



**IMPACT OF A PROPOSED PATENT RESTORATION
UNDER HATCH-WAXMAN ON FEDERAL BUDGET AND
HOSPITAL COSTS**

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**PricewaterhouseCoopers
1301 K Street NW
Washington, DC 20005**

Executive Summary

The Medicines Company asked PricewaterhouseCoopers (PwC) to estimate the impact on the federal budget and hospitals of proposed legislation that would enable patent restoration for its drug Angiomax under the Hatch-Waxman Act upon the payment of a fee. The proposal would authorize the Director of the Patent and Trademark Office (PTO) to accept certain applications filed after current statutory deadlines if the Director determines that such delay was unintentional and the applicant petitions PTO within a specified time frame. Under the proposal, which passed the House as H.R. 6344 in 2008 (which modified the provision reported by the Senate Judiciary Committee in S. 1145 in 2008), any affected company would be subject to a fee that would offset the federal budgetary impact of restoring the patent. In the case of Angiomax, the proposal establishes that fee at \$65 million.

For purposes of this analysis, PwC has reviewed the official budget estimate of the patent restoration provision in S. 1145 that was published by the Congressional Budget Office (CBO) in February 2008. In addition, PwC has also reviewed a recent study of the impact on hospital costs of Angiomax and its alternatives that was conducted on more than 400,000 patients in the Premier Hospital System.

PricewaterhouseCoopers' findings are as follows:

- **The impact on the federal budget would be neutral or reduce the deficit within the 10-year Congressional budget window FY2009-FY2018.**
 - The federal costs and lost tax revenues from restoring the Angiomax patent, estimated to total \$49 million by CBO in its February 2008 budget estimate of Angiomax patent restoration, would be fully offset by the Angiomax \$65 million fee (after accounting for interactions with other taxes in the economy).
 - Applying the savings demonstrated in the Premier study, the restoration of the Angiomax patent and \$65 million fee payment (\$49 million net) would decrease the deficit by a net amount of \$83 million over the FY2009-FY2018 period and by \$400 million over the FY2009-FY2028 period.
- **Patent term restoration bends the healthcare cost curve downward by lowering hospital costs.**
 - Based on the same assumptions used by CBO last year, PricewaterhouseCoopers estimates that the hospital savings generated by patent restoration would exceed the costs over a 20-year period (see Appendix for a discussion of PwC's methodology and assumptions).
 - Applying the savings demonstrated in the Premier study, we further find that the patent restoration for Angiomax would reduce hospital costs by \$700 million in the first 10 years and \$7.0 billion over a 20-year period.

Impact on the Federal Budget

Restoring the patent for Angiomax with the \$65 million fee would be neutral or would reduce the federal budget deficit. In 2008 CBO estimated the costs of the almost five-year restoration as follows:

- Increases in federal mandatory spending of \$19 million over the period FY2010-FY2018, particularly for Medicaid and retirees' premiums under the Federal Employees Health Benefits program;
- Lost federal revenues of \$30 million over the period FY2010-FY2018, the result of higher health insurance premiums, which would increase the amount spent by employers for tax-favored health insurance and reduce the amount spent on taxable wages.

The proposed fee of \$65 million would offset the increased spending and lost revenues as estimated by CBO. Specifically, the gross fee of \$65 million would be collected from the patent holder in FY2010 assuming prompt enactment of the proposal. The net government receipts under CBO conventions would be \$49 million, the amount needed to offset the increased spending and lost tax revenues.¹

Additionally, applying the savings established in the Premier data, patent restoration would result in net savings to the federal government of \$34 million. Combined with the \$65 million fee (\$49 million net), the budget savings over the 10-year budget period FY2009-FY2018 would be \$83 million, providing funding potentially available for appropriation.²

Impact on Hospital Costs: Bending the Curve Downward

Restoring the patent term for Angiomax would have two major effects on hospital spending. First, restoration of the patent would delay entry of a generic equivalent for almost five years and increase hospital costs for the drug during that period. Second, restoration of the patent would increase the number of patients treated with Angiomax (as a result of further marketing and education regarding the proper use of Angiomax), which would lead to increased hospital savings to offset the increased drug costs (CBO recognized, based on the data then available, that total hospital costs with use of Angiomax are lower than with other drug therapies). The patent restoration would also encourage the additional research that is necessary to obtain FDA approval for new uses of Angiomax in areas such as open heart surgery, peripheral artery disease, and stroke. CBO recognized hospital savings for additional patients treated with Angiomax in its estimates, but limited its analysis to the 10-year budget window as explained in its February 2008 cost estimate.

Extending CBO's Analysis. CBO estimated that the net cost to hospitals of patent restoration would be about \$1 billion over the FY2009-FY2018 period. During the next 10-year period, FY2019-FY2028, PricewaterhouseCoopers estimates, based on CBO's same assumptions that the additional use of brand and generic versions of Angiomax would result in savings to hospitals that exceed the predicted increases in drug costs. Specifically, under patent restoration, the \$1.5 billion of additional costs of Angiomax (or generic bivalirudin) during the period FY2019-FY2028 would save hospitals \$3.5 billion in other costs for a net savings of \$2.0 billion in that second 10-year period. On a net basis, hospitals would save \$1.0 billion from patent restoration over the 20-year period, FY2009-FY2028. Net savings would continue to accrue in all future years. See 2008 CBO Assumptions in Exhibit A below.

Applying Findings from the Premier Data. Since CBO completed its estimate, the Premier data on Angiomax has shown that the actual net cost savings to hospitals from using Angiomax are larger than previously estimated. PricewaterhouseCoopers has recalculated the impact of the legislation using the higher savings figures. With the more recent Premier data, we estimate net hospital savings over the first 10 years, FY2009-FY2018, of \$700 million and net hospital savings for the full 20-year period of \$7.0 billion. See 2009 Data in Exhibit A below.

¹ CBO assumes an offset of 25 percent to the gross fee to account for interactions with other taxes in the economy.

² The \$83 million is the sum of the \$34 million in savings established by the Premier data and the \$49 million net fee.

Exhibit A

Hospital Costs and Savings Under Patent Restoration FY2009 to FY2028			
<i>Savings (Costs) in \$ Billions</i>	Fiscal Years		
	2009-2018	2019-2028	2009-2028
Based on 2008 CBO Assumptions			
Gross Costs (Prescription Drugs)	(\$2.3)	(\$1.5)	(\$3.9)
Savings in Other Hospital Costs	<u>\$1.3</u>	<u>\$3.5</u>	<u>\$4.8</u>
Net Hospital Savings (Costs)	(\$1.0)	\$2.0	\$1.0
Based on 2009 Data			
Gross Costs (Prescription Drugs)	(\$2.3)	(\$1.5)	(\$3.9)
Savings in Other Hospital Costs	<u>\$3.0</u>	<u>\$7.9</u>	<u>\$10.9</u>
Net Hospital Savings	\$0.7	\$6.4	\$7.0

Note: Numbers may not sum to totals due to rounding.
Source: PricewaterhouseCoopers 2009.

Impact of a Proposed Patent Restoration under Hatch-Waxman on Federal Budget and Hospital Costs

The Medicines Company asked PricewaterhouseCoopers (PwC) to estimate the impact on the federal budget and hospitals of proposed legislation that would enable patent restoration for its drug Angiomax under the Hatch-Waxman Act upon the payment of a fee.

The proposed legislation, which passed the House as H.R. 6344 in 2008 (which modified the provision reported by the Senate Judiciary Committee in S. 1145 in 2008), would authorize the Director of the Patent and Trademark Office (PTO) to accept certain applications filed after current statutory deadlines if the applicant petitions PTO within a specified time frame and the Director determines that the applicant's delay was unintentional. Under the proposal, any affected company would be subject to a fee that would offset the federal budget costs of restoring its patent.

Specifically, this provision could lead PTO to accept an application for restoration of the patent term for Angiomax (bivalirudin), an anticoagulant used in conjunction with certain coronary procedures in hospital settings. The Medicines Company, which holds the patent for Angiomax, missed the statutory filing deadline for its application to restore the patent term authorized under the Drug Price Competition and Patent Term Restoration Act. Under the proposed bill, PTO could grant nearly five years of additional patent protection to Angiomax upon payment of a fee. In the case of Angiomax, the proposal establishes that fee at \$65 million.

Impact on the Federal Budget

Background

The patent for the anticoagulant Angiomax will expire in March 2010; however, the drug has received an additional six months of exclusivity under the FDA's pediatric exclusivity program, bringing the exclusivity date up to September 2010. If PTO accepted the late application under the new authority provided by the proposed bill, the patent term would be extended until December 2014, and exclusivity would be extended to May 2015 taking into account the pediatric program.

According to the Congressional Budget Office's (CBO) 2008 official budget estimate of the patent restoration provision in S. 1145, delaying the entry of generic versions of Angiomax by nearly five years would have two effects on hospitals' costs as follows:

- Increase the average price paid for the drug by hospitals for patients receiving Angiomax.
- Reduce hospital costs for services furnished to additional patients who would be treated with the drug as a result of additional marketing and educational efforts, which the company will not undertake if it loses its patent in 2010 (total hospital costs for individuals treated with Angiomax in its current uses are lower than costs for individuals whose treatment involves alternative drug therapies).

In addition, the Angiomax patent restoration will also likely reduce hospital costs in new treatment areas to which the drug's use would be expanded, because the manufacturer would have the economic incentive to invest in the testing necessary to receive FDA approval for the use of Angiomax in these new treatment areas.

Budget Impact under Congressional Budget Office's 2008 Estimate--Budget Neutral

CBO estimated the 10-year budget cost of the Angiomax patent restoration at \$49 million over the FY2009-FY2018 budget period.³ Its estimate accounted for increases in federal mandatory spending of \$19 million over the period FY2010-FY2018, particularly under Medicaid and for retirees' premiums under the Federal Employees Health Benefits program. The CBO estimate also included lost federal revenues of \$30 million over the period FY2010-FY2018, the result of higher health insurance premiums, which CBO estimated would increase the amount spent by employers for tax-favored health insurance and reduce the amount spent on taxable wages.

The proposed fee of \$65 million would offset the federal budget impact estimated by CBO. Specifically, the gross fee of \$65 million would be collected from the patent holder in FY2010 assuming prompt enactment of the proposal. The net collections under CBO scoring conventions would be \$49 million, the amount needed to offset the increased spending and lost tax revenues.⁴

With the fee offset, the proposed legislation would result in net federal budget savings over the 20-year period, FY2009-FY2028. Specifically, as discussed above, accounting for the fee offset, there would be no net federal budget cost from enactment of this legislation over the FY2009-FY2018 period. Hospital cost savings in the FY2019-FY2028 period, described in more detail in the following sections, would result in net federal budget savings over the 20-year period, FY2009-FY2028.

Budget Impact after Incorporating New Data--\$83 Million Savings

PricewaterhouseCoopers also reviewed the findings from a study of more than 400,000 patients who were treated with heparin or Angiomax in various combinations in the Premier Hospital System. Using the Premier data, Professor Daniel Kessler of Stanford University found that using Angiomax (bivalirudin) alone compared to the typical treatment of heparin results in net savings per patient that are significantly higher than the savings assumed by CBO.⁵

If the Premier savings data are taken into account, patent restoration would result in savings to the federal government of \$34 million, during the FY2009-FY2018 period. Combined with the \$65 million fee (\$49 million net), the budget savings would be \$83 million in the first 10 years, FY2009-FY2018, providing funds that would potentially be available for other spending.⁶ Budget savings would continue and grow in subsequent periods. The budget savings, including the fee, would be \$317 million in the next 10-year period, FY2019-FY2028.

Impact on Hospital Costs: Bending the Cost Curve Downward

Current projections of U.S. spending on healthcare present a path that is unsustainable. One of the principal goals of healthcare reform is to "bend the cost curve," that is, reduce the growth of healthcare costs. To investigate whether the proposed legislation would bend the growth curve, PricewaterhouseCoopers estimated the impact in terms of the net cost to hospitals after accounting for the increases in prescription drug costs due to the restoration of the patent, offset by reductions in other hospital costs from additional use of Angiomax that would occur if the patent were restored. Our analysis shows that extending the Angiomax patent bends the curve downward whether we base our analysis on assumptions that are consistent with CBO's 2008 estimate or on assumptions consistent with the more recent Premier study (see Appendix for PwC's methodology and assumptions, as well as for a sensitivity analysis).

³ Congressional Budget Office, "S. 1145: Patent Reform Act of 2007," Cost Estimate, February 15, 2008. The Congressional Budget Office estimate assumes that Angiomax is the only drug affected by S. 1145. S. 1145 did not include the fee included in H.R. 6344.

⁴ CBO assumes an offset of 25 percent to the gross fee to account for interactions with other taxes in the economy.

⁵ Kessler, et al., "Effects of Bivalirudin on Costs and Outcomes of Treatment for Cardiac Illness," unpublished study provided by Professor Daniel Kessler, Stanford University, August 2009.

⁶ The \$83 million is the sum of the \$49 million net fee and the \$34 million in savings established by the Premier data.

Extending CBO’s Analysis--Long-term Savings. Our model results, based on CBO assumptions, are summarized in the first panel of Exhibit 1 below and replicate published estimates from CBO in 2008. During the first 10-year budget period, FY2009-FY2018, hospitals would have additional prescription drug costs of \$2.3 billion, which would be offset by savings in other hospital costs of about \$1.3 billion due to additional use of Angiomax under the patent restoration. The net costs of \$1.0 billion match CBO’s official estimates in 2008. During the next 10-year period, FY2019-FY2028, PricewaterhouseCoopers estimates that the additional use of Angiomax would result in higher drug costs, but savings to hospitals would continue and significantly exceed the drug costs. As a result, under patent restoration, the \$1.5 billion of additional use of Angiomax (or generic bivalirudin) during the period FY2019-FY2028 would save hospitals \$3.5 billion in other costs for a net savings of \$2.0 billion in the second 10-year period. Accordingly, consistent with CBO’s analysis, hospitals, on net, would save \$1.0 billion from patent restoration over the 20-year period, FY2009-FY2028. Net savings would continue to accrue in all future years.

Applying the Premier Data--Short-term and Long-term Savings. The CBO estimate assumed that hospital spending falls by almost two dollars for each dollar spent on Angiomax. The more recent research based on the 2009 Premier data suggests that hospital costs fall an average of \$4.30 for each dollar spent. Keeping other assumptions consistent with CBO, the savings based on the 2009 study, therefore, would be \$700 million in the first 10 years and \$6.4 billion over the next 10 years (see the second panel in Exhibit 1). During the first 10 years, the gross costs would be the same as under the CBO assumptions, or about \$2.3 billion. However, the Premier data show that those costs would be more than offset by \$3.0 billion in savings to hospitals from greater use of Angiomax. The net savings in the second 10-year period would be greater, about \$6.4 billion after accounting for the cost of the drug, amounting to an estimated \$7.0 billion in hospital cost savings over the 20-year period (see Net Hospital Savings in Exhibit 1 below and Appendix for further detail on the savings established by the Premier data).

Exhibit 1			
Hospital Costs and Savings Under Patent Restoration FY2009 to FY2028			
Savings (Costs) In \$ Billions	Fiscal Years		
	2009-2018	2019-2028	2009-2028
Based on 2008 CBO Assumptions			
Gross Costs (Prescription Drugs)	(\$2.3)	(\$1.5)	(\$3.9)
Savings in Other Hospital Costs	<u>\$1.3</u>	<u>\$3.5</u>	<u>\$4.8</u>
Net Hospital Savings (Costs)	(\$1.0)	\$2.0	\$1.0
Based on 2009 Premier Data			
Gross Costs (Prescription Drugs)	(\$2.3)	(\$1.5)	(\$3.9)
Savings in Other Hospital Costs	<u>\$3.0</u>	<u>\$7.9</u>	<u>\$10.9</u>
Net Hospital Savings	\$0.7	\$6.4	\$7.0

Note: Numbers may not sum to totals due to rounding.
Source: PricewaterhouseCoopers 2009.

Summary

PricewaterhouseCoopers, based on assumptions incorporated by CBO in its estimate of the patent restoration legislation, estimates that hospitals would have net savings of roughly \$1 billion over the next 20 years if the patent for Angiomax was restored. PwC further estimates, based on more recent data, that hospitals would have savings of \$700 million in the first 10 years and \$7.0 billion over the 20-year period FY2009-FY2028 if the Angiomax patent is restored.

The impact of patent restoration would be neutral to the federal budget during in the FY2009-FY2018 period, under the CBO assumptions, given the \$65 million fee. Net savings in hospital costs accruing in the FY2019-FY2028 period would result in net federal budget savings over the 20-year period, FY2009-FY2028, even under the CBO assumptions. Further, using the assumptions about savings from the 2009 Premier data, patent restoration would result in \$83 million in net savings to the federal government in the first 10 years as well.

Appendix: Methodology and Sensitivities

PricewaterhouseCoopers' Base Case Estimate

PricewaterhouseCoopers developed its "base case" estimate of the 20-year impact of the patent restoration on hospital costs by building a model based on the official Congressional Budget Office (CBO) cost estimate of the patent restoration provision in S. 1145 issued in February 2008. To do this, PwC incorporated all the assumptions used by CBO in its official cost estimate and extended them for an additional 10 years. We discussed the CBO methodology and assumptions with CBO staff at a meeting on February 5, 2008 and in various telephone conversations. Finally, in several areas where additional information was needed for the model, PwC included information from the literature on prescription drug patents and information supplied by The Medicines Company.

PricewaterhouseCoopers tested the accuracy of its finished model by comparing the 10-year estimates of hospital spending with those quoted by CBO in its official cost estimate of hospital spending on the drug and resulting savings to hospitals in other patient-care costs. The PwC base case model is consistent with the CBO cost estimate that found hospitals would spend about \$2 billion more for the drug and save about \$1 billion in other patient-care costs over the FY2009-FY2018 period.

Exhibit 2 below provides a summary of the key assumptions in the PwC base case estimate along with an indication of the magnitude of the assumptions and their sources. Many of the key assumptions are the ones used by CBO. For example, CBO provided us with their specific assumptions about Angiomax (brand and generic) revenues during FY2010-FY2012 in the absence of a patent restoration. Other assumptions were developed by PwC to match certain features of the CBO estimate. For example, the 5.5% growth rate for Angiomax revenues during FY2013-FY2028 under current law is based on the CBO growth rate between FY2011 and FY2012, the last years for which CBO provided us explicit revenue assumptions. PwC's assumptions about the additional use of Angiomax under the patent restoration are calibrated to match the CBO estimate (approximately 17% higher utilization). Our estimate that additional use of Angiomax under the patent restoration would reduce hospital costs by \$1.92 for each additional \$1 in Angiomax treatments (92 cents net savings after accounting for the cost of Angiomax) is also calibrated to the CBO score.⁷ Finally, the PwC estimate adopts the CBO assumption that the additional use of Angiomax would arise from more aggressive marketing efforts by the manufacturer under the patent restoration. The drug's use could also be expanded to new treatment areas, because The Medicines Company would have the economic incentives to invest in the testing necessary to receive FDA approval for the use of Angiomax in these new treatment areas. It is our understanding that CBO did not directly incorporate potential savings from this expansion in their analysis and our estimates did not either.

⁷ PwC estimated that Angiomax use would expand by roughly \$500 million over the FY2011-FY2018 period. This \$500 million times \$1.92 equals \$960 million, i.e., approximately the \$1 billion estimated by CBO.

Exhibit 2

Key Assumptions Behind PricewaterhouseCoopers Base Case Estimate		
	Assumption	Source
Angiomax/Bivalirudin Revenues Under Current Law (Valued at Brand Price)		
FY2010	\$500 M	Conversation with CBO Staff
FY2011	\$550 M	Conversation with CBO Staff
FY2012	\$580 M	Conversation with CBO Staff
Growth rate FY2013-FY2028	5.5% per year	Calculated Growth Rate FY2011-FY2012
Generic Penetration and Relative Price		
Price Discount	75%	Conversation with CBO Staff
Market Share	90%	Conversation with CBO Staff
Transition Period	5 years	Conversation with CBO Staff
Angiomax /Bivalirudin Revenues Under Proposal		
Percent Increase in use from Baseline	17%	Calibrated to CBO estimate
Savings from Increased Use	\$1.92 per \$1.00	Conversation with CBO Staff
Ultimate Market Share of Brand	10%	Conversation with CBO Staff
Patent Restoration Period		
Angiomax	Oct 2010 to May 2015	The Medicines Company, adopted by CBO

Source: PricewaterhouseCoopers 2009.

Savings Based on Premier Hospital Study

In addition to its base case model, PricewaterhouseCoopers reviewed the findings from a study of more than 400,000 patients who were treated with heparin or Angiomax in various combinations.⁸ The data, which were collected by Premier Hospital System, were analyzed by Professor Daniel Kessler of Stanford University, who provided the unpublished results to PricewaterhouseCoopers.

The Premier study shows that using Angiomax (bivalirudin) alone compared to the typical treatment of heparin results in net savings of \$2,443 per patient. The savings in practice are likely to be lower because bivalirudin is sometimes used with glycoprotein inhibitors (GPI), a combination which results in a net savings of only \$1,038 per patient according to the study. Marketing and education efforts by the manufacturer, if the patent was restored, would probably lead to uses of Angiomax and GPI's that would produce savings somewhere in between the two values. The PricewaterhouseCoopers' findings in Exhibit 1 above are based on the assumption that the net savings would be roughly \$1,700 per use, so each dollar spent on Angiomax would lower hospital costs by approximately \$4.30 per dollar (\$3.30 net savings after accounting for the cost of Angiomax). Applying only this change to the CBO assumptions (i.e., \$4.30 in place of \$1.92) results in estimated savings of \$700 million during the FY2009-FY2018 period and savings of \$6.4 billion over the FY2019-FY2028 period.

⁸ Kessler, et al., "Effects of Bivalirudin on Costs and Outcomes of Treatment for Cardiac Illness," unpublished study provided by Professor Daniel Kessler, Stanford University, August 2009.

Additional Sensitivity Tests

PricewaterhouseCoopers also investigated the impact on net hospital costs under an alternative assumption about the price of generic bivalirudin compared to the price of branded Angiomax, which is shown in Exhibit 3. The net hospital savings (costs) in the CBO estimate and PwC's base case are based on the CBO's assumption that the generic price of bivalirudin, after a transition period of about five years, would be 75% less than that for branded Angiomax, which is consistent with the experience of branded prescription drugs that have low manufacturing costs and many generic competitors in the market after two years.⁹ The Medicines Company believes that fewer generic companies will enter the market for generic bivalirudin because the manufacturing process is complicated and expensive and the market may not be sufficiently large. If that is correct and the generic price for bivalirudin fell by 50% instead of 75% without the patent restoration, the net cost to hospitals during the budget period FY2009 to FY2018 would be about \$500 million instead of CBO's estimate of about \$1 billion. The 20-year net savings would be \$1.4 billion instead of net savings of \$1 billion under the CBO assumptions. See the "CBO Savings Assumption" panel in Exhibit 3 below.

If the savings assumption is revised to reflect the Premier data, as shown in the Revised Savings Assumption panel of Exhibit 3, patent restoration results in net hospital savings in the first 10-year period of \$700 million under the assumption that the generic price discount is 75% (as discussed above) and \$1.2 billion under the assumption that the generic discount is only 50%. Total hospital savings over the 20-year period are \$7.0 billion under the assumption that the generic price discount is 75% and \$7.5 billion under the assumption that the generic discount is only 50%.

Exhibit 3

Net Hospital Savings under Patent Restoration Alternative Scenarios for Generic Price and Savings Per Treatment FY2009 to FY2028			
Savings (Costs) in \$ Billions	Fiscal Years		
	2009-2018	2019-2028	2009-2028
CBO Savings Assumption			
CBO Assumption (75% Generic Discount)	(\$1.0)	\$2.0	\$1.0
Alternative Assumption (50% Generic Discount)	(\$0.5)	\$1.9	\$1.4
Revised Savings Assumption (2009)			
CBO Assumption (75% Generic Discount)	\$0.7	\$6.4	\$7.0
Alternative Assumption (50% Generic Discount)	\$1.2	\$6.3	\$7.5

Note: Numbers in columns may not sum to totals due to rounding.

Source: PricewaterhouseCoopers estimates 2009.

The net budget costs to the federal government over the 10-year budget period FY2009 to FY2018, given the \$65 million fee (\$49 million net), is zero under the CBO assumption about hospital savings from the use of Angiomax and the 75% generic price discount (not shown in Exhibit 3). Under all other assumptions, the \$65 million fee would result in net federal budget savings over the 10-year budget period FY2009-FY2018. Under all assumptions, patent restoration results in a net federal budget savings over the 20-year period FY2009-FY2028.

⁹ For example, see Berndt, et al., "Authorized Generic Drugs, Price Competition, and Consumers' Welfare," *Health Affairs*, May/June 2007.



For information about this report, contact:

Jack Rodgers
PricewaterhouseCoopers
1301 K Street NW
Washington, DC 20005
Telephone: (202) 414-1646
Jack.Rodgers@us.pwc.com