

Medicare Part D at Age Five: What Has Happened to Seniors' Prescription Drug Prices?

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INTRODUCTION

The Medicare Part D benefit program became effective on January 1, 2006, a little more than five years ago.

As Congress debated various provisions of the Medicare Modernization Act of 2003, critics worried that because the newly available drug benefit insurance would increase seniors' demand for prescription drugs, prices of prescription drugs used by seniors would increase substantially, resulting in dramatically increasing Medicare expenditures. In 2005 the Medicare Trustees projected that in 2009, Part D federal government payments would be \$94.5Bn and payments by Medicare beneficiaries would be \$13.6Bn, yielding a total projected 2009 Part D cost of \$108.1Bn;¹ in 2010 the Medicare Trustees reported that actual 2009 costs were \$54.4Bn federal government plus \$6.1Bn beneficiary payments for a total cost of \$60.5Bn, 44% less than projected in 2005.² What happened, and why? Former Congressional Budget Office Director Peter Orszag has identified the "primary cause" of the cost reduction as lower than expected bids submitted by prescription drug plans offering coverage, stating "The bids are coming in, and the pricing is coming in better than anticipated, and that is likely a reflection of the competition that's occurring in the private market."³ But what enabled competitive prescription drug plans to offer unexpected lower bids? While undoubtedly there are many reasons underlying this development, in this IMS Institute for Healthcare Informatics report we focus on the role of the declining daily cost of therapy as patent protection expired and generic entry took place, and competitive prescription drug plans passed on these cost savings to Part D beneficiaries.

More specifically, focusing on the ten therapeutic classes having the largest volume of Medicare Part D prescriptions in 2006, we examine trends in the average daily costs of therapy in each of these classes in the five years since Medicare Part D was launched. We find that expirations of patent protection and the substitution of generics for brands played a major role in eight of the ten classes experiencing declines in average daily cost of therapy between 2006 and 2010, and that in aggregate, between January 2006 and December 2010 average daily costs declined from \$1.50 to \$1.00 per day (the rounded number results are coincidental). Given anticipated expiration of patent protection for additional products between 2011 and 2015, as well as other market development assumptions, we project 2011-2016 daily cost trends in these ten therapeutic areas and find that, absent new surprises, by the end of 2015 aggregate costs per day will decline further to \$0.65 per day, a number coincidentally equal to the beneficiary age at which Medicare Part D benefits currently become available. Hence, when generic drug savings are taken into account, average daily costs of therapy for the top therapeutic classes in Part D will have fallen on a sustained basis between 2006 and 2015. This reflects the Schumpeterian life cycle process of "creative destruction" in biopharmaceutical markets, in which over time R&D investments produce medical advances having finite market exclusivity generating further funding for R&D, that then make way for generic copies available to patients at low costs for many years, enabling the savings and benefits of biopharmaceuticals to flow to the next generation of medical advances.

DATA AND METHODS

The data sources and methodology employed in this research are in general similar to, but differ slightly from that employed in our previous analysis (Berndt and Aitken [2010]). We utilize IMS Medicare Part D prescription data from the IMS PlanTrak database; IMS Health represents 100% of Part D plans, and combined with IMS' National Prescription Audit (NPA), measures the prescription volume associated with those plans.⁴ The NPA is projected to national levels, based on a sample of retail and mail order outlets. Using data on the total number of prescriptions dispensed, we identified the ten therapeutic classes in 2006 having the greatest Medicare Part D prescription volumes. These ten Uniform System of Classification (USC) classes, ranked in order of prescription volumes, are: lipid regulators (USC 32110, plus Vytorin and Zetia), angiotensin converting enzyme ("ACE") inhibitors (31110), calcium channel blockers (31300), beta blockers (31410), proton pump inhibitors (23420), thyroid hormone (72120), angiotensin II (31120), codeine and combination products (02230), antidepressants (64340), and seizure disorders (20200). In 2006 and 2010, these top ten classes represented respectively 39.9% and 42.1% of Medicare Part D prescriptions dispensed, and 38.2% and 35.1% of retail/mail order purchases from wholesalers and (in some relatively infrequent cases) directly from manufacturers.

For each of the molecules in these ten classes, we employed data from IMS' National Sales Perspective that tracks invoices from wholesalers/manufacturers to retail and mail order pharmacies. These detailed invoice data provided monthly quantities and unit costs of extended

units sold at the form-strength level. Based on dispensing data from the IMS National Prescription Audit, we computed average daily cost of therapy as follows: At each form-strength level, we multiply cost per extended unit (e.g., tablet, capsule, vial, etc.) times average extended unit consumption per day (“DACON”, in IMS parlance) times extended unit share of class, and then sum this up over all form-strengths of all products in the particular USC therapeutic class. This calculation is done on a monthly basis, and is also aggregated to annual periodicity, for each therapeutic class. Based on annual Part D prescription quantity data from the IMS PlanTrak data source, we construct a weighted average aggregate average cost per day of therapy over the entire ten therapeutic classes, both monthly (January 2006–December 2010) and annually (2006–2010). The daily cost of therapy calculations are therefore interpreted as being based on acquisition prices paid by pharmacies; they include prompt payment discounts, but do not include discounts extended directly to Part D beneficiaries, pharmacy margins and manufacturer rebates paid to third-party payers such as Medicaid, private health benefit insurers and Part D private prescription drug plans.

Looking to the future, we then simulate/project 2011–2015 daily cost of therapy trends, under the following assumptions: We take the IMS Institute's current expectations of the timing of forthcoming expirations of patent protection in each of these ten therapeutic classes, we assume no new “blockbuster” drugs are launched in 2011–2015 in these classes, and we employ class-specific standard generic erosion curves benchmarked to 2006–2010 data.

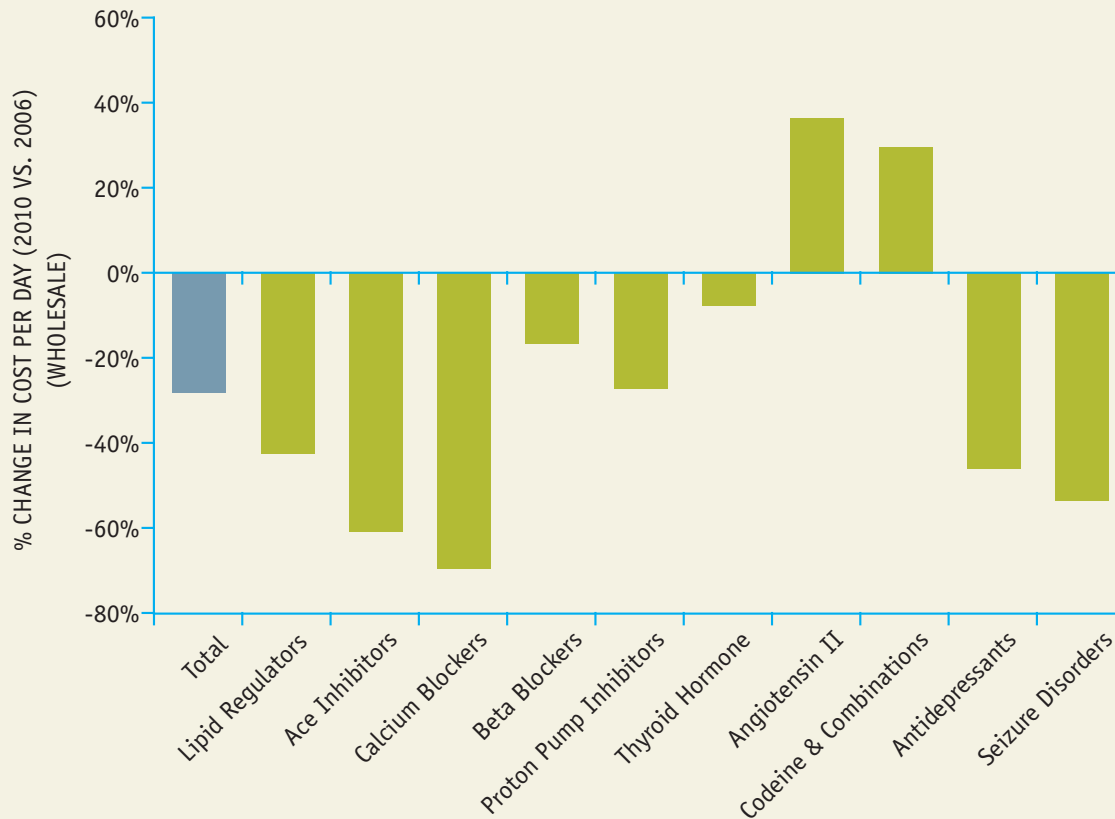
Exhibit 1: Dates of Historic and IMS Anticipated Expiration of Patent Protection, by Therapeutic Class

Part-D Rx Rank	Class	Expired before 2006	Expired 2006-2010	Expiring 2011-2015	Protected Beyond 2015
1	Lipid Regulators	None	Zocor (6/2006), Pravachol (4/2006)	Lipitor (11/2011)	Crestor (7/2016), Zetia (4/2017), Vytorin (4/2017)
2	Ace Inhibitors	Vasotec (2/2000), Zestril (6/2002), Accupril (4/2003)	Lotrel (4/2007)	Tarka (2/2015)	None
3	Calcium Channel Blockers	Sular (11/1998), Cardizem, Others	Norvasc (3/2007)	None	None
4	Beta Blockers	Brevibloc (12/2003)	Toprol-XL (7/2007), Coreg (9/2007)	Bystolic (12/2012)	Coreg CR (4/2016)
5	Proton Pump Inhibitors	Prilosec (11/2002)	Prevacid (11/2009)	Nexium (11/2014), Aciphex (5/2013)	Dexilant (12/2020)
6	Thyroid Hormone	Synthroid (Branded Generic), Others	None	None	None
7	Angiotensin II	None	Cozaar/Hyzaar (2/2010)	Diovan (9/2012), Avapro (3/2012)	Benicar (10/2016)
8	Codeine & Combinations	Percocet, Others	None	Oxycontin (4/2013)	None
9	Antidepressants	Prozac (8/2001)	Zoloft (6/2006), Effexor XR (6/2010)	Cymbalta (7/2014), Lexapro (3/2012)	Pristiq (2/2022)
10	Seizure Disorders	None	Lamictal (1/2009), Topamax (3/2009), Depakote ER (6/2009)	Keppra XR (9/2011)	Lyrica (12/2018)

The dates on this chart represent the judgment of the IMS Institute for Healthcare Informatics as to the dates on which patent protection would expire (or has expired) for the relevant product. Actual expiration of patent protection could occur earlier or later for particular products.

Source: IMS Institute for Healthcare Informatics; National Sales Perspectives; National Prescription Audit, Dec 2010

Exhibit 2: An Average 30% Reduction in the Daily Cost of Therapy Has Occurred within the Top Ten Part D Classes between 2006-2010



Source: IMS Institute for Healthcare Informatics; National Sales Perspectives; National Prescription Audit, Dec 2010

For each class, we assume 2011–2015 brand price and volume growth is constant, and equal to mean pre- and post-patent protection expiration historical growth rates from 2006 to 2010. We also assume that the form-strength distributions within these classes remain constant at their 2010 values for the respective molecules.⁵ We assume that generic prices fall consistent with standard historic generic erosion curves. Given these assumptions, we project cost per day of therapy over the January 2011–December 2015 time frame. Products and dates of expirations of patent protection assumed by the IMS Institute in these projections, as well as prominent historical expirations of patent protection in these ten therapeutic classes, are given in Exhibit 1 on the previous page.

FINDINGS: THE TRACK RECORD FROM THE FIRST FIVE YEARS

From the time of the Medicare Part D launch in 2006 through the end of 2010, on average over the ten largest volume Medicare Part D therapeutic classes, there has been a cumulative 30% decline in the annual average daily cost of therapy (Exhibit 2). Cost declines have occurred in four of the five cardiovascular related classes, with the largest decline seen in calcium channel blockers, and successively smaller declines in ACE inhibitors, lipid regulators, and beta blockers. A daily cost increase occurred among the angiotensin II receptor antagonists, where only Cozaar/Hyzaar lost patent protection in 2010, and physicians/consumers migrated toward the remaining Diovan, Avapro and Benicar brands. Substantial daily cost declines also occurred in the central nervous system classes of antidepressants and seizure disorders, and smaller

declines within the proton pump inhibitors (some of which are now available in less costly over-the-counter versions frequently not covered by Medicare Part D, therefore understating price declines experienced by seniors) and for the thyroid hormone medicines, for which there has not been any expiration of patent protection for quite some time (Exhibit 1). The only other class experiencing a daily cost increase is the codeine and codeine combination product class, which also experienced no expirations of patent protection during 2006-2010.

Daily cost of treatment trends on an annual basis are presented in Exhibit 3, along with compound average annual growth rates (CAGRs). Negative CAGRs were greater than 20% for the calcium channel blockers and ACE inhibitors (both of which experienced generic entry in 2007), were between 10% and 20% for three classes – seizure disorder, antidepressants, and lipid regulators (with significant patent expirations in 2009, 2006 and 2006, respectively), and were less than 10% among the proton pump inhibitors, beta blockers, and thyroid hormone products.

In contrast, daily cost of therapy increases occurred annually among the angiotensin II receptor antagonists, and for the codeine and combination products, where prices leveled off in more recent years.

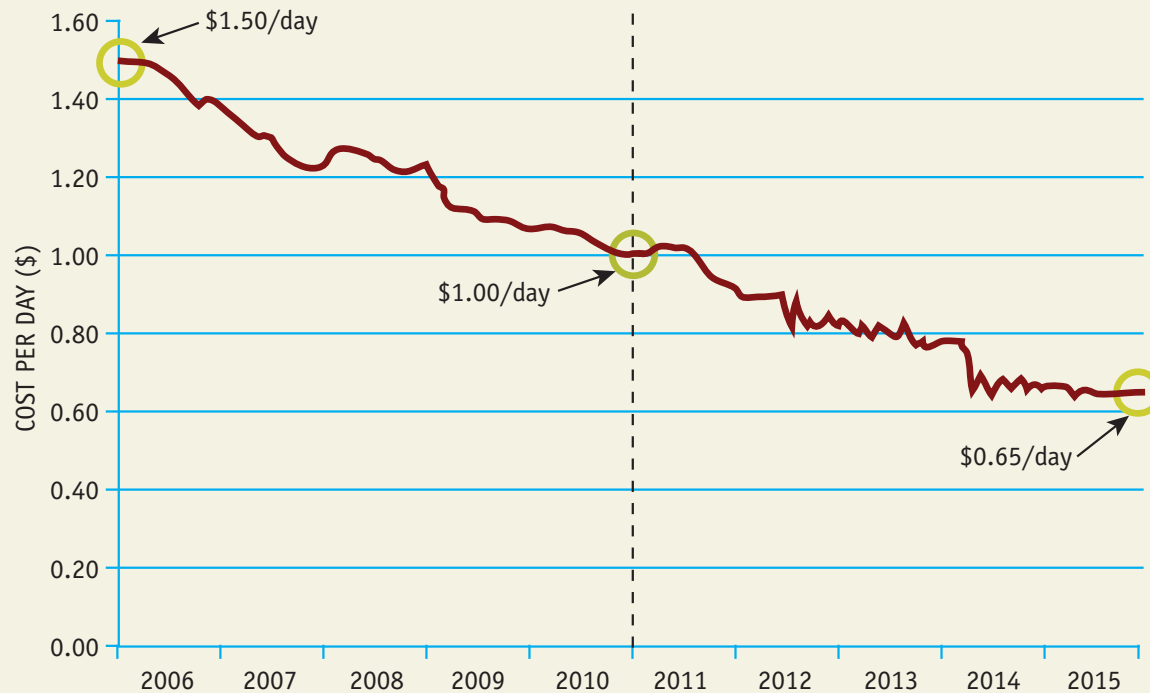
Exhibit 3: Since 2006, the Average Daily Cost of Therapy Has Declined in Eight of the Top Ten Medicare Part D Therapy Areas

2006 Part-D Rx Rank	Class	2006	2007	2008	2009	2010	CAGR %
1	Lipid Regulators	2.43	1.72	1.50	1.37	1.34	-13.7%
2	Ace Inhibitors	0.57	0.51	0.38	0.27	0.23	-20.4%
3	Calcium Channel Blockers	1.22	0.83	0.52	0.43	0.38	-25.3%
4	Beta Blockers	0.37	0.31	0.23	0.29	0.31	-4.1%
5	Proton Pump Inhibitors	3.21	3.13	3.01	2.77	2.35	-7.6%
6	Thyroid Hormone	0.26	0.25	0.23	0.24	0.24	-2.1%
7	Angiotensin II	1.76	1.90	2.06	2.31	2.41	8.1%
8	Codeine & Combinations	1.09	1.22	1.34	1.43	1.42	6.7%
9	Antidepressants	1.39	1.05	0.83	0.77	0.74	-14.5%
10	Seizure Disorders	2.30	2.40	2.42	1.40	1.06	-17.5%
	Top 10 Classes	1.45	1.28	1.19	1.12	1.02	-8.4%

Source: IMS Institute for Healthcare Informatics; National Sales Perspectives; National Prescription Audit, Dec 2010

Exhibit 4: The Big Picture: Sustained Declines in Average Daily Cost of Therapy between January 2006 and December 2015

Top 10 Part D Therapeutic Classes



Source: IMS Institute for Healthcare Informatics; National Sales Perspectives; National Prescription Audit, Dec 2010

One way of summarizing these various trends is simply to plot the average daily cost of therapy aggregated over the top ten Medicare Part D prescription volume classes, on a monthly basis from January 2006 through December 2010. Coincidentally, as seen in the left half of Exhibit 4, between January 2006 and December 2010 the average daily cost of therapy in these classes declined by a third, from \$1.50 to \$1.00, or more colloquially, from “a buck fifty to a buck a day.”

Cumulative January 2006–December 2010 declines by therapeutic class are presented in the middle columns of Exhibit 5. In the first 60 months of Medicare Part D, from January 2006 through December 2010, cumulative average daily costs of therapy declined by greater than 50% within four classes (calcium channel blockers, ACE inhibitors, seizure disorders, and antidepressants), were between 30% and 50% among the lipid regulators and proton pump inhibitors, and were less than 20% for beta blockers and thyroid hormone products. In contrast, over the same time period the cumulative average daily cost of therapy increased by 11.9% for codeine and combination products, and by 22.3% for the angiotensin II receptor antagonists implying annualized average cost increases of 2.9% and 5.2%, respectively.

Exhibit 5: Aggregate Change in Daily Cost of Therapy from January 2006 to December 2015 is 57%, with Variations across Classes

2006 Part-D Rx Rank	Class	January 2006 Cost of Therapy	December 2010 Cost of Therapy	Projected December 2015 Cost of Therapy	2015 vs 2006 Aggregate Percent Change
1	Lipid Regulators	2.57	1.32	0.65	-74.7%
2	Ace Inhibitors	0.59	0.22	0.26	-55.9%
3	Calcium Channel Blockers	1.22	0.36	0.41	-66.4%
4	Beta Blockers	0.37	0.31	0.17	-54.1%
5	Proton Pump Inhibitors	3.31	2.26	1.31	-60.4%
6	Thyroid Hormone	0.28	0.26	0.27	-3.6%
7	Angiotensin II	1.73	2.11	1.08	-37.6%
8	Codeine & Combinations	1.16	1.30	1.17	0.9%
9	Antidepressants	1.56	0.75	0.36	-76.9%
10	Seizure Disorders	2.27	1.08	1.12	-50.7%
	Top 10 Classes	1.50	1.00	0.65	-56.7%

Average price calculation: Weighted Average Cost/Day = Tablet cost X Tablets per day X Tablet share of class (this calculation performed at the form strength level, then summed to class level).

Source: IMS Institute for Healthcare Informatics; National Sales Perspectives; National Prescription Audit, Dec 2010.

FINDINGS: PROJECTIONS/SIMULATIONS FOR THE NEXT FIVE YEARS

A natural question that arises is whether this general decline in average daily cost of therapy from “a buck fifty to a buck a day” observed between January 2006 and December 2010 is an historical oddity unlikely to occur again, or whether this important cost phenomenon is likely to continue for years to come. To begin to address that issue, we have projected annual 2011–2015 and monthly January 2011–December 2015 average daily costs of therapy for the same ten Medicare Part D largest prescription volume classes, based on a number of assumptions (see Data and Methods discussion above for further details). First, we employ IMS Institute’s current estimates of the timing of forthcoming expirations of patent protection in these ten classes. Second, we assume there are no new “blockbuster” product launches within these classes during the 2011–2015 time frame; based on the IMS Institute’s research on product development pipelines, we believe this assumption is a plausible one for these classes. Third, we assume that brand–generic erosion curves follow historic patterns in these therapeutic classes, thereby generating generic price and utilization projections. Finally, we assume branded prices and volume continue consistent with recent trends, both pre- and post-expiration of patent protection. This last assumption may overstate future brand volume growth, as there is evidence of recent slowing branded volume growth, a decline in patient office visits and fewer patients beginning new chronic therapy treatment.⁶ The fact that there are relatively few remaining brands having substantial market

shares in these ten classes between 2011–2015 implies that our assumptions regarding brand price and volume growth are unlikely to have a major impact on aggregate future daily cost trends.

As seen in the last three columns of Exhibit 5, over the entire ten therapeutic classes, the projected average daily cost of therapy falls from \$1.00 per day in December 2010 by an additional 35% to \$0.65 per day, resulting in a cumulative -57% change between January 2006 and December 2015. Between December 2010 and December 2015 the average daily cost of therapy drops by more than 40% in five of the ten classes: lipid regulators -50.8% (Lipitor patent protection expiration expected November 2011), beta blockers -45.2% (Bystolic patent protection expiration expected December 2012), proton pump inhibitors -42.0% (Aciphex patent protection expiration expected in May 2013 and Nexium expected in November 2014), angiotensin II receptor antagonists -48.8% (Avapro patent protection expiration expected in March 2012 and Diovan expected in September 2012), and antidepressants -52.0% (Lexapro patent protection expiration expected March 2012, Cymbalta expected in July 2014). Average daily therapy costs are projected to increase modestly between December 2010 and December 2015 for the ACE inhibitors (18.2%), calcium channel blockers (13.9%), thyroid hormone products (3.8%) and seizure disorders (3.7%) classes, already heavily genericized with little, if any, expected expiration of patent protection between 2011–2015, and to decline modestly for codeine and combination products (-10.0%). Despite the modest expected price increases in these four classes, since 2006 all

but codeine and combination products will have experienced declines in average daily cost of therapy, while average daily cost of therapy for codeine and combination products will have increased a penny.

The “big picture” pattern of sustained decline in average daily cost of therapy in the ten largest volume Medicare Part D classes over the entire decadal time period from January 2006 through December 2015 can be seen visually by observing the steadily downward sloping line in Exhibit 4. While there are some “bumps” at times when the patent protection for a blockbuster drug is expected to expire, or when patent protections for several other branded drugs are anticipated to expire near each other in time, after which substantial generic entry is expected, the general conclusion we draw is that cost declines observed in the first five years of Medicare Part D (the left half of Exhibit 4) can be expected to continue (the right half of Exhibit 4). In aggregate over these ten classes, the 2006–2015 decade is one of steadily decreasing average daily costs of therapy.

DISCUSSION

The research findings reported here update and expand upon the analysis in our earlier research (Berndt and Aitken [2010]). In the previous research we focused on nine therapeutic classes, each of which had at least some initial generic entry between 2006 and 2009, representing about 18% of US total prescription volume in 2005. Here we report daily cost trends in the ten largest Medicare Part D retail/mail order prescription volume therapeutic classes in 2006, regardless of whether they experienced any initial generic entry since 2006; we also extend our historical analysis here by one year to 2010. These ten

largest volume classes encompassed 39.9% of all prescriptions dispensed in the retail/mail order sector in 2006, and 42.1% in 2010. Under a specified set of assumptions, here we also projected price trends in 2011–2015, given available information on the expected dates of expiration of patent protection for drugs still on patent in 2010.

Our principal finding is that expiration of patent protection and the substitution of generics for brands played a major role in eight of the ten classes experiencing declines in average daily cost of therapy between 2006 and 2010, and that in aggregate, between January 2006 and December 2010 average daily costs declined from \$1.50 to \$1.00 per day (the rounded number results are coincidental). Given the anticipated expirations of patent protection occurring between 2011 and 2015, as well as other continued market development assumptions and absent new product surprises, we project daily cost declines in aggregate over these ten therapeutic areas will continue over the 2011–2015 time period, with Part D prescriptions in December 2015 costing on average \$0.65 per day of therapy, a number coincidentally equal to the beneficiary age at which Medicare Part D benefits currently become available. Hence for those seniors eligible for Part D benefits at age 65, average costs of drug therapy will have fallen from a buck-fifty to sixty-five cents a day.

Since our analytical framework involves incorporation of brand to generic substitution as brands lose patent protection, thereby measuring average cost of a molecule over its brand and generic lifecycle, our results differ substantially from those recently published by the AARP

(Schondelmeyer and Purvis [2011]); the latter treats brands and generics of the same molecule as distinct products, and ignores cost savings achieved by brand to generic substitution. Notably, in 2010, for those products having a comparable generic available at the form strength, the IMS Institute reports that 93% of the prescriptions were dispensed as generic, up from 90% in 2006.⁷ The AARP prescription drug price measurement procedure differs from the U.S. Bureau of Labor Statistics price measurement methodology, which identifies and incorporates brand-generic substitution in its price index computations.⁸ The importance of capturing these brand-generic within molecule substitutions has recently been confirmed in a study released by the U.S. Government Accountability Office [2011] (GAO). Based on prescription drug utilization data from the Blue Cross Blue Shield Federal Employee Program, the GAO identified 100 commonly used drugs. When brands and generics of the same molecule were treated as separate products, the 2006Q1–2010Q1 average annual price increase was 6.6%; however, when brand and generic versions of the same molecule were combined and the observed substitution between them was incorporated, average prices over the same time period increased only 2.6% annually.⁹

The cost calculations in our analysis are based on acquisition prices paid by retail and mail order pharmacies. Since they do not include pharmacy margins, rebates to private and public prescription drug plans, and subsidies from Medicare to insurers, and discounts extended directly to Part D beneficiaries, our daily cost of therapy trends might differ from those actually experienced by Medicare Part D

beneficiaries. Moreover, we focus on Part D prescriptions dispensed in the retail and mail order environment; prices of specialty and other drugs dispensed in the hospital and outpatient setting may have differing trends.

Our 2011–2015 projections are based on the IMS Institute’s estimates of when expiration of patent protection will occur for those brands still patent-protected in 2010, and on historic patterns in brand-generic erosion. To the extent actual dates of expiration for patent protection and generic entry differ from those expected by the IMS Institute, future brand-generic erosion curves differ from that observed historically, and new “blockbuster” products are launched in these ten therapeutic classes, actual future daily cost of therapy trends may differ from those projected in this study.

Useful and informative future research suggested by this analysis involves a more detailed examination of changes since 2006 in the quantity of Medicare Part D prescription drugs dispensed, that according to the IMS Institute have increased 61% in volume from 541Mn prescriptions in 2006 to 871Mn in 2010,¹⁰ and the relationship between this increased access to therapies and the decline in the average daily cost of therapy over time.

This analysis also highlights that the dynamics of medicine costs are affected substantially by the impact of expiration of patent protection, which can generally be predicted several years in advance of their occurrence. Unlike medical devices, physicians’ services and hospitalizations, the costs of medicines regularly decline by up to 90% following expiration of patent protection. The extent to

which these medicine price dynamics are understood and incorporated into aggregate cost projections associated with new private or public healthcare programs or policy initiatives is currently unclear to us, but the unique Medicare Part D experience suggests that new approaches to the aggregate cost analyses of medicines merit further scrutiny and consideration to avoid substantial errors in estimating future program costs.

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FOOTNOTES

¹Medicare Trustees 2005 Annual Report, p. 105.

²Medicare Trustees 2010 Annual Report, p. 189.

³As quoted in “CBO Lowers 10-Year Cost Estimate Of Medicare Prescription Drug Benefit”, 30 January 2007, available online at <http://www.medicalnewstoday.com/releases/61768.php>, last accessed 9 June 2011.

⁴For further details concerning PlanTrak, see <http://www.imshealth.com/portal/site/imshealth/menuitem.a46c6d4df3db4b3d88f611019418c22a/?vgnextoid=0c20362d14b73210VgnVCM100000ed152ca2RCRD&cpsextcurrchannel=1>.

⁵Hence, while new branded products in these therapeutic classes launched between 2006 and 2010 are included in the sample, potential new branded products are not included in the 2011-2015 projections. A review of molecules in late-stage development in these therapeutic classes suggests that there will be few if any blockbuster products launched in the 2011-2015 period.

⁶IMS Institute for Healthcare Informatics [2011].

⁷IMS Institute for Healthcare Informatics [2011].

⁸For further discussion, see Berndt and Aitken [2010] and the references cited therein.

⁹The degree of overlap in the two calculations was almost 100%, “at least 95% of the utilization in one basket was also in the other.” (U.S. Government Accountability Office [2011], pp. 2, 7.)

¹⁰IMS Institute for Healthcare Informatics [2011].

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