

Medicare Part D Plans Deliver Significant Savings on Innovative, Breakthrough Medicines

Survey Finds Private Sector Negotiations Provide Both Savings and Choice, Making Government Interference Unnecessary

As a result of Part D, over 39 million Medicare beneficiaries now have comprehensive prescription drug coverage. Part D enrollees are saving an average of \$1,200 per year on the cost of their medications, and over 80% are satisfied with their plan. Marketplace competition under Part D has produced significant savings for beneficiaries and taxpayers, as well as expanded choices for patients and their doctors. Overall, Part D savings have been much larger than anticipated. Average beneficiary premiums dropped to \$22 per month in 2007, which is 42% below original estimates. In addition, the CMS actuary recently projected \$113 billion in Part D savings over the next 10 years, with \$96 billion directly attributable to competition leading to lower-than-expected plan bids.¹ Lower Part D bids have largely been driven by plans' ability to secure substantial price discounts and rebates on drugs furnished to Medicare beneficiaries. This is the case for medicines that treat the most common conditions afflicting the elderly population, as well as for innovative, breakthrough therapies that target cancer and other rare and devastating diseases. The significant discounts and beneficiary savings on innovative "single source" Part D medicines were found in a retail price survey conducted by BIO using publicly available information. These savings demonstrate that mandatory government negotiation for such therapies is unnecessary, and would likely lead to reduced patient access to current and future medical breakthroughs without providing significant savings.

Summary:

- **Part D plans negotiate significant discounts on single-source therapies.** Part D plans were effective at negotiating discounts on the innovative, single-source therapies we surveyed. The average mail-order Part D prices for a broad range of breakthrough therapies covered by five large national prescription drug plans (PDPs) were found to be as much as 20% lower than drugstore.com and 17% lower than Costco internet mail-order cash prices. These discounts equated to average Part D savings of nearly \$137 per therapy per month compared to drugstore.com and \$142 per therapy per month compared to Costco.
- **The Part D benefit structure provides even greater savings for Medicare beneficiaries at the pharmacy counter.** The vast majority of beneficiaries pay much less than the negotiated Part D retail prices when they fill their prescriptions at the pharmacy. Negotiated discounts between manufacturers and Part D plans, combined with negotiated rebates, also translate to reduced beneficiary monthly premiums and cost-sharing amounts. When actual out-of-pocket spending on drugs covered under Part D is compared to cash prices for those drugs, beneficiary savings are much greater.

- **Part D plans provide access to a wide array of innovative therapies.** Like the Department of Veterans Affairs (VA) pharmacy benefit, the discount internet mail-order pharmacies Costco and drugstore.com limit the availability of certain breakthrough medicines, including several of the latest cancer therapies, which are widely available to Medicare beneficiaries under Part D. Marketplace competition under Part D provides Medicare beneficiaries with both expanded access to cutting-edge treatment options and significant savings.

Background:

Senators Ron Wyden and Olympia Snowe recently introduced a bill (S. 250) that would require the federal government to negotiate directly with the manufacturers of “single source drugs without therapeutic equivalents” covered under Part D. This category of therapies, while accounting for only a small share of overall drug spending, includes “first-in-class” breakthrough therapies that have become the standard of care for a variety of rare and devastating diseases. Sens. Wyden and Snowe claim that private plans are unable to negotiate significant price discounts on Part D drugs.² In a January 22 letter to the editors of the *Washington Post*, Sens. Wyden and Snowe also contend that the popular mail-order pharmacies Costco and drugstore.com offer even cheaper prices than Part D plans “without limiting the drugs available.”³

Previous studies have shown that Part D plans obtain average discounts of 27%, and as high as 56%, off the cash prices of common drugs, refuting claims by Sens. Wyden and Snowe that private plans are ineffective price negotiators.⁴ To date, however, comparative pricing analyses have focused on the drugs most commonly used by Medicare beneficiaries. The focus on such drugs is understandable, as over 73% of pharmaceutical spending in the 65 years and older population is concentrated in only 5 therapeutic classes in which there are a number of drugs that work in similar ways: cardiovascular agents, antihypertensives, hormones, central nervous system agents, and gastrointestinal agents.⁵ Because S. 250 would specifically require the federal government to negotiate on “one-of-a-kind” medicines for which there are few treatment alternatives, BIO performed a retail price survey to assess the Part D discounts offered by major national PDPs for a group of innovative, single-source drugs and biologics. The purpose of this survey was to determine whether the Part D marketplace was working to provide patient access and comparable discounts for these single-source therapies.

Methodology:

To conduct this survey, BIO selected a sample of 25 innovative drugs and biologics eligible for coverage under Medicare Part D (Exhibit 1). In identifying the therapies to include in our sample, we focused on oral and self-injected therapies developed by BIO member companies that treat serious and life-threatening diseases, including cancer, multiple sclerosis, HIV/AIDS, rheumatoid arthritis, osteoporosis, hepatitis C, chronic kidney disease, and organ transplant rejection. The drugs and biologics in our sample

represent some of the latest treatment breakthroughs for their respective diseases. A number of these therapies were granted “orphan” status by the FDA because they target a rare disease. Many of the therapies were also approved by the FDA under a “priority review,” because the agency deemed they serve an unmet clinical need or significantly improve upon the existing treatment options for a given disease.⁶

To obtain a comparative retail benchmark, we determined the cash prices for a typical monthly dosing regimen of each of the therapies in our sample at Costco and drugstore.com internet mail-order pharmacies.⁷ We focused our Part D price survey on five of the top nationwide PDPs by beneficiary enrollment in 2006.⁸ Using CMS’ Medicare.gov Prescription Drug Plan Finder, we obtained the negotiated mail-order prices for the monthly drug regimens available to beneficiaries under each PDP, and then calculated an average for each drug regimen across all five plans. The PDP prices listed on the Medicare.gov Web site represent the negotiated prices beneficiaries would pay if they were exposed to the full cost of their Part D drugs (i.e., when they are in the “doughnut hole”). Since the Costco and drugstore.com prices available online are available on internet-only mail-order prescriptions, we compared their prices to the PDP mail-order prices, to provide an “apples-to-apples” comparison.⁹ Exhibit 2 displays the results of our survey for each of the single-source therapies we selected.

Key Findings:

The negotiated Part D prices for all of the single-source therapies in our survey were lower than the cash prices available through Costco and drugstore.com. The Part D negotiated prices for the innovative drugs in our sample were on average 11.6% lower than Costco prices and 10.5% lower than drugstore.com prices. The dollar amounts associated with these savings were also quite substantial, averaging \$141.75 and \$136.93 per therapy per month compared to Costco and drugstore.com, respectively. The savings available through the lowest Part D negotiated drug prices from among the five plans were as high as 23% compared to Costco and 26% compared to drugstore.com for individual therapies. In addition, a comparison between the cash prices charged by national chain retail pharmacies in three states, California, Missouri, and Florida, and the negotiated retail prices available under the PDPs included in our survey revealed even greater savings under Part D, averaging 17% across the innovative therapies in our sample. These results confirm that Part D plans are able to effectively negotiate discounts with manufacturers for innovative, single-source therapies. The discounts obtained for our survey of innovative therapies were comparable to the substantial Part D savings for more commonly prescribed brand-name drugs reported in prior studies.

The actual savings to Medicare beneficiaries are much greater than those reflected in the negotiated Part D retail and mail-order prices. The savings reported in Exhibit 2 are based on comparisons between the full negotiated Part D mail-order list prices and the discount cash prices charged by Costco and drugstore.com. Also not reflected in

negotiated Part D list prices are the rebates plans receive from manufacturers, which are an important contributor to the lower-than-expected premiums and costs of Part D coverage. In addition, Medicare beneficiaries filling their Part D prescriptions at the pharmacy are exposed to a far lesser share of their drugs costs because of cost-sharing. It is only when enrollees must satisfy a plan deductible or enter the “doughnut hole” that they are exposed to the full Part D negotiated drug prices. However, a 2006 study by PricewaterhouseCoopers found that only 8% of all Medicare beneficiaries are affected by the “doughnut hole.”¹⁰ In addition, in 2007, beneficiaries had more opportunities to enroll in plans that provided gap coverage.

Certain single-source therapies from our sample were not available through either Costco or drugstore.com, and were also left off the VA national formulary. Contrary to the previous statements made by Sens. Snowe and Wyden in their January 22 *Washington Post* letter to the editor, this analysis found that the Costco and drugstore.com internet mail-order pharmacies *do* limit the drugs they make available to customers. For example, neither drugstore.com nor Costco offered three of the latest, targeted cancer treatments, Sutent, Nexavar, and Sprycel, which were all found on every PDP formulary we examined. These and other therapies we analyzed were also not available under the VA national formulary (Exhibit 1), which is used by the VA to secure additional discounts from manufacturers. Studies have shown that the VA national formulary restricts access to some of the latest, cutting-edge treatments, including many single-source drugs and biologics.

Conclusion:

The findings from this survey highlight the effectiveness of the competitive forces operating under Part D to achieve enhanced patient access to new and innovative medicines while containing costs for beneficiaries and taxpayers. Contrary to claims made by proponents of direct government negotiation under Part D, a comparison between the prices available under the top PDPs and those available through discount mail-order pharmacies Costco and drugstore.com reveal that private plans are able to negotiate significant discounts for innovative therapies. Part D plans also secure additional rebates from manufacturers that are not reflected in the negotiated retail and mail-order list prices for drugs, but rather, are passed on to beneficiaries in the form of lower monthly premiums and reduced cost-sharing amounts. Unlike the VA and the internet-only discount pharmacies we surveyed, in addition to savings, Part D provides beneficiaries with expanded access to many of the latest medical breakthroughs, including those targeting cancer. Thus, proposals that call for mandatory government interference in determining prices for drugs covered under Part D, such as S. 250, will only undermine the current success of the program, and harm seniors’ access to innovative medicines.

Exhibit 1: Sample of Single-Source Part D Therapies

Innovative, Single-Source Drugs and Biologics Included in the Survey, with VA Formulary Status and Additional Information

Medication	Indication	On VA National Formulary? ¹¹	Additional Notes*
Tarceva (erlotinib)	Non-small cell lung and pancreatic cancer	No	PR
Gleevec (imatinib)	Chronic myeloid leukemia (CML) and gastrointestinal stromal tumor (GIST)	Yes (with restrictions)	PR, O
Sutent (sunitinib)	Advanced renal cell carcinoma (RCC) and gastrointestinal stromal tumor (GIST)	No	PR
Sprycel (dasatinib)	Chronic, accelerated, or myeloid or lymphoid blast phase CML with resistance or intolerance to prior therapy; Philadelphia chromosome-positive acute lymphoblastic leukemia with resistance to prior therapy	No	PR, O
Nexavar (sorafenib)	Advanced renal cell carcinoma (RCC)	No	PR, O
Revlimid (lenalidomide)	Multiple myeloma and deletion 5q myelodysplastic syndromes (MDS)	No	PR, O
Femara (letrozole)	Postmenopausal women with hormone receptor positive early breast cancer	No	PR
Targretin (bexarotene)	Cutaneous manifestations of cutaneous T-cell lymphoma	No	PR, O
Thalomid (thalidomide)	Multiple myeloma and erythema nodosum leprosum (ENL)	No	PR, O
Aromasin (exemestane)	Postmenopausal women with estrogen receptor positive early breast cancer	No	O
Enbrel (etanercept)	Rheumatoid arthritis; psoriatic arthritis; ankylosing spondylitis; psoriasis	No	
Humira (adalimumab)	Rheumatoid arthritis; psoriatic arthritis; ankylosing spondylitis	No	
Raptiva (efalizumab)	Chronic moderate to severe plaque psoriasis	No	
Sensipar (cinacalcet HCL)	Secondary hyperparathyroidism in patients with chronic kidney disease (CKD) on dialysis; hypercalcemia in patients with parathyroid carcinoma	No	PR, O
Renagel (sevelamer HCL)	Control of serum phosphorus in patients with CKD on hemodialysis	Yes	
Avonex (Interferon beta -1a)	Relapsing forms of multiple sclerosis	Yes	
Betaseron (Interferon beta-1b)	Relapsing forms of multiple sclerosis	Yes	
Copaxone (glatiramer acetate)	Relapsing-remitting multiple sclerosis	Yes	
Forteo (teriparatide)	Postmenopausal women with osteoporosis who are at high risk for fracture	No	
Pegasys (peginterferon alfa 2a)	Chronic hepatitis C virus infection	Yes	
CellCept (mycophenolate mofetil)	Prophylaxis of organ rejection in patients receiving allogeneic renal, cardiac or hepatic transplants	Yes	PR
Prograf (tacrolimus)	Prophylaxis of organ rejection in patients receiving allogeneic liver, kidney, or heart transplants	Yes	PR, O
Rapamune (sirolimus)	Prophylaxis of organ rejection in patients aged 13 years or older receiving renal transplants	Yes	PR
Fuzeon (enfuvirtide)	HIV-1 infection in combination with other antiretroviral medications	Yes	PR
Reyataz (atazanavir sulfate)	HIV-1 infection in combination with other antiretroviral agents	Yes (with restrictions)	PR

*PR=Priority Review Status; O=Orphan Drug Status

Exhibit 2: PDP Negotiated Mail-Order Savings

Average Price Discounts on Innovative Therapies under Part D Compared to Cash Prices Listed at Costco and drugstore.com Internet Pharmacies*

Medication	Strength	Quantity	Compared to Costco		Compared to drugstore.com	
			% Savings	Dollar Savings	% Savings	Dollar Savings
Tarceva (erlotinib)	150 mg	30 tablets	-9%	\$265.84	-16%	\$541.81
Gleevec (imatinib)	100 mg	30 tablets	-5%	\$33.45	-12%	\$91.03
Sutent (sunitinib)	50 mg	30 capsules	<i>Not Available at Costco</i>		<i>Not Available at drugstore.com</i>	
Sprycel (dasatinib)	70 mg	60 tablets	<i>Not Available at Costco</i>		<i>Not Available at drugstore.com</i>	
Nexavar (sorafenib)	200 mg	120 tablets	<i>Not Available at Costco</i>		<i>Not Available at drugstore.com</i>	
Revlimid (lenalidomide)	10 mg	30 tablets	<i>Not Available at Costco</i>		<i>Not Available at drugstore.com</i>	
Femara (letrozole)	2.5 mg	30 tablets	-8%	\$19.19	-5%	\$11.09
Targretin (bexarotene)	75 mg	100 capsules	-12%	\$285.43	-6%	\$126.95
Thalomid (thalidomide)	200 mg	28 capsules	<i>Not Available at Costco</i>		<i>Not Available at drugstore.com</i>	
Aromasin (exemestane)	25 mg	30 capsules	-15%	\$41.98	-9%	\$21.78
Enbrel (etanercept)	50 mg inj.	4 vials	-13%	\$192.11	-11%	\$157.10
Humira (adalimumab)	40 mg inj.	2 vials	-13%	\$180.11	-11%	\$157.10
Raptiva (efalizumab)	125 mg	4 vials	<i>Not Available at Costco</i>		<i>Not Available at drugstore.com</i>	
Sensipar (cinacalcet HCL)	30 mg	30 tablets	-17%	\$57.38	-14%	\$43.87
Renagel (sevelamer HCL)	800 mg	180 tablets	-13%	\$39.83	-9%	\$25.43
Avonex (Interferon beta -1a)	30 mcg inj.	4 vials	-12%	\$195.41	-3%	\$38.62
Betaseron (Interferon beta-1b)	0.3 mg inj.	15 vials	-14%	\$253.48	-10%	\$175.47
Copaxone (glatiramer acetate)	20 mg. inj	30 vials	-9%	\$144.00	-9%	\$140.98
Forteo (teriparatide)	750 mg inj.	3 mL pen	-9%	\$63.23	-20%	\$154.93
Pegasys (peginterferon alfa 2a)	180 µg inj.	4 vials	-7%	\$110.04	-11%	\$195.54
CellCept (mycophenolate mofetil)	500 mg	100 tablets	-14%	\$84.13	-5%	\$29.92
Prograf (tacrolimus)	5 mg	100 capsules	-12%	\$244.39	-17%	\$373.14
Rapamune (sirolimus)	1 mg	100 tablets	-16%	\$131.29	-6%	\$43.88
Fuzeon (enfuvirtide)	90 mg inj.	60 vials	-12%	\$257.13	<i>Not Available at drugstore.com</i>	
Reyataz (atazanavir sulfate)	150 mg	60 capsules	-11%	\$94.76	-15%	\$136.02
Average Savings Per Therapy Per Month:			-11.6%	\$141.75	-10.5%	\$136.93

*Part D plans achieve additional savings from negotiated rebates, leading to lower premiums and lower costs of coverage. These additional savings are not included in the table.

¹ Centers for Medicare and Medicaid Services (CMS), Press Release, “Medicare Drug Plans Strong and Growing,” January 30, 2007.

² Letter to HHS Secretary Michael Leavitt from Sens. Olympia Snowe and Ron Wyden, December 6, 2006.

³ Letter to the Editors of the *Washington Post* from Sens. Olympia Snowe and Ron Wyden, “Negotiating Medicare Drug Prices Would Help,” January 22, 2007.

⁴ Centers for Medicare and Medicaid Services (CMS), Updated Report, “Medicare Drug Coverage Provides Significant Price Discounts and Savings,” September 20, 2006.

⁵ Stagnitti, M.N., “The Top Five Therapeutic Classes of Outpatient Prescription Drugs Ranked by Total Expense for the Medicare Population Age 65 and Older in the U.S. Civilian Noninstitutionalized Population, 2004.” Statistical Brief #153. December 2006. Agency for Healthcare Research and Quality, available at: http://www.meps.ahrq.gov/mepsweb/data_files/publications/st153/stat153.pdf.

⁶ Food and Drug Administration (FDA), “Fast Track, Accelerated Approval and Priority Review,” available at: <http://www.fda.gov/oashi/fast.html> (accessed January 2007).

⁷ If a drug was not listed the Costco or drugstore.com Web sites, BIO placed phone calls to the pharmacy to determine whether the product was available for purchase. In some instances, this resulted in receiving the Costco and drugstore.com pricing data over the phone. We acknowledge that certain products may be in limited distribution due to safety issues.

⁸ The PDPs (and sponsors) included the following: AARP Medicare Rx Plan (UHC-PacifiCare), Humana PDP Standard (Humana), Wellcare Signature (Wellcare), Medicare Rx Rewards Value (WellPoint), and YOURx Plan (Medco).

⁹ For comparative purposes, PDP mail-order prices displayed on the Medicare.gov Plan Finder tool reflect the full cost of drugs on a monthly basis. Most Part D plans require enrollees to obtain a 90-day supply in order to use the mail-order option.

¹⁰ PricewaterhouseCoopers, “Significance of the Coverage Gap Under Part D,” June 8, 2006.

¹¹ Department of Veterans Affairs, VA National Formulary, December 2006, available at: <http://www.pbm.va.gov/NationalFormulary.aspx>.