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THE HUMAN COST OF FEDERAL PRICE NEGOTIATIONS: The Medicare Prescription Drug Benefit and Pharmaceutical Innovation

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The 2003 Medicare Prescription Drug, Improvement and Modernization Act created a prescription-drug benefit, Medicare Part D, effective January 1, 2006. For the first time, the federal government will pay for the prescription medicines used by American senior citizens. Part D differs from other federal and state drug programs, which mandate specific price discounts. Instead, private-sector Pharmacy Benefit Managers (PBMs) — including such well-established firms as Medco, Blue Cross, and Aetna — negotiate with drug companies to set prices and formularies (lists of covered drugs) for enrolled patients.

Because the prescription drug benefit is projected to cost hundreds of billions of dollars over the next decade, some policymakers have called for changing Medicare Part D, to require federal negotiation of prescription-drug prices. Such a change would aim to use the purchasing power of the federal government to force prices below those that would be negotiated by the private sector.

In addition to cost reductions, however, this policy change portends other ancillary effects. In particular, this paper estimates the impact that federal negotiation of prescription drug prices would have on pharmaceutical research-and-development (R & D) investment through 2025. It argues that federal policymakers would have incentives to favor price reductions at the expense of more-inclusive drug formularies. This greater willingness of federal officials to exclude drugs from formularies would lower drug prices below those that otherwise would be set by the market. This, in turn, would reduce incentives for the capital market to invest in the research and development of new medicines.

This report quantifies the results of such a decline in capital investment. It presents the results of a simulation analysis that projects pharmaceutical R & D investment, assuming, under three different sets of parameters, federal price negotiations for prescription drugs beginning in 2007.

- In the baseline case, developed from National Science Foundation (NSF) data on historical investment trends, the cumulative decline in research and development investment would yield a loss of 196 new medicines, or about ten per year.

- Using the same NSF data with a more conservative assumption about the growth rate of research and development investment, the loss would be 107 new medicines, or about six per year.

- Using historical investment data gathered by the Pharmaceutical Research and Manufacturers of America, the loss would be 220 new medicines, or twelve per year.

In the short run, federal price negotiations would allow some consumers to receive medicines at lower prices, or, alternatively, would yield savings for federal taxpayers. The longer-term human costs of government price-negotiation, however, are likely to be large and adverse. This paper estimates that investment in new drug research and development would decline by approximately $10 billion per year. It estimates as well the effect of reduced pharmaceutical R & D investment on American life expectancies, or expected "life-years". Specifically, this work projects that federal price negotiations would yield a loss of 5 million expected life-years annually, an adverse effect that can be valued conservatively at about $500 billion per year, an amount far in excess of total annual U.S. spending on pharmaceuticals.

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The Human Cost of Federal Price Negotiations: The Medicare Prescription Drug Benefit and Pharmaceutical Innovation

Benjamin Zycher

INTRODUCTION

The 2003 Medicare Prescription Drug, Improvement and Modernization Act (MMA) substantially increased the medical benefits that the federal government finances for the elderly. Under Part D of the MMA, the federal government pays a significant portion of prescription drug costs of seniors covered by Medicare, beginning in 2006. Previously, only prescription medicines "incident to" the delivery of physician services had been covered as a Medicare benefit.

This benefit is not the only new provision of the MMA. Unlike previously existing federal and federal/state drug programs — such as those for veterans receiving drugs under Department of Veterans Affairs programs or Medicaid programs for low-income patients — the new Part D program does not attempt to reduce prices or spending by mandating specific price discounts from pharmaceutical producers. Indeed, the federal government under the MMA is proscribed from negotiating or imposing such discounts. Instead, such negotiations are left to private-sector insurers and other buyers — Pharmacy Benefit Managers, or PBMs — that negotiate with the pharmaceutical producers. The PBMs then offer Medicare enrollees choices of drug benefit plans, with differing premiums, drug prices, drug formularies (lists of drugs included in a given program), co-payments, and deductibles. Under the "noninterference" language of the MMA, the federal government is prohibited from "interfering" with those nego-

tiations by mandating price discounts, formularies, or other central features of the drug benefit plans. This provision is seen by many as a means of minimizing government involvement in the market for pharmaceuticals; for example, Senate Majority Leader Bill Frist argued in 2004 that "competition is better over time than price fixing."[1]

The new program will be large in terms of the number of enrollees and newly required federal spending, particularly with the growing population of baby-boom retirees. This has led to growing calls for a change in the "noninterference" provisions of the MMA, which would allow direct federal negotiation of price discounts for drugs; for example, Senator John Edwards has argued: "We [should] allow the government to use its bargaining power to bring down the costs of prescription drugs for all seniors."[2]

One important concern raised by the possibility of federal price negotiations for drugs is a decline in that research and development, and thus in pharmaceutical innovation.

If given such a mandate, Medicare would become the single largest purchaser of prescription medicines in the U.S., with powerful incentives for policymakers to use the attendant purchasing power to obtain large price discounts. Those price discounts clearly would have an additional effect: They would reduce the economic returns to investment in the research and development of new and improved drugs. So one important concern raised by the possibility of federal price negotiations for drugs is a decline in that research and development, and thus in pharmaceutical innovation. Some argue that this effect would be large; others maintain that it has been exaggerated.

This paper presents findings on the magnitude of that likely effect under the assumption that the noninterference provisions of the MMA are removed. The analysis presented below begins with previously published findings on the effects of growing government drug purchases on drug prices. Those findings are applied to historical data from the National Science Foundation (NSF) on research and development investment trends for pharmaceuticals, with three different cases — a base case and two alternative cases — examined for the range of likely resulting impacts on that research and development spending over the period 2007–25. The NSF data are supplemented with additional public data from the United Nations, the Organisation for Economic Co-operation and Development (OECD), and the Pharmaceutical Research and Manufacturers of America (PhRMA). Other published findings on the cost of drug development, on the effect of pharmaceuticals on life expectancies, and on the economic value of life-years are used to estimate the number of new and improved medicines that would fail to be developed, and the economic cost of that reduction in pharmaceutical innovation. The central findings can be summarized as follows:

- For a program of federal price negotiations assumed to begin in 2007, the average price reduction for drugs for the period 2007–25 would be about 21.8 percent, which can be interpreted as a saving for taxpayers or patients and as an implicit "tax" on pharmaceutical producers.

- This implicit tax would reduce pharmaceutical research and development investment annually by $5.6–11.6 billion, with the most likely effect at about $10 billion per year.

- This reduction in research and development investment will result in a loss of between 6 and 12 new medicines per year, with the most likely reduction at about 10.

- This reduced flow of new and improved medicines will cost Americans about 5 million life-years annually, which can be conservatively valued at about $500 billion annually, a figure far in excess of total annual U.S. spending on pharmaceuticals.

The discussion below proceeds as follows. Section II discusses differences in the negotiation incentives of the PBMs and the federal government. Section III offers a summary of federal pricing policies in other drug programs. Section IV presents a brief discussion of the simple economics of investment. Section V follows with a discussion of the methodology used for the analysis and a detailed presentation of the analytic findings. Section VI compares these findings with those in previously published research, and Section VII presents several conclusions. Appendix A offers a further discussion of the incentives confronting federal policymakers pursuing price negotiations with pharmaceutical producers, as contrasted with those shaping the decisions of the PBMs. Appendix B presents the data used in the analysis, and Appendix C presents charts of those data. Finally, Appendix D discusses briefly a recent report prepared by the Congressional Research Service on federal price negotiations for drugs.

CRUCIAL DIFFERENCES BETWEEN THE FEDERAL GOVERNMENT AND THE PBMS

The complex adoption and implementation of public policies inevitably must create winners and losers. Seen in this context, prices for drugs negotiated by the federal government in effect impose a tax on pharmaceutical producers in the form of realized prices lower than otherwise would be the case; and they generate an implicit revenue stream for current drug consumers in the form of those same lower prices, or for the beneficiaries of other government spending programs.[3]

Such negotiated prices may seem analogous to the price discounts familiar to patrons of large pharmacy chains or insurers that negotiate with drug producers or with various middlemen, but three crucial differences between such negotiators and the federal government are clear. First, it is likely that the federal government would enjoy greater market power in price negotiations than a given "large" private-sector purchaser could exercise; note that the Medicaid program before the implementation of the Medicare drug benefit was the largest single purchaser of prescription drugs, accounting for over 19 percent of national prescription drug expenditures in 2004.[4] The CMS projects that federal government drug purchases will be over 40 percent of the national total by 2010.[5] As a monopsonistic purchaser of pharmaceuticals, government can be predicted to attempt to lower both the prices it pays and the quantities purchased; the latter effect is the deeper implication of the more restrictive formularies likely to be observed in the context of federal price negotiations, as discussed in more detail below.[6]

Second, unlike private-sector purchasers serving customers seeking both low prices and formularies that contain the drugs that they demand, the federal government does not have "customers" as such.[7] Instead, it has individual voters and collective interest groups, the demands of which are registered in infrequent elections driven by perceived voter/interest group preferences on numerous issues of varying political importance. It is by definition the case that negotiations between drug producers and retailers (or their market proxies) hinge on the prices at which both parties are willing to include given drugs in formularies; profit-seeking firms are driven by the demands of their customers to pursue some balance between the benefits of low prices and the benefits of formularies that are more, rather than less, inclusive. For the federal government, on the other hand — that is, for federal policymakers — lower prices offer budget relief, that is, greater potential spending on other budget categories, while less inclusive formularies offer even more such budget benefits. The beneficiaries of drug use cannot take their business elsewhere without moving to some other country or by simply buying retail. While

Three crucial differences between such negotiators and the federal government are clear.

it is likely to be the case that more inclusive formularies yield some political benefits, particularly for specific medicines demanded by organized or visible patient groups, the latter are offset partially or wholly by the political benefits of higher spending on other budget categories. In short, the substitution of federally determined formularies in place of those determined under market competition deprives consumers of the right to opt for more favorable alternatives. Thus do the negotiation incentives of federal policymakers differ substantially from those of large private-sector buyers ultimately serving retail customers.

Third, the more powerful partial incentive of large private buyers to satisfy their customers (i.e., patients) with larger formularies has the long-term effect of preserving economic incentives for research and development investment greater than is the likely case for prices and formulary restrictions determined in negotiations with the federal government.[8] This effect is separate from the market incentives of the pharmaceutical research ("branded") industry to maintain research and development programs; those market incentives are independent of whether the buyer across the negotiation table is an insurer or the federal government.[9] But the weaker incentive of the latter to include given drugs in formularies automatically yields greater downward pressure on negotiated prices — drugs excluded from formularies are rewarded with a price of zero, and the federal government can be predicted to favor less inclusive formularies — and thus a reduction in expected returns to research and development.[10]

This problem of reduced long-term incentives for research and development investment inherent even (or particularly) in federal price negotiations is one dimension of the short time horizon confronting federal policymakers. Those policymakers have no claim, whether political or pecuniary, on the future benefits from ongoing investment; after all, many future patients are unavailable to vote today, and many of those who are available do not know that they will endure the future adverse effects engendered by the current investments — the future medicines — that are forgone.[11]

PRICES UNDER CURRENT FEDERAL DRUG PROGRAMS

Unlike the case for the new Medicare Part D, the government purchases drugs or establishes drug prices for Medicaid, Medicare Part B, the Department of Veterans Affairs pharmacy program, and for various programs under the Public Health Service Act (PHS). Each obtains drugs at discounted prices, but the computation and magnitudes of the respective discounts differ.

Medicaid drug spending in 2004 (federal and state) was about $36.6 billion (in then-year dollars), accounting for over 19 percent of total U.S. spending on drugs that year, having grown at about 9 percent per year since 2000, even after adjusting for inflation. Medicaid requires drug producers to participate in a national rebate (essentially, a price discount) program in order for their respective drugs to be included in the Medicaid formulary for a given state.[12] The rebate is determined by the average manufacturer's price (AMP) and by the manufacturer's "best" price paid by retail pharmacies and other large private-sector buyers. For brand-name drugs, the rebate is the greater of: (a) 15.1 percent of the AMP; or (b) the difference between the AMP and the best price.[13] (For generic drugs, the rebate is 11 percent of the AMP.) Under the first formula, the Medicaid rebate amounts to a straightforward excise tax of 15.1 percent of the AMP applied to Medicaid sales; note that the AMP, while not defined uniformly, is an average across several markets, so that it is, in some crude sense, a market price. Under the second formula, state Medicaid programs receive the best prices negotiated by large private-sector buyers, so that in effect, the rebate serves as an implicit tax on price discounts negotiated outside Medicaid because discounts offered to large private-sector buyers must be offered to the Medicaid programs as well.

Medicare Part B reimburses physicians and other medical providers for drugs used for such outpatient services as dialysis treatment and for drugs given to patients "incident to" physician services. Most are cancer and antinausea drugs taken orally, inhalation therapies,

and oral immunosuppressives. Medicare payments for Part B drugs over time have been based on a series of shifting computations: the physician's "acquisition" cost, varying percentages (at various times, 85–100 percent) of average wholesale price (AWP), and the lower of estimated acquisition cost and some percentage of AWP. These differing methods of computing payments for the providers have been implemented at various times because Part B reimbursements often have been found to exceed the actual prices at which the medical providers were able to obtain the drugs, yielding "overpayment."[14] Because of this perceived problem, the MMA established a new payment system for Part B based upon a drug producer's average sales prices (ASP), thus presumably reflecting market prices. But because the ASP includes price discounts negotiated with various buyers, the requirement that Part B prices reflect ASP in effect imposes a tax on such discounts negotiated with other buyers, as in the case of Medicaid discussed above.

The discounts incontrovertibly must reduce the perceived economic returns to research and development investment in the creation of new and improved drugs.

It is commonly reported that the Department of Veterans Affairs "negotiates" the prices that it pays for pharmaceuticals. That is a misconception: Under the 1992 Veterans Health Care Act, two price constraints are imposed. First, there is a minimum 24 percent discount from the AMP, often called the Federal Ceiling Price (FCP); in addition to the VA, this price is available to the Defense Department, the Indian Health Service, and the Coast Guard. Second, there is a Federal Supply Schedule (FSS) requirement that the pharmaceutical producers sell drugs to the VA at the "best price" offered private-sector buyers. These FSS "best prices" must be offered as well to many healthcare programs receiving federal funding; thus does the FSS "best price" requirement allow the federal government and many others to receive the benefits of private-sector negotiations without undertaking any negotiations themselves. The VA is entitled under the law to receive the lower of the FCP and FSS prices. The 24 percent discount under the FCP is explicitly a tax on drug prices; and the FSS best-price requirement, as in the case of both Medicaid and Medicare Part B, is a tax on negotiated prices.

Drug producers refusing to sell at these prices would be precluded from selling their products both to the VA through the FSS system and to Medicaid, thus shutting themselves out of 10–15 percent of their sales. For most pharmaceuticals, production costs per pill (or dose) are small, so that a loss of so significant a portion of sales — combined with a fixed period of patent protection — can wreak havoc with sales and pricing strategies designed to recoup large research and development costs. This is one manifestation of federal pricing power, the central implication of which is that the implicit tax, whether large or small, would be difficult to avoid.

The Public Health Service Act implements drug price discounts for such programs as Community Health Centers, Ryan White program grantees, and AIDS Drug Assistance Programs. Drug producers selling to such programs are required to offer discounts at least as large as the AMP discounts under Medicaid. Similarly, these prices implicitly impose a tax on market prices.

SOME SIMPLE ECONOMICS OF INVESTMENT

This experience with other federal drug programs demonstrates that the mandated price discounts, as they are defined and implemented, analytically are taxes not only on the prices paid for the drugs sold for the specific programs, but under some conditions also on the prices negotiated with large private-sector buyers for sales outside the federal programs.[15] As such, the discounts incontrovertibly must

reduce the perceived economic returns to research and development investment in the creation of new and improved drugs. This effect would be strengthened by federal price negotiations under Medicare; the central issue to be addressed is the magnitude of that effect.

Any investment is "efficient" (that is, expected to be profitable) as long as the anticipated future rate of return or stream of profits from the investment, adjusted for risk and other factors, is equal to or greater than the market rate of interest. This should be intuitively obvious: If the rate of return from an investment is expected to fall below the "cost of money," the investment should not be made. That future rate of return is determined in substantial part by the net price that the future products are likely to command; accordingly, taxes on that price, whether explicit or implicit, must reduce that future return by some amount.

So the tax will reduce investment, even if the lower rate of return remains at or above the market rate of interest. But if the tax reduces the future rate of return below the market rate of interest, investment will fall to zero because no part of the investment remains efficient.

This case of zero investment may seem extreme, but it is highly plausible under a broad set of conditions. Consider a market in which pharmaceutical research and development investments earn competitive returns (as contrasted with above-competitive returns); this outcome can obtain for two reasons. First, pharmaceutical products can be direct and indirect competitors; when finally approved for sale, their prices may yield only competitive rates of return.[16] Second, pharmaceutical producers invest in a portfolio of potential new products and drugs; it is efficient for such investments to be made until the last invested dollar is expected to yield only the market rate of return.[17] But in any given year, not all such investments will yield returns greater than or equal to the market rate of interest; some will prove to be losers. Some years will be relatively profitable in terms of research and development success and the market prices received for drugs, and other years will be afflicted with relatively heavy losses; investment outcomes over time are subject to random influences, so that the statistical distribution of returns over time has an average equal to the market rate of interest adjusted for perceived risk.[18]

But the implicit federal price-discount tax would not be imposed randomly; it is the drugs that finally are approved for sale that would be subjected to the tax. So large-scale federal price negotiation of drug prices would create a bias in the returns earned by pharmaceutical producers: Upside potential for the investments yielding approved drugs would be reduced, while downside potential for losing investments would remain unaffected. This means that average returns must decline. If the average expected return in the absence of federally mandated price discounts is at the market rate of interest, the introduction of discounts must yield a reduction in investment, and perhaps zero (or near zero) investment.[19] The only way for a producer to avoid this outcome is to reduce or eliminate investment in new drugs either riskier or prospectively less profitable, a market adjustment with highly adverse implications.[20] The upshot of this adjustment process is a market with less research and development investment — and fewer new medicines — than otherwise would be the case.

Large-scale federal price negotiation of drug prices would create a bias in the returns earned by pharmaceutical producers.

QUANTITATIVE ANALYSIS OF RESEARCH AND DEVELOPMENT INVESTMENT UNDER A FEDERAL PRICE NEGOTIATION SYSTEM

There is no dispute in the economics literature with respect to the downward effect of mandated price discounts upon research and development investment. The analytic issue to be addressed is the likely magnitude of that impact were the

noninterference provisions of the MMA to be repealed. We proceed as follows. We examine the published literature for empirical findings on the effect of federal drug purchases on the growth of drug prices. Those findings are applied to historical data on research and development investment trends for pharmaceuticals, in order to estimate the resulting future downward effect upon that investment. The period for which the projections are made is 2007–25. Other published findings are used to estimate the number of new drugs that would fail to be developed as a result of the reduction in research and development investment, the effect of pharmaceuticals on life expectancies, and the resulting economic cost created by federal price negotiations for drugs and the resulting decline in pharmaceutical innovation.

Because the other federal and state drug programs already in operation impose downward price pressures of varying kinds, empirical literature is available that links those price effects with government spending on drugs. In particular, a recent paper by Santerre *et al*. presents empirical analysis of the historical price effects of increases in the governmental share of total pharmaceutical spending.[21] That paper reports a decline in the growth of real pharmaceutical prices from 1962 through 2001, yielding reduced research and development investment and fewer new medicines.[22] In brief, the statistical analysis presented in Santerre *et al*. finds an annual reduction of 1.2 percent in the growth of real drug prices attendant upon each 10 percent increase in the government share of drug spending before 1992, and an annual reduction in drug prices of 5.3 percent for each 10 percent increase in the spending share after 1992.[23] Note that these are annual reductions in the growth rate of drug prices and thus would compound over time.

Santerre *et al*. use those econometric findings to estimate the research and development investments forgone because of the rising share of government pharmaceutical spending, and then use Lichtenberg's empirical findings on the effect of pharmaceutical research and development investment on life expectancies in the U.S. to derive an estimate of the life-years lost because of the price effects of the growing governmental share of drug spending.[24] Santerre *et al.* estimate that for 1962 through 2001, forgone research and development investment was $251–256.3 billion. Given Lichtenberg's estimate that an additional life-year is obtained from a research and development investment of $1,345, the estimated loss in terms of life-years over the period is between 186.6 million and 190.5 million, or roughly 4.7 million per year. Using a range of $50,000–150,000 for the assumed value of a life-year lost, Santerre *et al.* conclude that the adverse effect of growing government drug purchases and attendant price impacts for the 40-year period is in the range of $9.3–28.6 trillion.

For the analysis reported here, U.S. pharmaceutical and biotechnological research and development investment data for 1985 through 2003, converted to year 2005 dollars, were obtained from datasets constructed by the National Science Foundation, and then compared or supplemented with data from the United Nations Industrial Development Organization, the Organisation for Economic Co-operation and Development, and the Pharmaceutical Research and Manufacturers of America.[25] Research and development investment spending during 1993–2003 grew at an annual compound rate of almost 8 percent; that rate was used in the analysis reported below to project annual investment data to the year 2025.

Just as annual investment in plant and equipment over time yields a "stock" of plant and equipment — the sum of the annual investments minus annual depreciation — the data on annual investment in pharmaceutical research and development allow a calculation of the U.S. pharmaceutical research and development capital stock. This capital stock can be thought of as the plant, equipment, intellectual advances, and other assets created with the annual investments, minus depreciation. At the outset of 1985, the pharmaceutical research and development capital stock is assumed to be six times 1985 investment; this is a standard investment/capital assumption used in a number of published economic analyses.[26] Annual depreciation is assumed at 8 percent, so that for each year, the capital stock is that remaining from the previous year, plus new investment.[27] The annual data and projections are shown in Table B1 of Appendix B. Table 1 presents the data and projections for both investment and the capital stock at five-year intervals

Table 1. Pharmaceutical Research and Development Investment and Capital (billions of year 2005 dollars)		
Year	Total Investment	Total Capital
1985	3.3	19.8
1990	5.3	32.1
1995	9.4	55.4
2000	13.5	87.9
2005	20.6	131.1
2010	30.3	199.2
2015	44.4	296.8
2020	65.2	438.5
2025	95.7	645.4

Note: Totals may not sum from Table B1 because of rounding
Source: Table B1

in the assumed absence of federal price negotiations for Medicare Part D. Annual investment is projected to grow from $13.5 billion in 2000 to $95.7 billion in 2025; the respective figures for the capital stock are $87.9 billion and $645.4 billion.

Data from the CMS show an increase in the federal spending share for drugs, from 9.4 percent in 1992 to 16.9 percent in 2004, rising to a projected 39.7 percent in 2006 and 43.4 percent in 2015.[28] Almost all this increase after 2004 is due to the effect of the MMA on Medicare drug spending, which is projected in 2015 to be almost 70 percent of all federal drug spending.

The empirical analysis presented by Santerre *et al.*, summarized above, implies strongly that downward pressure on drug prices will intensify as the public-sector share of total drug spending increases. Using the lower estimate of that effect reported by Santerre *et al.*, together with the CMS projection of the federal and total government spending share for drugs, we can estimate the resulting percent downward effect — the implicit tax — on drug prices.

Table 2 presents those projections of the federal and total government shares of national drug spending and the adjusted downward price effects (compound "tax" rates) implied by the Santerre *et al.* analysis as applied to the increasing federal share after 2005. The implicit tax estimates are adjusted by: (1) assuming a 5 percent implicit price tax as an effect of all government drug purchases before 2006; (2) holding constant for all subsequent years the 2006 federal government spending share; and (3) assuming a marginal implicit price tax of 1.2 percent per 10 percent increase in the federal share of total drug spending, compounded annually.[29] We adopt these conservative assumptions because it is appropriate to estimate a lower bound on the research and development effects of federal price negotiations and because some downward pressure on prices can be expected as a result of negotiations between the pharmaceutical producers and the Medicare Part D PBMs even in the absence of negotiations by the federal government. The major increase in the federal drug spending share projected by the CMS is in 2005–06, from 17.2 percent to 39.7 percent. Under the assumptions described above, the implicit tax on pharmaceutical prices would rise from 5 percent in 2005 to 13.1 percent in 2010 to over 35 percent in 2025. For 2007–25, the average implicit tax is 21.8 percent.

This prediction is moderately lower than the 27.5 percent price differential estimated by Santerre *et al.* for 1962–82, and lower than the 28–38 percent figure for 1992–2001 estimated as a consequence of market purchases by all levels of government. Note that their analysis did not include federal purchases

Table 2. Federal/Total Government Drug Spending Shares and Implied Compound Tax Rates (percent)			
Year	Federal Share	Total Government	Federal Implied Tax[a]
1985	6.5	14.8	0[b]
1990	8.1	18.1	0[b]
1995	10.9	21.5	0[b]
2000	13.1	22.9	0[b]
2005	17.2	28.0	5[b]
2006	39.7	46.8	7.9
2010	41.7	49.4	13.1
2015	43.4	50.7	20.1
2020	43.4[b]	50.7	27.5
2025	43.4[b]	50.7	35.3

[a]Assumes cumulative tax of 5 percent in 2005, no increase in federal spending share after 2006, and an implicit tax of 1.2 percent per 10 percent federal spending share
[b]Assumed
Source: See above, n. 5, and author computations

for Medicare. Moreover, the sheer size of the Medicare drug program can be predicted to strengthen the monopsony (purchaser) pricing power of the federal government, an effect likely to be increased further by any threat to exclude given drugs not only from Medicare formularies but from Medicaid and other public formularies as well. Accordingly, the available empirical evidence suggests that a price reduction of 1.2 percent per 10 percent spending share, compounded annually, represents a conservative assumption — a lower bound — for the likely price effect for pharmaceuticals attendant upon federal negotiations over Medicare drugs.

A downward price effect imposed in the short or medium term will affect current investor behavior, since the research and development (and regulatory approval) process for new drugs is about ten years or longer. From the viewpoint of a pharmaceutical producer considering a particular investment in research and development, the implicit tax affects the present (discounted) value of the expected future revenue stream.[30] As intuition suggests, simple analytics show that, as a first approximation, a compounded price effect of a given percent would reduce the present value of the net revenue stream by that same percent.[31]

It is possible that pharmaceutical research and development investment is so profitable that this implicit tax would have little effect. Were that true, we would expect to observe substantial new entry into the market. As discussed above, it is possible as well that a zero investment outcome would be observed, as the tax might reduce expected returns below the market rate of interest. A conservative assumption for purposes of developing projections is proportionality: The implicit annual compound 1.2 percent tax imposed by federal price negotiations would reduce research and development investment by that percentage, also compounded annually.[32] Table 3 presents projections analogous to those in Table 1 under the assumption that the implicit tax is imposed beginning in 2007.

The data and projections presented in Table B1, as summarized in Table 3, yield conservative estimates of the investment effects of the implicit tax inherent in federal price negotiations for pharmaceuticals. The cumulative decline in research and development investment for 2007–25 is predicted to be $196 billion in year 2005 dollars, or $10.3 billion per year. The predicted decline in 2025 in the pharmaceutical research and development capital stock is $133.1 billion. If we assume a marginal investment cost of $1 billion per new drug, the decline in research and development investment implies the loss of about 196 new medicines over the simulation time period, or roughly ten new medicines per year.

Santerre *et al.* estimate a cumulative reduction in pharmaceutical investment of about $261 billion (in year 2005 dollars) for 1962–2001, or about $6.5 billion per year on average.[33] As described above, that estimate flows from a conceptual experiment similar to that reported here, with somewhat different estimation methodologies applied. More important, that analysis examines price behavior in the absence of federal price

Table 3. Total Pharmaceutical Research and Development Investment and Capital with Implicit Federal Price Negotiation Tax (billions of year 2005 dollars)

Year	Investment		Capital	
	No Tax	1.2 Percent	No Tax	1.2 Percent
2005	20.6	20.6	131.1	131.1
2010	30.3	26.8	199.2	189.3
2015	44.4	37.0	296.8	265.5
2020	65.2	51.2	438.5	369.4
2025	95.7	70.7	645.4	512.2

Note: Totals may not sum from Table B1 because of rounding
Source: Table B1

Table 4. Total Pharmaceutical Research and Development Investment and Capital with Implicit Federal Price Negotiation Tax: First Sensitivity Case (billions of year 2005 dollars)				
Year	Investment		Capital	
	No Tax	1.2 Percent	No Tax	1.2 Percent
2005	19.2	19.2	129.0	129.0
2010	23.3	20.6	177.6	169.6
2015	28.4	23.6	229.7	207.6
2020	34.5	27.1	288.4	246.6
2025	42.0	31.0	356.8	288.4

Note: Totals may not sum from Table B2 because of rounding
Source: Table B2

negotiations under Medicare, a condition that largely explains the increased investment effect reported here, an outcome of the projected price effects of the sharp increase in the 2006 federal spending share for pharmaceuticals, assumed constant after 2006.

The findings of empirical research are often heavily affected by certain underlying assumptions, sometimes in subtle ways, so it is useful to change those assumptions to see the degree to which the findings are "sensitive" to those changes. One parameter discussed above is the use of the historical growth rate during 1993–2003 for pharmaceutical research and development investment — almost 8 percent per year — as the growth rate assumed for the period through 2025 in the absence of federal price negotiations. Smaller assumed growth rates would reduce the projected effect of the implicit negotiation tax, while larger assumed future investment would increase that effect.

Table 4 presents a first sensitivity case, in which research and development investment in the absence of a federal negotiation effect is assumed to grow at 4 percent per year, half the rate (almost 8 percent) observed in the NSF data for 1993–2003. This sensitivity case is a bit arbitrary — why half? — but a 50 percent reduction in the growth rate is a useful "compromise" between a drastic reduction in assumed investment and only a small reduction that would not make much difference. Under this assumption, cumulative research and development investment between 2007 and 2025 is projected to decline $107.1 billion, or about $5.6 billion per year as a result of federal price negotiations. The decline in the projected capital stock in 2025 is $68.4 billion. Under this lower investment growth assumption, the decline in projected investment attendant upon federal price negotiations implies the loss of 107 new medicines over the simulation period, or about six new medicines per year.

Table 5. Total Pharmaceutical Research and Development Investment and Capital with Implicit Federal Price Negotiation Tax: Second Sensitivity Case (billions of year 2005 dollars)				
Year	Investment		Capital	
	No Tax	1.2 Percent	No Tax	1.2 Percent
2005	39.4	39.4	231.4	231.4
2010	48.0	42.4	343.0	326.6
2015	58.4	48.6	457.9	412.5
2020	71.0	55.7	583.8	497.8
2025	86.4	63.9	728.0	587.2

Note: Totals may not sum from Table B3 because of rounding
Source: Table B3

Table 6. Projected Declines in Investment and Development of New Medicines, 2007–25				
	Cumulative Investment (billions of year 2005 dollars)	Annual Investment	Cumulative Medicines	Annual Medicines
Base Case	196.0	10.3	196	10
First Sensitivity Case	107.1	5.6	107	6
Second Sensitivity Case	220.4	11.6	220	12

Source: Author computations in Tables B1–B3

Table 5 presents a second sensitivity case, in which the historical research and development investment data from PhRMA are used to project investment with and without federal negotiation effects on prices.[34] The assumed annual compound growth rate for investment in the absence of the tax is 4 percent, as in the first sensitivity case, but the levels of investment are higher than in the NSF data, particularly after 1990. The cumulative investment decline through 2025 is projected to be $220.4 billion, or about $11.6 billion per year. The predicted decline in the research and development capital stock is $140.8 billion; the projected decline in investment for this case implies a loss of about 220 new medicines, or about 12 per year.

Table 6 summarizes the projected decline in the development of new drugs for the three cases.

These estimates of the future reduction in the flow of new and improved medicines can be used to project resulting effects on lost life-years for Americans. Lichtenberg estimates that between 1960 and 1997, each pharmaceutical research and development investment of $1,345 yielded an expected gain of one life-year.[35] If we assume, crudely, that figure to be $2,000 in year 2005 dollars, the investment decline, projected in the base case at about $10 billion annually as a consequence of federal price negotiations, would result in 5 million life-years lost each year. At an assumed $100,000 per life-year,[36] the economic cost of this effect would be about $500 billion per year, far in excess of total annual U.S. spending on pharmaceuticals.[37] As discussed above, the assumptions underlying the base-case investment projections are highly conservative;[38] accordingly, the effects summarized as the base case in Table 6 and then expressed in terms of lost life-years and economic costs can reasonably be viewed as a lower bound on the prospective effects of federal price negotiations for pharmaceuticals.

Another approach is to ask how the projected annual decline in the number of new medicines compares with the annual number of new drug approvals by the FDA over the last several years. Table 7 presents those data. For 1995–2005, there were on average 98 new drug approvals annually. Our base-case projection of annual new medicines lost is about 10 percent of that figure. For 2000–05, new drug approvals averaged 62 annually; our base-case projection is about 16 percent of that figure.[39] Accordingly, it is reasonable to observe that the tax effects projected here are not trivial. In particular, the adverse investment effects are likely to be concentrated on drug research that otherwise would serve smaller populations, riskier treatments, and drugs expected to prove relatively less profitable.

Table 7. FDA New Drug Approvals	
Year	Approvals
2006[a]	13
2005	15
2004	29
2003	40
2002	93
2001	97
2000	98
1999	84
1998	145
1997	232
1996	207
1995	44

[a] Through August 9, 2006
Source: www.centerwatch.com/patient/drugs/druglist.html and www.fda.gov/cder/approval

RELATED RESEARCH FINDINGS

Other research findings are available and can be compared with those presented here. Using data for the 15 largest pharmaceutical producers, Vernon estimates that implementation of European-type price regulation by the federal government would yield a decline in research and development investment of 36–48 percent.[40] Golec *et al.* estimate that the mere proposal of pharmaceutical price restraints in the Health Security Act by the Clinton administration in 1993 reduced research and development spending by $1 billion despite the fact that the proposal was never enacted into law. That figure is $1.24 billion in 2005 dollars and was 15 percent of pharmaceutical research and development spending that year.[41] Abbott and Vernon estimate that small price reductions of about 5 percent would yield declines in research and development investment of 5 percent but that price reductions of 40–45 percent would drive research and development spending down by 50–60 percent.[42] Santerre *et al.* find an annual reduction of 1.2 percent in the growth of real drug prices attendant upon each 10 percent increase in the government share of drug spending before 1992, and an annual reduction in drug prices of 5.3 percent for each 10 percent increase in the spending share after 1992.[43]

The International Trade Administration of the U.S. Department of Commerce estimates that the pharmaceutical price controls imposed by some members of the OECD, if extrapolated to the OECD more broadly,would reduce sales revenues by 25–38 percent and research and development investment by 11–16 percent.[44] Giaccotto *et al.* find a 6 percent change in research and development spending attendant upon a 10 percent change in the growth of real drug prices.[45] The implicit tax estimated above (Table 2) attendant upon a federal spending share of 39.7 percent is 35.3 percent in 2025; the Giaccotto *et al.* estimate would have been about 24 percent using the same methodology. Vernon finds that regulation of U.S. pharmaceutical prices yielding profits equal to those observed on average in non-U.S. markets would reduce research and development investment by 23.4–32.7 percent.[46] Finally, Vernon *et al.* find that a reduction in drug prices of 10 percent would engender a reduction in research and development spending of 5.83 percent.[47]

Table 8 summarizes these comparative findings. Notwithstanding differences in conceptual experiments and methodologies, the findings presented here are broadly consistent with those reported elsewhere in the published literature.

CONCLUSIONS

Federal price negotiations for drugs under Medicare Part D would reduce costs for taxpayers and perhaps patients, but those effects can be achieved only at the cost of reduced pharmaceutical

Table 8. Comparison of Empirical Findings

Author	Finding
Vernon (2002–03)	European-style price regulation yields R & D decline of 36–48 percent
Golec, Hegde, Vernon	Proposed price controls yield R & D decline of 15 percent
Abbott and Vernon	Price reductions of 40–45 percent yield R & D decline of 50–60 percent
Santerre, Vernon, Giaccotto	OECD price controls reduce revenues by 25–38 percent and R & D investment by 11–16 percent
U.S. Dept. of Commerce	OECD price controls reduce revenues by 25–38 percent and R & D investment by 11–16 percent
Giaccotto, Santerre, Vernon	10 percent change in prices yields 6 percent change in R & D spending
Vernon (2005)	Profit reduction to non-U.S. average yields R & D reduction of 23.4–32.7 percent
Vernon, Santerre, Giaccotto	Price reduction of 10 percent yields reduced R & D spending of 5.83 percent
Zycher	Simulated projection of reduced R & D investment of 35.3 percent in 2025 based upon federal spending share of 39.7 percent

innovation, projected in this research to be substantial. While the average effect across the population in terms of life expectancy may or may not be "small," depending on somewhat subjective perspectives on the value of lost days, months, or even years, the effects are likely to be large by any definition for particular patient groups. That the reduced flow of new medicines, summarized above in Table 6, clearly will not be trivial underscores the stakes for individuals suffering from such specific conditions as cancer, diabetes, or Alzheimer's disease.

One crude measure of the value of pharmaceutical technology is total spending on medicines. As noted above, a conservative estimate of the average annual future economic loss — in terms of forgone life-years — caused by reduced pharmaceutical research and development investment is $500 billion, an amount far greater than total U.S. spending on drugs both now and in the future, as projected by the CMS. This suggests that the short-term gains would be outweighed greatly by the longer-term losses; that those losses will be inflicted disproportionately upon patient groups cannot be a source of indifference.[48]

The federal government, of course, buys many things, and the results here do not suggest that the U.S. economy writ large would benefit from the absence of federal negotiations over prices in any market. In most other contexts, the federal government is both the price negotiator and the consumer and so has some interest in preserving both the availability of given goods and technological advances; the latter may be particularly true in the context of national security capital demanded by a permanent bureaucracy. In many contexts, both the federal government and the given producer have market power, so that negotiation over price may yield outcomes closer to those that would emerge under competitive conditions. This "bilateral monopoly" condition is unlikely to characterize negotiations over prices for drugs that are not unique within a given class.[49] Most important, most goods do not exhibit the combination of large fixed costs and low marginal production costs that characterize most pharmaceuticals. The upshot of this almost unique condition is the opportunity to drive very hard price bargains without harming availability in the short term. But the longer term is the problem, the adverse effects upon which federal policymakers have relatively weak incentives to address.

The fiscal crisis inherent in Medicare is far greater than the short-term savings that federal price negotiations might yield, but the resulting longer-term costs caused by reduced pharmaceutical innovation are large. So once again, we are confronted with a stark choice: Cheap drugs in the here and now would prove expensive indeed tomorrow.

Appendix A: Further Observations on the Incentives of Federal Policymakers

Economists may disagree about many things, but absent among them is the role of incentives in the determination of choice behavior. Whether shaping the choices made by individuals in isolation or in groups acting collectively, the nature and power of the relevant incentives can be used to predict decisions and outcomes, at least directionally, in both the private and public sectors. With respect to the latter, the incentives confronting policymakers and agency administrators making decisions under a given set of rules, constraints, and opportunities will yield particular kinds of choices, while a different set of incentives or institutional arrangements will engender different outcomes.

These initial observations are trivial, but seemingly few people apply them to emerging public policy issues as those specific legislative and regulatory choices come to the fore. Such policy choices can significantly affect individuals, firms, industries, and the economy, so the importance of analyzing the incentives of policymakers as a tool with which to predict the implications of policy choices ought not to be ignored.

As discussed in Section II, the incentives of federal policymakers are inherently biased in favor of current budget savings at the expense of greater, rather than lesser, inclusiveness of federal drug formularies, relative to the case for private profit-seeking intermediaries balancing the demand of customers pursuing both price savings and formulary inclusiveness. This has the short-term effect of reducing the number of drugs included in the formularies; because of this relatively weaker incentive to include given drugs in formularies, prices can be predicted to be lower than in the alternative case.[a1]

The narrow long-term effect of these lower prices must be a reduction in the flow of research and development investments in pharmaceuticals, in turn yielding fewer medicines and higher medical costs (and greater suffering) over time.[a2] The pharmaceutical producers — which are entities with infinite lives — have incentives to preserve the flow of efficient research and development investments; those incentives are consistent with the partial incentives of private purchasers to make formularies more, rather than less, inclusive.[a3] In this sense, the profit motive leads the pharmaceutical producers implicitly to represent the interests of future patients, while the large profit-seeking retail buyers implicitly represent the interests of current patients.[a4] It is reasonable to predict that the bargaining process between pharmaceutical producers and the firms serving retail customers will yield current prices and investment flows that are roughly efficient.

A different long-term dynamic emerges in a world in which the incentives of federal policymakers transform pharmaceutical pricing into an implicit tax/transfer mechanism. As noted above, the stream of relatively large price discounts negotiated by the federal government is analogous to a flow of tax revenues distributed to drug consumers (or to the beneficiaries of other budget programs) in the form of ongoing price savings. For any given drug, there is a negotiated price (or price discount), P*, that maximizes the present value of the flow of price savings.[a5] Prices higher than P* (i.e., smaller discounts) would yield a smaller flow of price savings but a higher stream of research and development investment.[a6] Prices lower than P* would yield a smaller flow of price savings because of more stringent formulary exclusions imposed by the drug producers[a7] and clearly engender a lower stream of research and development investment. A price lower than P* may make both consumers and producers worse off and therefore cannot be the optimal price or price discount. The observation to be made here is that the incentives of federal policymakers lead them systematically to demand prices lower than P*.

Consider the decision-making environment confronting a policymaker driven to use tax and expenditure policies to maximize political support.[a8] Additional tax revenues (in this context, price savings on drugs) always serve the interests of policymakers as long as the price discounts in the short run do not create economic effects that over time offset the price-discount stream more than fully during the policymakers' terms in office.[a9] In other words, as long as industry

adjustments to adverse policies take longer than the terms of current policymakers, their net political incentive is to transfer as much wealth as possible from the producers to their constituencies.[a10] In the absence of constraints on the choices made by current policymakers — the extreme case — the federal government would pay only the marginal production cost for drugs, thus maximizing the current flow of price savings while ignoring the obvious adverse effects for future investment in research and development and production capacity.

Such constraints do exist, of course. The longer-term adverse effects of current policy choices should be resisted in some measure by the political parties, which to a degree have longer time horizons than given policymakers, who in turn might have incentives to take such effects into account to the extent that they receive funding and other kinds of support from the parties. Some patient groups and others will oppose actions yielding important expected declines in the future delivery of medical and pharmaceutical services. The pharmaceutical sector is an interest group of nontrivial influence. In addition, to the extent that policymakers can hide their behavior from voters, they might choose to demand smaller drug price discounts than otherwise would be the case.[a11]

Even in the presence of such constraints, policymakers can be predicted to negotiate a price lower (price discounts that are greater) than the price P* that maximizes the present value of the flow of price savings as long as their political time horizons are shorter than the period over which the industry would adjust fully to the implicit tax inherent in the actual negotiated price. Moreover, the short time horizon of the policymakers leads them to favor preservation of the negotiated price below P*, because a lower price yields a larger stream of price savings (implicit tax revenues) immediately, while the longer-term benefits of the larger research and development investments yielded by P* will accrue politically to their successors. In short, negotiation of prices lower than P* yields a political equilibrium (or trap) in which no current policymaker has an incentive to choose policies avoiding or reducing the adverse research and development effects of the negotiated prices.[a12]

Table B1. Historical and Projected Data on Pharmaceutical Research and Development: NSF Data and Investment Growth of 7.967 Percent (millions of year 2005 dollars)

Year	No Tax		1.2% Tax	
	R & D Investment	Pharm. K Stock	R & D Investment	Pharm. K Stock
1985	3300.457	19802.74	3300.457	19802.74
1986	3413.256	21631.78	3413.256	21631.78
1987	3801.306	23702.55	3801.306	23702.55
1988	4492.512	26298.85	4492.512	26298.85
1989	4991.193	29186.14	4991.193	29186.14
1990	5289.415	32140.66	5289.415	32140.66
1991	6122.809	35692.22	6122.809	35692.22
1992	7075.956	39912.8	7075.956	39912.8
1993	8227.823	44947.6	8227.823	44947.6
1994	8721.927	50073.72	8721.927	50073.72
1995	9352.944	55420.76	9352.944	55420.76
1996	9176.832	60163.93	9176.832	60163.93
1997	11215.93	66566.75	11215.93	66566.75
1998	12731.79	73973.2	12731.79	73973.2
1999	12751.26	80806.6	12751.26	80806.6
2000	13513.83	87855.9	13513.83	87855.9
2001	10959.36	91786.79	10959.36	91786.79
2002	15616.86	100060.7	15616.86	100060.7
2003	17709.58	109765.4	17709.58	109765.4
2004	19121.03	120105.2	19121.03	120105.2
2005	20644.98	131141.8	20644.98	131141.8
2006	22290.38	142940.8	22290.38	142940.8
2007	24066.93	155572.5	22049.29	153554.9
2008	25985.06	169111.8	23524.33	164794.8
2009	28056.07	183638.9	25098.04	176709.3
2010	30292.14	199239.9	26777.03	189349.6
2011	32706.42	216007.1	28568.34	202769.9
2012	35313.12	234039.7	30479.48	217027.8
2013	38127.58	253444.1	32518.48	232184.1
2014	41166.35	274334.9	34693.87	248303.2
2015	44447.31	296835.4	37014.8	265453.8
2016	47989.76	321078.4	39490.99	283708.4
2017	51814.54	347206.6	42132.82	303144.6
2018	55944.16	375374.3	44951.39	323844.4
2019	60402.91	405747.2	47958.52	345895.4
2020	65217.02	438504.5	51166.81	369390.6
2021	70414.82	473838.9	54589.73	394429.0
2022	76026.88	511958.7	58241.63	421116.3
2023	82086.22	553088.2	62137.83	449564.9
2024	88628.49	597469.7	66294.68	479894.4
2025	95692.18	645364.3	70729.61	512232.4

Table B2. Historical and Projected Data on Pharmaceutical Research and Development: NSF Data and Investment Growth of 4 Percent (millions of year 2005 dollars)				
Year	No Tax		1.2% Tax	
	R & D Investment	Pharm. K Stock	R & D Investment	Pharm. K Stock
1985	3300.457	19802.74	3300.457	19802.74
1986	3413.256	21631.78	3413.256	21631.78
1987	3801.306	23702.55	3801.306	23702.55
1988	4492.512	26298.85	4492.512	26298.85
1989	4991.193	29186.14	4991.193	29186.14
1990	5289.415	32140.66	5289.415	32140.66
1991	6122.809	35692.22	6122.809	35692.22
1992	7075.956	39912.8	7075.956	39912.8
1993	8227.823	44947.6	8227.823	44947.6
1994	8721.927	50073.72	8721.927	50073.72
1995	9352.944	55420.76	9352.944	55420.76
1996	9176.832	60163.93	9176.832	60163.93
1997	11215.93	66566.75	11215.93	66566.75
1998	12731.79	73973.2	12731.79	73973.2
1999	12751.26	80806.6	12751.26	80806.6
2000	13513.83	87855.9	13513.83	87855.9
2001	10959.36	91786.79	10959.36	91786.79
2002	15616.86	100060.7	15616.86	100060.7
2003	17709.58	109765.4	17709.58	109765.4
2004	18417.96	119402.2	18417.96	119402.2
2005	19154.68	129004.7	19154.68	129004.7
2006	19920.87	138605.2	19920.87	138605.2
2007	20717.70	148234.5	18980.85	146497.6
2008	21546.41	157922.1	19506.01	154283.8
2009	22408.27	167696.6	20045.70	161986.8
2010	23304.6	177585.5	20600.33	169628.2
2011	24236.78	187615.4	21170.30	177228.2
2012	25206.25	197812.4	21756.04	184806.0
2013	26214.5	208201.9	22357.98	192379.5
2014	27263.08	218808.9	22976.58	199965.7
2015	28353.61	229657.8	23612.30	207580.8
2016	29487.75	240772.9	24265.60	215239.9
2017	30667.26	252178.3	24936.98	222957.7
2018	31893.95	263898.0	25626.94	230748.0
2019	33169.71	275955.9	26335.98	238624.2
2020	34496.50	288375.9	27064.65	246598.9
2021	35876.36	301182.2	27813.47	254684.4
2022	37311.41	314399.0	28583.01	262892.7
2023	38803.87	328051.0	29373.85	271235.1
2024	40356.02	342162.9	30186.56	279722.9
2025	41970.26	356760.2	31021.77	288366.8

Table B3. Historical and Projected Data on Pharmaceutical Research and Development: PhRMA Data and Investment Growth of 4 Percent (millions of year 2005 dollars)				
Year	No Tax		1.2% Tax	
	R & D Investment	Pharm. K Stock	R & D Investment	Pharm. K Stock
1985	3464.677	20788.06	3464.677	20788.06
1986	3964.784	23089.8	3964.784	23089.8
1987	4577.237	25819.85	4577.237	25819.85
1988	5371.467	29125.73	5371.467	29125.73
1989	5948.222	32743.9	5948.222	32743.9
1990	6745.617	36870	6745.617	36870
1991	7665.755	41586.16	7665.755	41586.16
1992	9165.684	47424.95	9165.684	47424.95
1993	10286.71	53917.66	10286.71	53917.66
1994	10922.01	60526.26	10922.01	60526.26
1995	12494.13	68178.29	12494.13	68178.29
1996	14231.85	76955.88	14231.85	76955.88
1997	16446.92	87246.32	16446.92	87246.32
1998	19037.71	99304.33	19037.71	99304.33
1999	21190.91	112550.9	21190.91	112550.9
2000	24642.32	128189.1	24642.32	128189.1
2001	28845.77	146779.8	28845.77	146779.8
2002	30595.28	165632.7	30595.28	165632.7
2003	34284.17	186666.2	34284.17	186666.2
2004	36879.41	208612.3	36879.41	208612.3
2005	39431.30	231354.7	39431.30	231354.7
2006	41008.55	253854.8	41008.55	253854.8
2007	42648.89	276195.3	39073.45	272619.9
2008	44354.85	298454.6	40154.54	290964.9
2009	46129.04	320707.2	41265.53	308953.2
2010	47974.21	343024.9	42407.27	326644.2
2011	49893.17	365476.1	43580.59	344093.3
2012	51888.90	388126.9	44786.38	361352.2
2013	53964.46	411041.2	46025.53	378469.5
2014	56123.04	434280.9	47298.96	395490.9
2015	58367.96	457906.4	48607.63	412459.3
2016	60702.67	481976.6	49952.50	429415.0
2017	63130.78	506549.2	51334.59	446396.4
2018	65656.01	531681.3	52754.91	463439.6
2019	68282.25	557429.0	54214.53	480579.0
2020	71013.54	583848.3	55714.54	497847.2
2021	73854.09	610994.5	57256.05	515275.5
2022	76808.25	638923.2	58840.21	532893.7
2023	79880.58	667689.9	60468.20	550730.4
2024	83075.80	697350.5	62141.23	568813.2
2025	86398.83	727961.3	63860.56	587168.7

Chart CI. Base Case R & D Investment

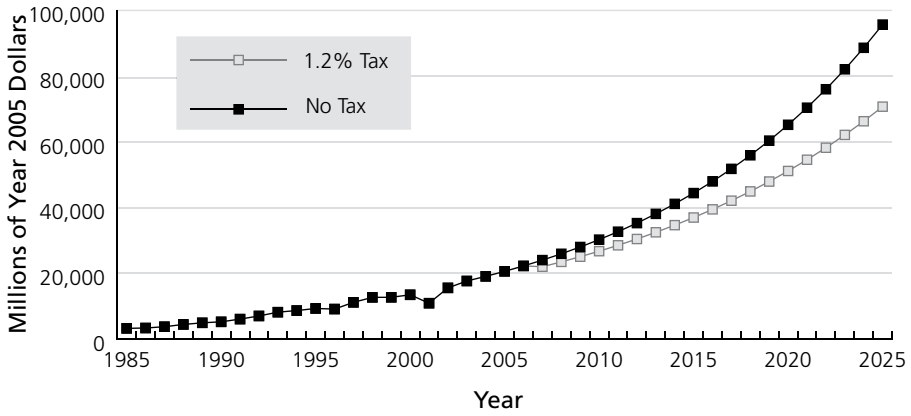


Chart C2. Base Case R & D Capital Stocks

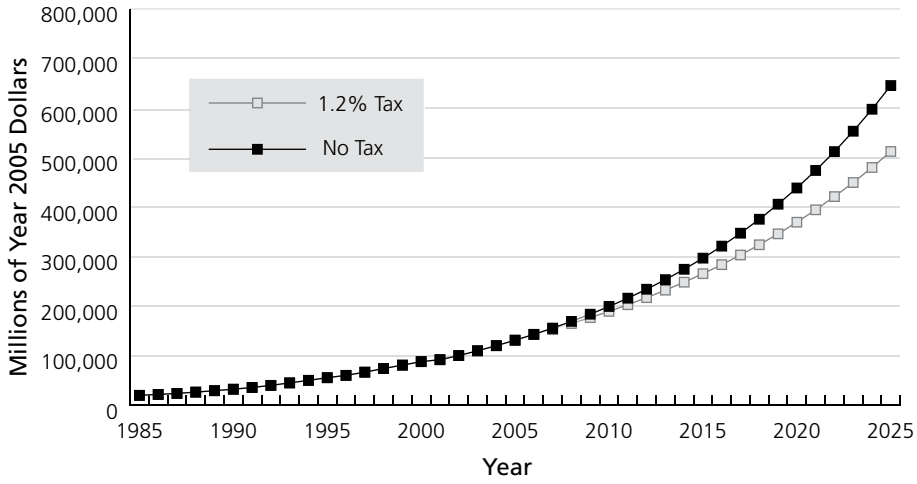


Chart C3. First Sensitivity Case R & D Investment

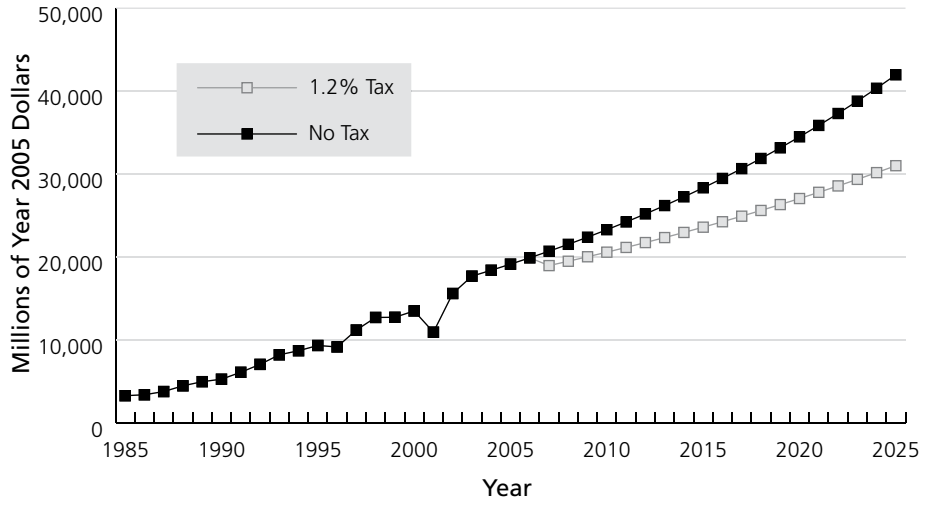


Chart C4. First Sensitivity Case R & D Capital Stocks

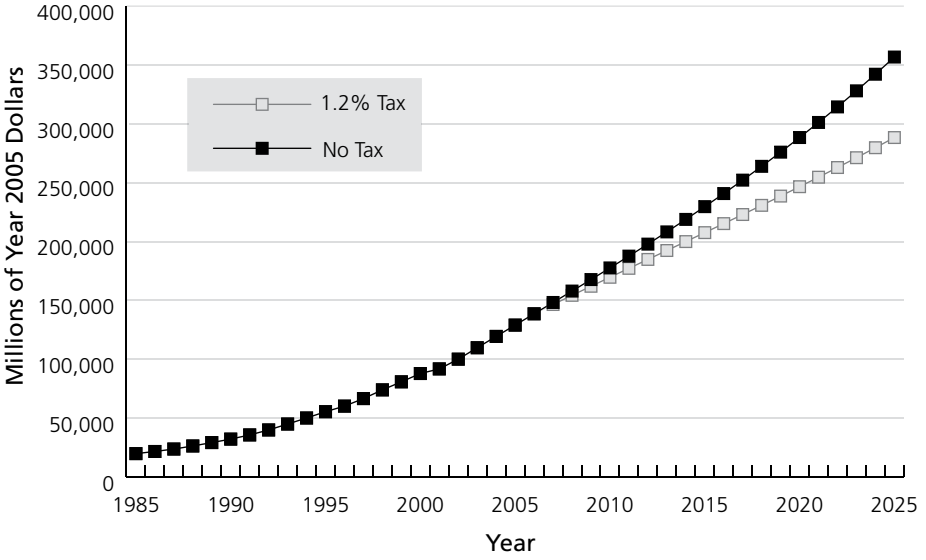


Chart C5. Second Sensitivity Case R & D Investment

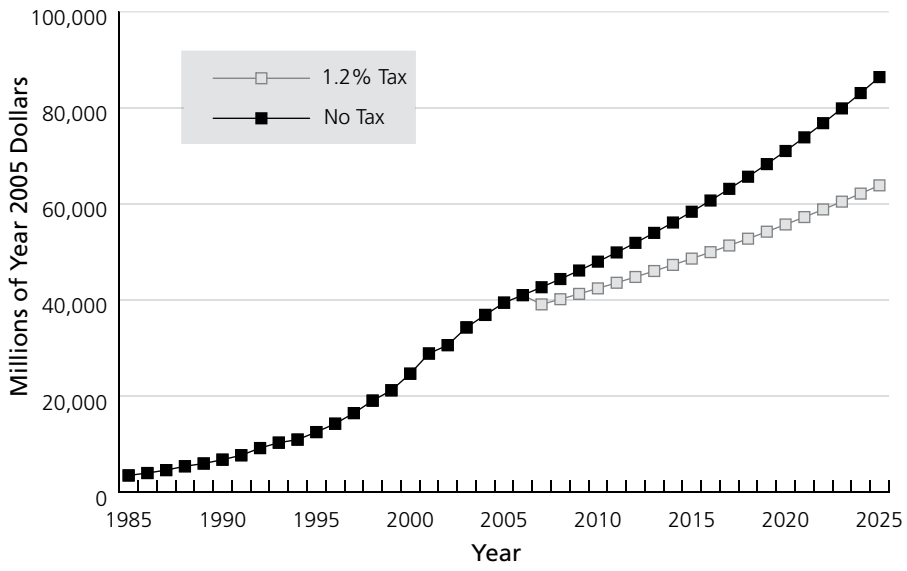
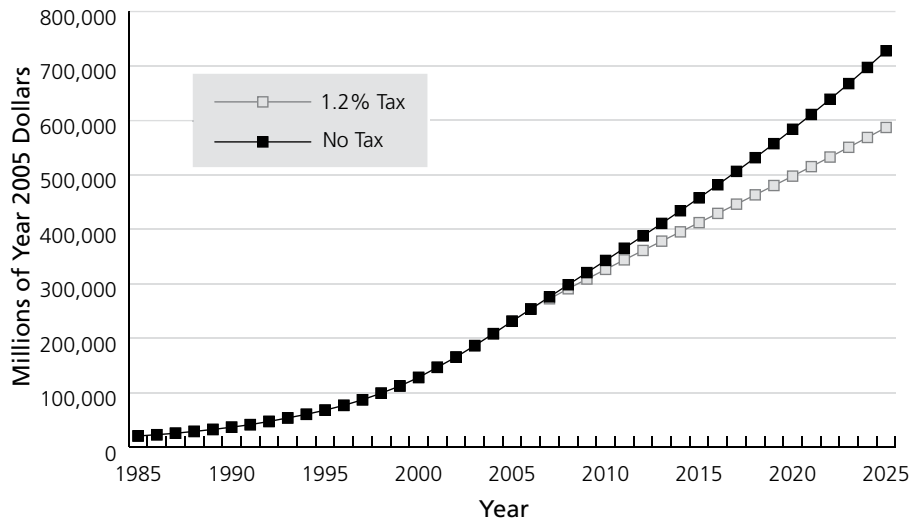


Chart C6. Second Sensitivity Case R & D Capital Stocks



Appendix D: Brief Observations on the Congressional Research Service Report on Federal Price Negotiations for Drugs

The Congressional Research Service (CRS) has prepared a brief analysis of the arguments for and against federal negotiation of drug prices for Medicare beneficiaries.[d1] Summary observations on that paper are as follows.

The paper argues that differential pricing ("price discriminate") of drugs flows from the monopoly power of the producers attendant upon the issue of patents, as well as the presence of "numerous channels of distribution from manufacturer to consumer." This argument is poor at best: Differential pricing is fully consistent with competitive conditions[d2] and even in the absence of patent restrictions on entry and the like can yield improved economic efficiency. This is particularly the case with such goods as drugs with low marginal production costs; differential pricing can enable producers to cover large fixed costs while still producing aggregate levels of output that equate marginal cost and marginal value.

The discussion of the VA pricing system is incorrect, in that it fails to distinguish between the mandated minimum 24 percent discount from the AMP (the FCP) and the FSS requirement that the pharmaceutical producers sell drugs to the VA at the "best price" offered to private-sector buyers. These are not "negotiated" prices, particularly given that FSS "best prices" must be offered as well to many health-care programs receiving federal funding; thus does the FSS "best price" requirement allow the federal government and many others to receive the benefits of private-sector negotiations without undertaking any negotiations themselves. The VA is entitled under the law to receive the lower of the FCP and FSS prices.

The discussion of third-party (middlemen) markups is poor: Wholesalers and the like reduce various types of transaction costs. Why else would profit-seeking firms utilize them? The elimination of such layers of market participants by a large government program does not by simple virtue of that fact improve "efficiency." Instead, it shifts the various transaction costs onto someone else: the taxpayers, the drug producers, the consumers, and so on. While it may be the case that federal involvement would reduce various kinds of transaction costs, that ought not to be assumed; and the experience with other federal procurement programs is not encouraging.

The paper argues that the "plethora of choices" under Medicare Part D "is not universally viewed as a positive outcome." Even in principle, consumers cannot be made better off with fewer options; cost reductions might be one effect of fewer options, which is why no market has an infinite number of competitors, but a federal takeover of such market functions as price negotiations is not obviously consistent with that goal.

The paper in its discussion of the arguments against federal price negotiations fails to consider the differing incentives of federal policymakers and large private buyers in terms of the tradeoffs between low prices and more inclusive formularies.

Finally, the paper argues that "there is very little evidence that quantifies the degree to which reductions in retail prices would lead to fewer new products being introduced." That is simply incorrect: Various works by Santerre, Vernon, Lichtenberg, and others referenced above are examples.

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Endnotes

1. See Lee Bowman, "Democrats vs. Bush on Medicare Drug Plans," Scripps Howard News Service, February 20, 2004.

2. *Ibid*. See also Kevin Freking, "Democrats to Unveil Drug Benefit Changes," *Seattle Post-Intelligencer*, June 26, 2006. Net federal spending on the new Medicare drug benefit is now estimated by the Centers for Medicare and Medicaid Services (CMS) at $746 billion over the period 2006–16. See U.S. Department of Health and Human Services, "Secretary's Progress Report IV on the Medicare Prescription Drug Benefit," prepared by Mike Leavitt, secretary of Health and Human Services, June 14, 2006. See also Kaiser Daily Health Policy Report, "Group of Democrats to Introduce Legislation Overhauling Medicare Drug Benefit," June 27, 2006; and idem, "House Members Seek Vote on Bill to Revise Medicare Prescription Drug Benefit," July 21, 2006.

3. Strictly speaking, the implicit "revenue" stream is the perceived greater total net value of drugs — total drug value minus total drug spending — but that is a minor complication ignored here, in part because lower prices might yield higher consumer spending under some demand conditions.

4. The measurement of this monopsonistic pricing power of the federal government as a drug purchaser lies beyond the scope of this paper; but it is useful to bear in mind that quite apart from the mere magnitude of its purchases, the federal government has the power to threaten actions affecting the profitability of ongoing pharmaceutical investments, as well as the power to threaten the imposition of price controls in various forms. For summary spending data, see Kaiser Commission on Medicaid and the Uninsured, "The Medicaid Program at a Glance," May 2006. For more detailed tables, see U.S. Department of Health and Human Services, at http://www.cms.hhs.gov/NationalHealthExpendData.

5. See unpublished spreadsheet projections from the CMS, available from the author upon request.

6. For a discussion of the formulary restrictions imposed upon the Veterans Health Administration pharmacy program, see Frank R. Lichtenberg, "Older Drugs, Shorter Lives? An Examination of the Health Effects of the Veterans Health Administration Formulary," Medical Progress Report No. 2, Manhattan Institute for Policy Research, October 2005.

7. The U.S. Postal Service, Amtrak, and other such federal agencies are a partial exception to this generalization. Most federal agencies in effect offer to Congress an aggregated basket of services in exchange for a lump-sum budget, even in such cases as entitlement programs for which the annual budgets cannot be determined precisely in advance.

8. See John A. Vernon, Rexford E. Santerre, and Carmelo Giaccotto, "Are Drug Price Controls Good for Your Health?" Medical Progress Report No. 1, Manhattan Institute for Policy Research, December 2004.

9. These private incentives to invest in research and development are powerful in the absence of expected price controls and similar disincentives, in that the market value ("market capitalization") of the firms incorporates the present value of the capital created by research and development investments.

10. For most drugs, fixed costs are large while marginal production costs are low. So, pushed to the extreme, drug producers would be willing in the short run to accept very low prices for given drugs — even if those prices do not cover the associated fixed costs — as long as the negotiated price is greater than the marginal production cost. This effect might be tempered by the realization that acceptance of a very low price for one drug might make negotiations over other drugs more difficult; in any event, the greater willingness of the federal government to exclude given drugs from formularies, because of its weaker incentives to satisfy its "customers," implies automatically that prices negotiated with the federal government will be lower than those negotiated with large private buyers, ceteris paribus. Note that the Bush administration disputes this effect, citing a 2005 memo from Richard Foster, chief actuary of the CMS, arguing: "We believe that direct price negotiation by the secretary would be unlikely to achieve prescription drug discounts of greater magnitude than those negotiated by [private] Medicare prescription drug plans responding to competitive forces." See Kaiser Daily Health Policy Report, June 27, 2006. That assertion is inconsistent with the experience in 2001 with the drug Cipro, produced by Bayer Pharmaceuticals; for a brief summary of that episode, see Benjamin Zycher, "Healthy Profits Have Healing Powers," *Los Angeles Times*, October 25, 2005. Nor is it consistent with the experience of the federal child vaccine program; see the Institute of Medicine of the National Academy of Sciences, *Financing Vaccines in the 21st Century* (Washington, D.C.: National Academies Press, 2004), chapter 5. In a larger context, it is not clear why the Bush administration would oppose such federal price negotiations merely because they would have no net price effect; what, then, would be the harm?

11. This discussion of federal incentives is developed further in Appendix A.

12. Producers are required also to participate in the Veterans Health Administration pharmacy program in order to have drugs included in Medicaid formularies.

13. There is a further geographic adjustment determined by the Consumer Price Index (CPI-U).

14. Note that reimbursement for the actual price paid by the provider yields no compensation to the provider for the direct medical services associated with administration of the drugs (e.g., an injection, or patient monitoring), unless reimbursement for the direct medical services "incident to" the drugs (e.g., cancer treatment) is sufficient to compensate the providers for those services. This lack of compensation for narrowly defined medical services related to the administration of the drugs is, in effect, a tax on the drug-related medical services, which in principle is borne by both the providers and the drug producers in some proportion determined by demand and supply conditions.

15. The requirement that price discounts negotiated with private-sector buyers be given to federal programs, whether directly or indirectly, may have the effect of limiting the discounts negotiated privately, in that the total cost of a given discount is greater than the narrow cost of giving it to the private buyer. But this must make both the private buyer and the drug producer worse off, in that the latter is constrained from offering a (larger) discount to which it otherwise would agree. Another way to see this is to recognize that under most conditions, differential pricing — different prices for different consumer subclasses — moves the drug market toward efficient levels of output and greater utilization of drugs; most-favored-nation types of required discounts are inconsistent with that goal.

16. Thus do so-called me-too drugs yield competition rather than a waste of investment resources, as some observers have argued, even apart from the differential medical benefits of alternative drugs in a class for individual patients. Even in the absence of competition, a drug with full patent protection can yield returns above, equal to, or below competitive levels, depending upon past costs, current production costs defined broadly, and market prices.

17. The interest rate in this context is the market rate for the relevant risk class of investments.

18. If this were not the case — if the average expected return systematically is higher than the market rate of interest — new producers would enter the market, increasing competition, thus driving down future expected prices and the expected returns to investment.

19. In the extreme case, the upper end of the statistical distribution of expected returns simply would be truncated.

20. That is, producers can restore (imperfectly) the mean expected return at the market rate of interest by truncating the lower end of the statistical distribution.

21. See Rexford E. Santerre, John A. Vernon, and Carmelo Giaccotto, "The Impact of Indirect Government Controls on U.S. Drug Prices and R&D," *The Cato Journal* 26, no. 1 (winter 2006): 143–58. See also Section VI below for a discussion of related literature.

22. An earlier paper found that more than one-third of the new drugs introduced between 1980 and 2001 would not have been developed had the rate of pharmaceutical price increases been limited to that of the consumer price index. See C. Giaccotto, R. E. Santerre, and J. A. Vernon, "Pharmaceutical Pricing and R&D Growth Rates," *Journal of Law and Economics* 48, no. 1 (2005): 195–214.

23. Santerre *et al.*, pp. 151–52. The authors are careful to note that other market and policy shifts beginning in the early 1990s may account for part of the larger post-1992 decline in the real growth rate of drug prices. Their elasticity estimate is consistent with those reported in other empirical research: 0.58, 0.61, and 0.54–0.68, respectively, in Giaccotto *et al.*; F. M. Scherer, *Industry Structure, Strategy, and Public Policy* (Boston: Addison-Wesley, 1996), chapter 9; and U.S. Department of Health and Human Services, "Prescription Drugs: Spending Controls in Four European Countries," 1994.

24. Frank R. Lichtenberg, "Sources of U.S. Longevity Increase, 1960–1997," NBER Working Paper No. 8755, 2002.

25. The deflator used was the chained GDP deflator for private equipment and software investment; see *Annual Report of the Council of Economic Advisers*, Table B-7, February 2006. See National Science Foundation, IRIS database, at www.nsf.gov/statistics/iris; idem, *Research and Development in Industry*, various annual issues; idem, *National Patterns of Research Development Resources*, 2003; idem, *Survey of Industrial Research and Development*, 2001; United Nations Industrial Development Organization, Industrial Statistics Database, INDSTAT4, 2003, ISIC Revisions 2 and 3; Organisation for Economic Co-operation and Development, STAN Database, at www.oecd.org/sti/stan; and Pharmaceutical Research and Manufacturers of America, *Industry Profile* 2006.

26. See. e.g., Charles Wolf, Jr., and Benjamin Zycher, *European Military Prospects, Economic Constraints, and the Rapid Reaction Force*, RAND Corporation MR-1416-OSD/SRF, 2001. Because one central question addressed in this paper is the effect of the implicit federal negotiation tax upon the projected pharmaceutical research and development capital stock for 2007–25, the initial capital stock assumed for 1985 is far less important than may seem to be the case, in that under an assumed annual depreciation rate of 8 percent, only about 18 percent of the 1985 capital stock would remain in 2007, and less than 5 percent would remain in 2025.

27. At an annual depreciation rate of 8 percent, about 21 percent of the capital from a given research and development project would remain at the end of the 20-year patent period. This is consistent with the general observation that drug prices tend to fall about 80 percent with the introduction of generic competition at the end of the patent period, in that the value of the remaining capital at any given point is the present value of the remaining net revenue stream, itself a function of generic competition and other market factors.

28. See above, n. 5.

29. Note that all of these assumptions are highly conservative. The available empirical analysis shows that existing public-sector drug programs depress prices by far more than 5 percent, that the federal spending share is certain to increase after 2006 because of the growing Medicare population, and that the 1.2 percent tax assumption is the compound tax rate before 1992 estimated by the Santerre *et al.* analysis, which is far lower than the compound tax rate (5.3 percent) estimated for the period after 1992. Even without any further increase in the total government spending share after 2006, and even assuming only a 1.2 percent implicit price tax per 10 percent federal spending share, compounded annually, the price effect by 2025 would be over 35 percent.

30. The negotiation tax does not affect the fixed cost — estimated by Dimasi *et al.* at about $800 million for the year 2000 — of bringing a new drug to market, and we assume for simplicity that it does not affect expected future prices after the patent period. It may reduce competition (and thus increase prices) during the patent period, but that is a complication beyond the scope of this paper. See J. A. Dimasi, R. W. Hansen, and H. G. Grabowski, "The Price of Innovation: New Estimates of Drug Development Costs," *Journal of Health Economics* 22 (2003): 151–85.

31. Consider an investment expected to cost C, after which expected revenues during the patent period are PQ, where P is price, and Q is quantity sold. The patent period is g years, after which expected revenues are pq, where p and q are the parameters analogous to P and Q. The market interest rate is r. An unbiased first approximation of the present value of expected profit π in the absence of federal negotiation is

$$\pi = [(PQ/r)-(PQ/(r(1+r)^g)) + pq/r(1+r)^g] - C.$$

Since C, p, q, g, and r by assumption are unaffected by federal price negotiations, they can be ignored. If PQ is reduced by some percentage, π declines by that same percentage. Again, this is independent of the interest rate r and the patent period g. Q might change disproportionately with P, but even the direction of the change in Q is unclear, as formulary restrictions might reduce Q even as P is reduced through negotiations.

32. In other words, the assumed elasticity of research and development investment with respect to price is 1. This is a conservative assumption because implicitly it assumes away the possibility that a given negotiation tax will reduce investment to zero. For a classic discussion of the marginal efficiency of investment, see J. Hirshleifer, *Investment, Interest, and Capital* (Englewood Cliffs, N.J.: Prentice-Hall, 1970), chapters 3 and 6.

33. Above, n. 21.

34. See Pharmaceutical Research and Manufacturers of America, above, n. 25. These investment data generally are larger than the NSF data, particularly after 1990; the source of the differences is beyond the scope of this paper, although it is likely to be some combination of definitions and inclusions and exclusions. Note also that the PhRMA data are for domestic members of PhRMA only.

35. Above, n. 24.

36. See Kevin M. Murphy and Robert H. Topel, "The Economic Value of Medical Research," in *Measuring the Gains from Medical Research*, ed. Kevin M. Murphy and Robert H. Topel (Chicago: University of Chicago Press, 2003). The Murphy/Topel estimate of the value of a life-year is $160,000.

37. The CMS projects total U.S. drug spending in 2015 at about $450 billion in nominal (then-year) dollars. If we assume an annual inflation rate of 2 percent, that amount is about $369 billion in year 2005 dollars. We ignore here the marginal economic cost ("deadweight loss") caused by the federal tax system; even if we assume it to double the economic cost of federal spending (by another $160 billion in year 2005 dollars), the value of the life-years lost is still about the same as total national resource consumption for drugs. See Benjamin Zycher, "A Preliminary Benefit-Cost Framework for Counterterrorism Public Expenditures," RAND Corporation MR-1693-RC, May 2003.

38. Above, n. 29.

39. Note that the earlier part of the 1995–2005 period coincided with the implementation of the Prescription Drug User Fee Act, which may account in part for the relatively large number of approvals in 1996–2002.

40. John A. Vernon, "Drug Research and Price Controls," *Regulation* 25, no. 4 (winter 2002–03): p. 22–25. Vernon notes clearly that price-control regimes vary substantially across Europe, that substantial uncertainty afflicts the econometric findings, and that the estimates are crude.

41. Joseph Golec, Shantaram Hegde, and John Vernon, "Pharmaceutical R & D Spending and Threats of Price Regulation," NBER Working Paper, 2006. The estimated decline in research and development spending is 12 percent if we use the data from PhRMA. See Pharmaceutical Research and Manufacturers of America, above, n. 25.

42. Thomas A. Abbott and John A. Vernon, "The Cost of U.S. Pharmaceutical Price Regulation: A Financial Simulation Model of R & D Decisions," *Managerial and Decision Economics*, forthcoming.

43. Above, n. 21.

44. U.S. Department of Commerce, International Trade Administration, *Pharmaceutical Price Controls in OECD Countries*, December 2004, pp. 25–31.

45. Giaccotto *et al.*, above, n. 22.

46. John A. Vernon, "Examining the Link between Price Regulation and Pharmaceutical R & D Investment," *Health Economics* 14, no. 1 (January 2005): p.1–16.

47. Above, n. 8.

48. For a more detailed discussion of this issue, see John A. Vernon, Joseph H. Golec, and W. Keener Hughen, "The Economics of Pharmaceutical Price Regulation and Importation: Refocusing the Debate," *American Journal of Law & Medicine* 32 (forthcoming in 2006).

49. See John E. Calfee, Mario Villarreal, and Elizabeth Dupré, "Biotechnology Drugs, Traditional Pharmaceuticals, and Price Controls," manuscript, American Enterprise Institute, June 3, 2006.

a1. For states implicitly purchasing drugs under Medicaid rebate requirements, this incentive may be weaker in that states receive marginal subsidies between 50 percent and, as an upper limit, 83 percent from the federal government. The average in FY 2004 was 60.2 percent; the highest was 77.08 percent for Mississippi.

a2. See above, n. 8.

a3. In simple terms, "efficient" in this context is the investment flow that yields an expected economic return for the "marginal" (last) investment equal to the market rate of interest.

a4. Because, broadly, the drug producers must produce goods valued by patients, and because, more narrowly, differential pricing (crudely, high prices for those willing to pay them and low prices for others) in the context of low marginal costs enables the firms to expand sales and increase profits by reducing prices for some consumers, the interests of drug producers and current patients to a substantial degree are aligned even in the short run.

a5. Note that P* is not necessarily the economically efficient price, which is a marginal price equal to marginal cost.

a6. The magnitude of the price discount affects the magnitude of the implicit stream of savings for consumers, but not proportionately: A discount of zero would yield no savings for consumers, while a price of zero also would yield no savings for consumers since drug producers would refuse to include those drugs in formularies. Therefore, bigger discounts are not necessarily better for consumers even in the short run. This is analogous to the "Laffer Curve" effect, much derided but in reality completely correct over some range of tax rates. In any event, if the drug producer could make more money by reducing the price, it would do so unilaterally.

a7. Prices lower than P* yield larger consumer savings on drugs included in formularies but consumer losses on drugs excluded from formularies; P* is defined to be the price that maximizes the flow of price savings.

a8. Again, these taxes and expenditures can be implicit, as in the case of discounted pharmaceutical prices yielding savings for drug consumers or spending increases for the beneficiaries of other spending programs.

a9. For example, a very low price in the immediate term might drive the given pharmaceutical producer to cease production of the drug in question, possibly yielding very high prices soon thereafter. This sort of "present value" calculation is inherent in this discussion but will be avoided for purposes of simplicity.

a10. This should make intuitive sense: As long as current policymakers can continue to obtain "cheap" medicine, and as long as future patients' medical interests are not reflected in current voting, it is rational for current policymakers to favor policies transferring additional wealth to their constituencies.

a11. Evidence of such "shirking" behavior is weak. See Bruce Bender and John R. Lott, Jr., "Legislator Voting and Shirking: A Critical Review of the Literature," *Public Choice* 87, nos. 1–2 (April 1996): 67–100.

a12. The technical analysis yielding this conclusion is available from the author upon request.

d1. Jim Hahn, "The Pros and Cons of Allowing the Federal Government to Negotiate Prescription Drug Prices," CRS Report for Congress, February 18, 2005.

d2. Consider the ways in which theaters, restaurants, and myriad other sellers find ways to charge different prices to various consumer groups.

Notes

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The Center for Medical Progress (CMP) is dedicated to articulating the importance of medical progress and the connection between free-market institutions and making medical progress both possible and widely available throughout the world. The research and writing of CMP senior fellows David Gratzer, M.D., Regina Herzlinger, D.B.A., Peter Huber, Ph.D., and Benjamin Zycher, Ph.D., encourage the development of market-based policy alternatives to sustain medical progress and promote medical innovation.

Gratzer, Herzlinger, Huber, and Zycher are published in prominent publications such as the *Wall Street Journal*, the *Washington Post*, *National Review*, and the *Weekly Standard*. Herzlinger, the Nancy R. McPherson Professor of Business Administration Chair at the Harvard Business School, is widely recognized throughout the business and policy communities for her innovative research in health care. She predicted the unraveling of managed care, as well as the rise of consumer-driven health care and health-care-focused factories, two terms that she coined. Gratzer is currently working on a new book, *The Cure: How Market Reform Can Make American Health Care Better, Cheaper, and More Accessible*. Zycher is researching the economic and political effects of regulation, government spending, taxation, and the economics of the pharmaceutical sector.

In 2005, the CMP established the 21st Century FDA Task Force to devise and promote better science-based regulations at the FDA that will decrease the time and cost required for new drug development while increasing the safety and efficacy of the nation's drug supply. The Task Force is composed of experts from academia, industry, and the policy community, and will develop and disseminate proposals to reform the FDA's drug approval and safety monitoring procedures.

The CMP also publishes MedicalProgressToday.com, a web magazine that provides a weekly selection of the best published commentary, research and analysis of health-care issues from a free-market perspective. In addition, MPT solicits original spotlight op-eds on critical health-care topics, and convenes policy forums where leading scholars exchange views on important health-care issues. Contributors to MPT have included Newt Gingrich, Scott Gottlieb, J. Edward Hill, and other leading health-care experts.

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