of economic activity).

D(LPUB(-1)) = lagged value of the change from one year to the next of the logarithm of the government's share of pharmaceutical spending (growth of government influence).

D92 = 0/1 dummy variable taking on the value of 1 for years after 1991 to capture the effects of OBRA of 1990 and the Veterans Act of 1992 (change in the growth of government influence).

D(LRPP(-1)), D(LRPP(-2)) = lagged values of the change from one year to the next of the real drug price (i.e., the prior one and two years of real drug price growth).

WH = 0/1 dummy variable taking on the value of 1 after 1983 to capture the presence of the Waxman/Hatch Act.

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ENDNOTES

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. 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.

3. 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).

4. Center for Medicare and Medicaid Services, at http://www.cms.gov.

5. The AMP is the average price paid by wholesalers for products distributed for retail trade.

6. Prescription Drugs: Expanding Access to Federal Prices Could Cause Other Price Changes, GAO/HEHS-00-118.

7. The multiple regression results can be viewed in Appendix 1.

8. 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.

9. 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.

10. Because the government will not be purchasing all these drugs, the estimate of 60 percent does not perfectly coincide with our definition of our PUB variable (i.e., the government share of total drug purchases). Nevertheless, the fact that the government will be overseer of these drug purchases implies that it will still be exerting its considerable influence on these purchases. This important difference with our retrospective analyses should, however, be kept in mind.

11. The first assumption allows us to circumvent the difficulty (impossibility) of forecasting all future values of our regression models' independent variables. In a recent study by Scherer (2001), the real annual growth rate of pharmaceutical R&D expenditures was calculated to be 7.51 percent from 1962 to 1996. Therefore, in our forthcoming calculations, we will use this rate to predict future growth rates of R&D. For the second assumption, we will employ a real cost of capital of 11 percent (DiMasi, Hansen and Grabowski, 2003). The present value of R&D growing at a constant rate, g, in perpetuity, and discounted at the cost of capital, r, is simply R&D expenditures in period t+1 divided by r-g. In 2004, the Pharmaceutical Research and Manufacturers Association (PhRMA) reported that total member-firm expenditures on pharmaceutical R&D were $33.2 billion (for fiscal year 2003). Growing at a real rate of 7.51 percent, this would place 2008 R&D expenditures at approximately $47.7 billion, and present value R&D expenditures in perpetuity (in 2007) would be $1.37 trillion. We do not include the expenditures of biotechnology firms or venture capital funds, which provide an additional $30–40 billion in R&D investment per year that would also be influenced by government purchases and pricing regulation.

12. For consistency with our model specifications, the percentage increase in the government's share is calculated as the difference in logarithms of government's share pre- and post-policy.

13. This percentage decrease in price is calculated within the context of our constant-elasticity model specification; that is, we measure percentage changes as the difference in natural logarithms of real drug prices pre- and post-MMA enactment. When expressed as a percentage reduction off of pre-policy real drug prices, it results in roughly a 49 percent reduction in real drug prices.

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