



Blue Cross
Blue Shield
Blue Care Network
of Michigan

MICHIGAN HEALTH POLICY FORUM

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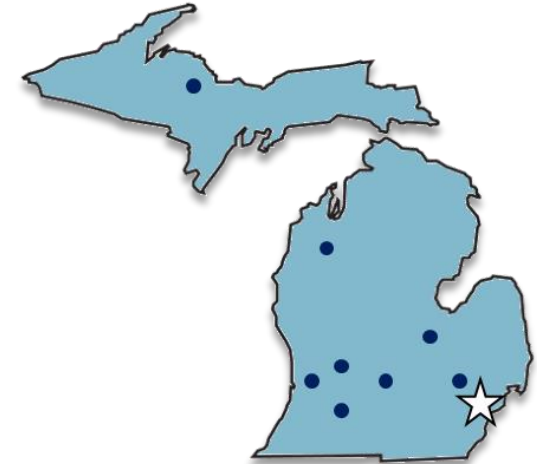
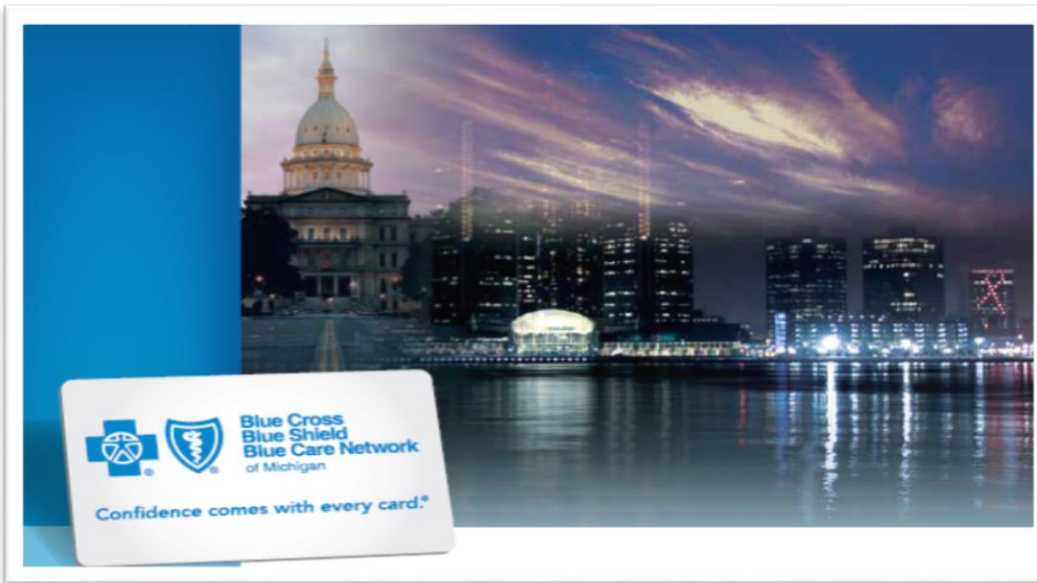
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- About BCBSM
- Prescription drug overview
- Patents and exclusivity periods
- Manufacturer strategies to prevent competition
- Generics and biosimilars
- Manufacturer drug pricing
- Health plans

About Blue Cross Blue Shield of Michigan



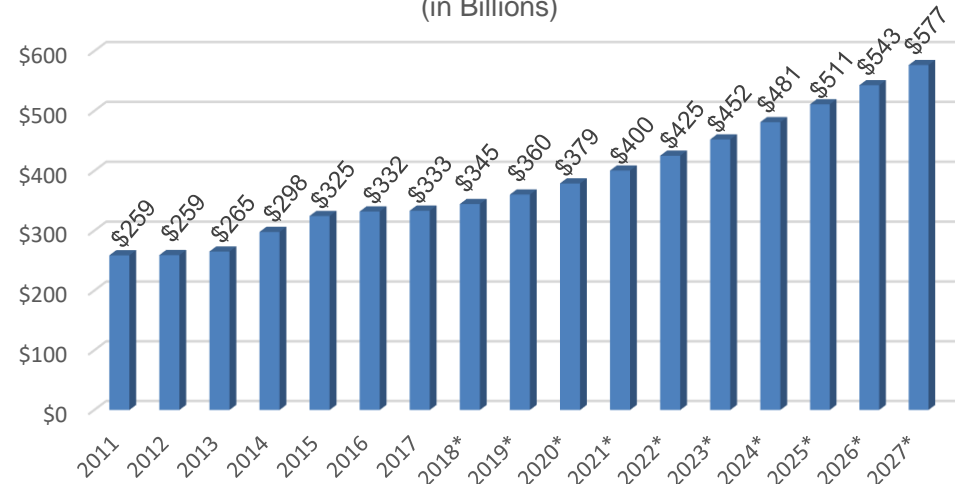
- A nonprofit mutual insurance company founded in 1939
- The largest nonprofit mutual health insurer in Michigan, serving **6.1 million people nationwide**
- Headquartered in Detroit, with more than 8,100 Michigan employees across the state
 - A large IT employer, with more than 1,000 tech employees
- As part of our commitment to the state, Blue Cross moved a majority of employees to the core cities of Detroit, Grand Rapids and Lansing

- Nearly 100 million health care claims processed in 2017, with an average claims expense of \$63 million per day.
- 28.7 million prescriptions processed in 2018 totaling over \$3.4 billion.

Prescription Drug Overview

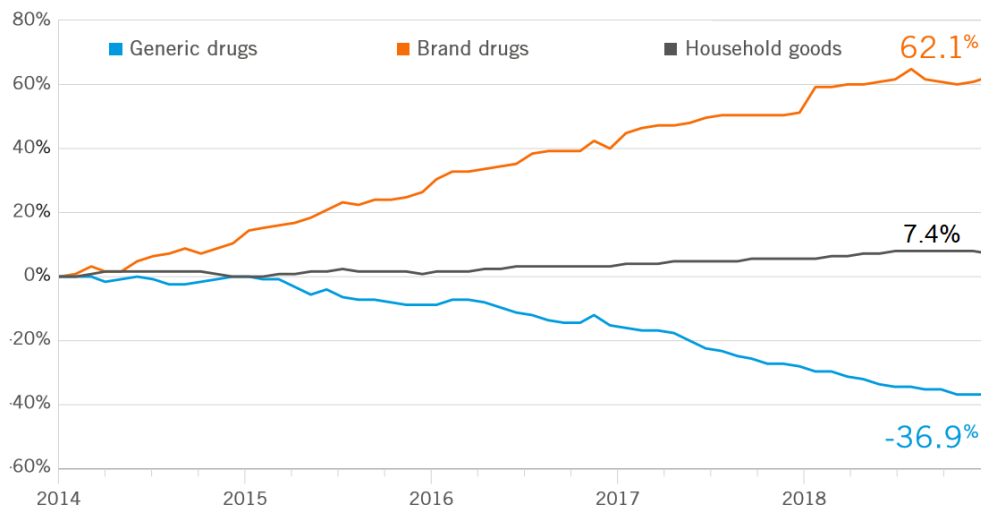
- Prescription drug expenditures continue to increase
- CMS forecasts expenditures to accelerate over 2018-2027 and average **5.6%**
- An influx of new and expensive innovative drugs into the market will help drive this trend

Prescription Drug Expenditures 2011-2027
(in Billions)



Source: CMS Office of the Actuary; Projections of National Health Expenditures – February 2019

Express Scripts Prescription Drug Price Index 2014-2018



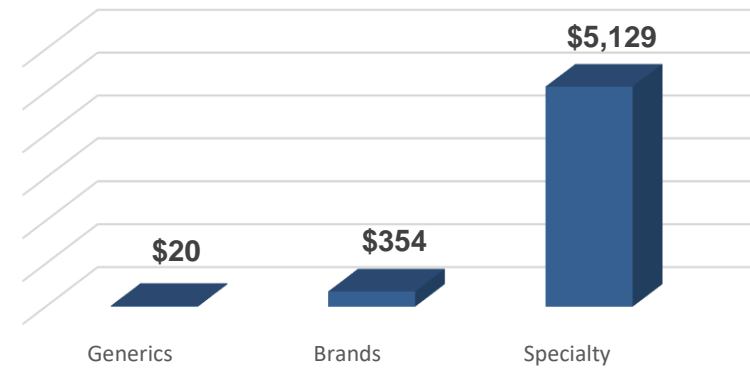
Source: Express Scripts 2018 Prescription Drug Trend Report

- The most commonly used brand drugs experienced a list price inflation of **62.1%**
- The most commonly used generic drugs price declined **36.9%**
- The most commonly used household goods rose **7.4%**

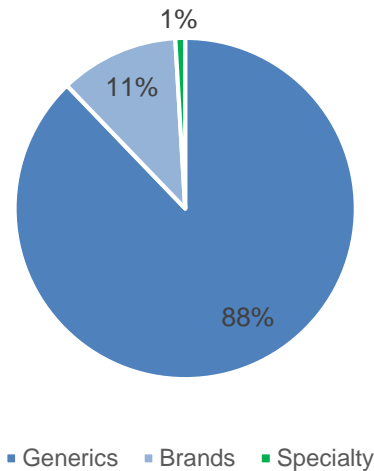
Prescription Drug Overview (continued)

- Generics account for **88%** of claims and **21%** of costs
- Brand name medications account for **11%** of claims and **41%** of costs
- Specialty medications account for **1%** of claims and account for **38%** of costs

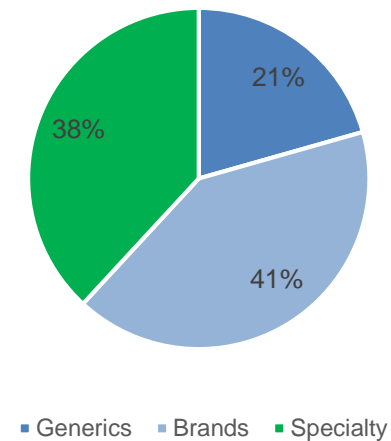
Average Cost per Prescription Claim (30-Day supply)



% Prescription Claims



% Prescription Costs



Source: BCBSM 2018 claims experience

Prescription Drug Overview (continued)

Twelve of the Most Expensive Drugs in 2018

| Drug | Cost per patient per year* | Benefit | Condition | Company |
|----------------------------------|--------------------------------------|----------|-------------------------------------|---------------------|
| Luxturna™ | \$850,000 | Medical | Genetic retinal disease | Spark |
| Exondys 51™ | \$800,000 ¹ | Medical | Duchenne muscular dystrophy | Sarepta |
| Ravicti® | \$790,000 | Pharmacy | Urea cycle disorder | Horizon |
| Spinraza® | \$750,000 ² | Medical | Spinal muscular atrophy | Biogen |
| Brineura™ | \$702,000 | Medical | CLN2 disease | BioMarin |
| Soliris® | \$540,000 | Medical | Paroxysmal nocturnal hemoglobinuria | Alexion |
| Hemlibra® | \$500,000 | Medical | Hemophilia | Genentech |
| Kymriah® Yescarta® (CAR-T) | \$373,000- \$475,000 ³ | Medical | Cancer | Gilead, Novartis |
| Vitrakvi® | \$393,000 | Pharmacy | Cancer | Bayer |
| Cuprimine® | \$380,000 | Pharmacy | Wilson's disease | Valeant |
| Kalydeco® | \$307,000 | Pharmacy | Cystic fibrosis | Vertex |

*Annual costs estimates are based on wholesale acquisition cost (WAC), average dosing and rounded; Luxturna™ and CAR-T are given as one-time treatments

¹Based on average weight; costs could exceed \$1 million per patient per year

²For first year, then \$375,000 annually

³Yescarta® and Kymriah® drug costs; total medical costs could exceed \$1 million

Prescription Drug Overview (continued)

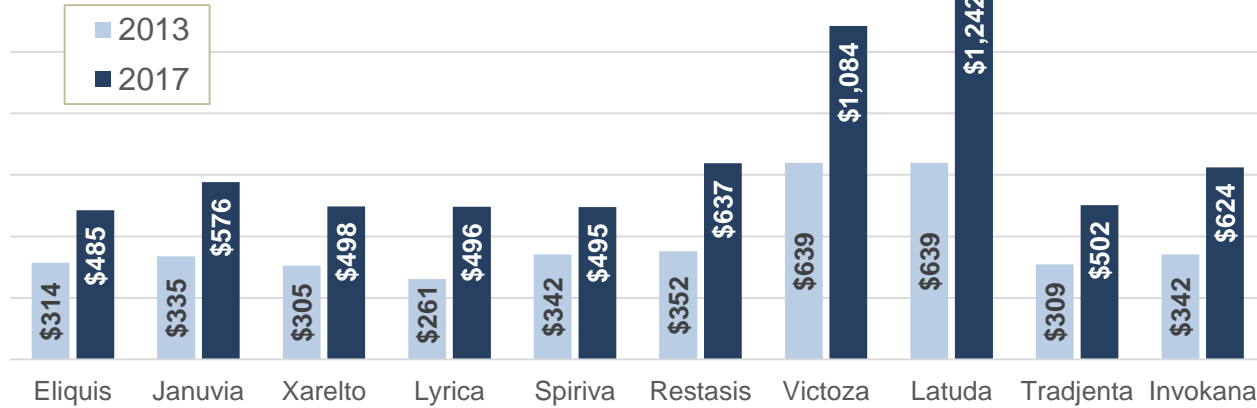
New Cancer Medications Approved in 2018

(Average cost per year or course of treatment is \$185,000)

| Drug Name | Manufacturer | Approval Date | Route | Estimated Monthly Cost | Estimated Annual/Course of Treatment Cost |
|--------------------------------------|-----------------------------------|----------------|-------------|------------------------|---|
| Copiktra (duvelisib) | Verastem | September 2018 | Oral | \$15,120 | \$181,440 |
| Erleada (apalutamide) | Janssen Oncology | February 2018 | Oral | \$11,409 | \$136,908 |
| Libtayo (cemiplimab-rwlc) | Regeneron Pharmaceuticals | September 2018 | Intravenous | \$9,100 | \$109,200 |
| Lorbrena (lorlatinib) | Pfizer | November 2018 | Oral | \$19,260 | \$231,120 |
| Lumoxiti (moxetumomab pasudotox-tdf) | AstraZeneca | September 2018 | Intravenous | \$22,500 | \$135,000 |
| Lutathera (lutetium Lu 177 dotatate) | Advanced Accelerator Applications | January 2018 | Intravenous | \$47,500 | \$190,000 |
| Talzenna (talazoparib) | Pfizer | October 2018 | Oral | \$17,490 | \$209,980 |
| Vizimpro (dacomitinib) | Pfizer | September 2018 | Oral | \$14,880 | \$178,560 |
| Vitrakvi (larotrectinib) | Loxo Oncology | November 2018 | Oral | \$32,800 | \$393,000 |

Prescription Drug Overview (continued)

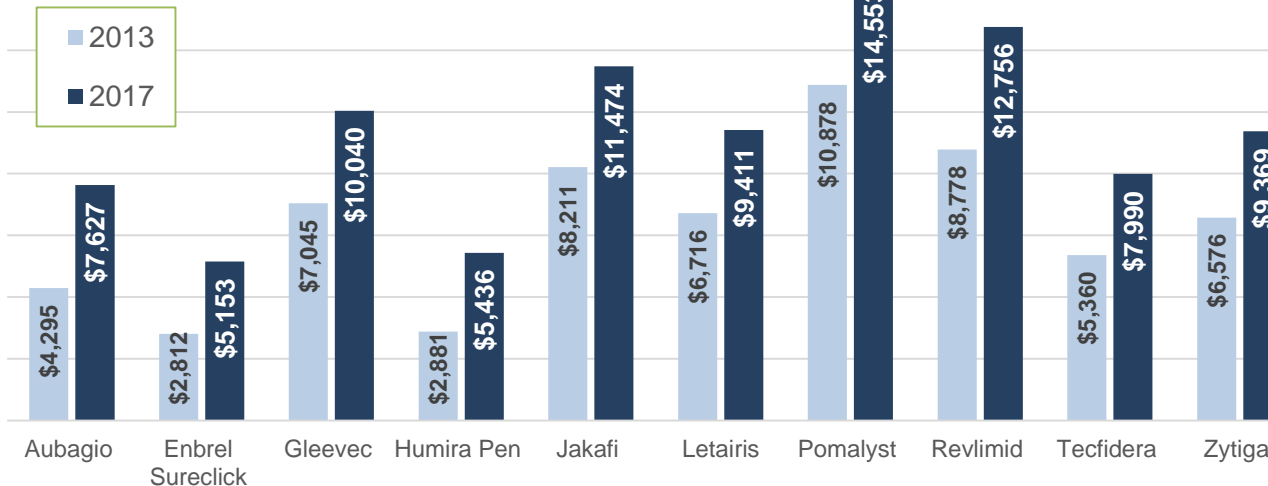
**Medicare Part D Average Spending Per Claim (Non-Specialty)
2013 vs 2017**



Price Increases*

- Average annual growth rate was **12.3%** for these 10 drugs
- Total spending on these drugs increased from **\$6.1B** to **\$17.3B**

**Medicare Part D Average Spending Per Claim (Specialty)
2013 vs 2017**



- Average annual growth rate was **11.6%** for these 10 drugs
- Total spending on these drugs increased from **\$4.3B** to **\$11.4B**

Source: Medicare Part D Drug Spending Dashboard, March 2019, available online @ www.cms.gov

*Represents gross drug costs

Patents and Exclusivity Periods

Patent: is a property right granted by the US Patent and Trademark Office anytime during the development of a drug. Patents protect a drug manufacturer's invention and prevent other manufacturers from marketing products covered by the patent, among other things. A patent term is **20 years** from the date of filing.

Exclusivity: is a period of time when a brand-name drug is protected from generic drug competition. There are different exclusivities for different situations. Exclusivity is designed to promote a balance between new drug innovation and generic and biosimilar drug competition.

Drugs

- Orphan Drug – **7 years**
- New Chemical Entity – **5 years**
- Generating Antibiotic Incentives Now (GAIN) – **5 years**
- New Clinical Investigation – **3 years**
- Pediatric Exclusivity – **6 months** added exclusivity

Biologics

- Market exclusivity – **12 years**
No application for a biosimilar may be approved
- Data Exclusivity – **4 years**
No application for a biosimilar may be submitted to FDA

Generics/Biosimilars

- Generic Drug Exclusivity – **0.5 years**
- Interchangeable Biosimilar Exclusivity – **1 - 3.5 years**

Analysis of the twelve best selling drugs in the US in 2017 revealed the following:

- Averaged **71** patents issued
- Averaged **15** years on the market
- Average list prices increased **68%** since 2012

Source: *I-MAK Overpatented, Overpriced: How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving up Drug Prices*. Available online @ www.i-mak.org

Top 12 grossing drugs of 2017

| | AVG/DRUG | TOTAL | RANGE |
|-------------------------------|-------------|-------------|------------------|
| NUMBER OF PATENT APPLICATIONS | 125 | 1498 | 48-247 |
| PATENTS ISSUED | 71 | 848 | 27-132 |
| PRICE CHANGE SINCE 2012 | +68% | N/A | -58%-163% |
| YEARS BLOCKING COMPETITION | 38 | 456 | 31-48 |
| YEARS ON THE U.S. MARKET | 15 | 176 | 6-21 |

AbbVie
HUMIRA

| | |
|-------------------------------|------------------|
| CONDITION(S) TREATED | Arthritis |
| NUMBER OF PATENT APPLICATIONS | 247 |
| NUMBER OF PATENTS ISSUED | 132 |
| PRICE CHANGE SINCE 2012 | +144% |
| YEARS BLOCKING COMPETITION | 39 |
| ON THE U.S. MARKET SINCE | 2002 |

Amgen
ENBREL

| | |
|-------------------------------|------------------|
| CONDITION(S) TREATED | Arthritis |
| NUMBER OF PATENT APPLICATIONS | 57 |
| NUMBER OF PATENTS ISSUED | 41 |
| PRICE CHANGE SINCE 2012 | +155% |
| YEARS BLOCKING COMPETITION | 39 |
| ON THE U.S. MARKET SINCE | 1998 |

Pfizer
LYRICA

| | |
|-------------------------------|--------------|
| CONDITION(S) TREATED | Pain |
| NUMBER OF PATENT APPLICATIONS | 118 |
| NUMBER OF PATENTS ISSUED | 68 |
| PRICE CHANGE SINCE 2012 | +163% |
| YEARS BLOCKING COMPETITION | 32 |
| ON THE U.S. MARKET SINCE | 2004 |

Johnson&Johnson
XARELTO

| | |
|-------------------------------|--------------------|
| CONDITION(S) TREATED | Blood Clots |
| NUMBER OF PATENT APPLICATIONS | 49 |
| NUMBER OF PATENTS ISSUED | 30 |
| PRICE CHANGE SINCE 2012 | +87% |
| YEARS BLOCKING COMPETITION | 31 |
| ON THE U.S. MARKET SINCE | 2011 |

Manufacturer Strategies to Prevent Competition

Sovereign Immunity

- Allergen transferred patents for Restasis to the St. Regis Mohawk Tribe in 2017
- St. Regis Mohawk Tribe exclusively licensed the rights back to Allergan
- Intent was to invoke sovereign immunity to dismiss patent challenges filed by generic makers
- US Supreme petitioned to hear Allergan's case

Pay for Delay

- Settlements between brand and generic drug makers to delay generic competition
- Supreme Court affirmed that settlements where brand manufacturers pay generics to settle patent litigation and delay entering the market could have "significant anticompetitive effects" and violate the antitrust laws
(*Actavis vs FTC 2013*)

REMS*

- Intended to help ensure that new drug benefits outweigh their risks
- Brand manufacturers have used REMS to block potential generic applicants from accessing product samples needed to create a generic or biosimilar
- FDA publishes a list of manufacturers potentially blocking samples
(*Current list published 2/7/19*)

Citizen Petitions**

- Intended to allow citizens to raise concerns on FDA policy
- Brand manufacturers have used to raise frivolous/questionable claims to prevent competition
- Roughly 40% filed a year or less before generic approval
- FDA denies the requested action for approximately 80% of petitions filed by drug companies

* Risk Evaluation and Mitigation Strategy (REMS)

** Feldman R, A Citizen's Pathway Gone Astray — Delaying Competition from Generic Drugs, N Engl J Med. 2017 Apr 20;376(16):1499-1501. doi: 10.1056/NEJMp1700202. Epub 2017 Mar 1

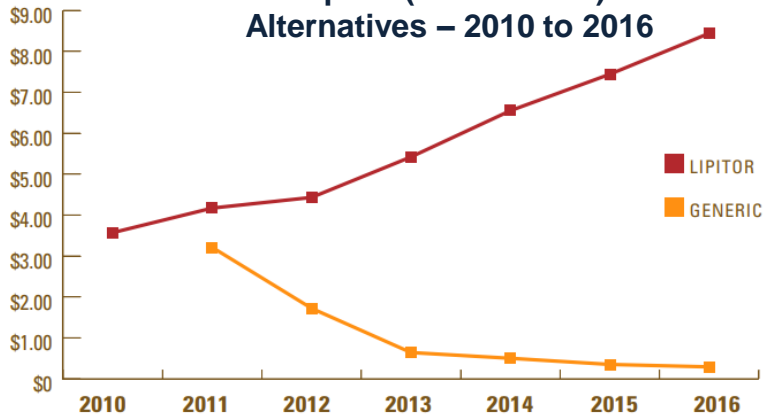
Generics

- Create competition
- Result in cost savings
- Example: Lipitor generics resulted unit cost to decrease below \$1 from >\$4

Biosimilars

- Create competition
- Result in cost savings
- Example: First biosimilar approved and marketed in the US is 17.4% below innovator price

Unit Price of Lipitor (atorvastatin) 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% | 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% |

Zarxio® vs Neupogen® List Price (480mcg Syringe)

Zarxio® (filgrastim-sndz)



Neupogen® (filgrastim)



\$0 \$100 \$200 \$300 \$400 \$500 \$600 \$700

Source: BCBSA Health of America: Rising costs for patented drugs drive growth of pharmaceutical spending in the U.S. Available online @ www.bcbs.com

Marketing and Drug Coupons

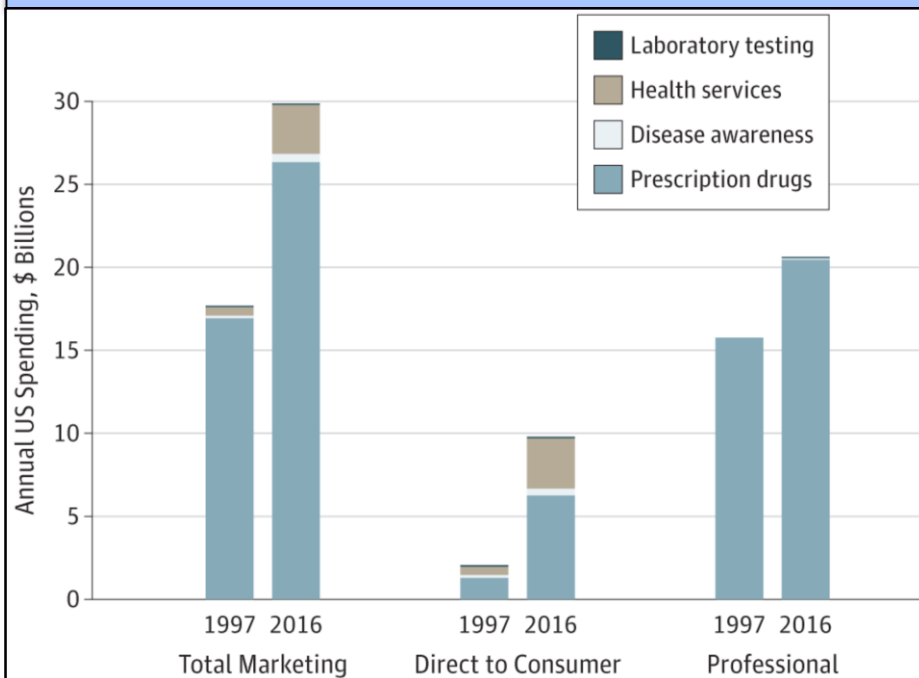
Marketing

- Medical marketing increased from **\$17.7B** in 1998 to **\$29.9B** in 2016
- DTC advertising accounted for the largest growth

Drug Coupons

- Coupon use has reached **18%** of all branded prescriptions filled under commercial plans and **42%** of specialty prescriptions

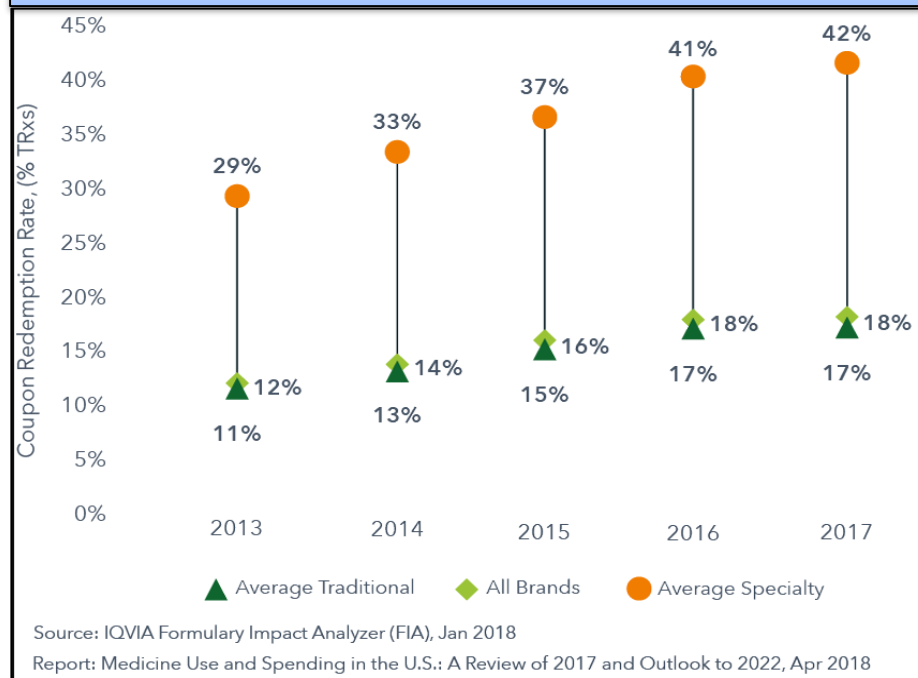
Medical Marketing in the US (1997 vs 2016)*



*Does not include spending on coupons, online promotion, and meetings.

Source: Schwartz LM, Woloshin S. Medical marketing in the United States, 1997-2016 [published January 8, 2019]. JAMA. doi:10.1001/jama.2019.19320

Coupon Redemption Rate in Commercial Plans for Branded Products by Product Type (2013 - 2017)*



Source: IQVIA Formulary Impact Analyzer (FIA), Jan 2018

Report: Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022, Apr 2018

*Coupon penetration rate is based on commercially insured patients only, cash patients are excluded and Medicare/Medicaid are precluded by law from the use of coupons. Specialty therapy areas have significant volume through mail-order pharmacies, which are not included in this analysis.

- Pharmaceutical Manufacturers set list prices for prescription drugs
- PhRMA reports that on average it takes 10 years and \$2.6B to bring a new drug to market
- Discounts and rebates attained by others in the supply chain contribute to reduced net prices
 - Government discounts, PBM negotiated rebates, patient coupons, wholesaler and pharmacy discounts
- Manufacturers can raise prices whenever they want.....and they do....
- Actions by pharmaceutical manufacturers, new high priced medications, steady price increases on existing products and investigations have raised questions about what really goes into drug pricing.
 - Senate Finance Committee Investigation into Gilead's pricing of Sovaldi for Hepatitis C revealed a pricing and marketing strategy designed to maximize revenue with little concern for access or affordability.*

Drug Companies Greet 2019 with U.S. Price Hikes

Michael Erman

JANUARY 2, 2019

NEW YORK (Reuters) - Drugmakers kicked off 2019 with price increases in the United States on more than 250 prescription drugs, including the world's top-selling medicine, Humira, although the pace of price hikes was slower than last year.

Source: Reuters. Available online @ www.reuters.com

Prescription Drug Costs Driven By Manufacturer Price Hikes, Not Innovation

Health news from NPR - Alison Kodjak
January 7, 2019 5:04 PM ET

The skyrocketing cost of many prescription drugs in the U.S. can be blamed primarily on price increases, not expensive new therapies or improvements in existing medications as drug companies frequently claim, a new study shows.

Source: NPR. Available online @ www.NPR.com

* Senate Finance Committee, The Price Of Sovaldi and Its Impact On The U.S. Health Care System December 2015. Available online @ www.finance.senate.gov



Prescription Drug Benefits

- Coverage of prescription medications
- Access to a nationwide network of pharmacies
- Preventive medications at \$0 cost
- Real-time drug pricing information
- Etc...



Member Protections

- Minimum loss ratio
- Out of pocket maximums
- Drug safety programs
- Etc...



Regulatory Compliance

- Network adequacy
- Drug formulary coverage standards
- Utilization management standards
- Etc...



Pharmacy Benefit Manager Contracting

- Claims processing
- Pharmacy networks
- Negotiate prescription drug rebates
- Etc...

Would knowing more about how pharmaceutical manufacturers price their medications be helpful?

