Executive Summary
Backgrounder
Published by The Heritage Foundation
No. 2225
January 12, 2009

How Medicare's Drug Pricing Can Hurt R&D

Cheryl S. Smith and Laura L. Summers

Given the sheer enormity of the growing Medicare program, Members of Congress and the new Administration should realize that any decisions they make regarding Medicare drug pricing could have an enormous impact on pharmaceutical research and development. This in turn would affect the quality of care for the baby boom generation, parts of which will begin retiring in 2011.

Before 2003, the federal Medicare program made no provision for a prescription drug benefit. That changed with the implementation of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Also known as the Medicare Modernization Act (MMA), this legislation authorized the introduction of Medicare Part D, an entitlement prescription-drug benefit for Medicare recipients. MMA represented the largest addition to the federal entitlement program since The Great Society.

MMA included a provision prohibiting the Secretary of the Department of Health and Human Services (HHS) from "interfering" in the private negotiations between drug manufacturers and the prescription-drug plans (PDPs) that deliver the Medicare benefit. MMA further stipulated that the Secretary not require a particular formulary or institute a price structure for the reimbursement of covered drugs under the Medicare program, though it did not prevent private PDPs from doing so.

The current law prohibiting the federal government from directly "negotiating" or setting drug prices for the Medicare Part D benefit is a topic of fierce congressional debate. While some argue such measures would relieve the financial strain on the federal budget, others maintain the residual effect would be counterproductive, as such measures have the potential to reduce pharmaceutical profits and stifle medical innovations, which, they claim, would ultimately save money and lives. Research shows that new and more effective drugs can substantially reduce disabilites from chronic disease, securing savings in federal programs that provide assistance to these patients, while improving the quality of their lives. This would especially be the case with the costly and devastating diseases of aging, such as Alzheimer's.

Alzheimer's and Entitlement Costs. Alzheimer's disease (AD) affects millions of Americans every year. In 1990, slightly more than 10 percent of the U.S. population aged 65 or older suffered from Alzheimer's. Using the same 10 percent ratio, the prevalence of Alzheimer's disease today would be around 3.7 million. Because of the aging baby boom generation and increasing portion of the population age 65 and older, however, studies estimate the

This paper, in its entirety, can be found at:
www.heritage.org/Research/HealthCare/bg2225.cfm
Produced by the Center for Health Policy Studies
Published by The Heritage Foundation
214 Massachusetts Avenue, NE
Washington, DC 20002–4999
(202) 546-4400 • heritage.org

number of Alzheimer's patients in the U.S. will have doubled from 1995 to 2015, and will have tripled from 2000 to 2040.

The individual cost of caring for an Alzheimer's patient can range anywhere from $18,400 annually for a patient with mild symptoms to $36,100 per year for a patient with severe symptoms. These represent conservative estimates, and do not take into account the enormous financial and economic burden of informal care given to Alzheimer's patients by family members, neighbors, and friends.

With the retirement of the baby boomers, the ranks of Alzheimer's patients will continue to swell to unprecedented numbers in the coming years; likewise, the cost of care is also predicted to continue to rise. In tandem, these trends present a unique and troubling picture for federal entitlements. This demographic evolution, the so-called graying of America, represents enormous, unsustainable costs with respect to the Medicare and Medicaid entitlement programs.

The Right Policy. For Medicare, the right policy is to preserve the market-based pricing that ensures not only the continued availability of drugs to treat diseases of aging, but also encourages critical research and development that could reduce these costs in the future.

Conclusion

Scientific research to develop delay-onset drugs for disease is extremely risky in terms of anticipated success and expected return. Pharmaceutical companies are more likely to invest in projects that yield the highest expected return—an expectation which is determined by how likely those projects are to succeed and increase consumer demand. In this case, the increasing demand for delay-onset drugs is driven by pending demographic shifts. Given this demand expectation for new drugs, pharmaceutical firms have been willing to invest in less-promising projects (such as delay-onset) in addition to the projects they believe will succeed. Funding for such ventures comes, in part, from profits yielded by Medicare Part D sales. Given a reduction in profits, a reduction in innovation is sure to follow. Clearly, the public pricing scheme used to pay for drugs invented and developed in the private market strongly affects the level of innovation.

In addition to affecting innovation, extending the "negotiation" power has a high potential to affect private prices. When government provides private firms with a large part of their returns from innovation, pricing policy is not innocuous. As discussed, public pricing is based solely on reference pricing, with private pricing serving as the scale. Were Medicare "negotiation" to be statutorily permitted, the private "best prices" against which public prices are benchmarked, would no doubt increase. In addition, guaranteeing "below average" prices for federally procured drugs when public purchases constitute nearly half the market share would be mathematically impossible without seriously raising the price for privately procured pharmaceuticals.

Price setting by the Secretary of Health and Human Services on behalf of Medicare Part D beneficiaries is politically attractive, but it is bad health policy. It is rife with potential hazards. Without question, pharmaceutical revenue—and R&D as a function of total revenue—would be reduced. The potential for numerous and varied residual effects on the treatment of disease, progress in reducing costly morbidity, and reductions of the quality of care for the next generation of retirees is—or should be—of even greater concern.

—Cheryl S. Smith is a Strategic Plan Development Manager for Health System Reform for the State of Utah, and a former Health Policy Fellow at the Center for Health Policy Studies at The Heritage Foundation. Laura L. Summers is a recent graduate of Brigham Young University with a Master's in Public Policy.

Backgrounder

Published by The Heritage Foundation

No. 2225
January 12, 2009

How Medicare's Drug Pricing Can Hurt R&D

Cheryl S. Smith and Laura L. Summers

Given the sheer enormity of the growing Medicare program, Members of Congress and the Administration should realize that any decisions they make regarding Medicare drug pricing could have an enormous impact on pharmaceutical research and development. This in turn would affect the quality of care for the baby boom generation, parts of which will begin retiring in 2011.

Before 2003, the federal Medicare program made no provision for a prescription drug benefit. That changed with the implementation of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Also known as the Medicare Modernization Act (MMA), this legislation authorized the introduction of Medicare Part D, an entitlement prescription-drug benefit for Medicare recipients. MMA represented the largest addition to the federal entitlement program since The Great Society.

MMA included a provision prohibiting the Secretary of the Department of Health and Human Services (HHS) from "interfering" in the private negotiations between drug manufacturers and the prescription-drug plans (PDPs) that deliver the Medicare benefit. MMA further stipulated that the Secretary not require a particular formulary or institute a price structure for the reimbursement of covered drugs under the Medicare program, though it did not prevent private PDPs from doing so.

The inability of the federal government to directly "negotiate" or set drug prices for the Medicare Part D

Talking Points

- New drug therapies—including those intended to delay onset of disease—hold great promise for treating patients faced with chronic disease and disability. Allowing the federal government to set drug prices for Medicare Part D would reduce pharmaceutical resources for medical innovations.
- Caring for an Alzheimer's patient costs about $18,000 to $36,000 annually per patient. The disease costs businesses more than $60 billion annually in health care ($24.6 billion) and absenteeism and lost productivity associated with informal care-giving ($36.5 billion). In 2005, Medicare and Medicaid costs for Alzheimer's beneficiaries totaled more than $112 billion; for 2010, those costs are estimated to exceed $184 billion.
- Research and development is critical to the pharmaceutical industry. If the government forces down the price of drugs below market levels, firms will have less revenue, and less incentive to invest in R&D, stifling the development of new health-enhancing, life-saving drugs.

This paper, in its entirety, can be found at:
www.heritage.org/Research/HealthCare/bg2225.cfm

Produced by the Center for Health Policy Studies

Published by The Heritage Foundation
214 Massachusetts Avenue, NE
Washington, DC 20002–4999
(202) 546-4400 • heritage.org

benefit is a topic of fierce congressional debate. While some argue such measures would relieve the financial strain on the federal budget, others maintain that the residual effect would be counterproductive, as such measures have the potential to reduce pharmaceutical profits and stifle medical innovations, which, they claim, would ultimately save money and lives. Research shows that such pharmaceutical innovations prevent disabilities from chronic diseases, while improving the quality of life for patients. This would especially be the case with the costly and devastating diseases of aging, such as Alzheimer's.

Alzheimer's and Entitlement Costs. Alzheimer's disease (AD) affects millions of Americans every year. In 1990, slightly more than 10 percent of the U.S. population aged 65 or older suffered from Alzheimer's. Using the same 10 percent ratio, the prevalence of Alzheimer's disease today would be around 3.7 million.[1] Because of the aging baby boom generation and increasing portion of the population age 65 and older, however, studies estimate the number of Alzheimer's patients in the U.S. will have doubled from 1995 to 2015,[2] and will have tripled from 2000 to 2040.[3]

The individual cost of caring for an Alzheimer's patient can range from $18,400 annually for a patient with mild symptoms to $36,100 per year for a patient with severe symptoms.[4] These represent conservative estimates, and do not take into account the enormous financial and economic burden of informal care given to Alzheimer's patients by family members, neighbors, and friends.

With the retirement of the baby boomers, the ranks of Alzheimer's patients will continue to swell to unprecedented numbers in the coming years; likewise, the cost of care is also predicted to continue to rise. In tandem, these trends present a unique and troubling picture for federal entitlements. This demographic evolution, the so-called graying of America, represents enormous, unsustainable costs with respect to the Medicare and Medicaid entitlement programs.

The Right Policy. For Medicare, the right policy is to preserve the market-based pricing that ensures not only the continued availability of drugs to treat diseases of aging, but also encourages critical research and development that could reduce these costs in the future.

Drug R&D: What Studies Show

Research and development is a critical component of the pharmaceutical industry. It is the driving force behind the development of new health-enhancing and life-saving drugs. As a result, the pharmaceutical industry is one of the most research-intensive industries in the United States.[5]

Recent research shows that the use of newer and more effective drugs can reduce and stave off disability, not only saving taxpayers' money in programs that assist disabled patients, but also in improving the quality of patients' lives. According to Frank Lichtenberg, a professor at the Columbia University Graduate School of Business, if doctors and patients did not have access to the pharmaceuticals developed since 1995, America's disability rolls would have increased by an estimated 30 percent.[6]

In a 2003 study, researchers estimated that the cost of developing a new drug averages around $800 million and that it takes about 12 years until

1. U.S. Census Bureau, "American Community Survey," 2006.
2. U.S. General Accounting Office, "Alzheimer's Disease: Estimates of Prevalence in the United States," HEHS-98-16, January 1998.
3. Ron Brookmeyer, Sarah Gray, and Claudia Kawas, "Projections of Alzheimer's Disease in the United States and the Public Health Impact of Delaying Disease Onset," *American Journal of Public Health,* Vol. 88 (1998), pp. 1337–1342.
4. "Statistics about the Financial Costs of Alzheimer's Disease," About.com, 2006, at *http://alzheimers.about.com/od/financialissues/a/Costs_Alzheimer.htm* (November 14, 2008).
5. Press Release, "R&D Spending by U.S. Biopharmaceutical Companies Reaches Record $58.8 Billion in 2007," PhRMA, March 2008.
6. Frank R. Lichtenberg, "Look Past Price for Health Care Value," *Investor's Business Daily*, November 12, 2008, at *http://www.ibdeditorials.com/IBDArticles.aspx?id=311378852946346* (December 29, 2008).

The Heritage Foundation LEADERSHIP FOR AMERICA

the new drug is ready for market.[7] Of those 12 years, about 4.5 years are spent developing the drug in the pre-clinical phase, and 7.5 years are spent testing the drug in clinical trials and seeking FDA approval.

The average cost of successfully bringing a new drug to market is high because it includes the expenditures on failed projects and tests, as well as the value of any investments the company missed while its capital was tied up developing the new drug.[8] The pharmaceutical industry typically has larger opportunity costs than other industries because of the amount of money and time it takes to develop a new drug. The $800 million estimate also accounts for the potential risk of not earning a profit—pharmaceutical companies do not earn a return on R&D investments unless the drug receives FDA approval.[9]

Research and development represents a significant portion of the estimated costs. This helps explain why the pharmaceutical industry spends more on research and development, relative to its sales revenue, than almost any other industry in the United States.[10] Research shows that slightly more than 20 percent of the pharmaceutical industry's revenue was spent on research and development in 2006 and 2007, and that the pharmaceutical industry's real spending on drug research and development has grown between three and six times over the past 25 years. The Congressional Budget Office (CBO) found that pharmaceutical firms invest as much as five times more in research and development, relative to their sales, than does the average U.S. manufacturing firm.

According to the National Science Foundation (NSF), American companies spent a total of $5.5 billion (in 2005 dollars) in pharmaceutical R&D in 1980. By 2003, this number had increased to more than $17 billion, representing an average real growth rate of 5 percent per year. According to the Pharmaceutical Research and Manufacturers of America (PhRMA), companies spent a total of $6 billion (in 2005 dollars) in pharmaceutical R&D in 1980. By 2004, this number had increased to more than $39 billion, representing an average real growth rate of more than 8 percent per year.[11] In 2007, America's pharmaceutical and biotechnology research companies invested $58.8 billion in research and development. This was an increase of nearly $3 billion from 2006.[12]

The increase in research and development spending over the last two decades has been closely matched by increases in pharmaceutical sales.[13] While the effect of these two variables is somewhat simultaneous, many assume that increased pharmaceutical sales lead to greater profits, which allow more research and development as well as product diversification.

However, profit is not the only factor that affects the level of research and development; advances in basic science, the ability to patent biological molecules, and the rising need to develop drugs that treat chronic illnesses greatly increased the amount of pharmaceutical research over the past few decades. Patenting biological molecules, for instance, has forced pharmaceutical firms to spend more on capital equipment and training in order to remain competitive in the growing field of biological research,

7. Joseph A. DiMasi, Ronald W. Hansen, and Henry G. Grabowski, "The Price of Innovation: New Estimates of Drug Development Costs," *Journal of Health Economics,* Vol. 22, No. 2 (2003), pp. 151–185.
8. *Ibid.*
9. *Ibid.*
10. *Ibid.*
11. *Ibid.* The difference between the NSF and PhRMA studies is that NSF's research includes only domestic firms' R&D spending, while PhRMA's research includes any R&D spending in the United States that is performed by the association's members, regardless if they are foreign or domestic companies. NSF's estimates also exclude spending on phase IV clinical trials (trials conducted after a drug has been brought to the market) and on the development of manufacturing processes.
12. Press Release, "R&D Spending by U.S. Biopharmaceutical Companies Reaches Record $58.8 Billion in 2007."
13. Congressional Budget Office, "Research and Development in the Pharmaceutical Industry," October 2006, p. 7, at *http://www.cbo.gov/doc.cfm?index=7615* (November 14, 2008).

and treating chronic illness involves developing drugs that generally require larger and longer clinical trials.[14]

How Government Drug Pricing Would Affect R&D

Drug prices play a role in the intensity of pharmaceutical R&D. Based on the nature of its product, the lengthy development time, and the intense regulatory environment, the pharmaceutical industry is one of the most research intensive industries in the United States. According to a study conducted by PhRMA, R&D intensity has grown by about 50 percent since 1970. Most of this growth occurred in the early 1980s, and since then the industry's R&D intensity has remained around 19 percent.[15] The relative stability of the pharmaceutical industry's R&D intensity suggests that firms find it profitable to invest the majority of their earned profit into their own drug research. When a successful drug generates a large cash flow, the firm's first incentive is to invest the money back into research and development for new drugs.

The stability of the pharmaceutical industry's R&D intensity also suggests that changes in drug prices can induce a real affect on a company's propensity to invest in R&D. If the price of a drug increases, firms earn more sales revenue and have a greater incentive to invest in research and development. If the real price of drug falls, firms will have less incentive to invest in R&D. A 2006 CBO study found that a 10 percent change in real U.S. drug prices increases the pharmaceutical industry's R&D intensity by almost 6 percent, everything else held constant.[16]

The CBO study also found that changes in drug prices have an effect on individual companies' expectations about profits. CBO researchers found that higher drug prices may provide incentives for pharmaceutical companies to complete existing projects faster, as well as encourage companies to undertake additional research.[17] Based on this study, it appears as though higher drug prices have a clear positive effect on R&D investment, spending, and intensity, contradicting the public's push to reduce the pharmaceutical industry's prices and profits.

Drug pricing in the public and private markets varies greatly. Pharmaceutical pricing in both the private and public sector is a complex process. The public sector uses a number of pricing "schedules" based almost entirely on prices extended in the private market. Prices extended to purchasers in the private market are primarily determined by market share and negotiating power. For purposes of comparison, our study considers both.

Existing Government Purchasing. Federal and state governments are major buyers of pharmaceuticals. In 2003, pharmaceutical purchases by federal and state governments accounted for more than 20 percent of total U.S. expenditures for outpatient prescription drugs.[18] The prices that federal and state governments pay for drugs vary considerably depending on the program through which they are purchased. The process by which these prices are determined is the result of the application of one of a number of programs, including the Federal Supply Schedule (FSS), the federal ceiling price program (FCP), the Department of Veterans Affairs' pharmaceutical prime vendor program, the Department of Defense's Military Treatment Facility (MTF) pharmaceutical program, the Medicaid rebate program, and the Public Health Service's 340B drug pricing program. In addition, a number of rebate programs, chargebacks, and statutory discounts add to the complex nature of the pricing structure.

The federal government, state Medicaid programs, and several non-federal public health enti-

14. *Ibid.*
15. *Ibid.*
16. *Ibid.*
17. *Ibid.*
18. Congressional Budget Office, "Prices for Brand-Name Drugs Under Selected Federal Programs," June 2005, at *http://www.cbo.gov/doc.cfm?index=6481* (November 14, 2008).

ties have access to prescription pharmaceuticals at considerably lower prices than do private purchasers. Qualifying federal entities may procure drugs listed on the FSS at prices equal to or lower than prices that drug manufacturers offer their most-favored private purchasers.

Under the Omnibus Budget Reconciliation Act of 1990 (OBRA), reimbursement for drugs covered by Medicaid is conditional on pharmaceutical suppliers listing their brand name drugs on the FSS. Federal law also imposes a ceiling price on FSS brand-name drugs procured by select federal purchasers and extends Medicaid rebated prices to a number of public health entities receiving federal assistance, such as community health centers and select public hospitals. In addition, the Veterans Administration (VA) may access prices even lower than those available on the FSS through national contracts with drug manufacturers that direct use of specific products.[19]

All federal drug price lists are determined by calculations based primarily on the Average Wholesale Price (AWP) of a drug. The AWP is a publicly available, suggested list price for sales of a drug by a wholesaler to a pharmacy or other provider. It is not the actual price that wholesalers charge but is used similarly to a sticker price in the automobile industry.

In 2003, the CBO estimated the average price paid to manufacturers relative to list price for brand-name, single-source drugs under selected federal programs. In order to estimate the prices, the CBO examined 130 single-source, brand-name prescription drugs that accounted for about 50 percent of U.S. sales through retail pharmacies and about 70 percent of U.S. sales of brand-name drugs through retail pharmacies in 2003. The average price paid by the federal government for pharmaceuticals that year ranged from a high of 63 percent to a low of 41 percent.[20]

Medicare and Private Markets. Mandating the extension of federal pricing for prescription drugs to a large group of purchasers, such as Medicare beneficiaries, could lower the prices for the federal government while raising prices for private purchasers. In a 2000 study examining the effects of expanding access to federal drug prices, the General Accounting Office (GAO), since renamed the Government Accountability Office, determined such price changes occur because drug manufacturers would be forced to charge beneficiaries and federal purchasers the same prices.

In order to protect revenues, pharmaceutical manufacturers would likely raise prices for federal purchasers. In addition, because federal prices are typically based on prices paid by non-federal pur-

Estimates of Prices Paid to Manufacturers

Relative to List Price for Brand-Name Drugs Under Selected Federal Programs in 2003

Federal Program	Average Price as a Percentage of List Price
Average Wholesale Price (AWP)	100%
Average Manufacturer Price (AMP)	79%
Non-Federal Average Manufacturer Price (Non-FAMP)	79%
Best price	63%
Federal Supply Schedule (FSS)	53%
Medicaid net manufacturer price	51%
340B ceiling price	51%
Federal Ceiling Price program (FCP)	50%
Price available to the Big Four	49%
VA average price	42%
DoD's Military Treatment Facility (MTF) average price	41%

Source: Congressional Budget Office, "Prices for Brand Name Drugs Under Selected Federal Programs," June 2005.

Table 1 • B 2225 heritage.org

19. U.S. General Accounting Office, "Prescription Drugs: Expanding Access to Federal Prices Could Cause Other Price Changes," GAO/HEHS-00-118, 2000.
20. Congressional Budget Office, "Prices for Brand-Name Drugs Under Selected Federal Programs."

chasers, large private purchasers that tend to pay lower prices, such as health maintenance organizations (HMOs) and other insurer manufacturers, would also see prices rise.[21]

In 2007, the U.S. Senate considered legislation aimed at striking the MMA's "non-interference" clause prohibiting the Secretary of Health and Human Services from interfering with negotiations between drug manufacturers and private plans in Medicare Part D.[22] The Congressional Budget Office determined that negotiations would likely be effective *only* if applied in tandem with pressure on drug manufacturers to secure price concessions. The CBO further determined the authority to institute a formulary, set prices administratively, or take other regulatory measures against firms failing to offer price reductions, could give the Secretary the ability to obtain significant discounts in negotiations with drug manufacturers. In the absence of such authority, however, the Secretary's ability to issue credible threats or take other actions in an effort to obtain significant discounts would be limited.[23] Volume and the ability to refuse to do business are determinants of the final acquisition price. Since government "negotiation" alone would likely fail to deliver any savings, it must be assumed that the desired effect would come as the result of negotiation as well as the ability to move market share.

In the pharmaceutical industry, HMOs and pharmacy benefit managers (PBMs) have committees of physicians and pharmacists who consider which drugs are therapeutic substitutes. When two or more drugs are found to be close substitutes, the plan considers which is the least expensive. The manufacturers of those drugs essentially bid for the business of the buyer, with the lowest-priced drug winning. The winner gains market share at the expense of its substitutes because the HMO makes the winner the default choice for its physicians and consumers.

A Secretary "negotiating" for lower prices for all Medicare beneficiaries would find it difficult to go through this process because, inevitably, drugs in every therapeutic class would be unavailable on any plan; thus, under such a scenario, Medicare would be unable to meet the pharmaceutical needs of a diverse group of seniors. Therefore, in the absence of a formulary, a negotiator for Medicare would be unable to exclude any drug and each manufacturer would fundamentally know that Medicare must purchase all products and the Medicare "negotiator" would have no bargaining leverage.

Current Pricing. There are three price measures important in understanding the payment system for prescription drugs in the retail pharmacy market: the average manufacturer price (AMP), the wholesale acquisition cost (WAC), and the previously discussed AWP. The AMP is an average of actual transaction prices. In contrast, the WAC and the AWP are list prices. The AMP is the average price paid by wholesalers to manufacturers or by retail pharmacies that buy directly from manufacturers for drugs distributed through retail pharmacies. It reflects all rebates paid by manufacturers to wholesalers and retail pharmacies. It does not include rebates paid by manufacturers to PBMs, Medicaid, or to other third-party payers.

Manufacturers are required to report the AMP to the Department of Health and Human Services' Centers for Medicare & Medicaid Services (CMS), which uses it to calculate the rebates that manufacturers are required to pay state Medicaid programs for sales to Medicaid beneficiaries. For manufacturers, such rebates are a cost of participating in the Medicaid market.[24]

The WAC represents manufacturers' published list price for sales of a drug (brand-name or generic) to wholesalers. In practice, however, the WAC is not

21. U.S. General Accounting Office, "Prescription Drugs: Expanding Access to Federal Prices Could Cause Other Price Changes."
22. Medicare Prescription Drug Price Negotiation Act of 2007, S.3 110th Cong., 1st Sess., Section 1.
23. Congressional Budget Office, "Re: Issues Regarding Price Negotiation in Medicare," letter to the Honorable Ron Wyden, April 10, 2007.
24. Congressional Budget Office, "Prescription Drug Pricing in the Private Sector," January 2007, at *http://www.cbo.gov/doc.cfm?index=7715* (November 14, 2008).

what wholesalers pay for drugs. To the extent that the WAC is meaningful in conveying information about actual transaction costs, the utility is limited to single-source drugs (brand-name drugs under patent protection). For those drugs, the WAC approximates the prices that retail pharmacies pay to wholesalers.

As noted previously, the AWP is merely a published list price for a drug sold by wholesalers to retail pharmacies and non-retail providers, and in practice is not what retailers actually pay for drugs but, instead, is often used as a basis for payment to retail pharmacies by, for example, the Medicaid program, PBMs, and health plans. Those organizations often pay pharmacies a price discounted off the AWP.[25]

Average Prices for Brand-Name Drugs Relative to the Average Wholesale Price

Purchaser	Average Price as a Percentage of List Price
Conventional retail pharmacies	83%
Mail-order pharmacies*	<=78%
Federal facilities	42%
Non-retail providers (excluding federal facilities)	<=74%
Best price*	64%

* Mail-order pharmacies and non-retail providers may receive rebates from manufacturers due to their ability to move market share for large numbers of customers. The estimates of average prices for mail-order pharmacies and non-retail providers do not account for rebates. Federal facilities and purchasers who pay the best price can also receive rebates, but the estimates of average prices for federal facilities and best price do account for these rebates.

Source: Congressional Budget Office, "Prices for Brand Name Drugs Under Selected Federal Programs," June 2005.

Table 2 • B 2225 heritage.org

Government and Non-Government Pricing. Comparing federally negotiated prices and non-federally negotiated prices is not a simple task. In order to make a fair comparison, the empirical analysis is based on elements of earlier studies done by the GAO and CBO. The GAO obtained information on the drug purchasing methods and prices available to the federal departments and agencies that spend the most on prescription drugs—the Department of Veterans Affairs (VA), the Department of Defense (DOD), and the Public Health Service (PHS). The GAO also obtained information from the Health Care Financing Administration (HCFA) on the rebates state Medicaid programs receive through the Medicaid drug rebate program. In addition, working with officials from the Health Resources and Services Administration's (HRSA) Office of Drug Pricing, the GAO determined the drug-price discounts available to public health entities that receive federal assistance.[26]

Using this information, the average prices paid for single-source drugs in the public sector were compared with those in the private sector. Then, because it is yet unknown what pricing schedule the federal government would follow (in the event such a practice were statutorily allowed), a weighted average price of federally procured single-source drugs was compared to a weighted average price of privately procured drugs. The weighted average prices used for our analysis came from a Congressional Budget Office report.[27]

To determine the weighted average price relative to the average wholesale price for single-source drugs, the CBO calculated the ratio of the cost of buying the quantities of the drugs in the sample at each price—the WAC, the AMP, the "best price," and the average prices paid by the different types of retail pharmacies (chain pharmacies, independent pharmacies, food stores with pharmacies, and mail-order pharmacies) and non-retail providers (hospitals, health maintenance organizations, clin-

25. *Ibid.*
26. U.S. General Accounting Office, "Prescription Drugs: Expanding Access to Federal Prices Could Cause Other Price Changes."
27. Congressional Budget Office, "Prices for Brand Name Drugs Under Selected Federal Programs," and Congressional Budget Office, "Prescription Drug Pricing in the Private Sector."

ics, home health care providers, nursing homes, and federal facilities)—divided by the cost of buying them at the average wholesale price.[28]

Impact on R&D. Based on the analysis of the data, the estimated effect of federally negotiated prices for Medicare Part D on pharmaceutical research and development sales would be dramatic and alarming.[29] Total prescription drug sales in 2007 amounted to $286.5 billion.[30] Given the 2007 estimates of both total pharmaceutical sales and total Medicare Part D expenditures, estimated non-Medicare Part D drug sales were $237 billion.[31] Understanding this, the amount of Medicare Part D expenditures was reduced by the difference between the average weighted private and public prices relative to AWP.

As a result, Medicare Part D expenditures would be reduced to $29.7 billion (60 percent of the original 2007 total). That total, combined with the non-Medicare Part D drug sales, indicates that total pharmaceutical sales (including sales using negotiated Medicare Part D prices) would be about $256.8 billion, representing a $29.7 billion (10.4 percent) *loss* in pharmaceutical sales revenue.

Considering the link between pharmaceutical sales revenue and R&D, the effect such a reduction would likely have on R&D investment can then be estimated. In 2007, U.S. pharmaceutical and biotech companies invested $58.8 billion in R&D, representing approximately 20.5 percent of total pharmaceutical sales. If pharmaceutical sales were reduced to $256.8 billion, the amount invested in R&D would be reduced to $52.4 billion. As a result, this would amount to a reduction of $6.4 billion (10.9 percent) in total pharmaceutical research and development.

Potential Revenue Loss Due to Federally Negotiated Medicare Part D Prices

	Billions of Dollars
Total U.S. prescription drug revenue	$286.5
Medicare Part D total expenditures	$49.5
Share of total revenue	17.3%
Reduction as a result of federal negotiation (40%)	$29.7
Total revenue post negotiation	$256.8
Total loss in prescription drug revenue	**$29.7**

Table 3 • B 2225 heritage.org

R&D Spending as a Function of Total Revenue of the Pharmaceutical Industry

	Billions of Dollars	
	2007	**2006**
Total Pharmaceutical Revenue	$286.5	$274.9
Total Amount invested in R&D	$58.8	$55.8
R&D as a Share of Total Revenue	**20.5%**	**20.3%**

Table 4 • B 2225 heritage.org

28. *Ibid.*
29. Using data from the National Health Expenditures for 1960–2006, the 2008 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and the Federal Supplementary Medical Insurance Trust Funds, and IMS Health, we estimated the reduction in Medicare Part D spending, assuming price negotiation and using the difference between weighted average private and public prices relative to the average wholesale price for single-source drugs. We subsequently determined how the Medicare Part D expenditure reduction would likely affect pharmaceutical sales overall. Finally, we calculated the estimated change in pharmaceutical R&D, given a reduction in total pharmaceutical revenues.
30. "IMS Health Reports U.S. Prescription Sales Jump 8.3 Percent in 2006, to $274.9 Billion," *IMS Health*, March 8, 2007, at *http://www.imshealth.com/portal/site/imshealth/menuitem.a46c6d4df3db4b3d88f611019418c22a/?vgnextoid=275b1d3be7a29110VgnVCM10000071812ca2RCRD&vgnextchannel=41a67900b55a5110VgnVCM10000071812ca2RCRD&vgnextfmt=default* (November 15, 2008).
31. The Boards of Trustees of the Federal Hospital Insurance and the Federal Supplementary Medical Insurance Trust Funds, *2008 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and the Federal Supplementary Medical Insurance Trust Funds Report*, March 25, 2008, p. 117, at *http://www.cms.hhs.gov/ReportsTrustFunds/downloads/tr2008.pdf* (November 14, 2008).

Potential Loss in Pharmaceutical R&D Due to a Reduction in Federal Sales

	Billions of Dollars
Total Revenue Post Negotiation	$256.8
Estimated R&D as a Share of Total Revenue	20.4%
Post-Negotiation R&D Investment	$52.4
Total Loss in Pharmaceutical R&D	**$6.4**

Table 5 • B 2225 heritage.org

Long-Term Costs. The long-term costs of "federally negotiated" drug prices for Medicare Part D would far outweigh the short-term gains. The pharmaceutical industry is characterized by risk and, as a consequence, has large up-front expenses to discover and develop new drugs. The new drugs may not be as effective as hoped and such uncertainty naturally results in high fixed costs for the innovator; however, once discovered and approved, production costs for pharmaceuticals are typically very low.

Exactly one-half of this equation is largely opaque to the American public. Consumers rarely understand the risk and financing involved in drug innovation. They are, however, keenly aware of large profits enjoyed by pharmaceutical manufacturers—profits driven by market prices for drugs far in excess of production costs. In an effort to quell public outcry, government officials are often tempted to moderate the costs borne by patients by using their power to force prices below market levels. This scenario represents time-inconsistent policy in the classic sense.[32]

The introduction of the Medicare Part D program vastly increased the market share of the federal government as a "buyer" of prescription drugs. Allowing the federal government to override private contract negotiations and use its massive purchasing power to "negotiate" prices, move market share, and change the price of drugs used by Medicare beneficiaries would only result in little to no short-term cost savings.

In the long run, however, exercising such power has the potential to severely reduce pharmaceutical research and development to a detrimental level. Entrepreneurs and scientists who endeavor to discover new drugs are today funded by venture capitalists and other providers of scarce financial resources. Without the financial returns that can be earned by an innovative new drug, these investments would decline. If expected future profits from a new drug cannot outweigh the risk of investment, the capital resources would be shifted into other sectors of the economy.

Our analysis indicated that a 40 percent decrease in pharmaceutical revenues, currently constituted by Medicare Part D sales, would result in reduced investment in R&D investment of about $6.4 billion. With less investment, American citizens would enjoy fewer new drugs than they would otherwise. The overwhelming body of academic research concludes that American health care benefits greatly from new drug innovation; therefore, it is in the national interest for these companies to continue research into new therapies.

The Boomer Crisis: The Special Challenge of Alzheimer's

Accelerated pharmaceutical research and development takes on a special urgency in light of the pending retirement of the enormous baby boom generation.

Alzheimer's disease represents an emerging dilemma for American policymakers. Because of the aging baby boom generation and increasing portion of the population ages 65 and older, recent studies estimate that the number of Alzheimer's patients in the United States will have doubled from 1995 to 2015[33] and tripled from 2000 to 2040.[34] According to a March 2007 article by the Alzheimer's Associa-

32. Fiona M. Scott Morton, "Prescription Drug Pricing and Negotiation: An Overview and Economic Perspectives for the Medicare Prescription Drug Benefit," testimony before the Committee on Finance, U.S. Senate, January 11, 2007.
33. U.S. General Accounting Office, "Alzheimer's Disease: Estimates of Prevalence in the United States," HEHS-98-16, January 1998.

tion, there are now more than 5 million people in the United States afflicted with Alzheimer's.[35] It is currently the seventh-leading cause of death in the United States.[36]

The greatest risk factor for Alzheimer's is increasing age. Most people who suffer from Alzheimer's are 65 and older, and the likelihood of developing Alzheimer's doubles every five years after age 65. After 85, the risk of developing Alzheimer's reaches nearly 50 percent.[37] Another risk factor is family history. Research has shown that those who have an immediate family member with Alzheimer's are two to three times more likely to develop the disease during their lifetime. This risk increases if more than one family member has the illness.[38]

Early onset memory disorders typically affect people in their 40s or 50s, but have been diagnosed in people in their 30s. It estimated that over a half million people between ages 30 and 50 have Alzheimer's disease or a related dementia.[39] Complications associated with the disease are vastly different for younger patients. Whereas older patients have grown children and are generally retired, younger patients are afflicted in their prime earning years; they often have children at home, as well as all the financial obligations associated with that stage of life. Since most general practitioners regard Alzheimer's as a disease of the aged, early-onset patients typically remain misdiagnosed. Recent technological advances, however, have made early detection and treatment more feasible.

Rising Costs. The costs associated with Alzheimer's disease are enormous and will continue to grow. The direct and indirect costs of caring for patients with Alzheimer's is estimated to be around $100 billion per year nationwide. This number includes formal health care expenses as well as informal costs of lost wages and time of both the patients and their caregivers.[40]

The annual individual cost of caring for an Alzheimer's patient can range anywhere from $18,400, for a patient with mild symptoms, to $36,132 for a patient with severe symptoms.[41] The average direct cost of caring for an Alzheimer's patient from diagnosis to death is $174,000.[42] Seven out of 10 people with Alzheimer's live at home (rather than in a nursing home), in which case 75 percent of the costs are typically absorbed by the family.[43]

Families and patients are not the only parties who bear the costs related to Alzheimer's disease. It is estimated that Alzheimer's disease costs businesses $24.6 billion in health care. Caregivers for Alzheimer's patients are estimated to cost businesses another $36.5 billion in absenteeism and lost productivity[44] as the majority of informal caregivers (over 59 percent) are employed either part time or full time.[45]

34. Brookmeyer, Gray, and Kawas, "Projections of Alzheimer's Disease in the United States and the Public Health Impact of Delaying Disease Onset."
35. National Center for Policy Analysis, "Cost of Alzheimer's Care to Rise," *Daily Policy Digest,* March 21, 2007, at *http://www.ncpa.org/sub/dpd/index.php?Article_ID=14331* (November 14, 2008).
36. *Ibid*.
37. *Ibid*.
38. "Basics of Alzheimer's Disease," Alzheimer's Association, 2006, p. 12.
39. "What is Alzheimer's?" Alzheimer's Association, 2008, at *http://www.alz.org/alzheimers_disease_what_is_alzheimers.asp* (November 14, 2008).
40. "About Alzheimer's, Frequently Asked Questions," American Health Assistance Foundation, 2008, at *http://www.ahaf.org/alzheimers/questions/frequentlyasked.html* (November 17, 2008).
41. "Statistics About the Financial Costs of Alzheimer's Disease," About.com, 2006, at *http://alzheimers.about.com/od/financialissues/a/Costs_Alzheimer.htm* (November 14, 2008).
42. "About Alzheimer's, Frequently Asked Questions," American Health Assistance Foundation.
43. "Statistics about the Financial Costs of Alzheimer's Disease," About.com.
44. *Ibid.*
45. "Caregiving in the U.S.," National Alliance for Caregiving & AARP, 2004.

A 2004 survey conducted by AARP revealed over 92 percent of family members with intense levels of care-giving report major changes in their working patterns: 83 percent arriving late/leaving early or taking time off during the day, 41 percent taking a leave of absence, 37 percent going from working full time to part time, 35 percent voluntarily terminating employment, 15 percent losing job benefits, 14 percent declining a promotion, and 12 percent choosing early retirement.[46]

The cost to the government is also high. Medicare costs for beneficiaries with Alzheimer's disease were $91 billion in 2005 and are expected to increase by 75 percent to $160 billion in 2010. Medicaid expenditures on residential dementia care were $21 billion in 2005. These costs are estimated to increase by 14 percent to $24 billion by 2010.[47] Medicaid spending per dementia patient is around $13,207 per year, compared to $4,454 a year per patient without dementia.[48]

In 2005, the Alzheimer's Association estimated that more than half of the 50 states in America provide more than a billion dollars in unpaid care each year.[49] The states which provided the most unpaid care in 2005 were California ($8.5 billion), Texas ($5.8 billion), New York ($5.2 billion), Florida ($4.6 billion), and Pennsylvania ($3.6 billion). With the baby boom generation reaching retirement and approaching the key age for Alzheimer's onset, it is expected that the costs associated with unpaid care will significantly rise in the next 10 to 20 years.

A 2006 AARP survey found that between 30 million and 38 million adult caregivers, ages 18 or older, provided care to adults with severe illness or disability. Table 6 was developed by AARP and contains estimates of the economic value of informal caregiving activities for high and low estimates of the number of caregivers. These estimates do not include the value of non-wage benefits, such as health insurance, or the value of the time family members devote to providing assistance in residential care settings, such as assisted living or nursing homes.

As indicated by Table 6, informal caregiving can be an enormous financial drain on both families and society. However, rising health care costs and limited access to retirement and nursing homes have forced many families to choose informal caregiving when faced with caring for an ill or disabled adult family member. This means informal care is now an increasing part of economic productivity that

Annual Economic Value of Unpaid Caregiving Activities in 2006

Assuming 1,080 Hours of Care per Year for Varying Caregiving Prevalence and Cost Estimates

Cost of caregiving per hour	High estimate	Low estimate
Number of caregivers	38 million	30 million
High ($19/hour) average private-pay cost of hiring a home health aide	$780 billion	$616 billion
Medium ($14.70/hour) average wage for aides and other workers in the home health industry	$603 billion	$476 billion
Low ($9.04/hour) median wage for all home health aides	$371 billion	$293 billion
Very low ($5.15/hour) federal minimum wage	$211 billion	$167 billion
AARP Public Policy Institute estimate, assuming 34 million caregivers and a cost of $9.63 per hour (the average of the medium, low, and very low costs per hour)	$354 billion	

Source: AARP *Issue Brief*, "Valuing the Invaluable: A New Look at the Economic Value of Family Caregiving," 2007, at *http://assets.aarp.org/rgcenter/il/ib82_caregiving.pdf* (December 12, 2008).

Table 6 • B 2225 heritage.org

46. *Ibid.*
47. *Ibid.*
48. National Center for Policy Analysis, "Cost of Alzheimer's Care to Rise."
49. *Ibid.*

is not captured by wages or other typical productivity measures.

Promising Therapies. New drug therapies hold great promise for treating Alzheimer's patients. Though Alzheimer's disease currently has no cure, there are several new treatments and medications that can delay Alzheimer's onset, as well as make life more livable for the millions of Americans with the disease. There are a number of Alzheimer's drugs currently approved and on the market; among them Aricept, Namenda, Exelon, and Razadyne. Each of these drugs is palliative—intended to reduce the severity of the symptoms rather than halting or delaying progression or postponing onset. However, this may be changed by novel approaches and intervention strategies using newer classes of Alzheimer's drugs, including secretase modulators and immunotherapy.

Estimates indicate that if the onset of Alzheimer's disease could be delayed by just one year there would be 210,000 fewer persons with Alzheimer's ten years later.[50] Leon *et al.* estimated that a one-month delay in the institutionalization of Alzheimer's patients could save as much as $1.12 billion annually.[51] Ernst *et al.* developed an economic model suggesting that if therapeutic intervention could slow disease progression to a two-point annual decline in the Mini Mental State Examination score of a moderately to severely demented person with Alzheimer's, then an annual cost of care savings of $3,700 could be realized.[52] Though the benefits of such therapeutic interventions are obvious, they require enormous investments in pharmaceutical research and development.

The Boom in "Boomers." America faces a demographic revolution; as the baby boom generation ages to retirement an increasing portion of the population will inevitably be constituted by those ages 65 and older. Without a doubt, this group of consumers will present an unprecedented demand for new drugs, including drugs to treat Alzheimer's disease. Studies estimate the number of Alzheimer's patients in the United States, now at 5 million, will triple between 2000 and 2040.[53]

Anticipating the demand associated with this emerging class of patients, pharmaceutical companies are now engaged in costly research to develop therapies intended to not only treat the symptoms of Alzheimer's, but to delay onset of the disease. As noted, it is estimated that a one-year delay would result in 210,000 fewer persons with Alzheimer's 10 years later.[54] Those effects are rippled when the cost of care is considered. A short delay of just one month is estimated to yield an annual savings of as much as $1.12 billion a year in terms of hospital or other institutional costs for Alzheimer's patients.[55] Other studies suggest even modest improvements in therapeutic intervention could result in an annual cost of care savings of $3,700 per patient.[56]

Conclusion

Scientific research to develop delay-onset drugs for disease is extremely risky in terms of anticipated success and expected return. Pharmaceutical companies are more likely to invest in projects that yield the highest expected return—an expectation which is determined by how likely those projects are to succeed and increase consumer demand. In this

50. Brookmeyer, Gray, Kawas, "Projections of Alzheimer's Disease in the United States and the Public Health Impact of Delaying Disease Onset."
51. Joel Leon, Chang-Kuo Cheng, and Peter J. Neumann, "Alzheimer's Disease Care: Costs and Potential Savings," *Health Affairs,* Vol. 17 (1998), pp. 206–16.
52. Richard L. Ernst, Joel W. Hay, Catherine Fenn *et al.*, "Cognitive Function and the Costs of Alzheimer's Disease," *Archives of Neurology*, Vol. 54 (1997), pp. 687–693.
53. Brookmeyer, Gray, and Kawas, "Projections of Alzheimer's Disease in the United States and the Public Health Impact of Delaying Disease Onset."
54. *Ibid.*
55. Leon, Cheng, and Neumann, "Alzheimer's Disease Care: Costs and Potential Savings."
56. Ernst, Hay, Fenn *et al.*, "Cognitive Function and the Costs of Alzheimer's Disease."

case, the increasing demand for delay-onset drugs is driven by pending demographic shifts.

Given this demand expectation for new drugs, pharmaceutical firms have been willing to invest in less-promising projects (such as delay-onset) in addition to the projects they believe will succeed. Funding for such ventures comes, in part, from profits yielded by Medicare Part D sales. Given a reduction in return on investment, a reduction in innovation is sure to follow. Clearly, the public pricing scheme used to pay for drugs invented and developed in the private market strongly affects the level of innovation.

In addition to affecting innovation, extending the "negotiation" power has a high potential to affect private prices. When government provides private firms with a large part of their returns from innovation, pricing policy is not innocuous. As discussed, public pricing is based solely on reference pricing, with private pricing serving as the scale. Were Medicare "negotiation" to be statutorily permitted, the private "best prices" against which public prices are benchmarked, would no doubt increase. In addition, guaranteeing "below average" prices for federally procured drugs when public purchases constitute nearly half the market share would be mathematically impossible without seriously raising the price for privately procured pharmaceuticals.

Price setting by the Secretary of Health and Human Services on behalf of Medicare Part D beneficiaries is politically attractive, but it is bad health policy. It is rife with potential hazards. Without question, pharmaceutical revenue—and R&D as a function of total revenue—would be reduced. The potential for numerous and varied residual effects on the treatment of disease, progress in reducing costly morbidity, and reductions of the quality of care for the next generation of retirees is—or should be—of even greater concern.

—Cheryl S. Smith is a Strategic Plan Development Manager for Health System Reform for the State of Utah, and a former Health Policy Fellow at the Center for Health Policy Studies at The Heritage Foundation. Laura L. Summers is a recent graduate of Brigham Young University with a Master's in Public Policy.