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Routing

Avoiding Medicare's Pharmaceutical Trap

by Doug Bandow

Executive Summary

The Medicare drug benefit will soon set a dangerous trap. In January 2006 the federal government is scheduled to start purchasing prescription drugs for more than 40 million seniors and disabled Americans through that new addition to the Medicare program. The enormous tax burden that will be required to fund the drug benefit will put constant pressure on politicians to limit spending. Some observers argue that the federal government should dictate the prices it pays for drugs. Though cloaked in the rhetoric of "negotiated prices," such proposals in fact amount to price controls. Unless the new benefit is delayed or repealed, it will set the stage for Congress to enact price controls on pharmaceuticals.

Economic theory and empirical evidence show that price controls cause enormous harm. Existing federal price controls have already cost Americans an estimated 140 million life-years. Applying such controls to Medicare purchasing would eliminate approximately 40 percent of all future pharmaceutical research and development and cost another 277 million life-years.

Rather than attempt to fix drug prices, Congress should reform Medicare by converting it to a program that provides premium support for the purchase of private insurance policies offering a broad array of options, including prescription drug coverage. Washington also should pressure other nations to lift their price controls, encourage patients to be more careful drug purchasers, and reduce unnecessary regulatory costs by reforming the federal Food and Drug Administration.

In the meantime, Congress should contain the spread of pharmaceutical price controls by delaying or repealing the Medicare drug benefit before it takes effect.

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Introduction

Health care is expensive. Spending on health care continues to rise, though the rate of growth has started to moderate after six straight years of acceleration: outlays increased 7.7 percent in 2003 compared to 9.3 percent the previous year.[1] Nevertheless, medical expenditures continued to outpace economic growth. Thus, researchers for the Centers for Medicare and Medicaid Services report that "health care spending represented 15.3 percent of GDP in 2003, up from 14.9 percent in 2002."[2]

Moreover, those analysts forecast that outlays will continue to increase faster than the rate of inflation and the economic growth rate. They expect medical expenditures to rise from 15.7 percent to 18.4 percent of GDP from 2005 to 2013.[3] "There is just not much optimism that we know how to control costs," observes Paul B. Ginsburg, president of the Center for Studying Health System Change.[4] As a result, health insurance premiums continue to increase; they were up 11.2 percent in 2004 (though that rate of increase was down marginally from 13.9 percent the year before).[5]

Equally important, medical expenditures continue to increase federal government outlays. The Congressional Budget Office warns that Washington's biggest health care programs, Medicare and Medicaid, threaten the nation's long-term fiscal solvency.[6] Outlays for the former "can be expected to increase sharply," explain government analysts, when the Medicare drug benefit takes effect in 2006.[7] The Bush administration was forced to acknowledge that its Medicare bill, set to take effect next year, will cost far more than originally projected. That admission set off widespread criticism from members of both parties.[8] Indeed, that program alone will add some $18.2 trillion to Medicare's unfunded liabilities, bringing the total to an astounding $68.4 trillion.[9]

Although hospital charges and professional fees are much larger than drug expenditures, the latter receive disproportionate public attention. People are more likely to blame pharmaceuticals for rising health care costs than any other factor.[10] Indeed, there may be no more politicized health care issue than pharmaceutical prices. Between 1993 and 2013 overall medical spending is expected to jump fourfold, but pharmaceutical spending will increase 10-fold.[11] Even though the rate of increase for drug outlays is falling, prescription drugs will "still be the fastest-growing health sector" between 2003 and 2005.[12]

The reasons for the rise are not mysterious. The elderly disproportionately consume drugs: Medicare beneficiaries (aged 65 or older and the disabled) make up less than 15 percent of the population but account for some 40 percent of all drug spending. The CBO predicts that spending on medicines will rise 10 percent annually over the next decade, significantly faster than other Medicare expenses and inflation generally.[13]

The American Association of Retired Persons issues regular reports on rising pharmaceutical prices. "Filling the same prescriptions from year to year is taking an ever-increasing share of consumer income, particularly for older consumers," complains the organization, a frequent critic of the drug industry.[14] John Rother, AARP's director of policy and strategy, declared: "Price increases hurt more than just AARP members. They break state Medicaid budgets and strain employers and health insurers."[15]

Indeed, aggregate pharmaceutical spending figures can be misleading. Throughout the 1990s pharmaceutical spending increased nearly twice as fast as did medical spending generally. But the bulk of the increase reflects increased use of newer and better drugs, not rising prices.[16] Moreover, drug spending remains a small portion of overall medical outlays—about 11 percent—and has started to moderate. Pharmaceutical spending increased 10.7 percent in 2003, down from a 14.9 percent increase in 2002.[17] Those numbers include spending on generics and pharmaceutical dispensing costs (which are rarely ever recognized, let alone criticized). Strip those out and revenues to brand-name manufacturers run about seven cents on the medical dollar.[18] (Recognition that other factors inflate costs

has led some insurers to require patients to buy from mail-order or online pharmacies in order to win bulk discounts.)[19]

But the facts rarely matter when it comes to prescription drugs. In the 2004 election campaign, the Democratic presidential ticket followed recent tradition by attacking the pharmaceutical industry. Moreover, legislators of both parties are proposing that Uncle Sam use his clout—derived from paying for about 60 percent of all drug purchases when the Medicare drug benefit becomes effective—to drive down pharmaceutical prices, creating a de facto system of price controls. Already, the Medicare formulary—that is, the list of drugs that private insurance plans will have to cover under the program—has become a political battleground.[20]

How the New Medicare Drug Benefit Works

The new pharmaceutical benefit, approved in 2003, is ostensibly voluntary. Beneficiaries can enroll at any time but, in order to limit adverse selection, those enrolling after their initial eligibility period will pay a lifetime penalty that increases the longer they delay enrollment. (Congress covered the gap in time between the new benefit's enactment and its implementation in 2006 by creating a program offering government-approved industry discount cards and a $600 annual subsidy for lower-income beneficiaries.)

Medicare beneficiaries who remain in the traditional fee-for-service program will choose a new prescription drug plan (PDP), and other beneficiaries will choose a Medicare Advantage health maintenance organization (HMO) or a regional preferred provider organization that covers pharmaceuticals. The administration has approved 10 national PDPs, as well as a number of regional PDPs. Beneficiaries will be able to choose from between 11 and 20 PDPs, depending on their state.[21] Medicare supplemental insurers will be barred from offering drug coverage to new enrollees. The new Medicare Part D will be financed through a mixture of general revenues, state payments (for seniors also eligible for Medicaid), and beneficiary premiums (which will be set to cover 25.5 percent of program costs).

The Medicare drug program is poorly designed. Under the standard benefit, Medicare beneficiaries will face a $250 deductible, be liable for 25 percent of the next $2,000 in expenses, and then be liable for all of the next $2,850 in expenses. Beyond that point, when an enrollee's total drug costs reach $5,100, the PDP will cover 95 percent of each enrollee's drug costs. The window during which beneficiaries will have no coverage has been termed the "doughnut hole." Plan premiums, deductibles, and limits on out-of-pocket expenditures will be indexed to plan spending.

Additional provisions are intended to address potential harmful incentives. Companies providing retiree coverage will receive billions of dollars in taxpayer subsidies to encourage them to continue to do so. PDPs will be paid on the basis of a combination of expected and actual costs. Taxpayers will underwrite PDPs suffering higher-than-expected expenses and will recoup money from PDPs if actual costs are lower than expected. Finally, taxpayers will finance 80 percent of drug costs above the so-called catastrophic threshold ($5,100).

Proponents of the new drug benefit expect competition among PDPs to help limit costs. Although the federal government will not dictate the prices paid for prescription drugs, it will regulate the PDPs' drug formularies, cost-containment measures, and pharmaceutical suppliers. It will also police any efforts by PDPs to discourage enrollment by sicker Medicare beneficiaries. Within those limits, PDPs will decide which drugs to cover and how much to pay for them. Since PDPs will be competing for consumers, they will have an incentive to obtain the best deals possible. Proponents of Part D argue that negotiation among PDPs and drug makers will put downward pressure on prices and will result in a range of formularies, drug prices, authorization requirements, and plan premiums.

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Even if proponents are correct, the drug benefit will place an enormous burden on taxpayers. The CBO estimates that the program will cost $850 billion in its first 10 years of operation (2006–15).[22] As noted earlier, the program creates a large unfunded liability; moreover, it does so at a time when the federal government already faces sizable budget deficits. That burden will put constant pressure on politicians to reduce costs.

So long as the drug benefit exists, it will create pressure—and an opportunity—for Congress to set prices for prescription drugs. At present, federal law states that the secretary of health and human services "may not interfere with the price negotiations between drug manufacturers and pharmacies and [PDP] sponsors."[23] Almost immediately after passage of the legislation, however, some legislators began clamoring to overturn that "noninterference clause." Sen. John McCain (R-AZ) called the ban on Washington's dictating prices "egregious and outrageous."[24] More than half a dozen bills have been introduced in Congress to remove the noninterference clause, many with bipartisan support.[25] Advocates of repealing the noninterference provision, and allowing the federal government to "negotiate" prices for Part D drugs, range from leading Democrats to the American Medical Association to former health and human services secretary Tommy Thompson.[26] But as former Medicare director Gail R. Wilensky notes, "Government doesn't negotiate prices—it sets them."[27]

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A Tempting Target for Price Controls

Drugs offer a uniquely attractive target for price controls because of their peculiar nature. The marginal cost of making the physical object—for example, a pill—is very small. The actual cost—including the *discovery* of that chemical compound and its healing effect—is not readily apparent. Research and development costs are mostly hidden, with research expenditures spread over years on unsuccessful as well as successful products. Given the necessary R&D investment and the number of "dry holes," the effective cost of making the first pill is enormous. However, the relatively low marginal cost of producing subsequent pills leads some people to demand a price closer to that marginal cost.

Price controls are also politically attractive because in the short term they cut medical expenses without reducing product access. Companies will continue to manufacture existing medicines, whereas the inevitable impact on R&D won't be evident for years. The harm inflicted on most patients won't ever be obvious, because it consists of losing something that has yet to be created. Indeed, the damage almost certainly won't be felt while the blameworthy politicians are still in office.[28] As economists Rexford Santerre and John Vernon note, "Even though a policy of regulated drug prices in the U.S. involves a tradeoff between short-run benefits and long-run costs, the former outcome often receives more attention in policy debates."[29] Yet as Santerre, Vernon, and their colleague Carmelo Giaccotto warn:

> These predicted long-run costs associated with the government's expanded influence [and thus restraint on prices] under the [Medicare drug benefit] appear to be quite high. . . . 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.[30]

The Case against Price Controls

The general case against price controls is clear. Price controls increase the quantity of a good demanded by consumers, depress supply, create shortages, shift activity to unregulated sectors, and encourage wasteful avoidance and evasion activity. The evidence of the malign effects of price controls dates back millennia.[31] As the Heritage Foundation's

Derek Hunter has observed, "No politician, over the course of 4,000 years of experience, has yet devised a humane system of price controls for consumers, free of shortages or a decline in the quality of the controlled goods or services."[32]

Recent American experience is no better.[33] As Kevin Hassett of the American Enterprise Institute put it, "Attempts to centrally control markets lead to wildly suboptimal outcomes."[34] Regulating drug prices also would be highly political, a constant war among competing lobbyists: anti-corporate interest groups, drug makers, insurance companies, patient groups, pharmacists, and most anyone else with an interest in the final price.[35] Any price chosen by government would be inherently arbitrary, and any result approaching a rational outcome would be purely accidental.

The case against price controls on pharmaceuticals is even stronger. Price controls imposed on pharmaceuticals would have more harmful long-term effects than most other government-fixed prices. Writes John Calfee of the American Enterprise Institute, the problems "go well beyond the economist's usual abhorrence of price controls and government allocation of resources."[36] The unique characteristics of the pharmaceutical marketplace, notably the importance of risky R&D investment with uncertain payoffs, make price controls particularly inappropriate.[37]

For instance, drug research failures far outnumber successes. Often, several firms spend millions or billions of dollars seeking remedies to the same diseases, but only one company succeeds. Sometimes none does. Calfee notes that "lines of research that have involved billions of dollars with little tangible success, but with an immense payoff if and when success is ever achieved, include the search for oral insulin to treat diabetes, treatments for nerve damage from diabetes, gene therapy, and better clot busters for heart attacks and strokes."[38] Two-thirds of the products that reach patients don't pay back their investment costs.

Moreover, the cost of drug development has been rising sharply. The cost of bringing one new drug to market in the 1980s was $100 million. Largely as a result of Food and Drug Administration regulations, that cost rose to more than $800 million by 2003.[39] With the FDA continuing to increase the amount of testing and information required for approval, there is no reason to expect development cost growth to moderate any time soon.[40] (Those costs already make it difficult for drug makers to pursue substances that appear to help a limited number of users.)[41]

It is also impossible to determine product value before actual sales. Financial projections made even when a drug is introduced often are erroneous. Some medicines expected to be big sellers flop. Others that are produced with only modest expectations flourish.[42] How could any arbitrarily imposed price reflect all of those considerations?

Foreign Price Controls

Foreign price controls on pharmaceuticals are already sacrificing the health of citizens of all industrialized countries. A study from the Brussels-based Centre for the New Europe noted how traditionally overburdened European medical systems are being pressed to spend more money. Europe's response has been to try to hold down spending on prescription drugs.[43] A U.S. Department of Commerce report found that members of the Organization for Economic Cooperation and Development (the world's leading industrialized states) most often use government controls, rather than market competition, to reduce drug expenditures.[44] Indeed, 11 OECD nations "rely on some form of price controls to limit spending on pharmaceuticals."[45]

The various types of controls include straight price setting, approval delays, procedural complications, restrictions on use and reimbursement, and reference pricing (e.g., setting the prices for all drugs in a therapeutic category, such as anti-coagulants or statins, equal to the average cost or the cost of the lowest-priced drug).[46] The rationale for the prices generated often is not shared with the firms that manufacture and market the products.[47] Governments often transform

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and expand their controls over time, especially when initial efforts yield less savings than hoped.[48]

European governments have succeeded in cutting drug prices. On average, brand-name drug prices are 81 percent higher in the United States than in Japan and West European states (though generics are cheaper in America).[49] However, that often comes at the price of higher health costs. The most obvious losers are foreign patients who are blocked from obtaining helpful medications by shortages or other government-imposed obstacles. Patricia Danzon and Michael Furukawa report that, because of lags in introduction and other obstacles, Europeans use fewer new drugs—sometimes far fewer, depending on the country—than Americans do.[50] The Boston Consulting Group, which conducted a similar study of the impact of foreign controls, concluded,

> Within OECD countries, patients experience reduced access to innovative medicines—launch delays of 1–2 years are typical, adoption rates are slower, and even peak penetration rates lag U.S. rates by 15–20 percent—and therefore are prevented from receiving the full therapeutic benefits of these drugs.[51]

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Similarly, the economic consulting firm Europe Economics reported that patients often wait years for access to even life-saving new medicines.[52] Recent research by Oliver Schoffski of Nuremberg University demonstrates that even though valuable drugs are ostensibly available to Europeans, many do not receive adequate drug treatments because of government reimbursement policies.[53]

Paradoxically, the more useful the drug and the more people it would help, the less likely it is that European governments will approve it quickly. Europe Economics explains that when governments expect the demand for a certain product to be great, they tend to demand larger pricing concessions.[54] That tactic exacerbates the perverse impact of price controls, since it targets what tend to be the most valuable drugs.[55]

Although the low marginal cost of pill production means companies have an incentive to continue supplying existing medicines at price-controlled rates, some companies (such as AstraZeneca) have begun to consider resisting what amounts to extortion and exploitation by withdrawing from select markets. If companies follow through on their threats to exit some markets, European consumers may lose access to drugs that are already on the market.[56] But even if companies continue to supply regulated markets, patients will lose. For many people and for many conditions, older drugs may prove satisfactory. But often they don't perform as well as newer drugs, which is why new medicines are developed and prescribed.

The Boston Consulting Group notes that reducing access to new drugs can threaten patient health.[57] That conclusion is buttressed by the substantial documentation of the benefits of new prescription drugs.[58] For instance, newer drugs address both psychosis and depression better than older treatments. The BCG reports that when it comes to depression, "Study evidence suggests that the newer drugs yield higher remission and response rates, coupled with a lower incidence of adverse events—side effects that drive patients to end therapy prematurely."[59] New medicines have had a particularly dramatic impact on cancer treatment. As a result, patients are desperate to get into clinical trials where new drug therapies—oncology drugs in particular—offer even a glimmer of hope.[60]

Here again, the greater the benefits of a new drug, the more hostility it will meet from government price fixers. For example, although British doctors acknowledge the enormous benefits of new anti-cancer drugs, they "are worried that the new drugs will hugely push up the bill for hospitals" and "expect to come under considerable pressure from patients to prescribe these drugs."[61] Unfortunately for British patients, their government-run health system is likely to sacrifice long-run health benefits to achieve short-run budget savings.

Indeed, Europe has gained a reputation for delaying and limiting patient access to

new cancer medications, as well as drugs for other conditions.[62] The *Wall Street Journal* reports:

> Innovative cancer drugs have gotten bogged down. . . . Herceptin, a new breast-cancer medication from San Francisco–based Genentech Inc., was approved two years ago by regulators in the U.S., where it benefited from an accelerated review offered to novel cancer therapies. It is still awaiting regulatory approval in most of Europe, where the drug will be marketed by Genentech's parent, Roche Holding Ltd. . . . Many European countries also attempt to restrict demand after new medicines reach pharmacy shelves. Drugs can be saddled with tight prescribing rules to limit consumption. Patients across Europe are fighting for improved access to older drugs such as Taxol, the world's top-selling anti-cancer drug, from Bristol-Myers Squibb Co.[63]

A combination of national and provincial controls similarly harms Canadian patients. In Canada, pharmaceuticals must be approved at both the national and the provincial level. Many never receive official approval. Even those that are approved see average marketing delays of up to two years.[64] Of 400 drugs considered for reimbursement by the Canadian province of Ontario between 1994 and 1998, only 24 were approved. Reference pricing in the province of British Columbia has given rise to dubious therapeutic judgments and has saved little money.[65] John Graham, then of Vancouver's Fraser Institute, reported that in British Columbia, "there is also evidence that the Reference Drug Program had negative consequences for patients' health."[66] More than a quarter of doctors in British Columbia reported that they had had to treat or even hospitalize patients because of government-mandated drug substitutions. Six of 10 had seen their patients' conditions deteriorate.[67]

The costs of withholding pharmaceuticals from patients include both enormous pain and suffering and the higher costs of alternative treatment. An ironic result of many OECD countries' price controls has been increases in other health care expenditures. Studies have documented how pharmaceutical use often reduces reliance on, and thus the expense of, costlier treatments.[68] The cost reduction is often greater than the price of the pharmaceuticals—sometimes by a huge margin.[69] Newer and better mental health medications reduce both physician appointments and hospital stays.[70] In British Columbia, reports Graham, "there was also some evidence of longer stays in hospital, and more visits to physicians and emergency rooms" as a result of reduced access to pharmaceuticals.[71] Increased use of statins, for instance, would reduce emergency room visits and hospitalization.[72] Indeed, there is evidence that substantial numbers of people in the United States and far more abroad are undertreated for such conditions as hypertension.[73]

Foreign price controls apparently have discouraged pharmaceutical R&D in other nations. Danzon and Furukawa write, "Overall, the relatively unregulated, more competitive structure of the U.S. market seems to result in relatively high prices for on-patent originator products [i.e., brand new patented drugs] and relatively high use of new products." As a result, "the U.S. structure appears more favorable to innovation."[74] The Commerce Department notes that American drug R&D has grown much faster over the past decade than R&D by European drug companies. "One of the factors that may be contributing to this relative decline," the Commerce Department observes, "is the regulatory and competitive environment for pharmaceuticals in Europe."[75] The Boston Consulting Group also opined that various controls had caused "an erosion of the vitality in the research-based biopharmaceutical industry" overseas.[76]

A perverse result of overregulation by OECD nations is that Americans reap the benefits of more domestic R&D.[77] Indeed, a number of European firms have moved their operations to America.[78] Some Europeans have noted that

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trend. Fabio Pammolli of the University of Florence has warned that the European industry is in an "increasingly vulnerable position."[79] European firms have begun to lag behind U.S. firms in innovative drug development.[80] The European Commission was concerned enough to contract with the European consulting firm Charles Rivers Associates to study innovation in the Continent's pharmaceutical industry. The report concluded that Europe's drug makers remained productive, but they were losing ground to American companies in some areas, such as development of new biologics.[81] Although CRA reported that many of the price control regimes, such as therapeutic reference pricing, had been implemented too recently to have affected the current drug pipeline, the practice "will reduce the returns to innovation and hence the incentives to invest in R&D."[82] Those and other regulations, concluded CRA, have encouraged relocation of R&D activities to America.[83]

Foreign Controls, Domestic Costs

Foreign citizens are not the only victims of foreign price controls. Americans suffer as well. Although European nations are imposing the regulations, the pharmaceutical market is global. The prices of patented drugs, including those produced in America, are as much as two-thirds lower in some European states than in the United States.[84] John Vernon of the University of Connecticut found that the share of a firm's pharmaceutical sales that comes from foreign markets is negatively correlated (-0.68) with a firm's profits.[85] As a result, explains the BCG, OECD governments are "in effect sharply reducing the *global* returns to pharmaceutical innovation and the global pool of cash available for research on new medicines."[86] As Hassett writes, "Lower revenues abroad have significantly eroded the resources available to U.S. firms for R&D investment."[87]

Extrapolating to a broader set of OECD nations, the Commerce Department quantifies the lost revenue at $18 billion to $27 billion annually, which "would represent a 25 to 38 percent increase . . . over actual 2003 revenues from sales of patented drugs in the OECD countries considered."[88] The BCG estimated the loss to be even greater: "Plainly put, if the OECD cost controls did not exist, revenues for innovative drugs would increase by 35–45 percent," an estimate it describes as conservative.[89] Presumably, firm share values are less than they otherwise would be, which also reduces the ability to raise research capital.

The Commerce Department estimates that those numbers translate into an annual R&D loss of between $5.3 billion and $8 billion, or as much as 17.1 percent of current spending on R&D.[90] There is no way to know exactly what new products are lost. Since past experience suggests that every $1.3 billion in R&D results in a new drug, OECD governments may be blocking, on average, the introduction of three to four new therapies every year.[91] The BCG estimates a substantially larger R&D loss of $17 billion to $22 billion,[92] which it believes probably reduces the number of new drug releases by as many as 13 per year.

Whatever the actual number may be, Americans are suffering as a result of foreign price controls. The Commerce Department's best estimate is that overseas price controls cost Americans between $4.9 billion and $7.5 billion annually in poorer health. The BCG estimates suggest a much higher figure. The Commerce Department writes: "Over the longer term, the benefits for consumers in the United States from deregulation of foreign drug prices and increased R&D would be expected to rise as a result of savings from hospitalization, fewer missed work days, and other medical cost savings. Obviously aggressive reforms among the OECD countries would accelerate this effect."[93] Indeed, the present value of even modest reductions in mortality due to cancer and heart disease run into the trillions of dollars.[94]

The American System

The ban on the federal government's using its near-monopsonistic buying power to set the prices of Part D drugs does not mean prices in that program will not be negotiated, only that they will not be artifi-

cially limited by government fiat. The U.S. system remains somewhat market driven, with prices negotiated by insurance companies, HMOs, and pharmaceutical benefit managers.[95] Thus, despite recent increases in pharmaceutical prices, the various forms of competitive negotiation embedded in today's health care system will continue to offer some price restraint even after the Medicare drug benefit takes effect.[96]

However, Washington is incrementally adopting policies similar to those of other countries that have nationalized their health care systems and controlled drug prices. As John Calfee writes, "The Medicare system itself is another prime example [of controlled prices] with arbitrary, contentious, and highly detailed controls over payments for medical technology, physicians, and other services."[97] Over the years, a number of serious proposals have been advanced to limit drug prices, though none has made it into law.[98] For instance, the Clinton administration's regulation-heavy Health Security Act, if passed, almost certainly would have included pharmaceutical price controls.[99] The mere threat of its enactment reduced the capital value of American pharmaceutical firms,[100] which reduced R&D. By one estimate, the debate over the Health Security Act reduced R&D in 1994 by $1.6 billion (in 2004 dollars).[101]

Even today, the United States is not free from arbitrary price controls on prescription drugs. Congress set modest limits on drug prices through the Omnibus Budget Reconciliation Act of 1990, which created the Federal Supply Schedule. That federal price list essentially requires that companies give the same discounts to the Veterans Administration, the Department of Defense, the Coast Guard, and the Public Health Service as are given to insurance companies and HMOs. The federal ceiling price is set by statute at 76 percent of the average wholesale price. The drug maker's failure to accept those controls results in a drug's exclusion from those programs and, more important, from Medicaid.

Medicaid also controls prices for the drugs it purchases. Drug makers must offer the program a rebate of either 15.1 percent or the largest discount they provide any private purchaser, whichever is greater. Any price increase above the general rate of inflation also must be rebated. Like most price controls, these are gamed by smart operators. Lawmakers complain that Medicaid has been overpaying for generics, for instance, because of manipulation of the official average wholesale prices.[102]

It is an open question whether those controls have saved the federal government money. As the Boston Consulting Group notes, "List prices are not really the best lens for viewing prices, since in the United States much of the price competition takes place in the form of confidential rebates negotiated between manufacturers and payors."[103] Those widespread but hidden discounts are limited by the OBRA requirement. Studies by the CBO and the General Accountability Office found that discounts to other buyers have fallen substantially. The CBO estimated a 50 percent drop in such discounts between 1991 and 1994, and the GAO found a similar decline.[104] Jeff Lemieux, formerly of the Progressive Policy Institute, has advocated dropping the mandate for exactly that reason.[105]

Medicaid's price controls have had another perverse impact. Since Medicaid accounts for a significant share of the drug market, tying Medicaid reimbursements to average prices encourages firms to raise prices where the gain from Medicaid reimbursement would exceed the revenue loss elsewhere. Mark Duggan of the University of Maryland and Fiona Scott Morton of Yale University's School of Management explain that "as a firm raises its price to non-Medicaid customers in the U.S. it will receive a higher price for all of Medicaid prescriptions filled. As government purchases become large, it is clear that linking prices in this way could create significant distortions in the private market." They estimate that non-Medicaid prescriptions cost 13.3 percent more in 2002 because of the Medicaid diktat. For some medicines, such as anti-psychotics and HIV/AIDS anti-virals, the impact is larger.[106]

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In addition to federal price controls, a number of states have attempted to control drug prices through reimbursements under Medicaid and state health care plans. Florida has demanded an additional rebate on top of the discounted price under federal law. Michigan has adopted a system of reference prices. So far, state restrictions cover only segments of the national marketplace. The threat of industry litigation has discouraged their spread.[107]

The limited federal price fixing through OBRA has cut prices for program beneficiaries while shifting some costs to private patients. The so-far modest state controls have reduced use of some newer drugs, but their ultimate reach remains unclear.[108] The impact of those measures on R&D is already being felt, however. The federal regulations alone cut R&D by $188 billion through 2001, at a cost of 140 million life-years and up to $21 trillion, depending on the value assigned to one year of human life.[109]

Unfortunately, the temptation to try to limit prices will only increase. A number of states, burdened by increasing Medicaid expenditures, are considering various restrictions, which ultimately could lead to a national patchwork of price controls. More significant, if the Medicare drug benefit goes into effect in January 2006, 60 percent of all drug spending in the United States will come from the federal government.[110] So long as the federal government is one of many buyers, the market will retain some semblance of competition. But next year Washington will move close to becoming a monopsonist—a monopoly buyer.

Some politicians would use that market power to extend the mandatory Federal Supply Service discount to Medicare. But what keeps the costs of the FSS from being larger than they are is its limited scope. Refusal to participate means that a drug maker loses sales to Veterans' Hospitals (which amount to about 1 or 2 percent of total sales) and Medicaid (another 18 percent). Thus, while those price controls may be arbitrary, they do not dominate the market.

Expanding the FSS to encompass Medicare-covered drugs, however, would bring another 40 percent of outpatient pharmaceutical sales under this scheme. Companies would have little choice but to participate in the FSS. Yet experience with OBRA suggests that drug makers may become less willing to grant any discounts to any purchaser. Although the Government Accounting Office recognizes that imposing the FSS is the preferred option of some legislators, the GAO warns that "mandating that federal prices for outpatient prescription drugs be extended to a large group of purchasers, such as Medicare beneficiaries, could lower the prices they pay but raise prices for others," including private payers and other federal programs.[111] Patricia Danzon warns that

> the losers from a requirement that retail customers be offered FSS prices could be managed care and other federal and nonfederal customers, who would face increased prices. The restrictions on discounts could also reduce best price rebates to Medicaid and hence increase taxpayer costs of financing the Medicaid program.[112]

Moreover, a large part of any gains from expanded discounts might be pocketed by pharmacies, rather than consumers who make their purchases outside of managed care plans.[113]

To the extent that an expanded FSS system lowered prices, it would act like more conventional price controls. That result also could be achieved more directly through repeal of the noninterference provision. The Medicare Modernization Act bars Washington from using its market power to drive down prices. However, the original 1965 Medicare Act included a similar prohibition on limiting hospital and physician fees, which was effectively overruled in 1983 when Congress adopted Diagnosis Related Groups for hospital services. As detailed earlier, legislators subsequently mandated discount drugs for Medicaid, the Department of Veterans Affairs, and other agencies.[114] After the Medicare bill's

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passage, several legislators proposed allowing the secretary of health and human services to "negotiate" for "discounts" that would look suspiciously like price controls. Most recently, in mid-March the Senate narrowly defeated an amendment to repeal the noninterference provision.

Were the federal government to impose price controls on 60 percent of all drug purchases, there would be a short-term financial benefit for taxpayers, but long-term health costs for patients would rise. A study published by the Manhattan Institute warns that applying existing VA and Medicaid controls to Medicare would "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."[115] Stricter limits would have an even more harmful impact.

That does not diminish the need to restrain Medicare costs, which threaten to explode because of increased demand resulting from the new program. However, that should be achieved by increasing the role of patients in choosing and paying for their care. As discussed below, Medicare needs to be transformed into a defined-contribution program. The federal government should provide cash support that would allow beneficiaries to choose their preferred health insurance policy. Patients thus would share the burden of waste while enjoying the benefit of reduced costs.

Pricing Drugs

Though we all enjoy the fruits of the recent burst in pharmaceutical R&D, no one wants to pay more than he or she needs to, even for something as valuable as medicine. But if no one can recoup the expense of developing new prescription drugs, no one will undertake that expense. It is common for industry critics to argue that prices are too high. But "too high" compared to what? Today we take for granted the existence of a multitude of life-saving medicines that didn't exist even a decade or two ago. Between 1980 and 2000, 520 new drugs were approved for the U.S. market.[116] Such progress does not come cheap. As noted earlier, it takes about $800 million to bring a new drug to patients. Industry R&D as a percentage of sales rose sharply in the 1950s, then slowed as real drug prices declined and federal regulatory requirements increased in the 1960s. However, Giaccotto, Santerre, and Vernon explain that "the 1980s witnessed a reversal in the trend with R&D intensity increasing from 8.9 percent to 14.8 percent in 1989."[117]

Rising prices are the reason for increasing expenditures on R&D. Vernon cites two impacts of price controls. First, they cut the return to R&D, discouraging investment. Second, they reduce the accumulation of funds available to invest.[118] Both factors are important. First, increased prices yield increased revenue, which is an important source of investment. Vernon writes:

> In a neoclassical world, with perfect information and well-functioning capital markets . . . [t]he firm will be indifferent about the source of investment finance. However, recent work—both theoretical and empirical—has demonstrated that the source of finance does matter. Cash flows, because they have a lower cost of capital relative to external debt and equity, exert a positive influence on firm investment spending. That has been particularly true for empirical studies of pharmaceutical R&D investment.[119]

Moreover, the added incentive to invest affects both internal and external investment.

Second, attracting outside capital is particularly important for "biotechnology firms that are 'burning cash' provided by equity investors and that have no current profits or sales to fund R&D spending."[120] Giaccotto, Santerre, and Vernon estimated that a 10 percent increase in drug prices yields a 6 percent increase in drug R&D.[121] Vernon assessed the

Were the federal government to impose price controls on 60 percent of all drug purchases, there would be a short-term financial benefit for taxpayers, but long-term health costs for patients would rise.

impact of a hypothetical price control regime that would impose "average" foreign controls on the U.S. market. He estimated such a measure would reduce R&D investment by 36.1 to 47.5 percent. Although he offered several caveats, Vernon concluded, "New price regulation in the United States could impose a very high cost in terms of foregone medical innovation."[122]

If prices and R&D are related, then controls on the former inevitably will turn into controls on the latter. Economic analyses of various forms of price controls consistently warn of serious and adverse consequences. Write Vernon and colleague Thomas Abbott, "Economic theory is unambiguous in its prediction that pharmaceutical price controls in the United States will diminish the incentives to invest in new drug R&D."[123]

Although industry critics seem to believe that we could get all the drugs we want for less money, there is an inevitable tradeoff between prices and new drug development. Giaccotto, Santerre, and Vernon report that the data "show that pharmaceutical R&D intensity changed considerably over the 50-year period from 1952 through 2001, and that the changes in R&D intensity share a striking direct relation with changes in real drug prices."[124] That doesn't mean government should pump up prices. There is no way for government to know where the balance should be struck; therefore government should not bias decisionmaking one way or the other. Drug prices should be determined as other prices are determined—by markets, not by political decisions.

Applying Medicaid and VA drug purchasing rules to Medicare would eliminate 40 percent of all future pharmaceutical R&D. The human cost of the lost R&D would be approximately 277 million life-years.

Where Would We Be Now?

Where would Americans be today if previous generations had insisted on imposing price controls on pharmaceuticals? In one study, Giaccotto, Santerre, and Vernon estimated what would have resulted had the government limited drug prices to the consumer price index in 1980. They estimated that R&D "intensity" (outlays as a percentage of sales) would have remained stable instead of nearly doubling.[125] Between $265 billion and $293 billion of R&D would have been lost—almost one-third of actual industry expenditures. That would have knocked 330 to 365 drugs out of the market, with huge economic and human costs.[126]

In another study, the three economists estimated the effects of applying to Medicare the sort of controls now imposed on drug prices in Medicaid and VA. Vernon, Santerre, and Giaccotto write, "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."[127]

The authors estimate that applying Medicaid and VA drug purchasing rules to Medicare would have devastating consequences. First, it would cut real drug prices by two-thirds.[128] As a result, "in 2008, total R&D expenditures [would] be approximately $30 billion, or about $17.7 billion less because of a sizable increase in government purchases."[129] Over time, that would eliminate 40 percent of all future pharmaceutical R&D, which has a present value of $372 billion. The human cost of the lost R&D would be approximately 277 million life-years,[130] which represents a loss of up to $41.5 trillion, depending on the value placed on an individual life.[131]

Writing separately, Vernon estimated the effects of imposing foreign price controls on American firms. To do that, he assumed profit margins for American drug manufacturers that were identical to those of overseas firms. He predicted that such a regime would cause "a decline in R&D intensity of between 23 percent and 33 percent."[132]

Another approach attempts to measure the impact of price controls on industry decisions to undertake or terminate specific R&D efforts. For instance, Abbott and

Vernon address how price controls would affect "early-stage product development decisions."[133] Not surprisingly, they find that "R&D investment is quite sensitive to U.S. price expectations, and policies regulating drug prices in the U.S. could lead to a significant decline in R&D expenditures."[134] The conclusion of their empirical analysis is sobering:

> Relatively modest price changes, such as 5 or 10%, are estimated to have relatively little impact on the incentives for product development. Our empirical estimates suggest that product development would decrease only about 5 percent. Steeper cuts, like those suggested by some proponents of importation from Canada (e.g., 40 to 45% reductions) would result in significant decreases in R&D investment. Our model suggests that investment in new products would decrease as much as 50 to 60%.[135]

Obviously, not every new product would ultimately yield a valuable medicine, but since firms can only imperfectly predict the value of even the best pharmaceuticals, the result would be a significant medical loss.

Moreover, price controls would affect the other end of the drug pipeline as well. Researchers at the Beacon Hill Institute for Public Policy Research at Suffolk University reviewed company decisions to end R&D efforts. They found that 20.7 percent of drugs in the R&D pipeline were abandoned because companies judged that they would not earn enough to warrant further investment. If drug price increases were limited to 3 percent, the economic termination rate would jump to 37.5 percent. By 2012, 49 drugs would be dropped, compared to only 27 without controls. Over the first dozen years of controls, 262 additional medicines would be put aside.[136] The loss would be significant: between 1991 and 2003, the FDA approved just 370 new drugs.[137]

Another way of assessing the cost of price controls is to compare the so-called consumer surplus generated from lower prices to the health benefits of the drugs forgone. Santerre and Vernon assumed a system that limited price hikes to the increase in the consumer price index from 1981 to 2000. The aggregate value of the money saved (and invested) would be $319 billion. However, the same regime would reduce R&D spending by between $264.5 billion and $293.1 billion, reducing new drug creation by 38 percent. Using $100,000 as the value of a life-year, they estimated that the costs of price controls would exceed the benefits by as much as 40 percent.[138] With academic understatement they conclude that "society may be better off discovering more efficient ways than price controls to improve access to existing drugs."[139]

Alternatives to Price Controls

How should drugs be priced? There is no one "right" answer. That is why private competition is a better mechanism than government fiat for setting prices. The marketplace responds to the complexity of supply and demand. Markets adjust investments in R&D to meet the demand for new drugs. Private competition between rival firms drives prices down.[140] Markets are hardly perfect. However, government's ability to assess medical needs and weigh pharmaceutical value is far more limited.

Government will inevitably influence the marketplace, even if only through public browbeating and the threat of political action. Far worse, however, would be for government to impose price controls, whether enacted formally by legislation or implemented informally through indirect controls. Vernon, Santerre, and Giaccotto warn, "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."[141]

Private competition is a better mechanism than government fiat for setting prices.

Price controls would not hold down the cost of Medicare; they would merely shift the cost to future generations.

Private Competition

The creation of the Medicare drug benefit makes price controls more likely, though no more appropriate or effective. As noted earlier, although increased demand will put upward pressure on prices, competition among private drug makers, providers, insurers, and benefit managers will continue to apply downward pressure on prices. For example, the Medicare drug discount cards, which were also created by the Medicare Modernization Act, have reduced prices for many seniors through a competitive process. One study last year figured an average 17.5 percent savings.[142] Moreover, the political focus on price controls distracts attention from the many ways that careful consumers can save money, ranging from comparison shopping to pill splitting to enrolling in company and state assistance programs.[143] Canadian analysts have found that patients using such techniques could buy many of their drugs as cheaply in America as in Canada.[144] Groups such as Consumers Union, which publishes *Consumer Reports* magazine, have inaugurated a program, including a website, on drug effectiveness, prices, and safety.

Medicare Reform

Nonetheless, the Medicare prescription drug benefit creates an uncomfortable tension: either the federal government must constrain drug spending, or the drug benefit will impose an increasing burden on taxpayers. Price controls would not hold down the cost of Medicare; they would merely shift the cost to future generations, who would be denied the healing power of forgone medical innovations. In fact, the CBO has concluded that, given the savings likely from private plans, "the Secretary would not be able to negotiate prices that further reduce federal spending to a significant degree."[145]

True cost containment requires fundamental Medicare reform. Medicare suffers from the problem of third-party payment that also bedevils the private insurance market.[146] In each market, the solution is much the same: giving patients both the opportunity to choose from among competing plans the health plan that best meets their needs and the responsibility to bear the cost of their choices.

Obviously, Medicare reform is no easy affair. It requires enabling enrollees to choose for themselves the most cost-effective benefit package. That benefit package could integrate pharmaceutical, physician, and hospital coverage; increase deductibles; and even set up a health savings account to finance uncovered expenses. To that end, beneficiaries should be allowed to buy a private plan of their choosing with a risk-adjusted federal voucher. That way they could shape their health coverage to match their own medical needs, financial positions, and sensitivity to risk.[147] Such reforms would reduce the risk that expenditures will explode once the Medicare drug benefit takes full effect.

Among the more serious legislative proposals to reform Medicare were Breaux-Frist I and Breaux-Frist II, named for then-senator John B. Breaux (D-LA) and Sen. Bill Frist (R-TN). Those proposals offered a voucher (called "premium support") that would be available for the purchase of a plan through either the government or a private insurer.[148] The Breaux-Frist proposals were based on the highly praised Federal Employees Health Benefits Program, under which federal workers choose among competing private plans. A similar proposal was later put forward by the National Bipartisan Commission on the Future of Medicare, cochaired by Sen. Breaux.[149] Developed before the passage of the Medicare drug program, each of those proposals would integrate pharmaceutical coverage and other types of coverage.

Many organizations, such as the Progressive Policy Institute and the Heritage Foundation, use Breaux-Frist as the basis for their own Medicare reform proposals.[150] The most serious reform measures tend to be similar in concept though they differ in details—principally the number of health plan options, the degree of enhanced support for lower-income beneficiaries, the mandatory benefits package, and the level of premium support. A number of

other ideas could supplement the premium-support concept, including health savings accounts as a plan option, more quickly raising the eligibility age for Medicare, allowing seniors to opt out of Medicare fully without loss of Social Security benefits, encouraging expansion of longer-term health insurance contracts, greater means testing for Medicare premiums, and allowing workers to prefund their future health care needs through retirement health savings accounts.[151]

Pushing Back against Foreign Price Controls

The United States could help contain drug prices and the spread of price controls by pressing other wealthy countries to pay market prices for pharmaceuticals. Americans are paying more than consumers in many other nations. U.S. citizens are not directly subsidizing foreign patients, but foreigners are unfairly free riding on American R&D.[152] Washington should push foreign governments to eliminate or relax their price control regimes as part of trade negotiations. Robert Goldberg of the Manhattan Institute argues that the United States "should make faster approval of new drugs, higher launch prices, and wider use of valuable new medicines a priority" when negotiating trade agreements.[153] The Bush administration has taken steps in that direction. It has created the position of assistant U.S. trade representative for pharmaceutical policy and sought to address drug pricing as part of the 2004 U.S.-Australia Free Trade Agreement. Former FDA administrator Mark B. McClellan, now head of the Centers for Medicare and Medicaid Services, devoted most of his September 2003 speech to the First International Colloquium on Generic Medicine in Cancún to the problem of global free riding on U.S. pharmaceutical R&D.[154]

Deregulating Pharmaceuticals

Finally, lawmakers can reduce drug prices and the cost of R&D by eliminating unnecessary regulation. The cost of the FDA's new drug approval process has grown to the point that it now takes up to 15 years and $800 million to produce one marketable new drug. That growth causes fewer new drugs to be introduced, delays their introduction, and increases prices. Research has shown that FDA regulation costs more lives than it saves.[155] Streamlining the FDA's drug approval process would make America's pharmaceutical sector more competitive and pharmaceuticals more affordable.

Conclusion

Americans like the benefits of advanced medicine. Nearly a third of increased health care spending in recent years reflects innovative treatments for cancer, heart disease, mental disorders, pulmonary ills, and trauma.[156] The future is likely to see even greater medical advances—at budget-straining prices.[157] For instance, the biotech revolution offers particular promise, with the prospect of tailoring drugs to people's individual genetic characteristics. "New biologicals coming out will revolutionize medicine," says John Smylie, CEO of the firm Security Health Plan. "When you come to the question of quality of life, how can you measure that in terms of health care costs? The pipeline is deep in biologic drugs under development, and they are all expensive."[158]

Although people want new, better drugs more quickly, they also want them for a lower price. Unfortunately, note Giaccotto, Santerre, and Vernon, "a stark tradeoff exists between greater access to prescription drugs today and pharmaceutical innovation tomorrow."[159] No wonder they argue that "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."[160]

Perhaps the most fundamental fallacy advanced by proponents of price controls is that drug spending represents only costs. In fact, pharmaceutical innovations offer the chance to beat cancer, to live a near-normal life despite MS or severe arthritis, or to avoid a heart attack. Those are almost priceless benefits. New medicines are expensive. But

Streamlining the FDA's drug approval process would make America's pharmaceutical sector more competitive and pharmaceuticals more affordable.

The Medicare drug benefit will tempt Washington politicians to regulate drug prices.

the lack of new medecines is even more expensive.

The Medicare drug benefit has set a dangerous trap. If it is allowed to take effect on January 1, 2006, it will tempt Washington politicians to regulate drug prices—and it will continue to do so as long as it exists. Alas, there's no such thing as a free lunch, especially when it comes to pharmaceuticals. If the federal government tries to force the pharmaceutical industry to provide more drugs for less money, Americans will pay with their health and lives.

Notes

1. Cynthia Smith et al., "Health Spending Growth Slows in 2003," *Health Affairs* 24, no. 1 (January–February 2005): 185.

2. Ibid., p. 186.

3. Stephen Heffler et al., "Health Spending Projections through 2013," *Health Affairs* (Web exclusive), February 11, 2004, p. W4-80, http://content.healthaffairs.org/cgi/content/abstract/hlthaff.w.79.

4. Quoted in Theresa Agovino, "Health Care Spending Growth Could Kick Up," *Contra Costa Times*, December 2, 2004, www.contracostatimes.com.

5. Milt Freudenheim, "Cost of Insuring Workers' Health Increases 11.2%," *New York Times*, September 10, 2004, pp. C1, C4.

6. Congressional Budget Office, "The Long-Term Budget Outlook," October 2000.

7. Heffler et al., p. W4-91.

8. Robert Pear, "Estimate Revives Fight on Medicare Costs," *New York Times*, February 10, 2004, p. A16.

9. The figure measures the present value of Medicare's unfunded liabilities over the infinite horizon. *2005 Annual Report of the Board of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds* (Washington: Government Printing Office, March 23, 2005), pp. 64, 105, 113, http://www.cms.hhs.gov/publications/trusteesreport/tr2005.pdf. See also Joseph Antos and Jagadeesh Gokhale, "Medicare Prescription Drugs: Medical Necessity Meets Fiscal Insanity," Cato Institute Briefing Paper no. 91, February 9, 2005, http://www.cato.org/pubs/briefs/bp91.pdf.

10. Kaiser Family Foundation, "Kaiser Health Poll Report: Pharmaceutical Companies and Rising Health Care Costs," January–February 2005, http://www.kff.org/healthpollreport/feb_2005/8.cfm.

11. Heffler et al., p. W4-80.

12. Ibid., p. W4-90.

13. Congressional Budget Office, "Issues in Designing a Prescription Drug Benefit for Medicare," October 2002, p. ix.

14. David J. Gross, Stephen W. Schondelmeyer, and Susan Raetzman, "Trends in Manufacturer Prices of Brand Name Prescription Drugs Used by Older Americans, 2000 through 2003," AARP Public Policy Institute, June 2004, p. viii. See also David J. Gross, Stephen W. Schondelmeyer, and Susan Raetzman, "Trends in Manufacturer Prices of Brand Name Prescription Drugs Used by Older Americans—Second and Third Quarter 2004 Update," AARP Public Policy Institute, 2004.

15. Quoted in Heather Won Tesoriero, "Torrid Drug-Price Increases Pause," *Wall Street Journal*, December 6, 2004, p. A3. Actually, the measure of drug prices on which AARP relies (known as the "wholesale acquisition cost of medicine") reflects the prices paid by retailers rather than consumers. It is a less accurate measure of the prices that patients face than the prescription drug component of the medical consumer price index (CPI). Moreover, since passage of the Medicare drug benefit, the growth in prescription drug prices (2.7 percent, as measured by the prescription drug component of the medical CPI) has been less than half the growth in the wholesale index (7.2 percent). Prescription drug prices have also risen more slowly than prices for medical care generally (3.2 percent). See, e.g., Steve Cigich, "Prescription Medicine and Its Place in Medical Care CPI," Milliman, Inc., September 20, 2004, p. 2, http://www.phrma.org/publications/policy/2004-09-21.1082.pdf.

16. John E. Calfee, *Prices, Markets, and the Pharmaceutical Revolution* (Washington: American Enterprise Institute, 2000), p. 8.

17. Smith et al., p. 191.

18. Guy King and Donald N. Muse, "Components of Pharmaceutical Expenditures," Pharmaceutical Research and Manufacturers of America (PhRMA), August 2004, p. 1. Generics alone account for upwards of 45 percent of prescriptions and about 17 to 18 percent of outlays. Pharmaceutical dispensing costs run an equivalent amount. King and Muse, p. 2.

19. Milt Freudenheim, "Drugstores Fret As

Insurers Demand Pills by Mail," *New York Times*, January 1, 2005, pp. A1, C4.

20. Robert Pear, "Advisory Panel Lists Drugs It Wants New Law to Cover," *New York Times*, January 4, 2005, p. A14.

21. Robert Pear, "Many Insurers Set to Offer New Medicare Drug Plans," *New York Times*, September 24, 2005, p. A12.

22. Congressional Budget Office, "Updated Estimates of Spending for the Medicare Prescription Drug Program; Letter to the Honorable Joe Barton," March 4, 2005, p. 5, http://www.cbo.gov/ftpdocs/61xx/doc6139/03-04-BartonMedicare.pdf.

23. As quoted in John A. Vernon, Rexford E. Santerre, and Carmelo Giaccotto, "Are Drug Price Controls Good for Your Health?" Manhattan Institute Medical Progress Report no. 1, December 2004, p. 1.

24. Quoted in Pear, "Estimate Revives Fight on Medicare Costs."

25. The leading bills appear to be S 39, the Medicare Enhancements for Needed Drugs Act of 2005, introduced February 1, 2005, by Sen. Olympia Snowe (R-ME), and HR 367, the Medicare Equitable Drugs for Seniors Act of 2005, introduced January 26, 2005, by Rep. Jo Ann Emerson (R-MO). See also S 813, S 445, S 18, HR 563, HR 1626, and HR 2200 at http://thomas.loc.gov.

26. "Pricing Drugs," *Washington Post*, February 17, 2004, p. A18; Terri Shaw, "Prescription Drug Prices: Harnessing Medicare's Purchasing Power," Center for American Progress Medicare Policy Brief no. 1, January 27, 2004; Robert Pear, "A.M.A. Says Government Should Negotiate Prices," *New York Times*, October 17, 2004, www.nytimes.com; and Kristen Hallam, "U.S. Health Secretary Thompson Announces Resignation," Bloomberg, December 3, 2004, www.bloomberg.com. So reasonable does the idea sound that 80 percent of respondents in one poll supported the idea. Kaiser Family Foundation/Harvard School of Public Health poll, "Views of the New Medicare Drug Law: A Survey of People on Medicare," August 2004, chart 22, www.kff.org. A slightly smaller majority was evidenced in an Associated Press poll. Will Lester, "Many Cutting Dosages to Deal with Drug Costs," Associated Press, February 24, 2004.

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28. Calfee, *Prices, Markets, and the Pharmaceutical Revolution*, p. 38.

29. Rexford E. Santerre and John A. Vernon, "A Cost-Benefit Analysis of Drug Price Controls in the U.S.," AEI-Brookings Joint Center for Regulatory Studies, Publication 04-29, October 2004, p. 2.

30. Vernon, Santerre, and Giaccotto, p. 8.

31. See, e.g., Robert Schuettinger and Eamonn Butler, *Forty Centuries of Wage and Price Controls: How Not to Fight Inflation* (Washington: Heritage Foundation, 1979); and Fiona Scott Morton, "The Problem of Price Controls," *Regulation* 24, no. 1 (2001).

32. Derek Hunter, "Guaranteed Future Pain and Suffering: The Recent Research on Drug Price Controls," Heritage Foundation WebMemo no. 680, March 9, 2005, http://www.heritage.org/Research/HealthCare/wm680.cfm.

33. See, e.g., John Calfee, Testimony before the House Committee on Industrial Relations, State of Georgia, Hearings on House Bill 1061 (Pharmaceutical Price Controls), February 11, 2004, p. 3; and Morton, pp. 52–53.

34. Kevin A. Hassett, "Price Controls and the Evolution of Pharmaceutical Markets," American Enterprise Institute, draft paper, July 22, 2004, p. 2.

35. Calfee, Testimony, p. 6.

36. Calfee, *Prices, Markets, and the Pharmaceutical Revolution*, p. 2.

37. Hassett, "Price Controls and the Evolution of Pharmaceutical Markets," p. 2.

38. Calfee, Testimony, p. 5.

39. David G. Tuerck et al., "The Impact of Drug Reimportation and Price Controls: The U.S. and Massachusetts," Institute for Policy Innovation Policy Report 184, September 2004, p. 6.

40. Vernon, Santerre, and Giaccotto, p. 2.

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43. Stephen Pollard, Sean Gabb, and Alberto Mingardi, "The Human Cost of Pharmaceutical Price Controls in Europe: A Case for Reform," Centre for the New Europe, 2004, p. 5.

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70. Kessler, p. 19.

71. Graham, p. 24.

72. Boston Consulting Group, p. 17.

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