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Blue Health Intelligence

THE HEALTH OF AMERICA REPORT

RISING COSTS FOR PATENTED DRUGS DRIVE GROWTH OF PHARMACEUTICAL SPENDING IN THE U.S.



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EXECUTIVE SUMMARY

Analysis of a seven-year trend of utilization, price changes and overall spending shows that prescription drug spending has increased 10 percent annually for Blue Cross and Blue Shield (BCBS) members since 2010, an overall rise of 73 percent.¹ This upward trend is due to a small fraction of emerging, patented drugs with rapid uptake and large year-over-year price increases that are more than offsetting the continued growth in utilization of lower-cost generic drugs. These higher costs are being incurred by consumers and payers alike; while consumer out-of-pocket costs have risen just three percent annually for prescription drugs in total, they have risen 18 percent annually for patented drugs. Current trends suggest that this rapid rise in drug trend costs is likely to continue in future years.

Specific findings:

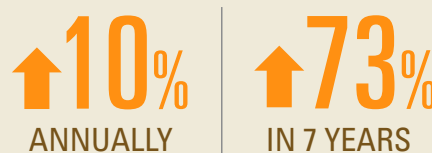
- Over the past seven years, generic drugs increased their share of total prescriptions filled from 66 percent to 82 percent, while brand drugs' share of total prescriptions declined from 34 percent to 18 percent.
- However, the rising cost of a narrow set of new drugs has resulted in the brand drug market maintaining 78 percent of total drug spending, roughly the same proportion it held in 2010.
- Specifically, the cost of brand drugs with patent protection and no generic alternatives—commonly referred to as single-source drugs—is rising at an average annual rate of 25 percent (and 285 percent since 2010), more than double the 10 percent average annual rate of spending for all drugs.
- These patent-protected single-source drugs now make up 63 percent of total drug spending, up from 29 percent of total spending in 2010, despite the fact that they comprise less than 10 percent of total prescriptions filled.
- After a lower-cost generic drug is introduced, the resulting increase in the number of generic manufacturers and the generic share of the market for that drug consistently yields a reduction in total spending within a drug class.

Many of the new brand drugs that are contributing to the rapid rise in drug spending can have life-changing health benefits by treating or managing serious conditions. However, the treatment benefits of these drugs can only be fully attained if they remain affordable over the long term.



STUDY FOUND...

Prescription drug spending for BCBS members



UPWARD TREND DUE TO A SMALL FRACTION OF EMERGING, PATENTED DRUGS USED TO TREAT CHRONIC DISEASES.



¹ The cost trends cited in this report are derived from Rx claims data and therefore do not include the impact of drug rebates but does include network discounts. Rebates vary by a number factors (e.g., market segment, insurer, manufacturer, etc). Reporting trend in this way is an industry and actuarial practice for commercial business.

Drug Market Share – Brand Versus Generic

Despite significant increases in the adoption rate for generics, brand drugs still comprise a dominant share of overall drug spending. As Exhibit 1 shows, generics have expanded from 66 percent of all prescriptions in 2010 to nearly 82 percent in 2016. The drop in the share of brand drugs, however, has not lessened their contribution to total prescription drug spending. In fact, that contribution has increased slightly from 77 percent to 78 percent. As generics approach 90 percent of all prescriptions, their rate of increase in share will inevitably begin to slow down. As a result, their ability to offset the rising cost of brand drugs through share growth will diminish.

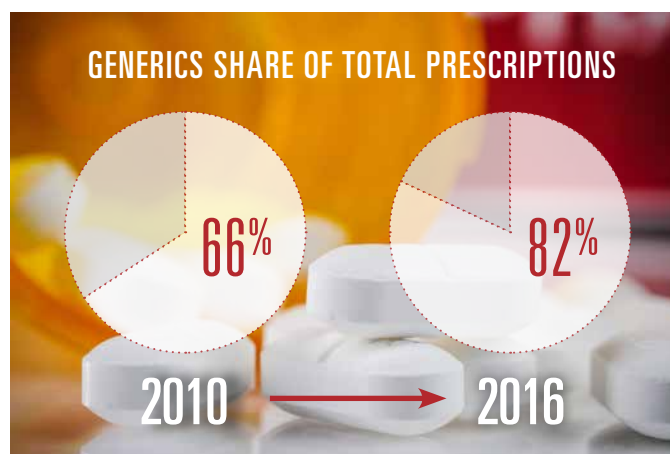


EXHIBIT 1: BRAND AND GENERIC SHARE OF PRESCRIPTIONS FILLED AND TOTAL SPENDING

TYPE OF DRUG	SHARE OF UTILIZATION		SHARE OF TOTAL SPENDING	
	2010	2016	2010	2016
GENERIC	66%	82%	23%	22%
BRAND	34%	18%	77%	78%

The average yearly rate of change in drug utilization, prices and total spending illustrates how brand prescriptions maintain such a large proportion of total drug costs. Exhibit 2 shows that total spending for generics is increasing only because of utilization; although generic drug utilization is up by nine percent, prices for these drugs have remained fairly flat. Meanwhile, brand drugs show a very different dynamic. Utilization is down for all brand drugs, but unit price has increased by an average of 17 percent each year, leading to a total increase in spending of 10 percent.

EXHIBIT 2: AVERAGE RATES OF INCREASE – 2010 TO 2016

TYPE OF DRUG	ANNUAL UTILIZATION ²	ANNUAL UNIT PRICE	ANNUAL SPENDING ²	CUMULATIVE SPENDING 2010 – 2016
GENERIC	9%	0%	9%	64%
BRAND	-6%	17%	10%	76%
TOTAL	5%	4%	10%	73%

2. Note: Total spending is based on BCBS negotiated rates prior to any drug rebates. Only the first nine months of data were available for 2016. To create an estimate for the full year, the average difference in utilization and allowed spending between Oct. 1 through Dec. 31 and Jan. 1 through Sept. 30 in the six previous years were calculated and used to create an adjusted fourth quarter result. This was then added to the first nine months of 2016.

Brand Drugs: Mixed Drug Markets Versus Single-Source Drug Markets

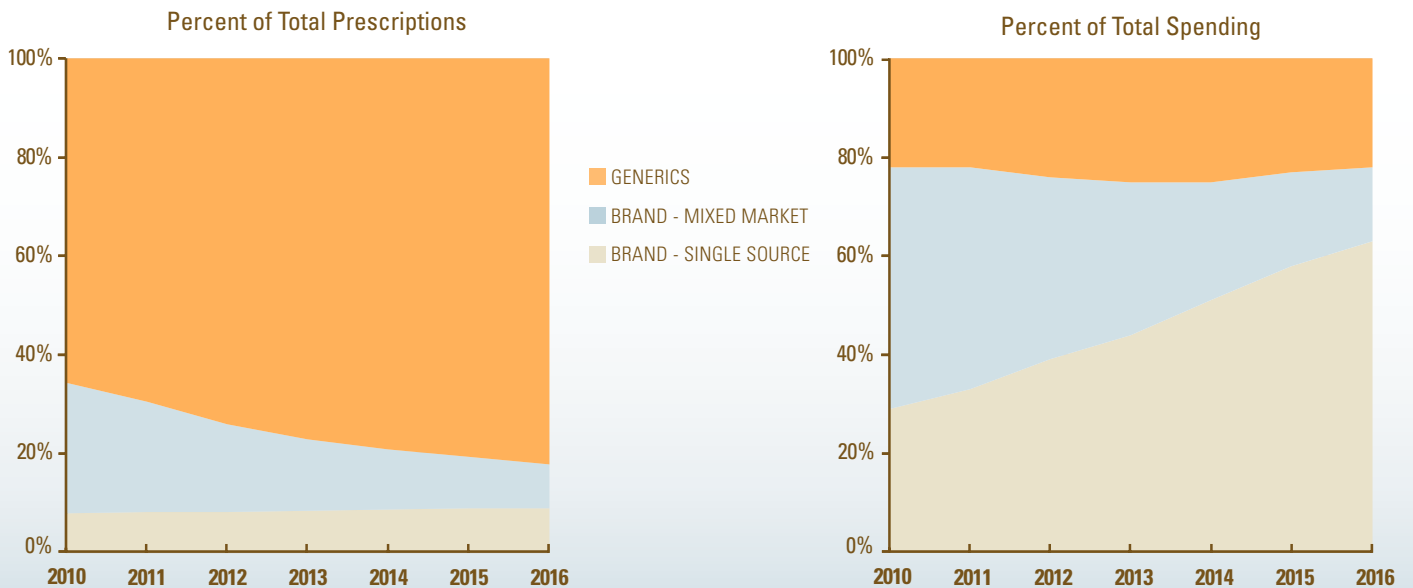
The cost dynamic for brand drugs can be more clearly understood if the market for these drugs is segmented into two: “mixed markets,” where brand drugs have a generic alternative, and “single-source markets,” where only patent-protected drugs exist. Data show that the single-source drug market contributes to significant increases in prescription drug spending. As Exhibit 3 illustrates, brand drugs in mixed markets experienced a 12 percent decline in utilization, a three percent increase in unit price and an overall 10 percent decrease in total annual spending. By contrast, single-source drugs, which make up 49 percent of all brand prescriptions in 2016, are increasing at a substantial annual rate in terms of utilization and price, generating a 25 percent increase in total annual spending—more than double the rate of increase in spending on all drugs.

EXHIBIT 3: AVERAGE RATES OF INCREASE OF BRAND DRUGS – 2010-2016

BRAND DRUG MARKETS	ANNUAL UTILIZATION	ANNUAL UNIT PRICE	ANNUAL SPENDING	CUMULATIVE SPENDING 2010 – 2016
MIXED-DRUG MARKET (Both Brand & Generics Drugs)	-12%	3%	-10%	-47%
SINGLE-SOURCE MARKET (Only Patented Drugs)	7%	17%	25%	285%

The rapid rate of spending increase in this single-source market is highlighted in the two charts in Exhibit 4. The left-hand chart represents share of total prescriptions by the three drug categories (generics, mixed drug market and the single-source market). The chart at right represents the total prescription spending for these same three categories. While generic utilization continues to increase well above 80 percent of all prescriptions filled, it is the single-source market, which represents less than 10 percent of all prescriptions filled, that commands a majority of the total drug spending, increasing from 29 percent to 63 percent over the seven-year period. Given these trends, we can expect total spending attributable to the single-source drugs to continue to rise in the future, possibly at an even more rapid rate.

EXHIBIT 4: SHARE OF PRESCRIPTIONS AND TOTAL SPENDING IN THREE DRUG MARKETS



The Single-Source Drug Market

Breaking down single-source drugs by broad drug group classifications as shown in Exhibit 5, reveals that a majority of drug groups had double digit price increases from 2010 to 2016, ranging from eight percent annually for patented asthma drugs to 30 percent for dermatological drugs.

EXHIBIT 5: DRUG GROUP ANNUAL UNIT COST INCREASES AND SHARE OF SPEND

DRUG GROUP*	ANNUAL UNIT COST INCREASE 2010 - 2016 (%)	SHARE OF SPEND 2015 (%)
SKIN CONDITION (Psoriasis, Eczema, Acne, etc.)	30	3
ANTIVIRALS (Hepatitis C, HIV)	19	14
HIGH CHOLESTEROL THERAPIES	18	2
CANCER	17	5
NEUROLOGICAL AGENTS (MS, Dementia, Alzheimer's, etc.)	14	10
DIABETES	14	17
ANTI-INFLAMMATORIES (Rheumatoid Arthritis, Inflammation, Pain, etc.)	13	15
ENDOCRINE/METABOLIC AGENTS (Growth Disorders, Thyroid Conditions, etc.)	12	3
STIMULANTS (ADHD, Narcolepsy, etc.)	10	2
ASTHMA	8	5
OTHER†	—	24

* Drug groups were created using Medi-Span's Generic Product Identifier (GPI) classification system with group labels revised for readability.

† Category contains 76 other drug groups with <2% share of spending each.

The top 25 single-source drugs make up more than half of drug spending in this market. The list, presented in Exhibit 6, shows that nearly all had rapid year-over-year growth in both utilization and unit price, with annual spending increases well into double digits. As noted in the introduction, the high cost of these drugs needs to be weighed, on a case-by-case basis, against their potential effectiveness in treating or managing serious conditions.

Nearly half of these drugs (12 of 25, which are shaded in Exhibit 6) are considered “specialty drugs⁵”. It is estimated that 17 of these drugs will have a long road to generic competition, and price relief is far from certain. Reasons for this delay include:

- Ten of these drugs have more than five years expected patent life remaining
- Four (Humira, Enbrel, Rebif, Stelara) are biologicals that, because of their complexity and complicated approval process, will be difficult and expensive for biosimilars to replicate. Biosimilars for Humira and Enbrel have already been approved, but launch has been delayed due to a variety of challenges, including manufacturing, interchangeability with the innovator product, uncertain market acceptance and unknown price savings
- Four (Lantus, Novolog, Levemir, Humalog) are insulins that have proven historically to be difficult to replace with generics due to their clinical and patent complexity
- Two (Lantus, Somatropin) have had other drug developers receive 505(b)(2) approval for new brand drugs that are similar to these established drugs but not true generics

As a result, low-cost generic alternatives to the majority of these drugs cannot be expected anytime soon.

SPECIALTY DRUGS THAT HAVE A LONG ROAD TO GENERIC COMPETITION:

DRUG	ANTICIPATED GENERIC DRUG ENTRY TO MARKET
HUMIRA	< 5 YEARS
HARVONI	15 YEARS
ENBREL	2-12 YEARS
COPAXONE 40	< 5 YEARS
REBIF	< 5 YEARS
TECFIDERA	6-9 YEARS
ATRIPLA	< 5 YEARS
REVLIMID	< 5 YEARS
SOVALDI	> 10 YEARS
GILENYA	< 5 YEARS
STELARA	6-9 YEARS
TRUVADA	< 5 YEARS



5. Specialty drugs are typically expensive medications used to treat complex chronic conditions and often require special handling, administration or monitoring. CVS specialty, Comprehensive Specialty Pharmacy Drug List

**EXHIBIT 6: TOP 25 SINGLE-SOURCE MARKET DRUGS IN TERMS OF SPENDING IN 2015 –
RATE OF INCREASE FROM 2010 TO 2016**

DRUG (Brand Name)	DRUG GROUP	ANTICIPATED MARKET ENTRY OF GENERIC COMPETITION* (in Years)	ANNUAL UTILIZATION	ANNUAL UNIT PRICE	ANNUAL SPENDING	CUMULATIVE SPENDING 2010 – 2016
Humira	Anti-Inflammatories	< 5 [†]	16%	15%	33%	465%
Harvoni	Antivirals	15		New After 2010 [‡]		
Enbrel	Anti-Inflammatories	2 – 12 ^{‡,§}	3%	14%	17%	159%
Lantus	Antidiabetics	Basaglar (Brand Competitor) Launched Dec. 2016	9%	13%	23%	250%
Copaxone	Neurological Agents	Generic for Copaxone 20 Launched Apr. 2015 < 5 years (Copaxone 40)	2%	11%	13%	111%
Novolog	Antidiabetics	< 5	15%	14%	32%	421%
Rebif	Neurological Agents	< 5 [†]	-7%	14%	6%	42%
Tecfidera	Neurological Agents	6 – 9		New After 2010 [‡]		
Advair	Antiasthmatic/ Bronchodilators	< 5 for Advair Diskus 6 – 9 for Advair HFA	-6%	8%	2%	13%
Victoza	Antidiabetics	6 – 9	39%	12%	56%	1325%
Vyvanse	Stimulant	6 – 9	16%	10%	28%	337%
Januvia	Antidiabetics	< 5	6%	12%	18%	176%
Lyrica	Anticonvulsants	< 5	2%	16%	19%	182%
Atripla	Antivirals	< 5	5%	8%	14%	115%
Somatropin [¶]	Endocrine/ Metabolic Agents	Several Approved Brand Products	5%	7%	12%	98%
Levemir	Antidiabetics	< 5	15%	13%	30%	393%
Revlimid	Assorted Classes	< 5	15%	6%	22%	231%
Sovaldi	Antivirals	> 10		New After 2010 [‡]		
Invokana	Antidiabetics	> 10		New After 2010 [‡]		
Gilenya	Neurological Agents	< 5	140%	8%	159%	30230%
Humalog	Antidiabetics	< 5	0%	14%	14%	118%
Stelara	Dermatologicals	6 – 9 [†]	53%	9%	67%	2074%
Truvada	Antivirals	< 5	22%	7%	31%	397%
Zetia	Antihyperlipidemics	Generic launched Dec. 2016	-4%	17%	12%	100%
Xarelto	Anticoagulants	6 – 9		New After 2010 [‡]		

* Launch dates are estimates only made by a combination of patent life remaining, additional exclusivity remaining and the outcome of patent litigation between manufacturers.

† These four drugs are biological drug products that requires a biosimilar replacement that is harder to produce than a typical generic. Biosimilars for Humira and Enbrel have already been approved by the FDA but launch has been delayed due to complexities of manufacturing, issues with interchangeability with the original innovator product, unknown market acceptance by prescribers and consumers and uncertain price savings, but far less than a typical generic.

‡ Drugs introduced after 2010 are not shown here because changes in their utilization and pricing are affected by new product “ramp up.” We have provided the results for these drugs in Exhibit A1 in the Appendix.

§ The window for Enbrel is highly variable due to extended patents in 2011 and 2012 and current litigation.

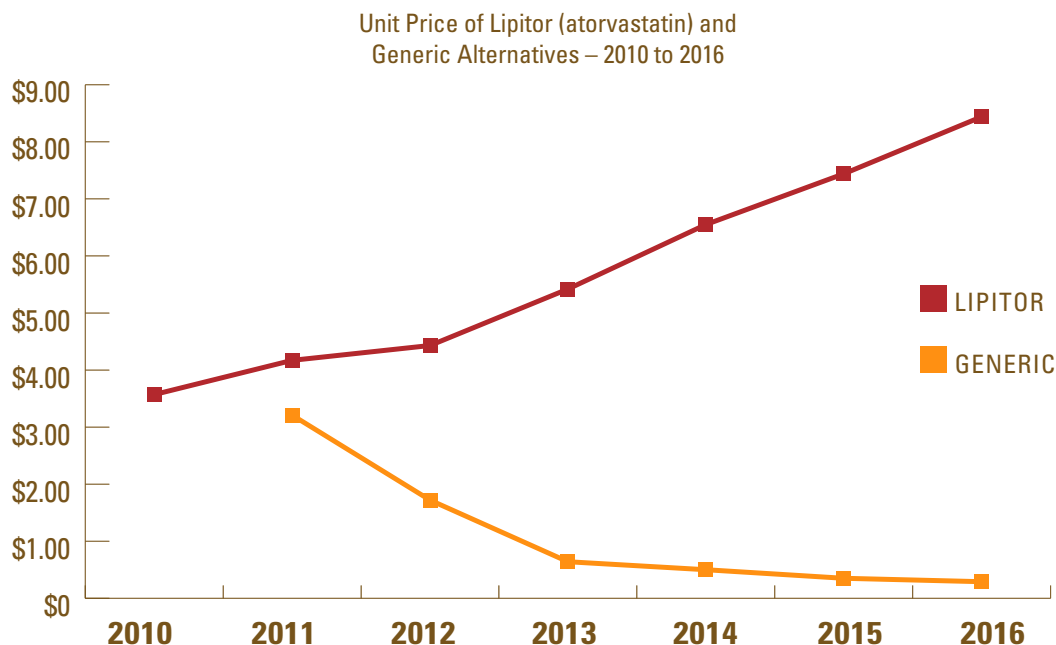
|| Basaglar and several brand Somatropin products approved through 505(b)(2) pathway, see bullet above.

¶ Brand names include Genotropo, Omnitrope, Norditropin and Humatrope.

Generics Reduce Cost by Shifting Drug Use

The introduction of generics into the marketplace lowers overall drug cost for the particular drug. For example, the total spending of Lipitor (atorvastatin) and its generic alternatives declined 78 percent between 2011 and 2016 following the loss of Lipitor’s exclusivity and the release of generic alternatives. Similarly, the total spending for Avapro (irbesartan) and its generics decreased 80 percent from 2011 to 2016. These large drops in cost are due to the rapid adoption of generics rather than price reductions among the brand drugs. Exhibit 7 illustrates this with data on two drugs (with four additional drugs in appendix Exhibit A2) for which generics were introduced into the market between 2011 and 2012. With remarkable consistency, generic drug prices initially start higher—though below the brand drug price—and then drop as more manufacturers bring a generic product to market. The brand-name manufacturers did not compete on price once generic competitors become available, and this large price disparity between the brand drug and its generic alternative causes consumers to switch rapidly to the generic, raising its share to 90 percent or more within a few years. The shift in use results in the dramatic drop in overall spending noted in the tables.

EXHIBIT 7: UNIT PRICES AND GENERIC SHARE BY YEAR OF SELECTED DRUGS

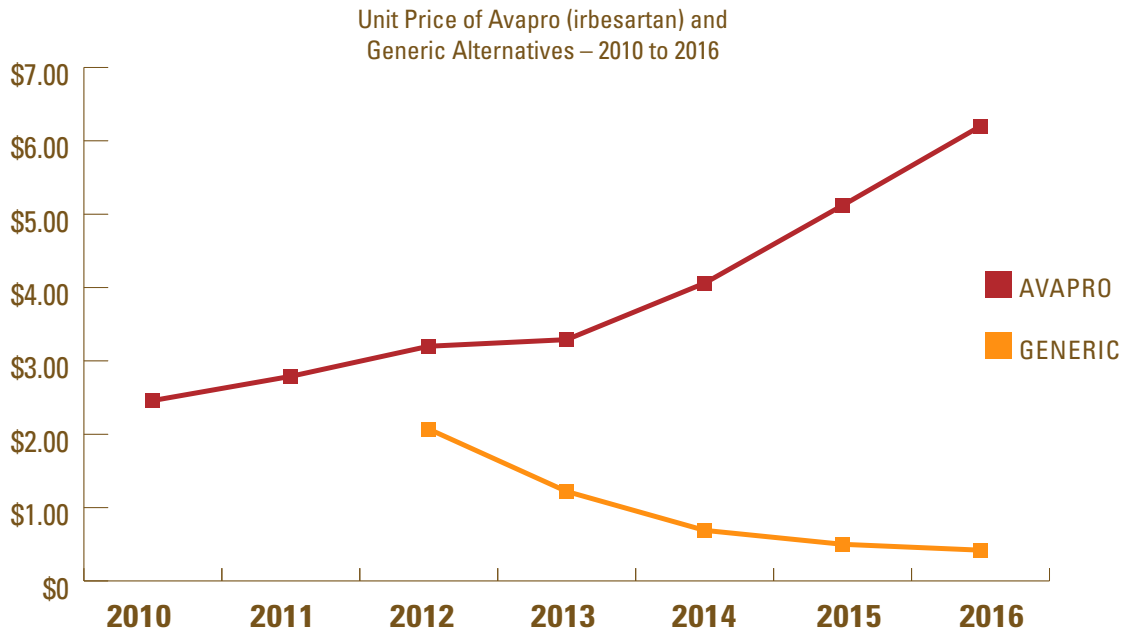


Market Share of Generic Alternatives by Year and Number of Manufacturers of Generics⁶

	2010	2011	2012	2013	2014	2015	2016
GENERIC SHARE	0.0%	8.0%	88.4%	96.3%	98.0%	98.8%	99.3%
MANUFACTURERS		2	11	14	16	16	15
SPENDING YEAR OVER YEAR	-	12%	-32%	-49%	-8%	-18%	-15%

6. At least 100 prescriptions per year.

EXHIBIT 7: UNIT PRICES AND GENERIC SHARE BY YEAR OF SELECTED DRUGS (CONTINUED)



Market Share of Generic Alternatives by Year and Number of Manufacturers of Generics⁶

	2010	2011	2012	2013	2014	2015	2016
GENERIC SHARE	0.0%	0.0%	66.0%	95.4%	97.2%	98.3%	98.9%
MANUFACTURERS			7	13	13	11	11
SPENDING YEAR OVER YEAR	-	8%	-19%	-39%	-35%	-24%	-18%

6. At least 100 prescriptions per year.

CONCLUSION

Over the seven-year study period, a limited number of patent-protected prescription drugs have driven the entire year-over-year increase in drug costs. Generics have only managed to offset the cost growth of these patented drugs by taking an increasing share of total prescriptions. Despite generics accounting for 82 percent of all prescriptions in 2016, patented drugs account for 63 percent of total spending. This 63 percent share of spending is more than a two-fold increase over their share in 2010, and this rise shows no signs of leveling off. Moreover, if the expansion of generic share slows down or if the number of drugs qualifying for patent protection increases in the coming years, these cost trends could rise even faster.

BCBS companies help customers maximize their prescription coverage to get the drugs they need at the most affordable cost. For example, members are encouraged to use generic prescription medicines, mail-order delivery and home infusion, when available, and follow medication plans as prescribed by their doctors.

METHODOLOGY NOTES

This is the twelfth study of the Blue Cross Blue Shield: The Health of America Report series, a collaboration between the Blue Cross Blue Shield Association and Blue Health Intelligence, which uses a market-leading claims database to uncover key trends and insights into healthcare affordability and access to care.

The report examines the medical claims of more than 30 million BCBS commercially-insured members per year (non-Medicare) and more than \$208 billion in prescription spending from January 2010 through September 2016.* Unit prices were computed as the total cost of the prescription divided by the days supplied, or the average daily price of the prescription.

For more information and to read past reports, visit www.bcbs.com/healthofamerica.

* Only the first nine months of data were available for 2016. To create an estimate for the full year, the average difference in utilization and allowed spending between Oct. 1 through Dec. 31 and Jan. 1 through Sept. 30 in the six previous years were calculated and used to create an adjusted fourth quarter result. This was then added to the first nine months of 2016.

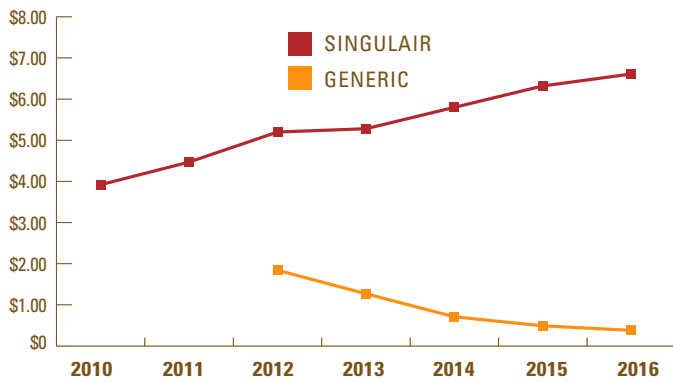
APPENDIX

Exhibit A1: New Drugs After 2010 Among Patent-Only Drugs in Terms of Spending – 2014-2015

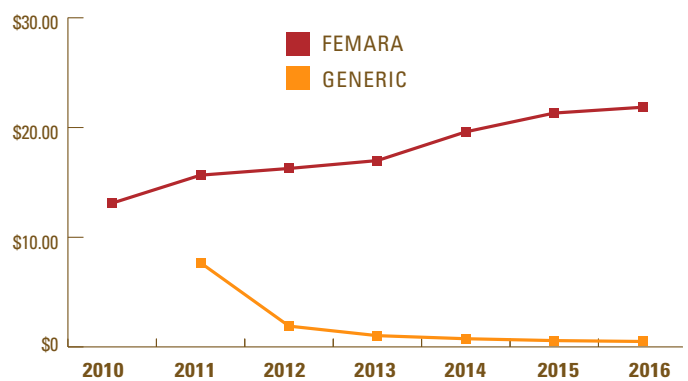
Commercial Name	Drug Group	Year Released	2014 to 2015 Increase - Utilization	2014 to 2015 Increase - Unit Price	2014 to 2015 Increase - Spend
Harvoni	Antivirals	2014	765%	-1%	751%
Tecfidera	Neurological Agents	2013	15%	9%	25%
Sovaldi	Antivirals	2013	-66%	-1%	-66%
Invokana	Antidiabetics	2013	95%	14%	123%
Xarelto	Anticoagulants	2011	23%	10%	38%

Exhibit A2: Unit Prices and Generic Share by Year of Selected Drugs

Unit Price of Singulair (montelukast) and Generic Alternatives – 2010 to 2016



Unit Price of Femara (letrozole) and Generic Alternatives – 2010 to 2016



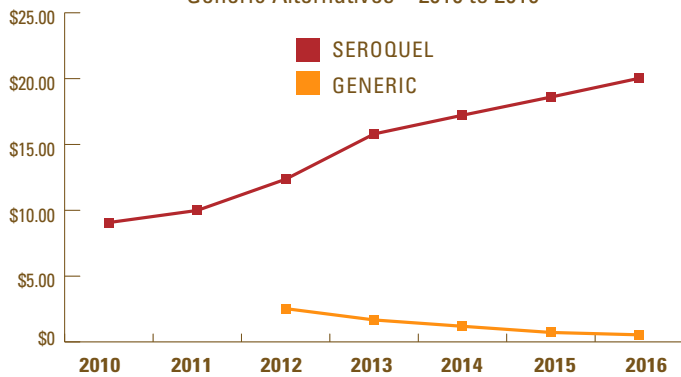
Market Share of Generic Alternatives by Year and Number of Manufacturers of Generics⁶

	2010	2011	2012	2013	2014	2015	2016
GENERIC SHARE	0.0%	0.0%	41.1%	98.3%	99.0%	99.3%	99.5%
MANUFACTURERS			13	18	21	24	25
SPENDING YEAR OVER YEAR	-	16%	-9%	-58%	-36%	-23%	-20%

Market Share of Generic Alternatives by Year and Number of Manufacturers of Generics⁶

	2010	2011	2012	2013	2014	2015	2016
GENERIC SHARE	0.0%	58.3%	94.8%	96.8%	98.1%	98.8%	99.0%
MANUFACTURERS		8	10	9	8	8	7
SPENDING YEAR OVER YEAR	-	-19%	-74%	-36%	-23%	-15%	-9%

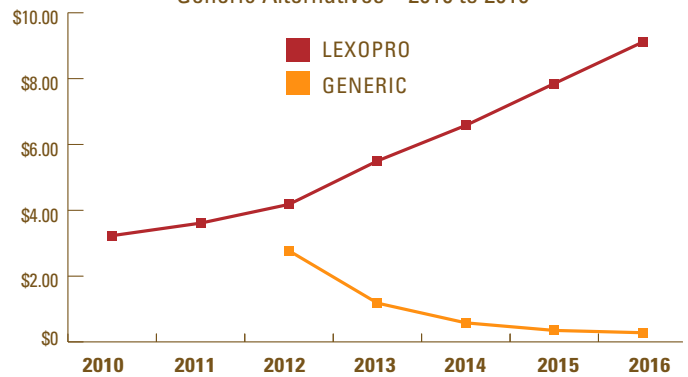
Unit Price of Seroquel (quetiapine) and Generic Alternatives – 2010 to 2016



Market Share of Generic Alternatives by Year and Number of Manufacturers of Generics⁶

	2010	2011	2012	2013	2014	2015	2016
GENERIC SHARE	0.0%	0.0%	59.9%	83.4%	85.5%	86.7%	88.4%
MANUFACTURERS			13	16	17	17	15
SPENDING YEAR OVER YEAR	-	16%	-32%	-30%	0%	-3%	-9%

Unit Price of Lexopro (escitalopram) and Generic Alternatives – 2010 to 2016



Market Share of Generic Alternatives by Year and Number of Manufacturers of Generics⁶

	2010	2011	2012	2013	2014	2015	2016
GENERIC SHARE	0.0%	0.0%	77.4%	96.9%	98.0%	98.6%	99.0%
MANUFACTURERS	0	0	9	17	20	22	25
SPENDING YEAR OVER YEAR	-	8%	-11%	-48%	-39%	-28%	-16%

6. At least 100 prescriptions per year.