



DATA POINT

Savings Available Under Full Generic Substitution of Multiple Source Brand Drugs in Medicare Part D

July 23, 2018

Executive Summary

- The Medicare program, through its Part D plans, spent almost \$9 billion on brand name drugs when therapeutically equivalent generics were available.
- If these prescriptions were instead dispensed as generics, the Part D program and its beneficiaries would have saved almost \$3 billion.

Introduction

High generic drug utilization rates hold down overall prescription drug spending growth.¹ By 2017, 90% of retail prescriptions filled in the US were for generic drugs.² In 2014, 85% of prescriptions paid by Medicare Part D plans were for generics, up from 61% in 2007,³ and rising to 86% in 2016, generics now account for 16% of total Part D spending in 2016.⁴ Prior investigations earlier in the Part D era estimated significant savings due to the high generic dispensing rate.⁵

Recent press coverage of price increases for brand drugs when generics are available

highlights a potential need for regulatory or policy action.⁶ In some rare cases, continued utilization of the brand name drug may be medically warranted.

Payments for prescription drugs under CMS's programs (Part B, Part D, and Medicaid) incentivize generic substitution in different ways. In Part D, tiered formularies with progressive cost-sharing rates are used rather than requirements on plans to direct pharmacies to substitute generics. In Part B, the Average Sales Price (ASP) for multiple source drugs declines over time as volume moves toward the generic competitors. Providers face the economic decision of

¹ IQVIA. Medicine Use and Spending in the U.S., 2017-2022. Available at <https://www.iqvia.com/institute/reports/medicine-use-and-spending-in-the-us-review-of-2017-outlook-to-2022>.

² *Ibid.*

³ Medicare Payment Advisory Commission (MedPAC). March 2017 Report to Congress: Chapter 14, Status Report on the Medicare Prescription Drug Program (Part D). Available at http://www.medpac.gov/docs/default-source/reports/mar17_medpac_ch14.pdf.

⁴ ASPE analysis of Part D Prescription Drug Event (PDE) data for 2016.

⁵ Sheingold S and Nguyen NX. Impacts of Generic Competition and Benefit Management Practices on Spending for Prescription Drugs: Evidence from Medicare's Part D Benefit. *Medicare & Medicaid Research Review*; 2014;4(1).

⁶ For example, see Jonathan D. Rockoff, "Pfizer Raises Prices for Dozens of Drugs." *The Wall Street Journal*; July 2, 2018.

purchasing the higher priced brand and receiving less than their acquisition cost in reimbursement, or purchasing the lower priced generic and earning a sometimes sizable markup.⁷ Medicaid imposes a similar reimbursement incentive on pharmacies, as well often mandating generic substitution, requiring prior authorization for brands, or preferring the generic through copays.⁸ Outside of HHS's direct regulatory purview, many commercial plans impose reference pricing limits on the selection of brand drugs, or do not offer brand drug coverage at all if a generic is available.

The Department has several proposals to improve incentives to use generic drugs. They have included removing impediments to generic entry, and increasing generic substitution via cost-sharing incentives.⁹ In this paper, we quantify potential reductions in gross drug costs paid by Part D plans and beneficiaries that could be realized with increased generic substitution rates.

Methods

We analyzed the Medicare Part D prescription drug events (PDE) data for calendar year 2016.¹⁰ We computed annual beneficiary counts and spending for each brand drug with one or more generic competitors at the molecule (or ingredient), form, dose, and strength level.¹¹ We did not have access to the "dispense as written" data element in our analytical extract.

We calculate potential savings as the difference in payments that would be made for the brand drug quantity if paid at the quantity-weighted median ingredient cost for directly comparable generics. This analysis

is performed at the unit level (pills, tablets, or capsules, for example). We also assessed the savings of this substitution at only the ingredient level, and at a lower estimated generic price (25th percentile of generic prices), as sensitivity analyses.

In addition to total savings at the programmatic level, we estimate beneficiary out-of-pocket payment differences for brands and their comparable generics. We do not estimate budgetary effects, effects on premiums, or changes in utilization due to decreased out-of-pocket spending.

As we will show, a significant amount of spending in 2016 for multiple source brand drugs went toward brand drugs with new generic competition, *before* the competitor was on the market. For this reason, we adjusted our savings for the month of initial generic entry, for these drugs. For example, Crestor's generic (rosuvastatin) was first sold in May 2016. Total Part D spending for this drug in 2015 and 2016 was \$2.88 billion and \$1.45 billion, respectively. Our methodology accounts for price increases taken by the brand drug manufacturer. We estimate that \$1.13 billion of Crestor's 2016 spending amount occurred prior to generic entry, and thus is not subject to substitution at the lower generic price. We did not include a transition period, for simplicity.

Our results are presented for total savings overall, savings due to substitution for the top 20 multiple source brands dispensed in 2016, and savings available for drugs that were in the top 10 of Part D drug spending in 2011 or 2012 but had generic competition by 2015. We also present an example of one top multiple source brand.

⁷ For an overview of Part B and Part D approaches to generic drug substitution, see OIG, Medicare Payments for Newly Available Generic Drugs, 2011. Available at <https://oig.hhs.gov/oei/reports/oei-03-09-00510.pdf>.

⁸ For an overview of Medicaid strategies to increase generic substitution rates, see <https://www.uspharmacist.com/article/trends-in-generic-drug-reimbursement-in-medicaid-and-medicare>.

⁹ See for example the FY 2019 President's Budget, which called for reforms to the 180 day exclusivity period for

ANDAs and reducing copayments for low-income Part D enrollees to \$0 for generic drugs.

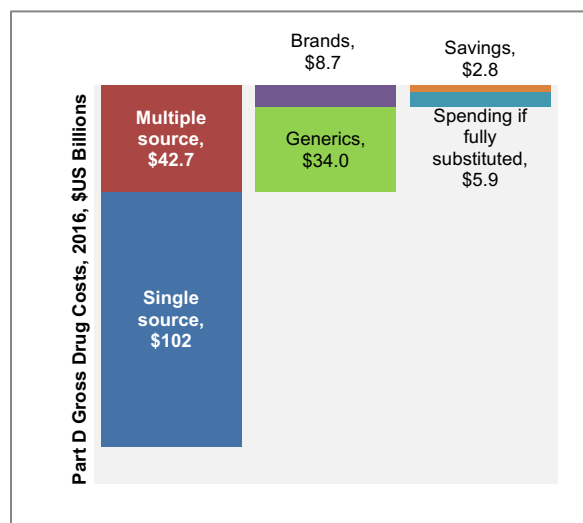
¹⁰ The PDE contains drug ingredient costs, dispensing fees, and benefit design and payment data that enable CMS to make payments to the plans and otherwise administer the Part D benefit.

¹¹ The PDE does not have prices net of rebates and discounts paid to payers. Brand prices may be overstated but they reflect the amounts paid to pharmacies and the amounts upon which beneficiary coinsurance is calculated.

Results

More 600 brand name drugs were dispensed and paid for by Part D plans in 2016, despite the presence of generic competition. Plans and beneficiaries paid \$8.7 billion for multiple source brands and \$34.0 billion for generics. Full substitution of multiple source brands would have resulted in total spending on generic drugs of \$39.9 billion, saving the Part D program and its beneficiaries \$2.8 billion in 2016. These estimates do not account for manufacturer rebates paid to Part D plans or pharmacy benefit managers (PBMs) or statutory discounts paid by manufacturers for brand name drugs, and thus may overstate savings to the program after accounting for the effects that rebates often have on premiums. See Figure 1.

Figure 1: Effects of Moving to Full Generic Substitution in Part D.¹²



Of this \$2.8 billion, \$2.25 billion is for brand name drugs that have faced generic competition for at least a full year (e.g. the first generic was available in 2015 or earlier). A further \$584 million in savings is estimated for substituting generics that were first launched in 2016 and therefore on the market for less than a full year. These

savings are likely to grow as additional generic competitors enter the market.

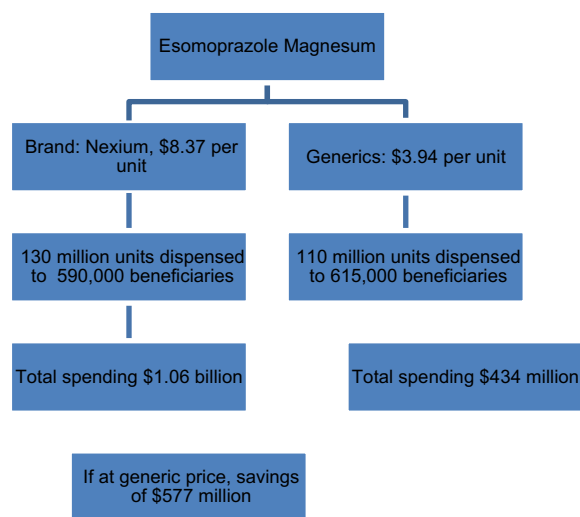
Beneficiaries spent \$1.1 billion out-of-pocket in cost-sharing for brand drugs with comparable generics, averaging twice as much out-of-pocket than for comparable generics. In 2016, multiple source brand drug cost-sharing averaged \$39.15, while generic cost-sharing for substitutable products was \$17.04. Beneficiaries could have saved over \$600 million in out-of-pocket payments had they been dispensed generic equivalent drugs.

A significant amount of this spending occurred among the top 20 multiple source brands. Substituting these drugs for generic competitors at their median prices would have saved the program and beneficiaries \$1.8 billion. See Appendix Table A for these drugs, and figure 2 below for an example.

In terms of beneficiary cost-sharing, we find similar results as for the overall calculation. Average per beneficiary spending is significantly higher for these brands than for the substitutable generics. (See Appendix Table A, also.) Brand drug cost-sharing averaged \$30.69, compared to \$22.41 for their generic equivalents. For 17 of the top 20 drugs, the ratio of brand to comparable generic out-of-pocket spending ranges from 117% (Namenda) to 1,476% (Lamictal) indicating significant per-drug savings are available for beneficiaries. In three cases (Abilify, Lovenox, and Tricor), beneficiary out-of-pocket costs are marginally higher for the generic than the brand drug. We believe this is due to the interaction of total drug costs and plan coverage in the coverage gap for generics (42% in 2016), meaning patients paid 58% coinsurance for generics that year. This compares to 25% plan coverage and a 50% statutory manufacturer discount for brand drugs in 2016.

¹² Single source includes payments for brand drugs prior to generic entry, e.g. \$1.13 billion of Crestor spending in the example used in the Methods section.

Figure 2: Example of Price Difference for One Top Multisource Brand.



2011 and 2012's Top 20 Brand Name Drugs with Generic Competition by 2015

The nature of the branded pharmaceutical market is for patented drugs to eventually face generic competition. In order to understand for how long multiple source brand drug spending may persist, we looked specifically at eleven drugs that were ranked in the top 20 of Part D spending in 2011 or 2012, and had generic competition by 2015.¹³ (See Appendix Table B.) Overall, Medicare Part D plans spent \$28 billion combined on these drugs in 2011 and 2012, but only \$563 million in 2016. (Plans and beneficiaries paid just \$3.1 billion for their generic competitors.) However, if pharmacies instead dispensed generics at a quantity-weighted median price in place of the brand name drug, Part D plans and

beneficiaries could have saved \$271 million (or nearly another 50%).

Sensitivity Analyses

In general, pharmacists are permitted to substitute generic drugs for brand drugs unless prohibited by the prescriber physician on the prescription, and if there is a direct therapeutic equivalent at the molecule (or ingredient), form, strength, and dose level. If pharmacists were permitted to substitute generics for brands at the ingredient name level rather than at the molecule, form, dose, and strength level, we estimate that an additional \$2 billion beyond the original estimate could be saved by the program and its beneficiaries. We recognize this may not always be feasible or within the scope of practice for pharmacists depending on state law. If pharmacies were able to reduce acquisition costs for generics to today's 25th percentile, through greater substitution authority, for example, we calculate additional savings of \$17 million or 6% beyond the \$2.8 billion original estimate. These limited savings are due to the nature of mature markets, where multiple generics have been competing on price.

Conclusion

Price reductions associated with generic competition have generated significant savings for the Part D program and its beneficiaries. However, incompletely aligned incentives for generic substitution leave significant savings uncaptured.

¹³ We excluded drugs that had initial generic competition in 2016 to ensure sufficient generic price competition was available.

Appendix Table A: Top 20 Multiple Source Brand Name Drugs Dispensed in Part D, 2016

Rank	Brand Name	Generic Name	GDC Paid	Savings if Fully Substituted	Beneficiary Out of Pocket (OOP) Payments	
					Per Beneficiary OOP for Multisource Brand	Per Beneficiary OOP for Comparable Generics ^(d)
1	NEXIUM	ESOMEPRAZOLE MAGNESIUM	\$1.06 billion	\$577 million	\$55.22	\$41.84
2	GLEEVEC ^(a)	IMATINIB MESYLATE	\$659 million	\$112 million	\$2,294.34	\$828.04
3	UNITHROID	LEVOTHYROXINE SODIUM	\$588 million	\$18 million	\$40.95	\$20.93
4	COPAXONE ^(b)	GLATIRAMER ACETATE	\$383 million	\$81 million	\$1,922.39	\$607.11
5	CRESTOR ^(a)	ROSUVASTATIN CALCIUM	\$322 million	\$229 million	\$169.92	\$36.29
6	LIPITOR	ATORVASTATIN CALCIUM	\$231 million	\$69 million	\$24.03	\$16.84
7	TOPROL XL	METOPROLOL SUCCINATE	\$196 million	\$23 million	\$38.86	\$30.10
8	XENAZINE	TETRABENAZINE	\$179 million	\$63 million	\$1,728.04	\$849.78
9	PLAQUENIL	HYDROXYCHLOROQUINE SULFATE	\$129 million	\$11 million	\$78.85	\$53.40
10	LOVENOX	ENOXAPARIN SODIUM	\$116 million	\$12 million	\$70.02	\$74.46
11	ZETIA ^(a)	EZETIMIBE	\$107 million	\$18 million	\$255.31	\$27.98
12	LIDODERM	LIDOCAINE	\$97 million	\$13 million	\$38.32	\$25.55
13	LASIX	FUROSEMIDE	\$97 million	\$9 million	\$6.46	\$4.82
14	LAMICTAL	LAMOTRIGINE	\$95 million	\$93 million	\$208.48	\$14.12
15	ABILIFY	ARIPIRAZOLE	\$93 million	\$57 million	\$47.15	\$48.22
16	KEPPRA	LEVETIRACETAM	\$84 million	\$82 million	\$246.53	\$19.38
17	TRICOR	FENOFIBRATE NANOCRYSTALLIZED	\$83 million	\$11 million	\$37.20	\$42.50
18	ENTOCORT EC	BUDESONIDE	\$79 million	\$5 million	\$301.26	\$54.43
19	ZEGERID ^(c)	OMEPRAZOLE/SODIUM BICARBONATE	\$79 million	N/A	\$74.79	\$47.40
20	NAMENDA	MEMANTINE HCL	\$59 million	\$26 million	\$58.46	\$50.09
TOTAL, TOP 20			\$4.7 billion	\$1.8 billion	\$30.69	\$22.41
TOTAL, MSB			\$8.7 billion	\$2.8 billion	\$39.15	\$17.04

(a) These drugs had generic competition first available only in 2016. Total GDC paid in this table will not match other estimates for the full year for these drugs. To compute these values, we took 2015 spending, multiplied it by the ratio of 2016 prices to 2015 prices, and assumed 2015 levels of utilization for each month before generic entry. For example, Crestor's generic was first available in May 2016, so we allowed for 4 months of brand sales at 2015 utilization levels (\$2.55 billion), resulting in \$322 million remaining brand spend while the generic competed against it. Gleevec's generic was launched in February 2016 and Zetia's in December 2016.

- (b) Copaxone has two marketed strengths – 20mg and 40mg. Sandoz marketed its generic glatiramer acetate 20mg beginning in 2015. Mylan began marketing its 40mg generic in 2017. Both Sandoz and Mylan currently market 20mg and 40mg strengths. Spending on the 40mg is not included in the table above; total spending for branded Copaxone in 2016 was actually \$1.4 billion. Due to data limitations in the PDE-based data source this substitution is estimated manually.
- (c) There is one generic available for Zegerid in the 2016 data and its price exceeds the brand drug price. We do not make that price substitution in our analysis and show Zegerid here as ranked by total brand spend.
- (d) Note that these amounts are directly from the PDE and not calculated based upon the simulated substitution.

Appendix Table B: Top Brands in Part D from 2011 and 2012 (Ranked in Top 20 Either year), With Generics by 2015, and Associated Savings

Brand Name	Molecule Name	Brand Spending, 2016	Generic Spending, 2016	Median Generic Price Ratio	Savings if Fully Substituted
ZYPREXA	OLANZAPINE	\$22.3 million	\$82.5 million	0.03	\$21.5 million
ABILIFY	ARIPIPRAZOLE	\$92.5 million	\$1.1 billion	0.38	\$56.9 million
SEROQUEL	QUETIAPINE FUMARATE	\$19.2 million	\$161.0 million	0.04	\$18.3 million
ACTOS	PIOGLITAZONE HCL	\$3.9 million	\$65.2 million	0.03	\$0.8 million
LEXAPRO	ESCITALOPRAM OXALATE	\$39.9 million	\$115.9 million	0.42	\$23.2 million
CYMBALTA	DULOXETINE HCL	\$19.6 million	\$507.0 million	0.16	\$16.5 million
LIPITOR	ATORVASTATIN CALCIUM	\$231.0 million	\$592.8 million	0.70	\$69.2 million
PLAVIX	CLOPIDOGREL BISULFATE	\$20.0 million	\$214.5 million	0.04	\$19.1 million
NAMENDA	MEMANTINE HCL	\$59.1 million	\$190.2 million	0.56	\$25.8 million
SINGULAIR	MONTELUKAST SODIUM	\$11.9 million	\$152.6 million	0.05	\$11.2 million
DIOVAN	VALSARTAN	\$44.0 million	\$268.1 million	0.13	\$8.0 million
TOTAL		\$563.3 million	\$3.1 billion		\$270.5 million