MARKETWATCH

Doughnut Holes And Price Controls

If Medicare could meet the benchmark drug prices of three other countries, Congress could eliminate the "doughnut hole"—but with a trade-off in R&D.

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ABSTRACT: In 2003 citizens of Canada, the United Kingdom, and France paid an average of 34–59 percent of what Americans paid for a similar market basket of pharmaceuticals. If the Medicare program were to pay comparable prices for pharmaceuticals, it would be possible to eliminate the "doughnut hole" in its prescription drug benefit and keep Medicare drug spending within the overall limits established by Congress. This provides Congress with a clear choice: reduce the level of cost sharing and improve beneficiaries' access to pharmaceuticals, or allow the pharmaceutical industry to use the higher prices to fund research and development and to engage in other activities.

PREFACE: *On 8 December 2003 President George W. Bush signed into law the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003. The landmark legislation was designed partly to provide Medicare beneficiaries with an entitlement to outpatient prescription drug coverage for the first time in Medicare's history, an issue that had become increasingly important to American seniors. In spite of the significance of this law, many details and even major turns remain murky to the lay public and analysts alike—indeed, an April 2004 survey by the Henry J. Kaiser Family Foundation revealed that 60 percent of seniors did not even know that MMA had been passed by Congress and signed into law.*

In an effort to bridge this information gap, Health Affairs *has encouraged the nation's leading Medicare analysts, whose views range along the political spectrum, to examine the new law and write their findings in papers that we could consider for publication. The best of these papers will be published as* Health Affairs *Web Exclusives over the coming months; also, under the aegis of a collaboration with the National Academy of Social Insurance, some of the papers will be considered for presentation at NASI's January 2005 meeting, which will focus on MMA implementation.*

The current paper by Gerard Anderson and colleagues explores some issues surrounding the infamous "doughnut hole" in the new Medicare drug benefit, which leaves a considerable coverage gap. Specifically, the authors examine whether the adoption of some mechanism to control pharmaceutical spending such as price controls would allow for the elimination of the "doughnut hole." The paper by Anderson and colleagues will certainly provoke controversy, given the industry's vigorous efforts to avoid price controls. Without question, there will be many efforts to close the "doughnut hole," and Anderson's proposal is only one of the first. A perspective by Patricia Danzon follows Anderson's paper.

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DOI 10.1377/hlthaff.W4.396

THE RECENTLY PASSED Medicare prescription drug legislation contains two provisions that when considered together offer a difficult policy choice for Congress. The first provision is an elaborate cost-sharing arrangement that includes a gap in coverage commonly known as the "doughnut hole." A second provision restricts the federal government from directly negotiating with drug companies over price. This paper examines whether the adoption of some mechanism such as price controls to contain drug spending would allow Medicare to eliminate the doughnut hole.

■ **Cost sharing.** In the recently passed legislation, most Medicare beneficiaries will pay $35 per month for prescription drug coverage.[1] The coverage will pay 75 percent of a beneficiary's prescription drug expenses up to $2,250; then there is a gap in coverage from $2,250 to $5,100 (the "doughnut hole"). Then coverage resumes, with Medicare paying 95 percent of a beneficiary's prescription drug expenses above $5,100.[2]

While most other public and private drug insurance programs use some type of cost sharing, a gap in coverage such as the doughnut hole is extremely rare. It was developed as a way to hold Medicare drug spending below a previously agreed-upon target of $400 billion over a ten-year period.[3] It was also designed to encourage beneficiaries to sign up if they were likely to have small drug bills while still protecting those likely to have large ones.

This elaborate system of cost sharing will make it difficult for many beneficiaries to know when they are paying 25 percent of expenses out of pocket, when they are in the doughnut hole paying 100 percent, and when they are paying only 5 percent out of pocket. This cost sharing may be particularly onerous for beneficiaries with multiple chronic conditions—the heaviest users of prescription drugs.

■ **Negotiation restriction.** Most other industrialized countries have instituted a variety of mechanisms to limit drug spending, including formularies, reference pricing, and price controls.[4] If the Medicare drug bill did not preclude Medicare from directly negotiating with drug companies, Medicare could probably obtain prices similar to those in other industrialized countries. At a minimum, these international prices could be used as a benchmark for Congress to evaluate U.S. prices that are obtained through drug discount cards or some other mechanism.

■ **Can Medicare eliminate the gap?** The key question addressed here is whether Medicare could eliminate the doughnut hole if it paid the same prices for pharmaceuticals as other countries pay. To answer this question it is important to know the following: (1) a reasonable international benchmark for pharmaceutical prices, and (2) what level of price discount would be necessary to eliminate the doughnut hole and still keep Medicare spending at the same level?

Price Comparison

■ **Data.** We obtained data on the prices of drugs in Canada, France, the United Kingdom, and the United States for January–September 2003 from IMS Health. These countries were chosen because they are similar in economic development but different in their approaches to regulating drug prices.

We compared the prices of a market basket of the thirty drugs with the highest total spending (including both brand-name and generic drugs) in the United States that are also sold in the other countries.[5] Each of the thirty items used to construct the index represents a specific manufacturer, compound, and form. For example, the top-selling pharmaceutical product in the United States was Lipitor, manufactured by Pfizer in tablet form. In 2003 the price of a 10 mg tablet of Lipitor was $1.81 in the United States, $0.99 in Canada, $0.67 in France, and $0.90 in the United Kingdom.[6]

■ **Methods.** We first determined the price of each of the thirty specific products for all available dosage strengths for each country. We then calculated a Laspeyres price index, using the quantity sold in the United States as the base.[7] The prices compared are the average wholesale prices (AWP)—those faced by major U.S. purchasers, not individual consumers

at pharmacies—because these are the prices that Medicare and other large purchasers would pay. However, since these purchasers rarely pay the full AWP, we also calculated the price index assuming a 20 percent discount. This figure is at the upper end of the discounts that the private insurers administering the Medicare drug benefit are reported to have negotiated with pharmaceutical companies.[8]

These methods differ slightly from those used recently by Patricia Danzon and Michael Furukawa.[9] They opted for greater representativeness, while we opted for greater standardization.[10] We chose this approach to simulate the prices that would be paid in the United States for the most commonly used products if U.S. usage were fixed but prices were the same as those in other countries.

■ **Comparison results.** Averaged over the market basket of thirty drugs and compared with U.S. prices, prices were 52 percent lower in Canada, 59 percent lower in France, and 47 percent lower in the United Kingdom (Exhibit 1). Assuming a 20 percent discount for U.S. purchasers, prices were 40 percent lower in Canada, 48 percent lower in France, and 34 percent lower in the United Kingdom.[11] These differences are greater than those reported by Danzon and Furukawa. One reason for this may be the methodological differences described above; another may be our use of more recent data (2003 versus 1999). U.S. pharmaceutical prices rose more rapidly during 1999–2003 than prices in other countries.[12]

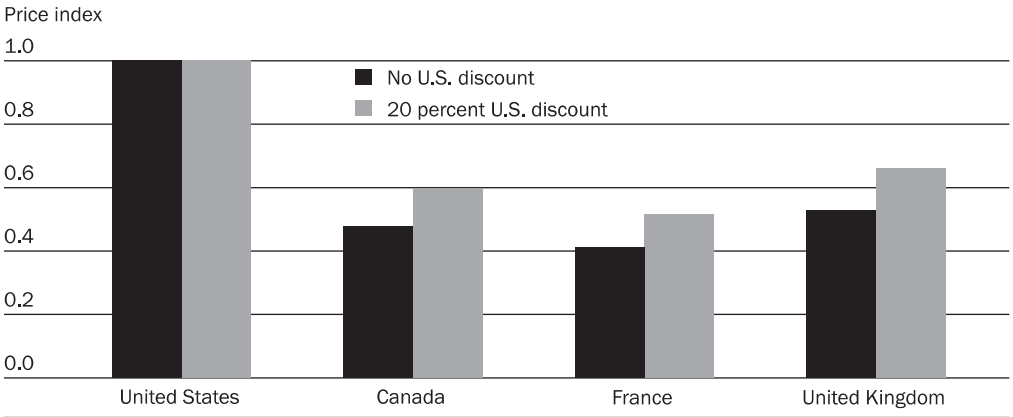
■ **Caveats.** The price differences noted above should be interpreted with several caveats in mind. First, since the market basket used for comparison was chosen to maximize standardization, it may not accurately reflect the average prices across the entire range of prescribed products in each country.[13] Second, our comparison is based on the assumption that the number of units in the United States is fixed. In reality, however, changes in prices would likely be accompanied by changes in the quantity prescribed. Third, the political and regulatory environment in each country may influence the results; for example, the French government may be more likely to pay higher prices to French manufacturers.

We now turn to our main question: If Medicare could regulate prices and obtain prices similar to those in Canada, France, and the United Kingdom, would this be sufficient to eliminate the doughnut hole?

Eliminating The Doughnut Hole

■ **A microeconomic simulation.** To determine the effects of eliminating the doughnut hole on drug spending, we developed a microeconomic simulation of the effects of Medicare Part D on beneficiaries' behavior.[14]

EXHIBIT 1
Relative Prices Of Thirty Pharmaceuticals In Four Countries, 2003



SOURCE: Authors' analysis of IMS Health data.
NOTE: Prices shown are relative to U.S. prices.

The model uses data from the 1999 Medicare Current Beneficiary Survey (MCBS) to simulate a scenario for 2006 by adjusting income, population weights, and drug spending based on data from the Medicare trustees' reports, the U.S. Census Bureau, and the National Health Accounts (NHA) from the Centers for Medicare and Medicaid Services (CMS) Office of the Actuary.[15] The model simulates the choices by Medicare beneficiaries whether to accept a drug plan of the type described in the Medicare prescription drug legislation. The choice is based upon whether the new plan offers net benefits to the beneficiary in the form of reduced premiums, reduced out-of-pocket drug costs, or greater protection from risk compared with existing coverage. Once a person chooses a plan, the effects on spending are estimated based upon an assumed spending elasticity of −0.3, with adjustments for the effects of deductibles, the doughnut hole, and stop-loss protection.[16]

The model was run using alternative assumptions about price discounts on prescription drugs and elimination of the doughnut hole. The current Medicare plan (referred to here as the "current legislation") was simulated with a coinsurance rate of 25 percent, a deductible of $250, and a doughnut hole beginning at $2,250 and ending at $5,100, with 5 percent coinsurance after that point. A premium subsidy of 74.5 percent was assumed for all Medicare beneficiaries.[17] Deductibles, coinsurance, and premium subsidies were adjusted for low-income beneficiaries to match as closely as possible the features of the bill passed.[18] It was assumed that drug purchasers would achieve a 20 percent price discount under the current legislation. An alternative (referred to here as "alternative benefit") was then modeled, with the doughnut hole eliminated and assuming a 45 percent price discount, with all other features identical to the current legislation.

■ **Overall effects.** The model indicates that under current legislation, Medicare beneficiaries' total drug spending in 2006 would be $101.9 billion, $44.5 billion of which would be financed by Medicare. Under the alternative benefit, drug prices were reduced 45 percent, and the doughnut hole was closed. Under this benefit, total spending in 2006 would be $73.6 billion (Exhibit 2). Medicare spending would be the same as under the current legislation in 2006, at $44.5 billion. The major reductions would be in out-of-pocket and other spending.

Our model is for 2006 only. Using estimated growth in per capita drug spending from the NHA and estimated growth in the Medicare population from the Medicare trustees' reports, we estimate that total Medicare drug spending during 2006–2013 would equal $667 billion under the current legislation. This is higher than the initial projections of the Congressional Budget Office (CBO, $408 billion) and the Bush administration ($534 billion).[19] Our out-year projections for Medicare spending for 2006–2013 would decline to $537 billion under the alternative benefit. The CBO and the administration have incorporated as-

EXHIBIT 2
Spending On Medicare Prescription Drug Benefits In 2006

	Model assumptions		Drug spending by Medicare beneficiaries in 2006 (billions of dollars)			
Model version	Stop-loss level ($)	Price discount (%)	Total drug spending	Medicare	Out of pocket	Third-party payers
Current legislation	5,100	20	101.9	44.5	31.0	26.4
Alternative benefit	2,250	45	73.6	44.5	19.1	9.9

SOURCE: Authors' simulation using data from the Medicare Current Beneficiary Survey (MCBS).

NOTE: "Current legislation" refers to provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003; "alternative benefit" is authors' simulation as described in text.

sumptions about beneficiaries' behavior that are more complex than our simple extrapolation of the Medicare actuaries' spending and population projections. This could explain their lower estimates.

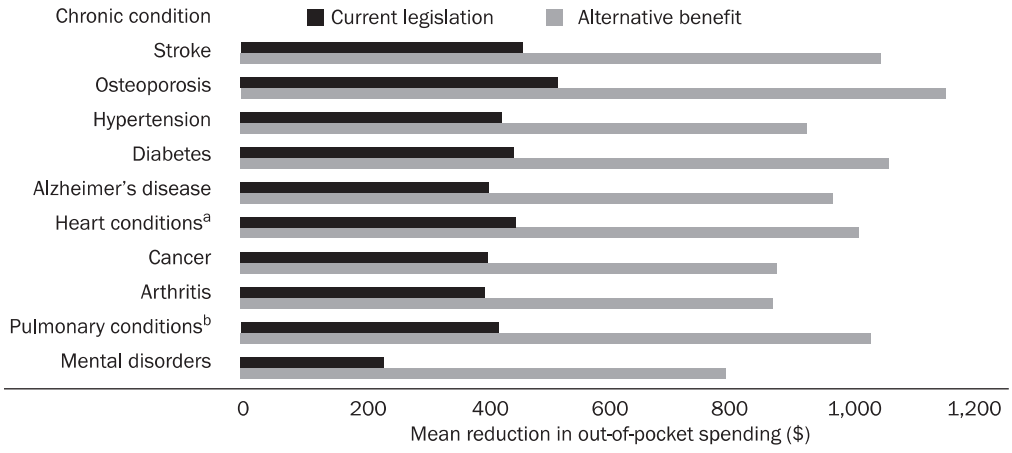
■ **Impact on beneficiaries with chronic conditions.** Elimination of the doughnut hole would affect Medicare beneficiaries in different ways. Here we highlight one group that would most likely benefit from the elimination of the doughnut hole: beneficiaries with multiple chronic conditions. These beneficiaries are the heaviest users of prescription drugs, and we assume for our analysis that all of them will enroll. In 1999 beneficiaries with five or more chronic conditions (15 percent of beneficiaries) filled an average of fifty prescriptions per year—almost one per week.[20] Also, these beneficiaries often forgo needed medications because the out-of-pocket costs are too high.[21]

We examined the effect of the Medicare drug benefit, with and without the doughnut hole, on people with ten specific chronic conditions. We compared the difference for each person in out-of-pocket drug spending between the current legislation and the alternative benefit.[22] Our calculations include all Medicare beneficiaries reporting one of these ten chronic conditions, whether or not they choose to accept the new drug benefit or stay with existing coverage.

Under current legislation. The typical savings under the current legislation for beneficiaries with one of the selected conditions is about $425, with a range of $235 for those with a mental disorder to $519 for those with osteoporosis (Exhibit 3). In general, the current legislation provides savings in out-of-pocket drug spending of more than $1,000 for 15–20 percent of people with one of these conditions, and savings of more than $500 for 25–30 percent of these beneficiaries (data not shown).

Under the alternative benefit. The alternative benefit would lead to much larger reductions in out-of-pocket spending—from $794 to $1,153—and 25 percent or more beneficiaries would reduce their out-of-pocket spending by at least $1,000 (Exhibit 3). The alternative benefit would reduce out-of-pocket spending for beneficiaries with no chronic conditions by $159, while for those with four or more chronic conditions, it would reduce out-of-pocket

EXHIBIT 3
Reduction In Beneficiaries' Annual Out-Of-Pocket Spending Under Current And Alternative Medicare Drug Benefits, By Specific Chronic Conditions



SOURCE: Authors' simulation using data from the Medicare Current Beneficiary Survey (MCBS).
NOTE: "Current legislation" refers to provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003; "alternative benefit" is authors' simulation as described in text.
[a] Includes hardening of the arteries, myocardial infarction, angina pectoris, congestive heart disease, and other heart conditions.
[b] Includes emphysema, asthma, and chronic obstructive pulmonary disease.

spending by $1,034 (Exhibit 4).

■ **Impact on the drug industry.** As we have shown, to eliminate the doughnut hole, drug prices for Medicare beneficiaries would have to be 45 percent lower than they are now. But what impact would lower U.S. prices likely have on the industry?

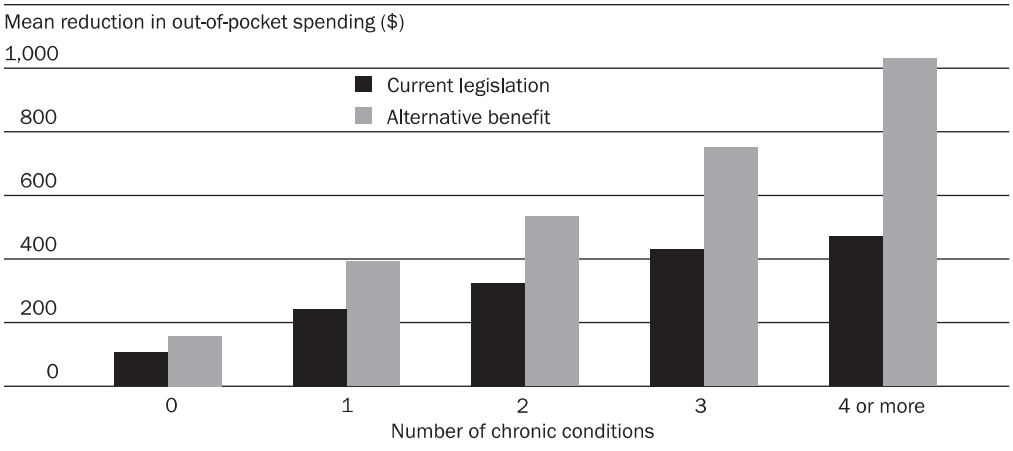
Lower U.S. prices might result in a loss in pharmaceutical research and development (R&D). U.S. manufacturers account for nearly half of the major drugs marketed worldwide.[23] At the same time, the United States constitutes 41 percent of the worldwide pharmaceutical market, followed by Europe (23.5 percent) and Japan (15.9 percent).[24] Any attempt to control U.S. prices, given the large percentage of international consumption, may affect investment in the industry and consequently pharmaceutical innovation.

Higher prices, especially for brand-name drugs, allow the industry to sponsor high levels of R&D investment in the United States. In 1999, 60 percent of domestic investment in R&D was made by the pharmaceutical industry ($33.9 billion), 34 percent was made by the National Institutes of Health ($18.9 billion), and the remaining 6 percent ($3.6 billion) was made by other entities such as universities and foundations.[25] This investment has resulted in considerable innovation. Between 1993 and 2003 more than 300 new medicines, biologics, and vaccines were approved by the U.S. Food and Drug Administration (FDA).[26]

There has been a wide range of estimates using vastly different methodologies to estimate the cost of bringing new drugs to market. Public Citizen, an advocacy organization, estimates the cost of drug development to be around $57–$71 million.[27] The Tufts Center for the Study of Drug Development has estimated the cost to be around $802 million.[28] Considerable investment in pharmaceutical R&D is necessary given the uncertainty in drug development.[29] Of every 5,000 medicines tested, only five on average are tested in clinical trials, and only one is approved for patient use. In addition, only three of ten marketed drugs produce revenues that exceed average R&D costs.[30] This pipeline of innovation is what may be jeopardized if U.S. drug prices are lowered.

Others have questioned the industry's record on innovation. The National Institute for Health Care Management (NIHCM) reports that from 1989 to 2000 the FDA approved 1,035 new drug applications. Of the drugs approved, 361 had new active ingredients, 558 were

EXHIBIT 4
Reduction In Beneficiaries' Annual Out-Of-Pocket Costs Under Current And Alternative Medicare Drug Benefits, By Number Of Chronic Conditions



SOURCE: Authors' simulation using data from the Medicare Current Beneficiary Survey (MCBS).
NOTE: "Current legislation" refers to provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003; "alternative benefit" is authors' simulation as described in text.

incrementally modified drugs, and 116 were identical to drugs already on the market. Of the 361 drugs with new active ingredients, 42 percent provided real clinical improvement over existing drugs. Of the 558 incrementally modified drugs, only 15 percent offered clinical improvement over existing drugs. Therefore, only 24 percent of these drugs offered clinical improvement over existing drugs. NIHCM concluded that a large proportion of R&D investment is spent developing drugs similar to those already on the market.[31]

Concluding Comments

Drug prices are 34–59 percent lower in Canada, France, and the United Kingdom than they are in the United States. These countries provide a benchmark for the drug prices Medicare could achieve. This should be a feasible benchmark considering that other large purchasers, notably the Department of Veterans Affairs (VA), have come close to international prices.[32] If Medicare could also meet this benchmark, then Congress could eliminate the doughnut hole in the Medicare drug benefit.

Several methods could be used to lower drug prices. One option is for Medicare to use a method similar to the approach it already uses to set prices for physician and hospital services. Another is for Medicare to set prices with pharmacy benefit managers (PBMs) for all covered drugs as it now sets prices with health plans for all covered services.[33] Under the current Medicare legislation, insurers or PBMs act as intermediaries between government and beneficiaries. The insurers or PBMs bid for Medicare business.[34]

Demand controls, such as cost sharing, are yet another method for controlling drug costs. A three-tier copayment system is the most common type of cost sharing in the United States. Reference pricing—requiring beneficiaries to pay the difference between a "reference price" set for drugs in a therapeutic class and a brand-name drug—is another type of cost sharing.[35] There is some evidence that reference pricing has lowered drug spending in some countries.[36] In addition to cost-sharing mechanisms, collection of better pharmacoeconomic information would allow the development of formularies that exclude drugs that are overpriced for their relative effectiveness and benefits.

POLICYMAKERS IN THE United States have a choice. It is possible to eliminate the doughnut hole if Medicare pays drug prices that are similar to the prices of Canada, the United Kingdom, and France. The trade-off is less pharmaceutical R&D.

The authors thank the Commonwealth Fund and the Robert Wood Johnson Foundation for support. The views expressed here are the authors' own.

NOTES

1. Beneficiaries who are dual eligibles (eligible for both Medicare and Medicaid) and those meeting income and asset requirements receive a full subsidy for the premium. Additional beneficiaries meeting income and asset requirements will receive partial premium subsidies.
2. In addition, the standard drug package has an annual deductible of $250 in 2006, rising in later years proportionally to Medicare spending.
3. The Congressional Budget Office has estimated that the prescription drug benefit will add $409.8 billion in spending during 2004–2013. However, the other provisions of the bill will lead to some savings, resulting in a total estimate of $394.8 billion in increased spending for the entire bill over this time period. Congressional Budget Office, "CBO Estimate of Effect on Direct Spending and Revenues of Conference Agreement on H.R. 1," Letter to the Honorable William Thomas, 20 November 2003, www.cbo.gov/showdoc.cfm?index=4808&sequence=0 (21 June 2004). The administration has projected much higher costs, however, due mainly to different assumptions about enrollment and spending growth. CBO, Letter to the Honorable Jim Nussle, 2 February 2004, www.cbo.gov/showdoc.cfm?index=4995&sequence=0 (21 June 2004).
4. J.P. Newhouse, "How Much Should Medicare Pay for Drugs?" *Health Affairs* 23, no. 1 (2004): 89–102.
5. We examined the top fifty U.S. products; twenty of these products were not sold in any of the other three countries in 2003.
6. Prices were adjusted from each country's currency units to U.S. dollars using 1 January 2003 exchange rates. Exchange rates were 0.6361 Ca-

nadian dollars per U.S. dollar, 1.0501 Euros per U.S. dollar, and 1.6114 pounds per U.S. dollar.

7. The units are generally tablets or some other form of pill, although sometimes doses of nasal spray.
8. Our analysis assumes that Canada, France, and the United Kingdom pay the full average wholesale price. Estimates of the potential U.S. discount vary widely. Danzon and Furukawa assumed an 8 percent discount from average manufacturers' price. P.M. Danzon and M.F. Furukawa, "Prices and Availability of Pharmaceuticals: Evidence from Nine Countries," *Health Affairs*, 29 October 2003, content.healthaffairs.org/cgi/content/abstract/hlthaff.w3.521 (21 June 2004). The CMS estimates that Medicare beneficiaries will be able to achieve a 10–15 percent average discount from retail price using discount drug cards. CMS, "Overview: Medicare Prescription Drug Discount Card and Transitional Assistance Program," www.cms.hhs.gov/discountdrugs/overview.asp (21 June 2004).
9. Danzon and Furukawa, "Prices and Availability of Pharmaceuticals."
10. Danzon and Furukawa averaged the prices for each pharmaceutical compound over the various available dosage strengths and forms, whereas we matched each dosage strength and form. Since there are some differences in the availability of dosages and forms sold in the four countries, our methodology leads to fewer product matches, but our matched products are standardized more closely. The thirty products were sold in a total of 105 dosage forms in the United States. Of these 105, 75 products matched in Canada, 52 matched in France, and 59 matched in the United Kingdom.
11. The 20 percent discount off U.S. prices only translates into an approximately 5 percent reduction in the ratio between the United States and other countries. For example, if a U.S. drug cost $1.00 and a Canadian drug cost $0.50 (that is, Canadian prices were 50 percent lower than U.S. prices), a 20 percent discount in the U.S. price would still lead to Canadian prices that are 37.5 percent lower than U.S. prices.
12. There were also new drugs introduced, changes in patent protection, and exchange rate fluctuations between 1999 and 2003.
13. Our sample represented 30 percent of total U.S. pharmaceutical sales in 2003.
14. For details, see D. Shea, B. Stuart, and B. Briesacher, "Participation and Crowd-Out in a Medicare Drug Benefit: Simulation Estimates," *Health Care Financing Review* 25, no. 2 (2003/2004): 47–61.
15. The simulations are run using the community-residing population in the MCBS, excluding approximately 5 percent of the sample residing in institutions. In addition, the results focus on changes in out-of-pocket drug spending, ignoring changes in premium costs.
16. The MCBS does not have information about the premium cost of existing prescription drug plans held by individuals. To assess the net value of a person's drug plan, we estimated the existing premiums paid using information on whether the person paid some, none, or all of their current premium; the type of plan; and what the person's drug costs are. The premium cost of the new Medicare benefit, however, is estimated by the simulation model. This is done recursively, by identifying who enrolls and what the premiums would have to be to break even. The recursion continues until the costs stabilize, and that provides an estimate of the Medicare premium cost.

    In addition, the changes in insurance coverage that a Medicare beneficiary might make in response to the new plan could have effects on premiums paid through employer plans, Medicare health maintenance organizations (HMOs), Medigap plans, and others. These changes, while important in assessing benefits, are difficult to forecast at this time. The elasticity estimate is based on M.V. Pauly, "Medicare Drug Coverage and Moral Hazard," *Health Affairs* 23, no. 1 (2004): 113–122.
17. Henry J. Kaiser Family Foundation, "Prescription Drug Coverage for Medicare Beneficiaries: A Summary of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003," 10 December 2003, www.kff.org/medicare/upload/28710_1.pdf (30 June 2004).
18. The simulation does not try to estimate the effect of nominal dollar copays on spending, for example.
19. R. Pear, "Bush Aides Put Higher Price Tag on Medicare Law," *New York Times*, 30 January 2004.
20. Partnership for Solutions, *Chronic Conditions: Making the Case for Ongoing Care* (Baltimore: Johns Hopkins University, 2002).
21. W. Hwang et al., "Out-of-Pocket Medical Spending for Care of Chronic Conditions," *Health Affairs* 20, no. 6 (2001): 267–278; and S.B. Soumerai et al., "Effects of Medicaid Drug-Payment Limits on Admission to Hospitals and Nursing Homes," *New England Journal of Medicine* 325, no. 15 (1991): 1072–1077.
22. As noted above, these estimates do not include the premium costs. The MCBS does not have an accurate estimate of these costs, so the benefit here is based solely on the out-of-pocket drug costs.
23. Hilty Moore and Associates, "Pharmaceutical In-

dustry—Segment Profile," 3 October 2002, www.hiltymoore.com/pdf_elements/Pharma.pdf (21 June 2004).

24. P. Feldstein, *Health Policy Issues, An Economic Perspective*, 3d ed. (Washington: Association of University Programs in Health Administration, 2003).
25. M. Gluck, *Federal Policies Affecting the Cost and Availability of New Pharmaceuticals* (Washington: Kaiser Family Foundation, July 2002).
26. Pharmaceutical Research and Manufacturers of America, "A Decade of Innovation," 2003, www.phrma.org/publications/publications/2003-10-16.855.pdf (21 June 2004).
27. Public Citizen, *Rx R&D Myths: The Case Against the Drug Industry's R&D "Scare Card,"* July 2001, www.citizen.org/documents/rdmyths.pdf (24 June 2004).
28. J. DiMasi, "The Price Of Innovation: New Estimates of Drug Development Costs," *Journal of Health Economics* 22, no. 2 (2003): 151–185.
29. PhRMA, "Why Do Prescription Drugs Cost So Much?" www.phrma.org/publications/publications/brochure/questions (24 June 2004).
30. Ibid.
31. National Institute for Health Care Management, "Changing Pattern of Pharmaceutical Innovation," May 2002, www.nihcm.org/innovations.pdf (24 June 2004).
32. W.H. von Oehson III, *Pharmaceutical Discounts under Federal Law: State Program Opportunities*, May 2001, www.ppsv.com/issues/pharm_discounts.pdf (24 June 2004).
33. Newhouse, "How Much Should Medicare Pay for Drugs?"
34. Ibid.
35. U.E. Reinhardt, "Perspectives on the Pharmaceutical Industry," *Health Affairs* 20, no. 5 (2001): 136–149.
36. Ibid.