



Why are the costs of Medications Increasing and What Can Be Done About It?

Troyen Brennan, MD

Translate. Interpret. Celebrate. Coordinate. Collaborate.
Invest. Engage. Contribute. Explain. Support. Question.
Reason. Expand. Achieve. Reach. Deliver. Create the
Future. Change. Lead. Network. Experience. Learn.

Increase in Prescription Drugs Costs was the Leading Health Care Issue of 2015

The New York Times

Sept. 20

“Drug Goes from \$13.50 a Tablet to \$750, Overnight”



REUTERS

Oct. 2

“Pfizer Raised Prices on 133 Drugs This Year, And It’s Not Alone”

**Bloomberg
Business**

Oct. 12

“Transatlantic Divide: How U.S. Pays Three Times More for Drugs”



Sept. 21

“Clinton Calls Drug Price Hike ‘Outrageous,’ Vows Plan”

THE WALL STREET JOURNAL.

Oct. 5

“For Prescription Drug Makers, Price Increases Drive Revenue”

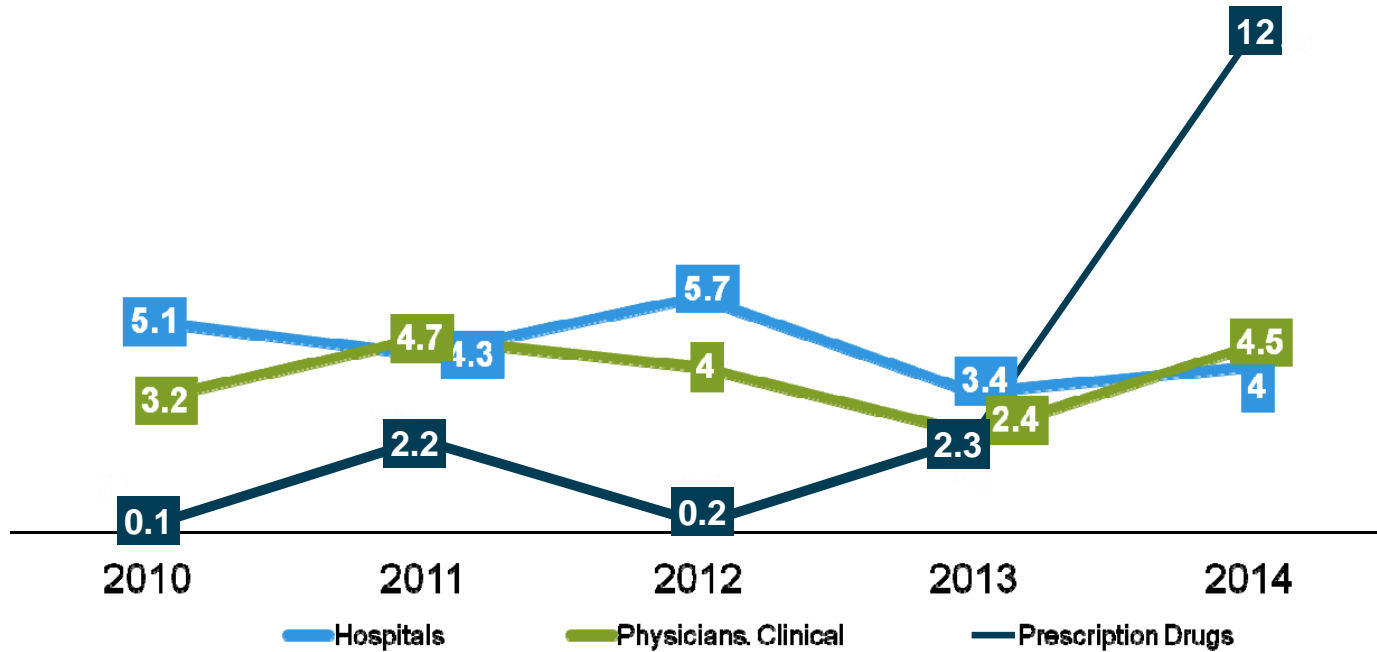
AP

Dec. 18

“Employers Battle Drug Costs”

And indeed the data does show that drug costs increased substantially in 2014 into 2015

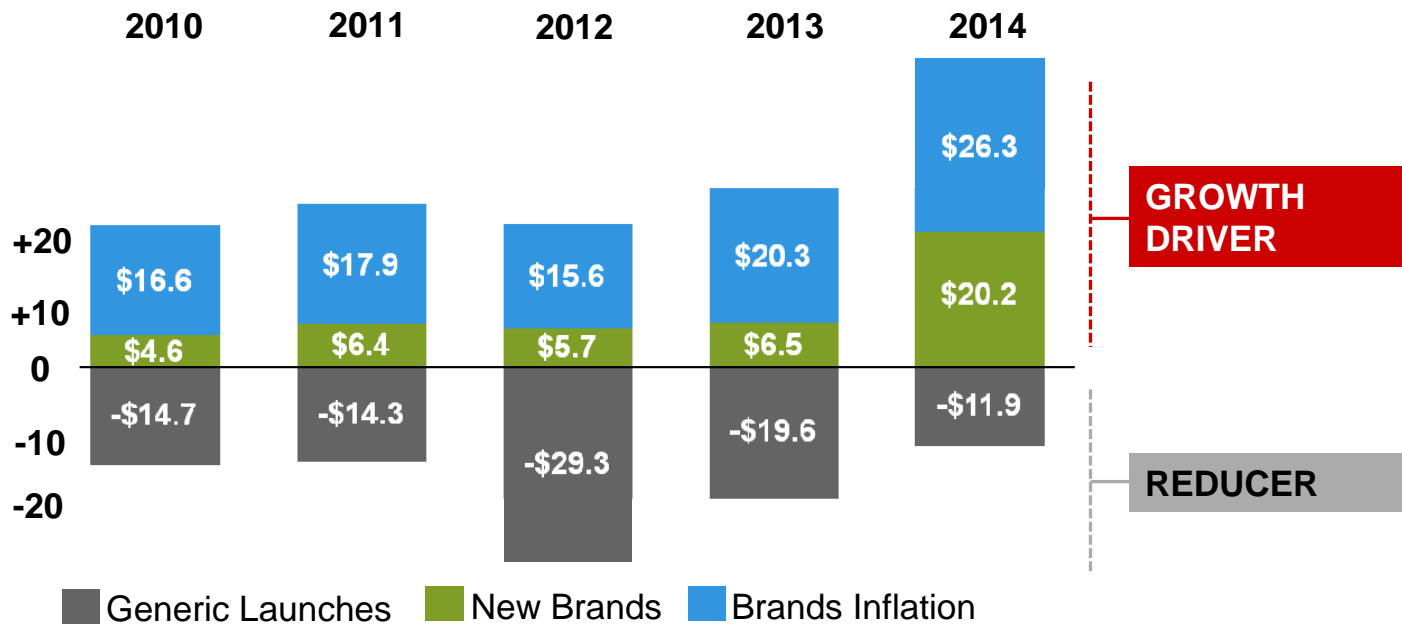
PERCENTAGE GROWTH IN HEALTH SPENDING BY CATEGORY



And indeed the data does show that drug costs increased substantially in 2014 into 2015

The Big Picture: Fewer Generic Breakouts, More Blockbuster Brands

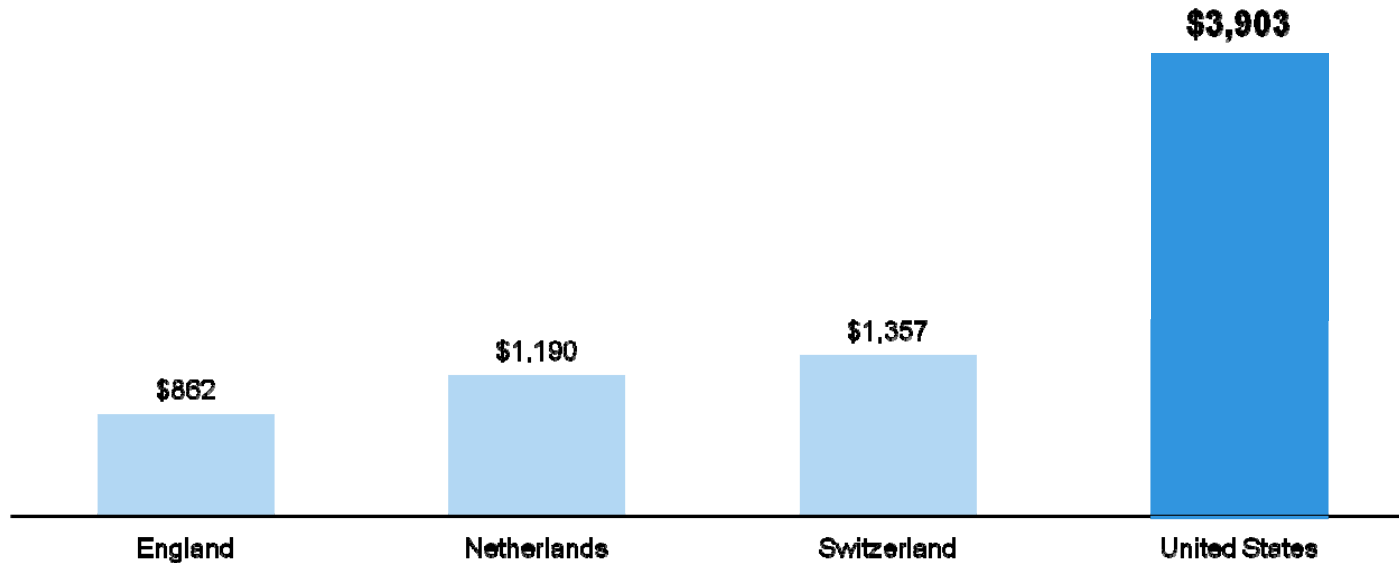
CONTRIBUTION TO GROWTH IN DRUG SPENDING, BY SPENDING GROWTH DRIVERS, IN \$US BILLIONS, 2010–2014



Source: IMS Institute for Healthcare Informatics. Medicines Use and Spending Shifts: A Review of the Use of Medicines in the U.S. in 2014.

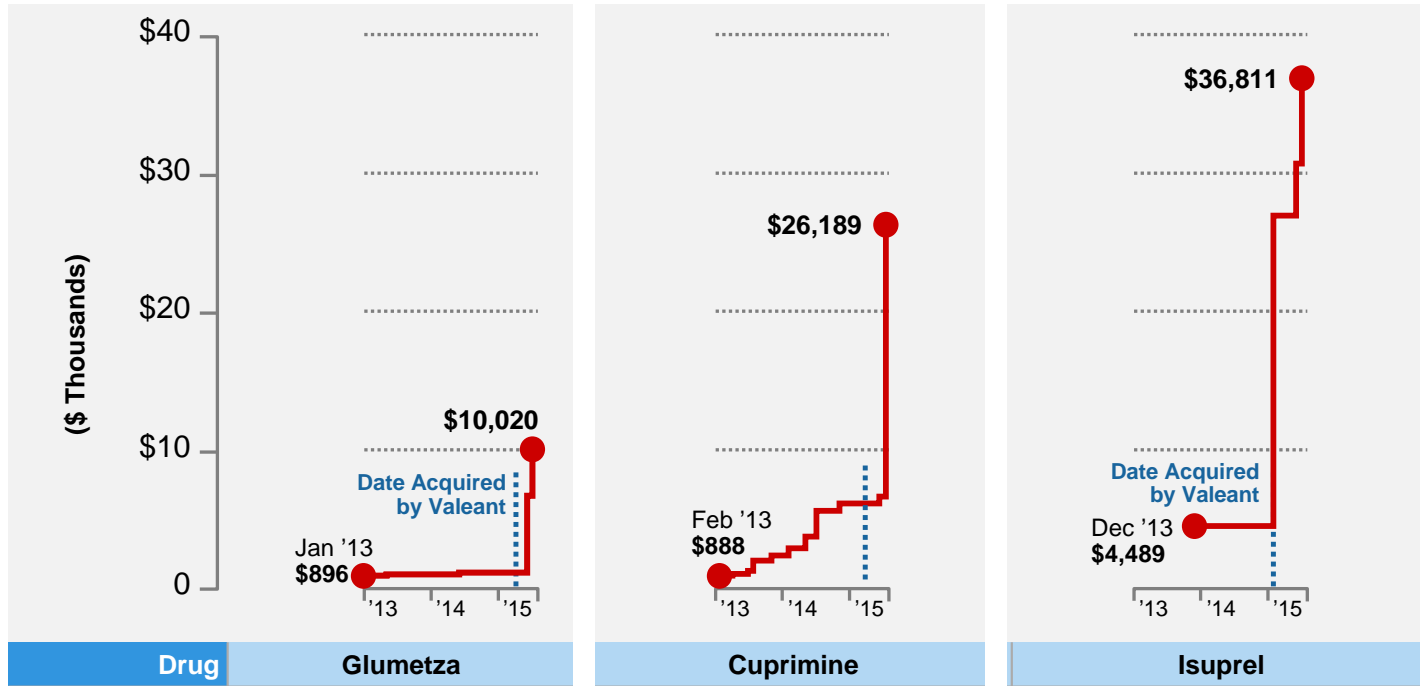
The Focus in the Press: Significantly Higher Prices for Brands in the United States

AVERAGE PRICE, 2013, FOR COPAXONE IN FOUR MARKETS



Source: International Federation of Health Plans Notes: U.S. average prices are calculated using commercial claims data from Truven MarketScan Research databases. Methods and sources for comparable countries can be found here: <http://www.ifhp.com/1404121>

And on Rapidly Rising Prices: Valeant Strategy Is To Buy and Mark Up

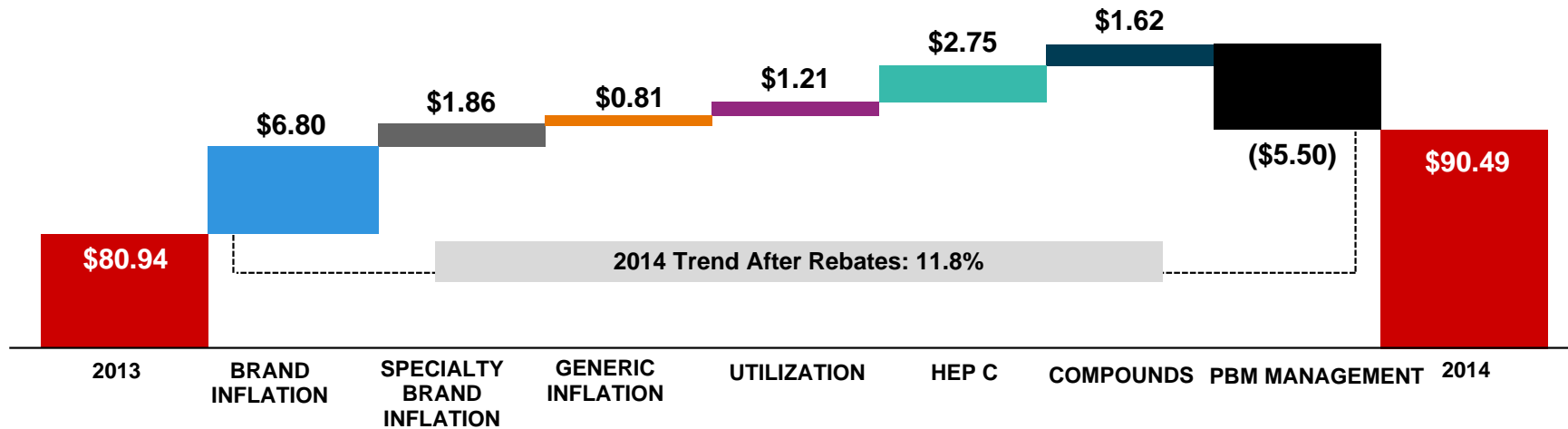


Prices have risen by as much as 29X the cost at launch

Note: The rights to Syprine, Cuprimine and Demser were acquired by Valeant in 2010. Source: AB Bernstein.
Pollack A. and Tavernise S., "Valeant's Drug Price Strategy Enriches It, but Infuriates Patients and Lawmakers." The New York Times, October 4, 2015

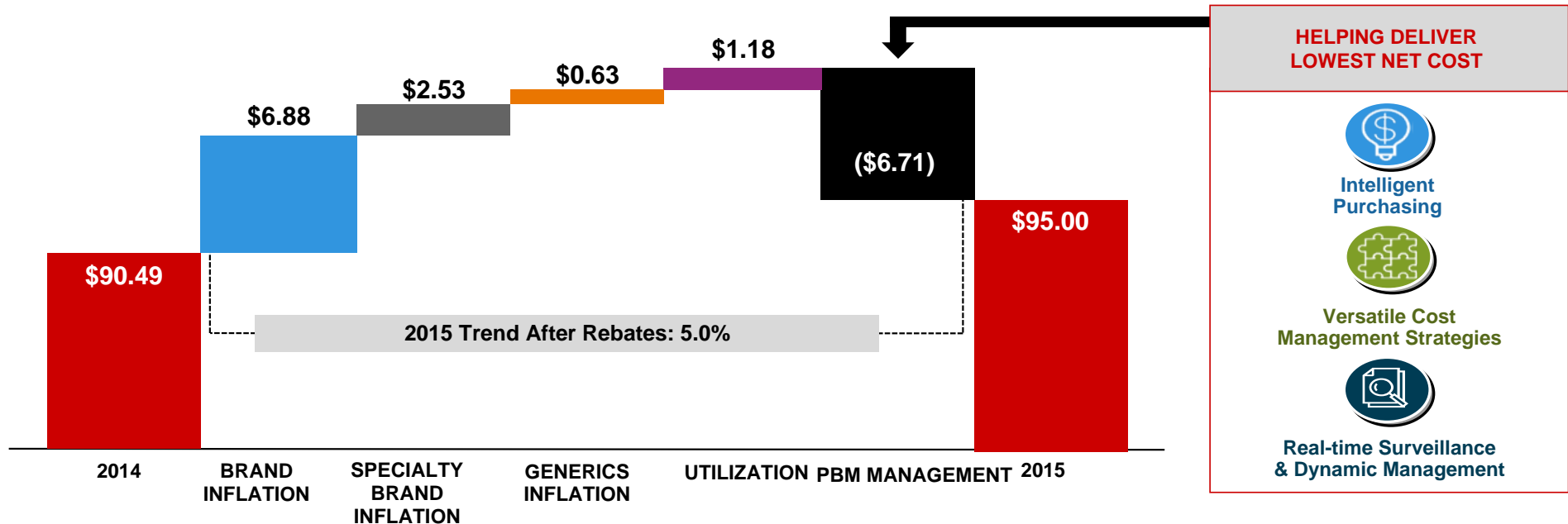
Double Digit Inflation in 2014 Was Driven by a Number of Factors

COMPREHENSIVE LOOK AT 2014 TREND DRIVERS

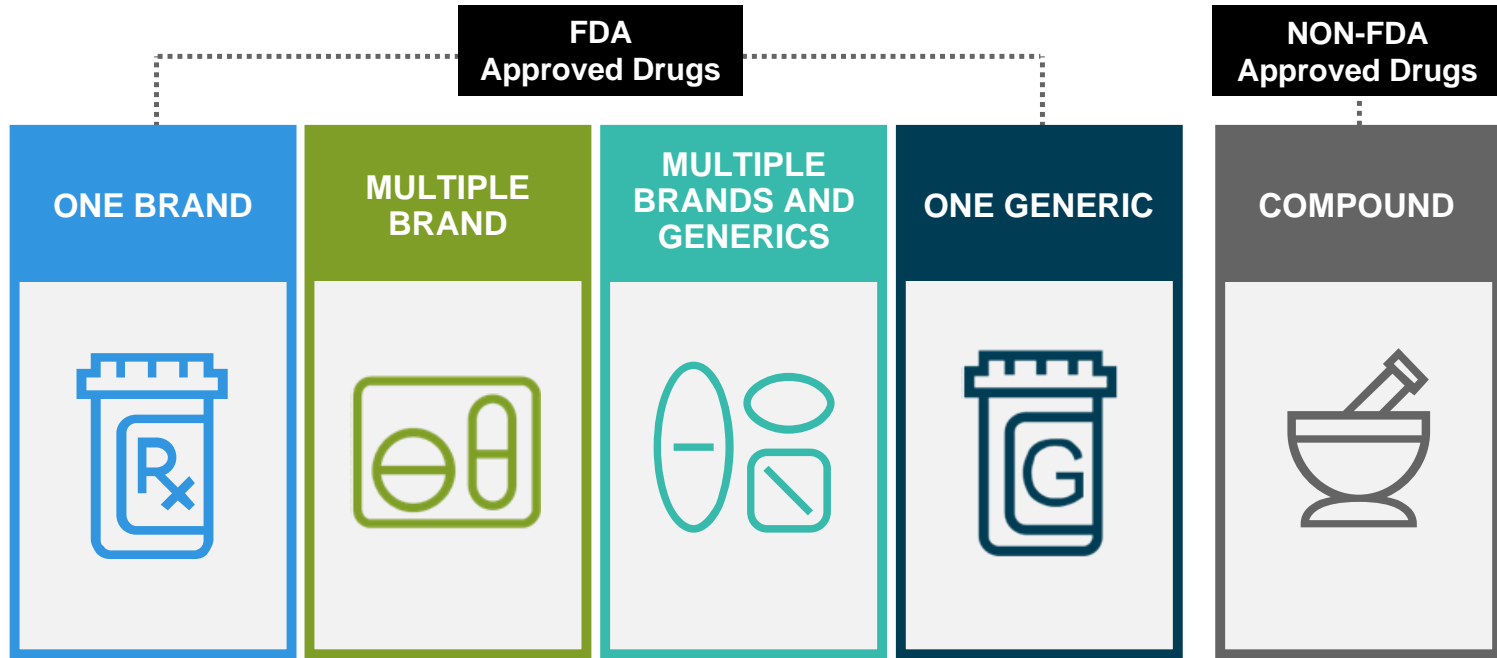


Detailed Analysis of 2015, Reveals Some Moderation and Key Targets for Controlling Costs

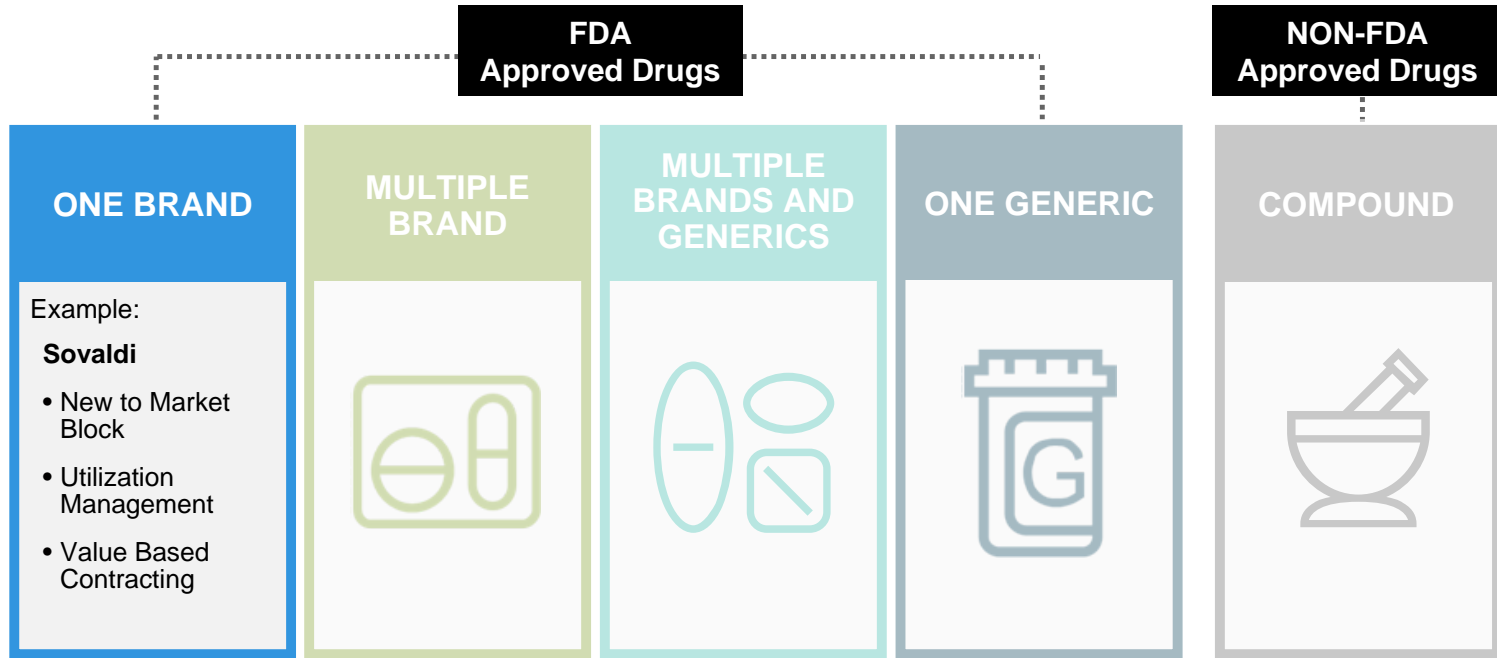
COMPREHENSIVE LOOK 2015 TREND DRIVERS



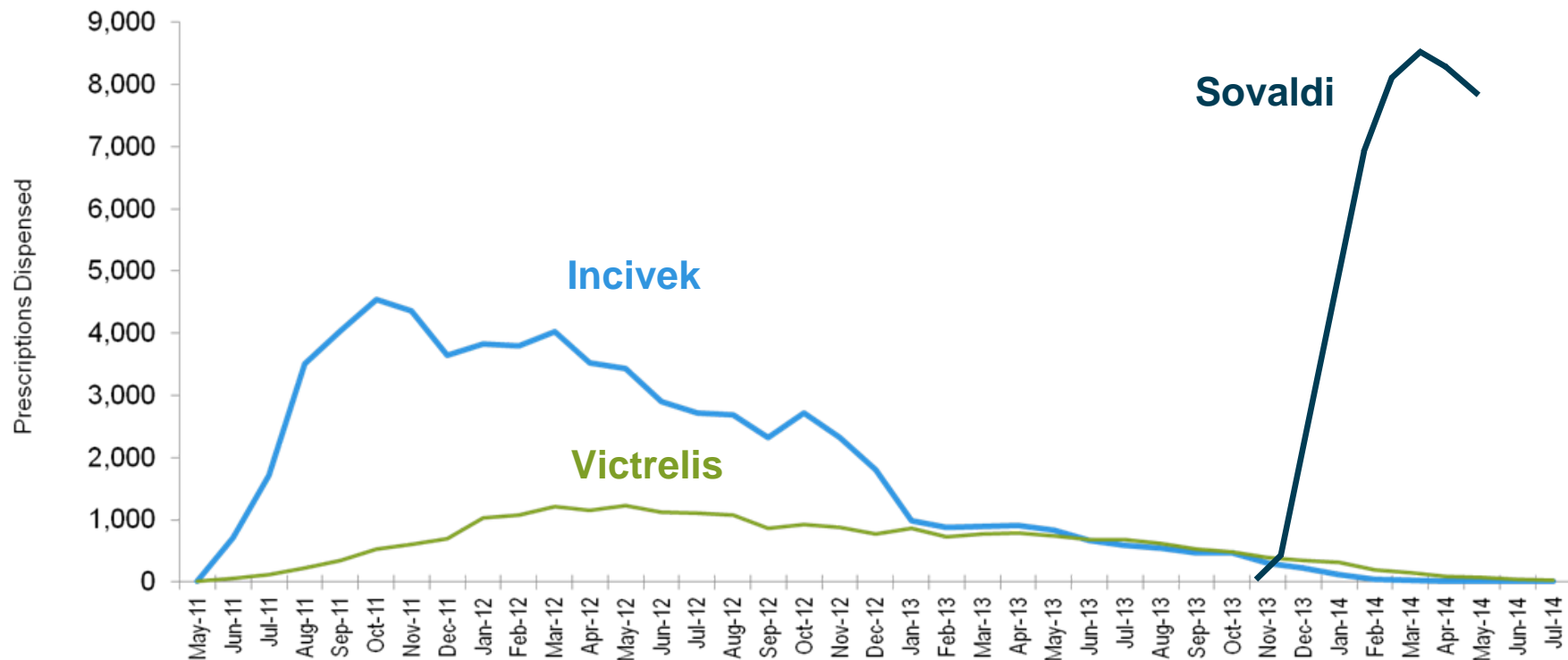
Our Approach: Helping Deliver Lowest Net Cost, While Ensuring Evidence-Based Health



Our Differentiated Approach: Helping Deliver Lowest Net Cost; Ensure Evidence-Based Health





One Brand: Sovaldi Replaces Other Hep C Drugs Due to Significantly Greater Efficacy

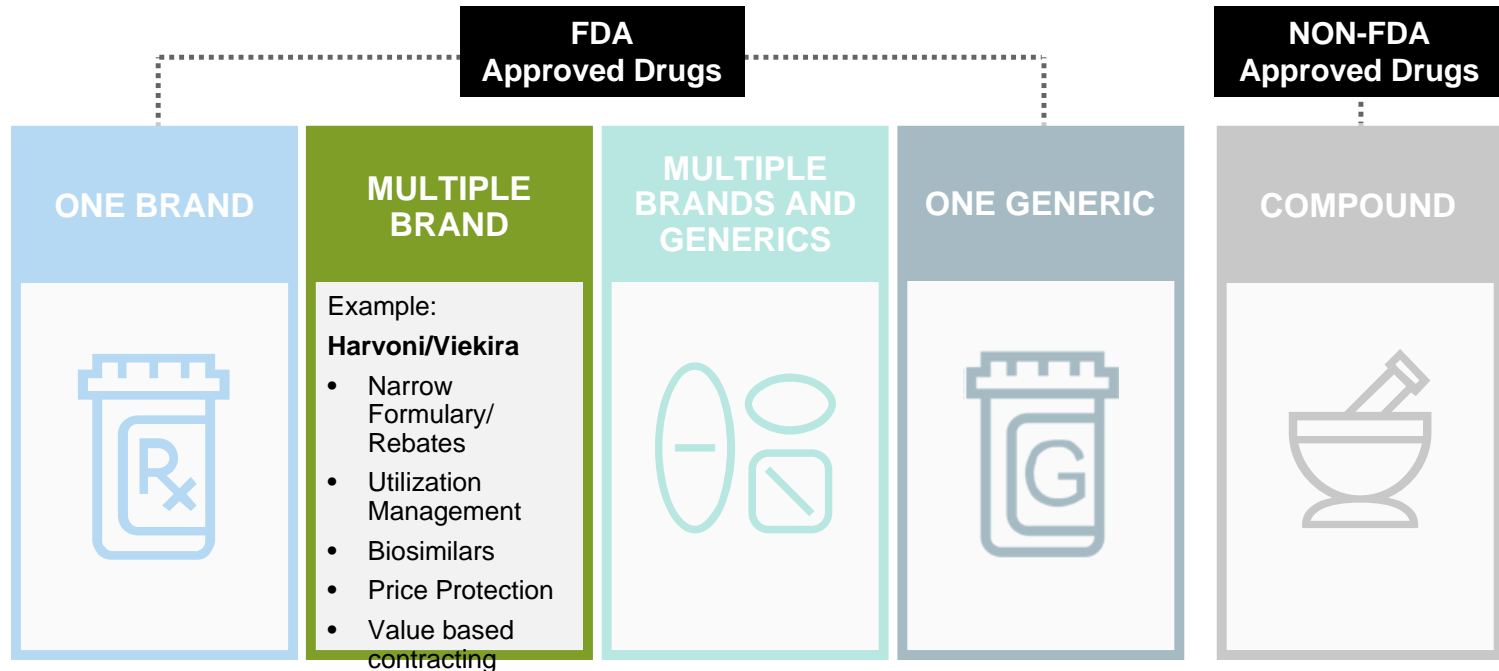


CVS/caremark analysis, 2015.

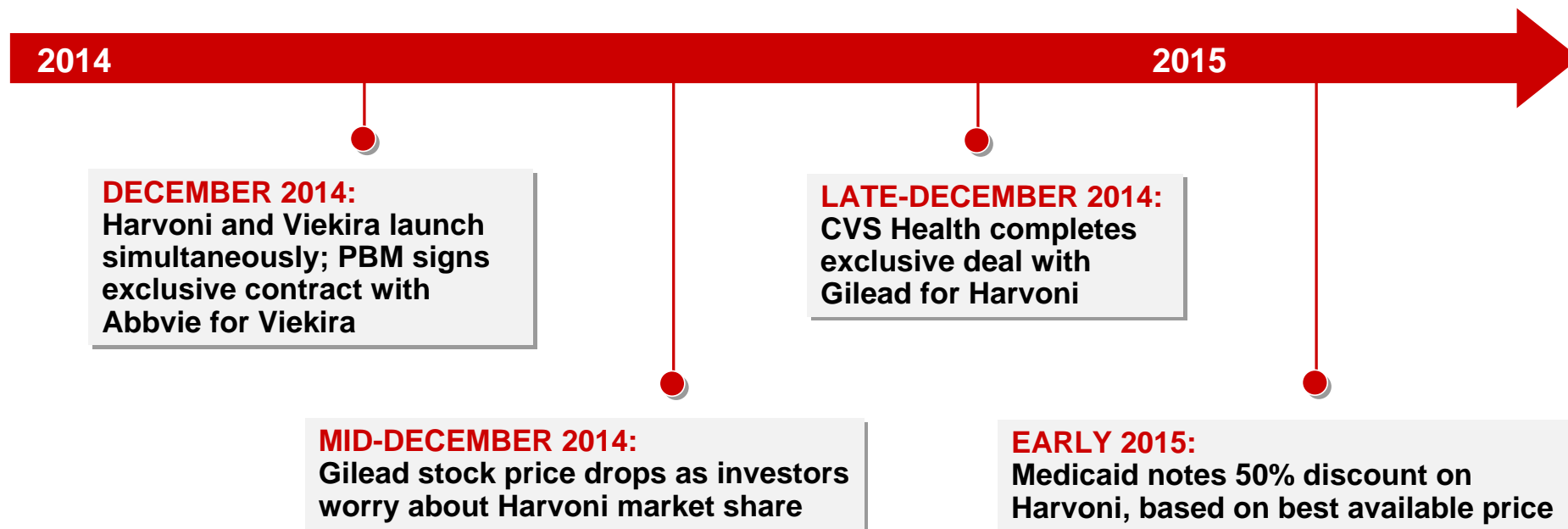
Insurers Take Varied Approaches to Managing Utilization of Sovaldi

MEDICARE	ILLINOIS MEDICAID
1. Any hepatitis C infection	1. Must be Metavir class 4 or greater
2. No consideration of interferon eligibility	2. Must be interferon ineligible
3. No limits on life expectancy	3. Life expectancy >12 months
4. Treatment available even if actively using alcohol/opiates	4. No evidence of substance abuse in the last 12 months
5. Re-treatment approved	5. "Once in a lifetime" restriction
 100% VARIATION IN CRITERIA 	

Our Differentiated Approach: Helping Deliver Lowest Net Cost, Ensure Evidence-Based Health

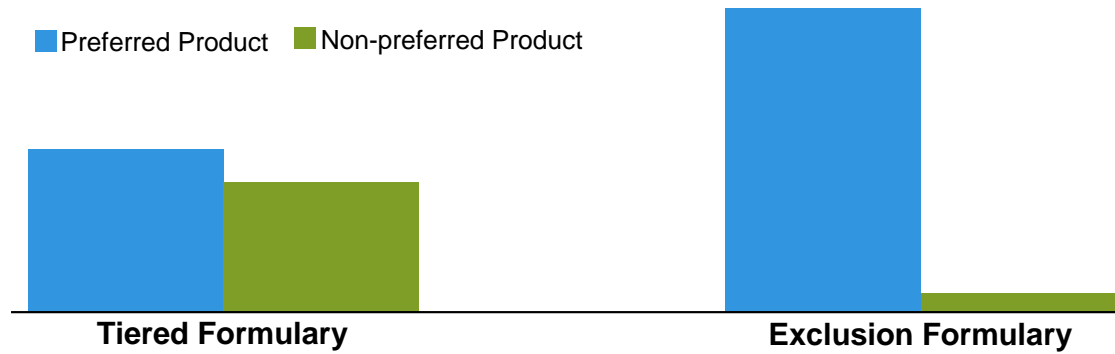


Multiple Brand: Intelligent Purchasing of New Hepatitis C Drugs Enabled by Competition



Multi-Brand Management Requires Plans to Adopt Exclusion Formularies

EFFECTIVE BEHAVIOR CHANGE



- CVS/caremark pioneered formulary exclusion in 2012 amid substantial consultant opposition
- Combined with new to market block, gives additional time to negotiate and get better financial value for our PBM clients

Key advantage: coupons do not work for formulary exclusions because plan designs cannot be subverted

The ability to exclude a product may vary based on the plan type, therapeutic category and other factors.

Although Held Up by Complex FDA Regulation, Biosimilars Are Coming

INTELLECTUAL PROPERTY & INNOVATION

By Benjamin P. Falit, Surya C. Singh, and Troyen A. Brennan

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HEALTH AFFAIRS 34,
NO. 2 (2015): 294-301
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The People-to-People Health
Foundation, Inc.

Biosimilar Competition In The United States: Statutory Incentives, Payers, And Pharmacy Benefit Managers

Benjamin P. Falit (bfalit@partners.org) is a resident physician in the Harvard Radiation Oncology Program, in Boston, Massachusetts.

Surya C. Singh is the corporate vice president of specialty client solutions and trend management at CVS Health in Lincoln, Rhode Island.

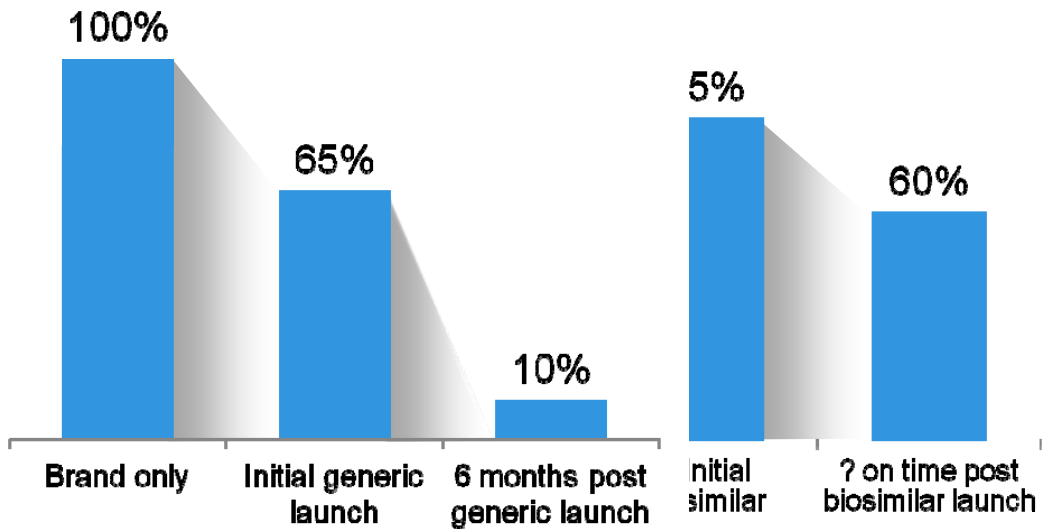
Troyen A. Brennan is the chief medical officer at CVS Health in Woonsocket, Rhode Island.

ABSTRACT Widespread adoption of generic medications, made possible by the Hatch-Waxman Act of 1984, has contained the cost of small-molecule drugs in the United States. Biologics, however, have yet to face competition from follow-on products and represent the fastest-growing sector of the US pharmaceutical market. We compare the legislative framework governing small-molecule generics to that which regulates follow-on biologics, and we examine management tools that are likely to be most successful in promoting biosimilars' adoption. The Biologics Price Competition and Innovation Act established an abbreviated pathway for follow-on biologics, but weak statutory incentives create barriers to entry. Many authors have raised concerns that competition under the

Regulatory Structure for Biosimilars Differs Significantly from Small Molecule Generics

Hatch Waxman act: no clinical trial needed; RAPID INCREASE IN COMPETITORS

once REGULATORY HURDLES

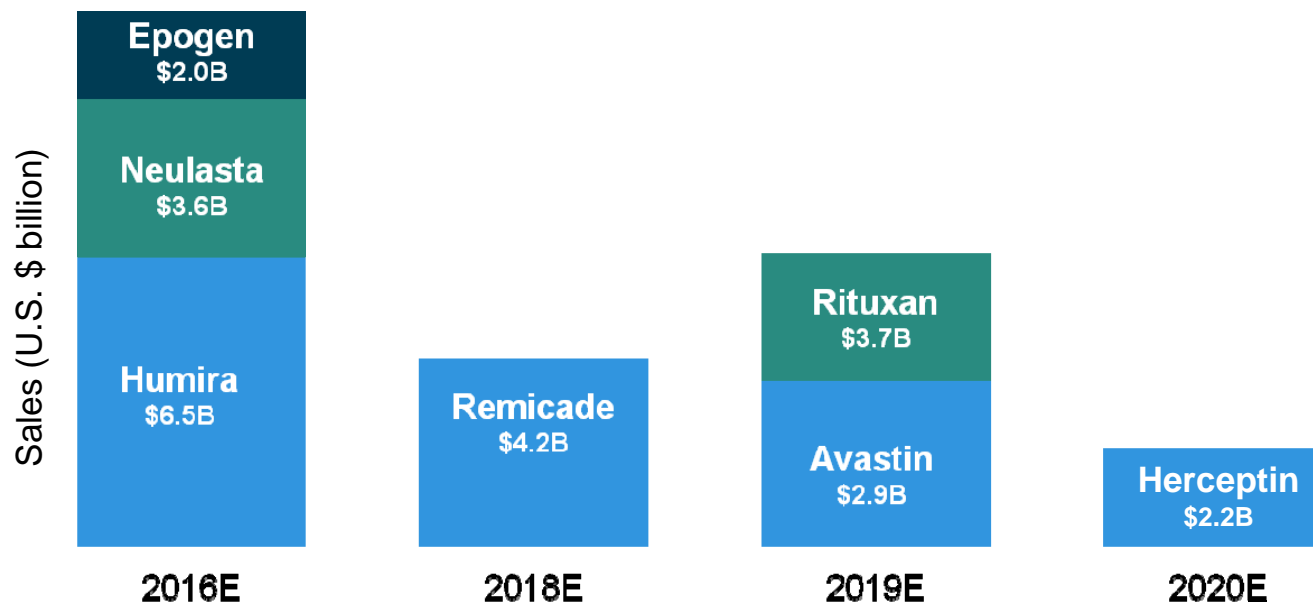


Adopting an exclusion formulary – blocking certain brands with available alternatives – is critical to drive lowest net cost.

1. The Effect of Generic Drug Competition on Generic Drug Prices During the Hatch-Waxman 180-Day Exclusivity Period, Bureau of Economics, FTC. April 2013. 2. The Economics of Biosimilars. American Health and Drug Benefits. Sept – Oct 2013.

Biosimilars Will Create Multiple Brand Formulary Paradigms in Many Categories

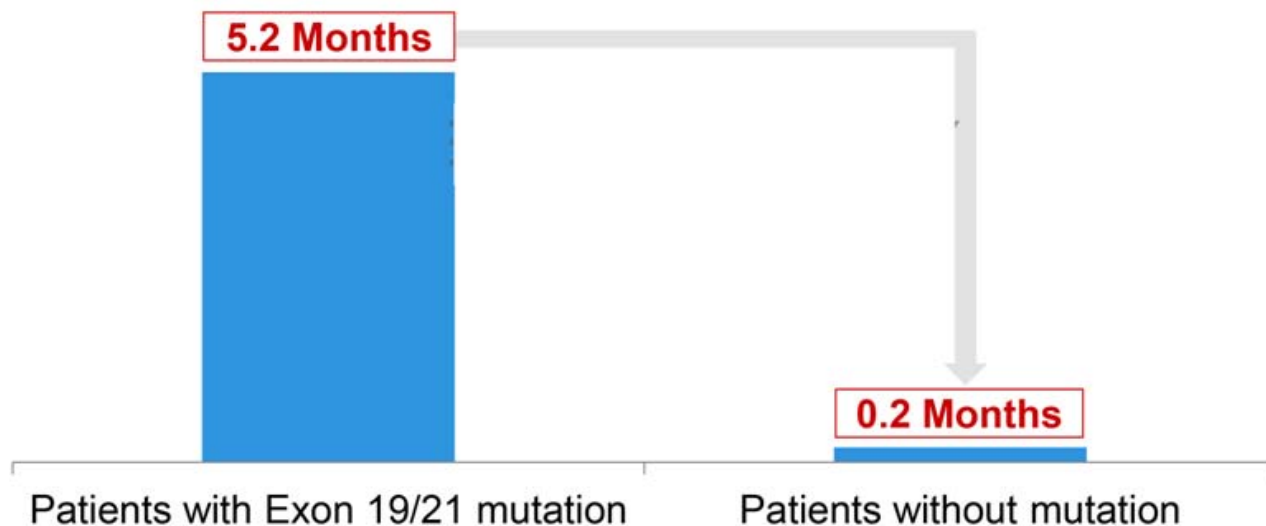
YEAR OF ANTICIPATED EARLIEST POSSIBLE MARKET ENTRY*



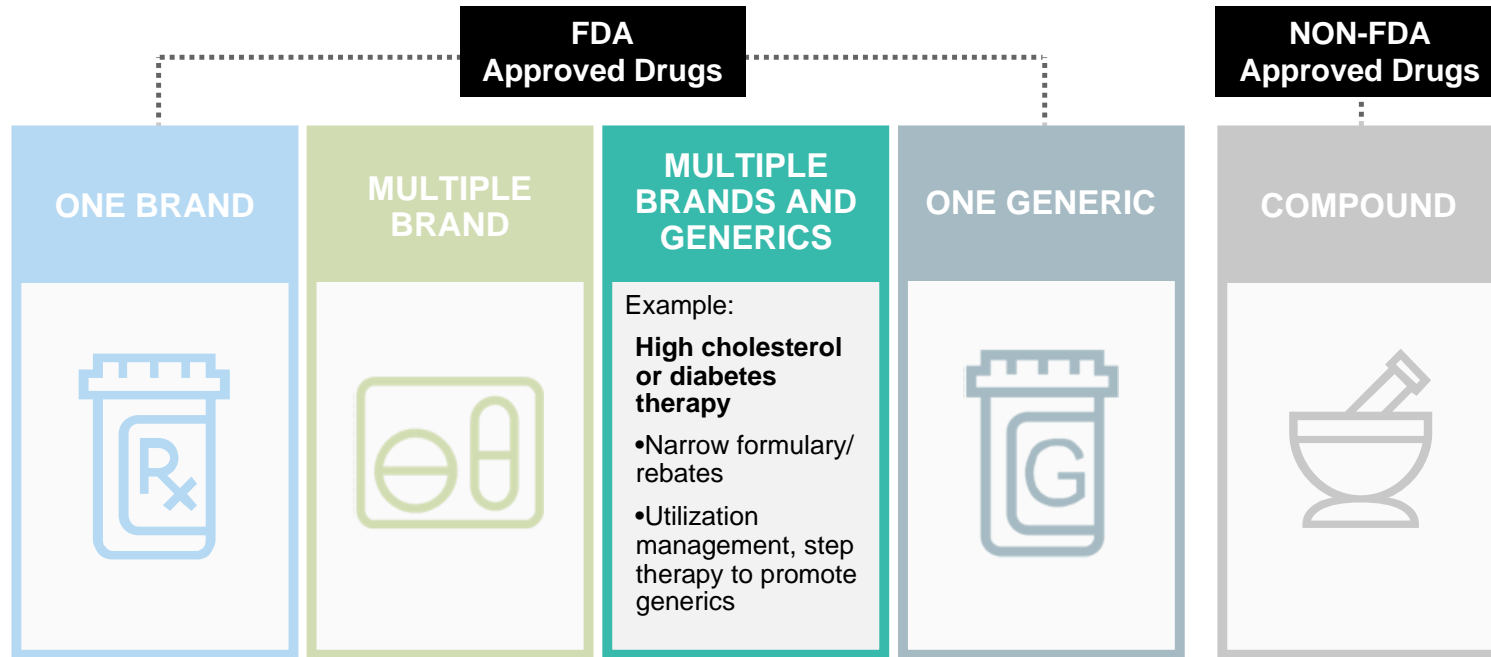
*Many of the drugs on this slide (except Enbrel and Humira) are primarily covered under the medical benefit and the impact on the client's pharmacy costs would likely be much smaller for these drugs.
 Source: CVS/caremark internal data, 2015. Note anticipated date earliest possible market entry.
 This slide contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS/specialty.

Our Approach to Value Based Contracting: Example Non-Small Cell Lung Cancer

TARCEVA EFFECTIVENESS IN EXTENDING PROGRESSION-FREE SURVIVAL



Our Differentiated Approach: Helping Deliver Lowest Net Cost, Ensure Evidence-Based Health



Competition: Expensive PCSK9 Inhibitors vs. Inexpensive Statin Therapy

CURRENT TREATMENT GUIDELINES

- ✓ Focus on reducing cardiovascular disease risk
- ✓ Emphasize lifestyle modifications
- ✓ Recommend statins, dosed at the appropriate intensity, in at-risk patients and those with cardiovascular disease



FAMILIAL HYPER-
CHOLESTEROLEMIA

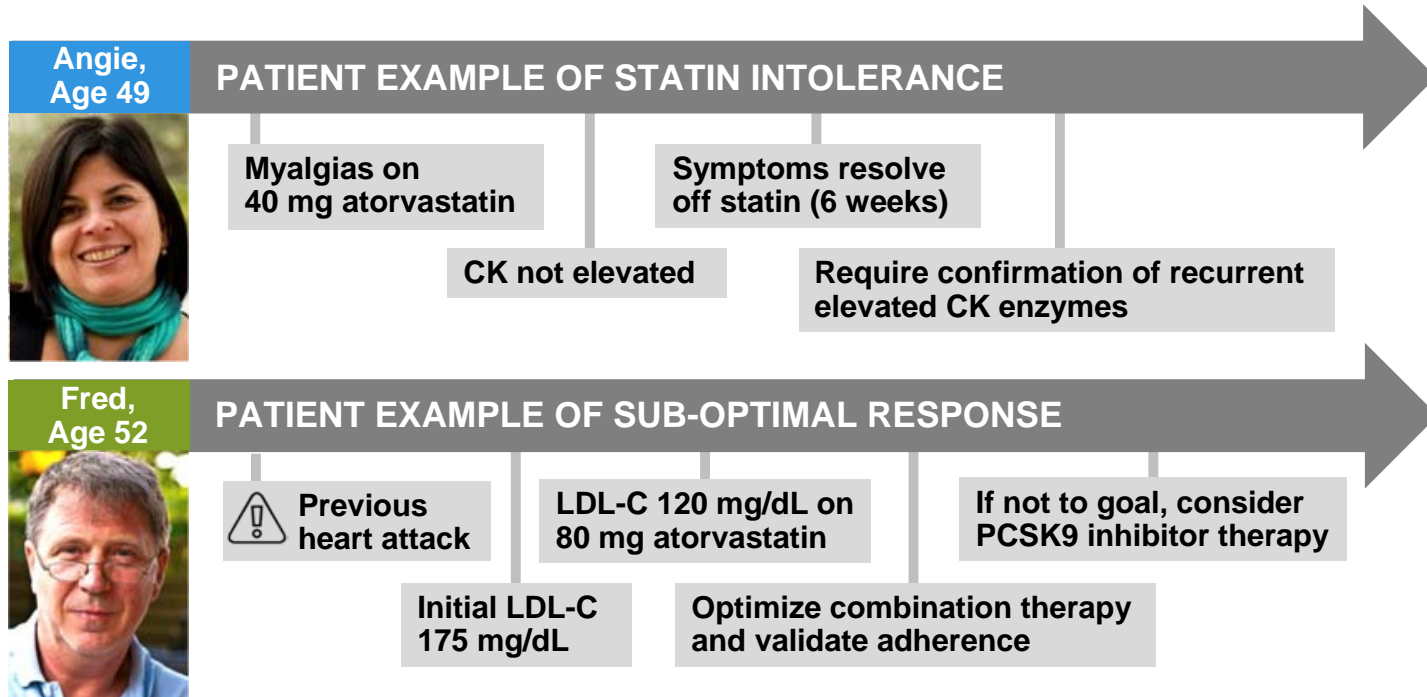


STATIN
INTOLERANCE



SUB-OPTIMAL
RESPONSE TO STATINS

Effective Cost Control Relies on Thoughtful Management Before Use of PCSK9 Inhibitors



Require prior authorization based on adherence and lab data

These are examples and not actual patients.

Current Guidelines Dismiss Use of Specific LDL Levels in Establishing Therapy

LOTS OF RECENT COMMENTARY

JAMA The Journal of the

One problem is that the recent ACC/AHA guidelines abandoned the longstanding principle that clinicians should treat patients to a specific LDL-C target.

William H. Shrank, MD,
MSHS
CVS Health,
Woonsocket, Rhode
Island.

Jane F. Barlow, MD,
MPH
CVS Health,
Woonsocket,
Rhode Island.

Troyen A. Brennan,
MD, JD
CVS Health,
Woonsocket,
Rhode Island.

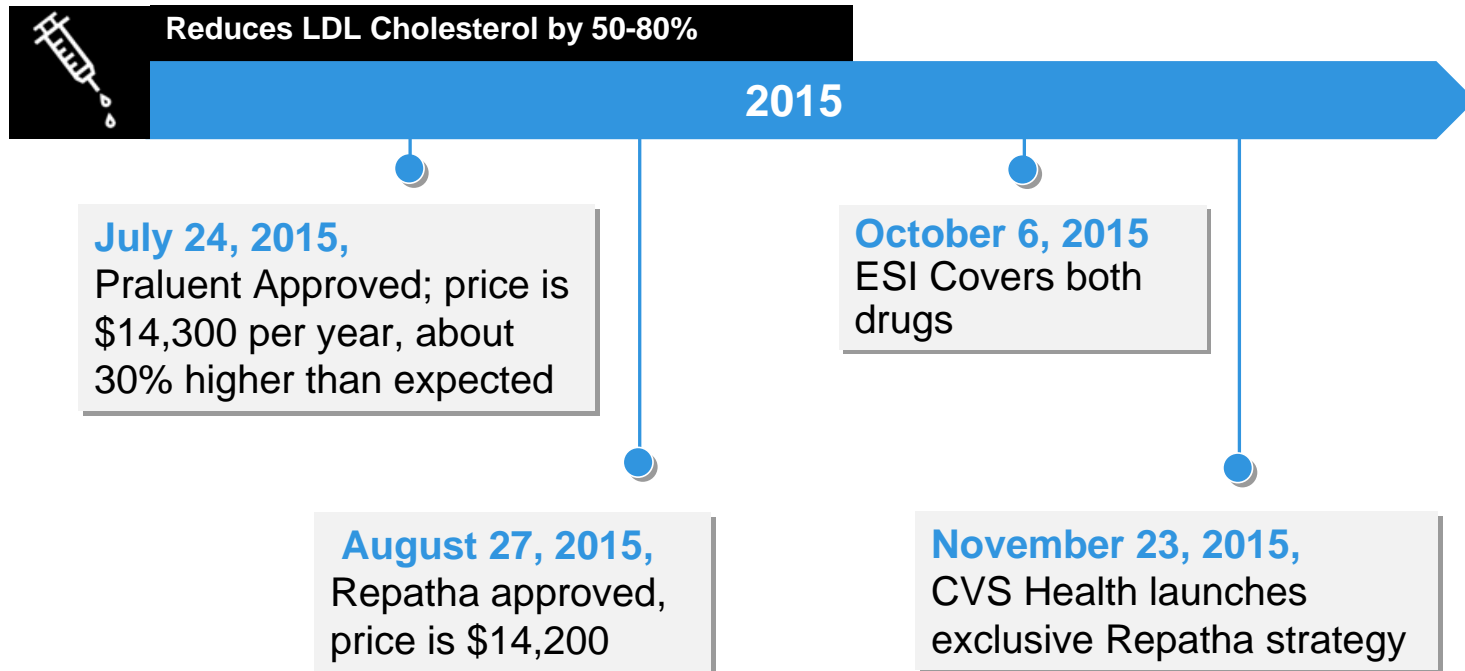
On July 25, the US Food and Drug Administration (FDA) approved alirocumab (Praluent), the first in a new class, the proprotein convertase subtilisin/kexin type 9 (PCSK-9) inhibitors. Approval of a second medication in the class is expected shortly. The injected medications are used to treat patients with hyperlipidemia, and early results suggest these drugs have a powerful effect on levels of low-density lipoprotein cholesterol (LDL-C), likely more potent than statins.¹ Although evidence continues to accumulate, the class appears to represent an important new development in hyperlipidemia management.

This class also poses a new challenge for health care payers. It is an expensive specialty medication that targets a very common condition; more than 73 million

this challenge in 2013, when little clinical evidence was available for this new class of medications.

One problem is that the recent ACC/AHA guidelines abandoned the longstanding principle that clinicians should treat patients to a specific LDL-C target. Prior to the release of the new guidelines, this group's earlier guidelines had always centered on stratifying patients by their cardiovascular risk, assigning an LDL-C target, and titrating medication use to reach that target. The newest set of guidelines noted that the trials on which those guidelines were based were not designed to test a treat-to-target approach.⁵ The authors modified the guidelines and now suggest that once patients are stratified based on risk, the most effective therapy should be initiated. For patients at

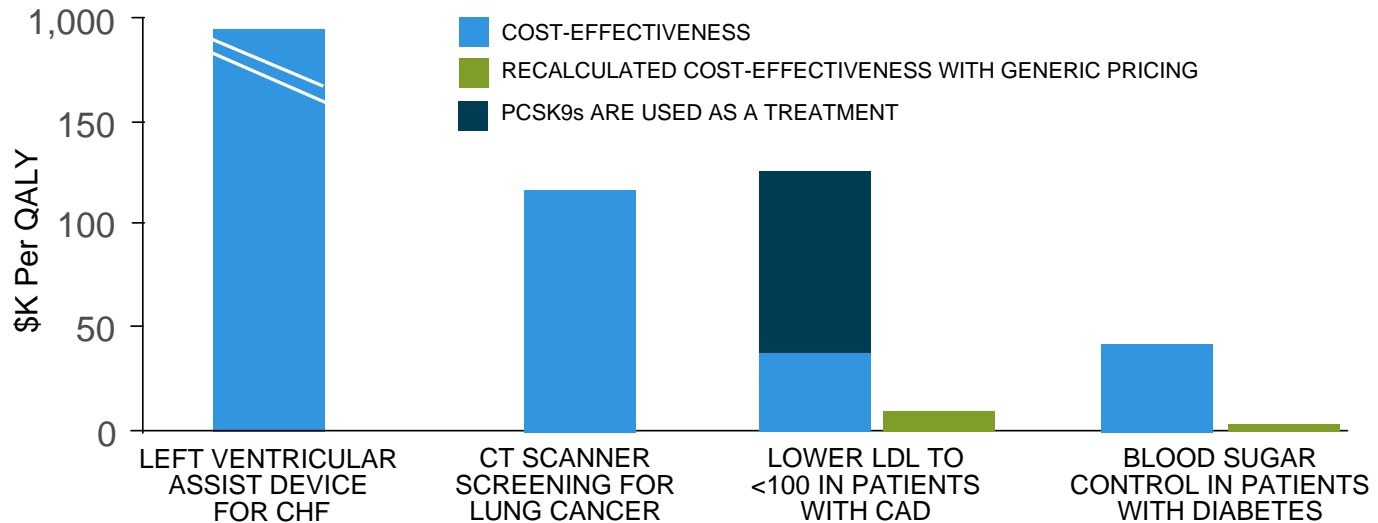
Versatile Management Programs then Complemented by Intelligent Purchasing



New to market block with exclusive formulary drives better pricing while providing clinically-appropriate alternatives.

Original Value Based Contracting: Programs Moving People from Brand to Generic

HEALTH CARE COST SAVINGS: ADHERENT VS. NON-ADHERENT

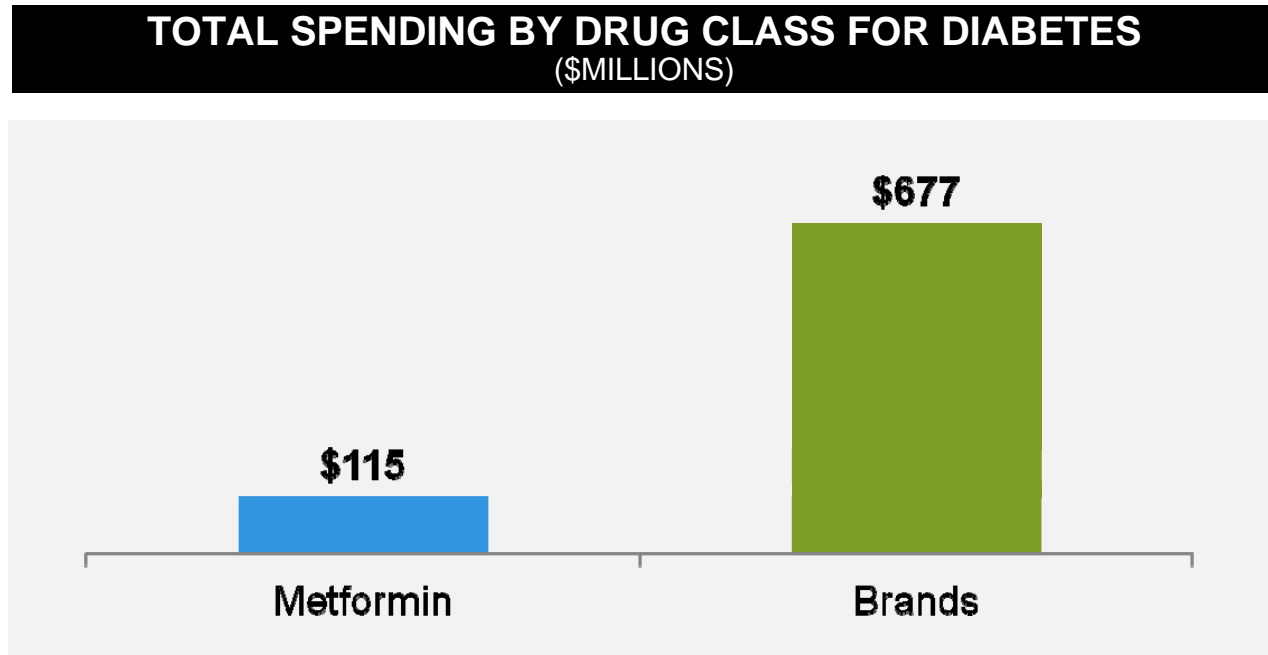


Cost effectiveness of health care interventions is measured in quality adjusted life years (QALY)

Sources: J.T. Cohen, P.J. Neumann and M.C. Weinstein, "Does Preventive Care Save Money? Health Economics And The Presidential Candidates," *New England Journal of Medicine*, 358(7) (Feb 14, 2008): 661-663. P.J. Mahadevia, L.A. Fleisher, K.D. Frick, J. Eng, S.N. Goodman and N.R. Powe, "Lung cancer screening with helical computed tomography in older adult smokers: a decision and cost-effectiveness analysis," *JAMA*, 289 (2003): 313-322. W.H. Shrank, N.K. Choudhry, J.N. Liberman and T.A. Brennan, "The Use Of Generic Drugs In Prevention Of Chronic Disease Is Far More Cost-Effective Than Thought, And May Save Money," *Health Affairs*, 30(7) (Jul 2011): 1351-1357.

Skillful Pharma Marketing Has Maintained High Brand Utilization, Leading to Higher Costs

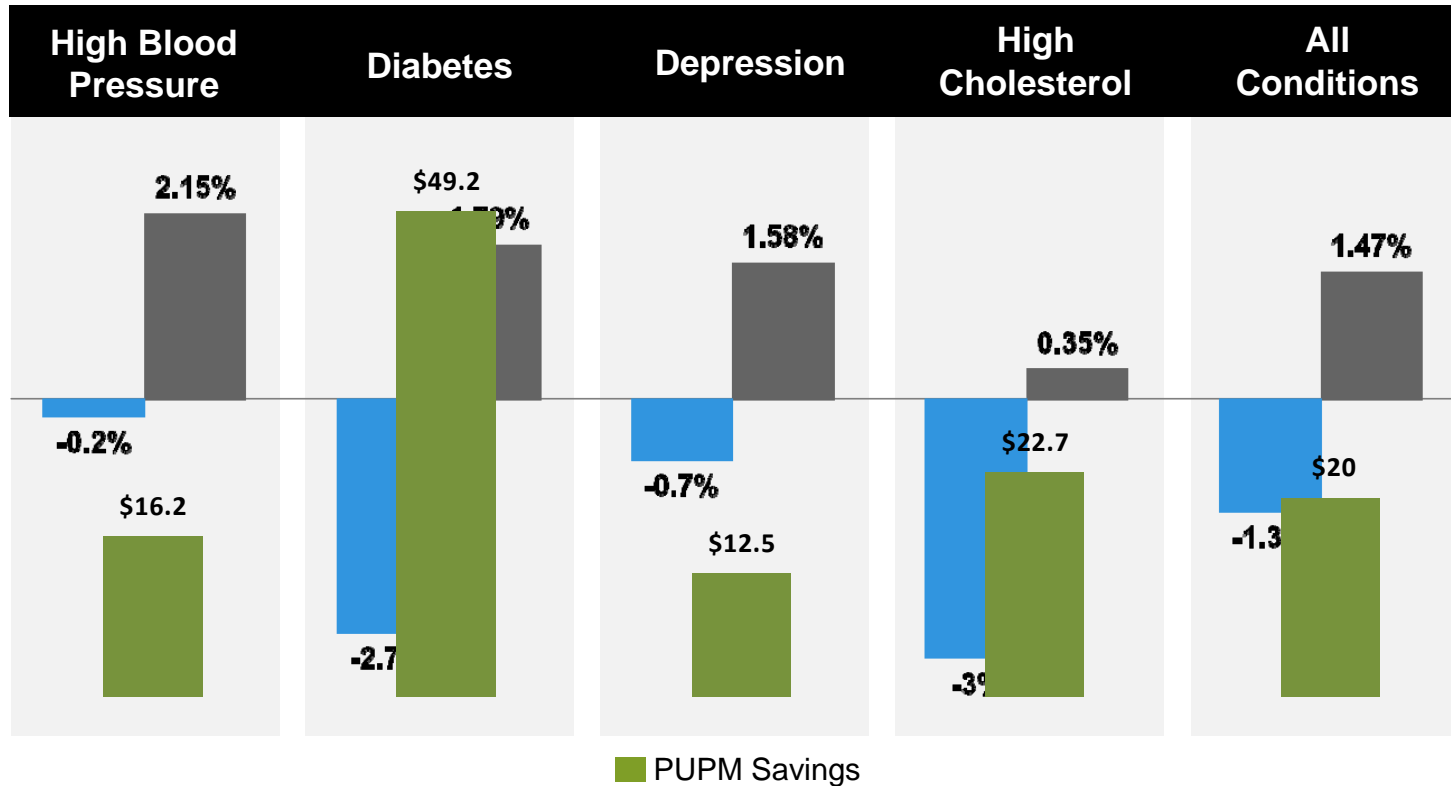
- Diabetes example: evidence based guidelines call for use of low cost generic metformin as the first step in therapy
- But nearly 50% of patients receive a brand first



Hence the need to adopt step therapy and formulary exclusions to drive lowest net cost while providing clinically-appropriate options

Publication: Patterns of Medication Initiation in Newly Diagnosed Diabetes Mellitus – Quality and Cost Implications (Desai, NR, et al. Am J Med 2012)

Formulary Strategy: Health First, Lower Costs



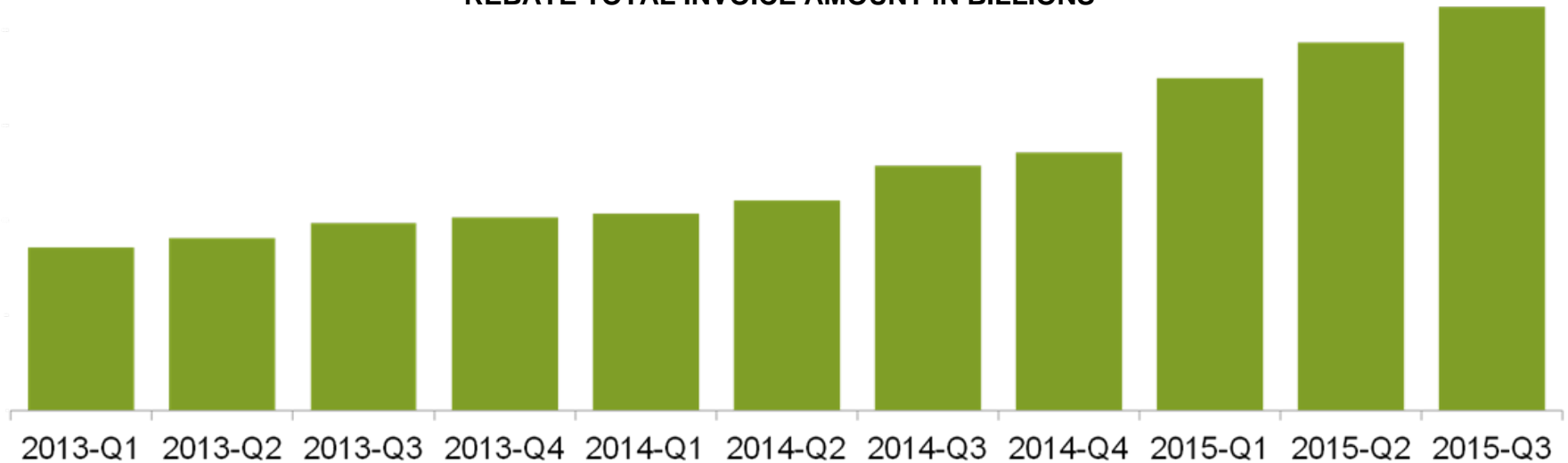
Formulary and UM edits are approved by Independent, Expert P&T Committee

CVS/caremark Analytics, 2015. Pending publication. PUPM = Per Utilizer Per Month

Intelligent Purchasing Leads to Rapid Increase in Rebate Value

GROWTH IN COMMERCIAL REBATES AND PRICE PROTECTION: 2013-2015

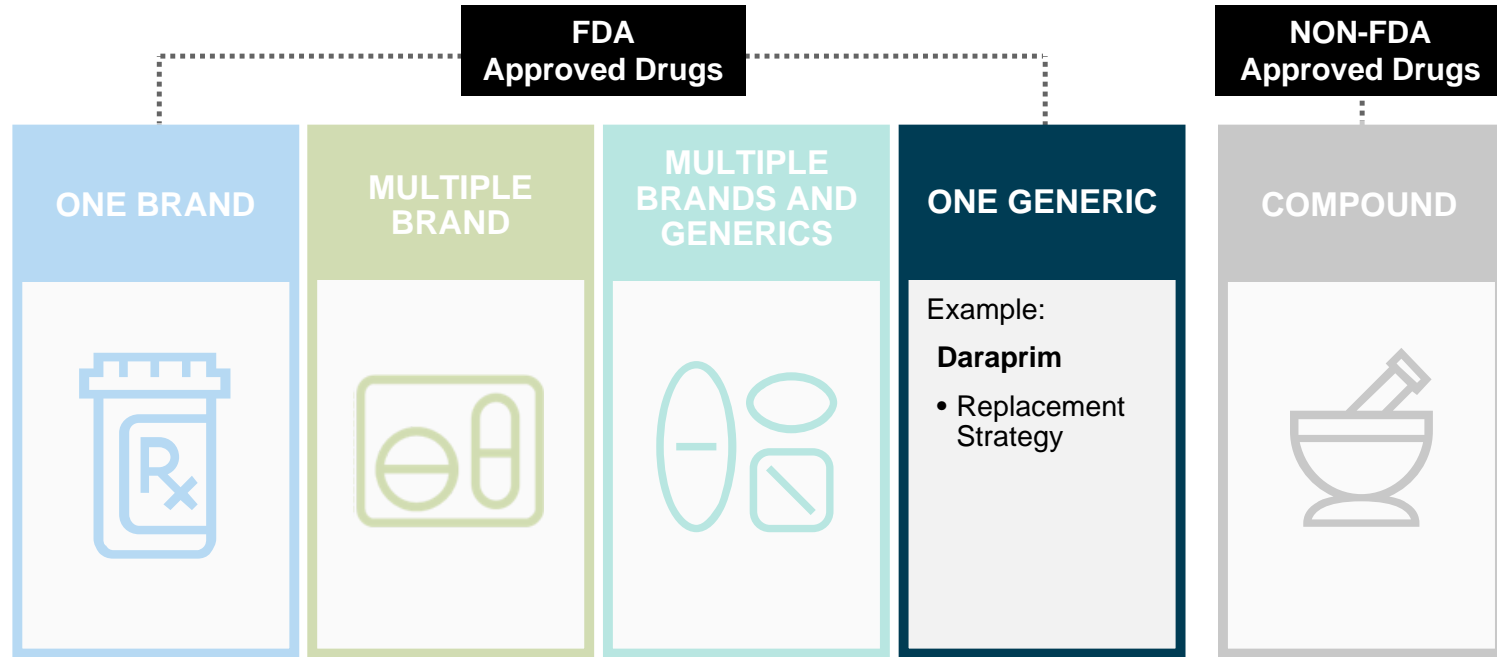
REBATE TOTAL INVOICE AMOUNT IN BILLIONS



Rebates are now 15% of total gross costs

* Commercial Book of Business includes Employers and commercial Health plans

Our Differentiated Approach: Helping Deliver Lowest Net Cost, Ensure Evidence-Based Health



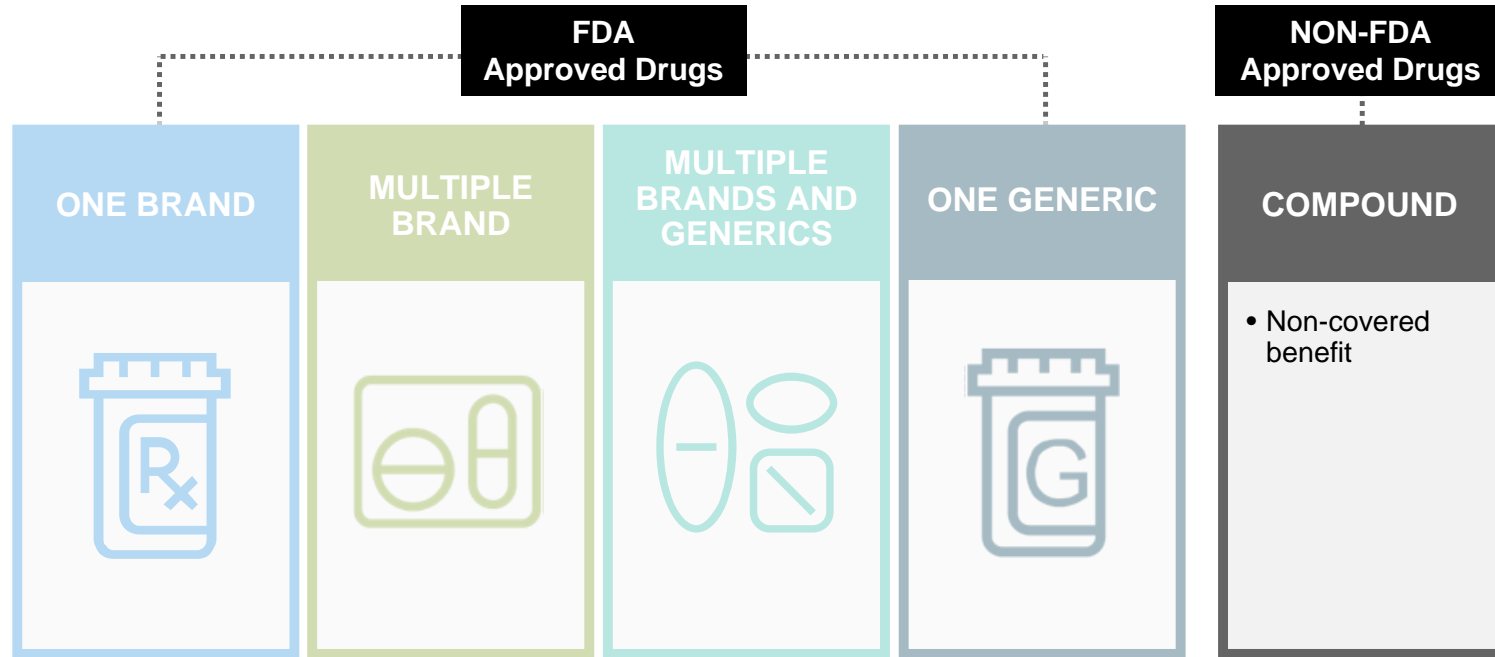
One Generic Example: Turing Labs and Daraprim

- Most generic categories have numerous competitors
- But FDA approval of new generics is now backed up by up to 4 years
- If there is only one generic in a rarely used category, it creates opportunity for predatory pricing
- Counter by compounding pyrimethamine ourselves



Source: Picture of Martin Shkreli www.towleroad.com and money.cnn.com

Our Differentiated Approach: Helping Deliver Lowest Net Cost, Ensure Evidence-Based Health



Use of Compounds Rising, Primarily for Application to the Skin

Non-FDA approved products, generally approved pharmaceuticals crushed into an emollient

Common ingredients include: steroids, anti-inflammatories, seizure medications (gabapentin), and anesthesia agents (ketamine), as well as “cures” (resveratrol)

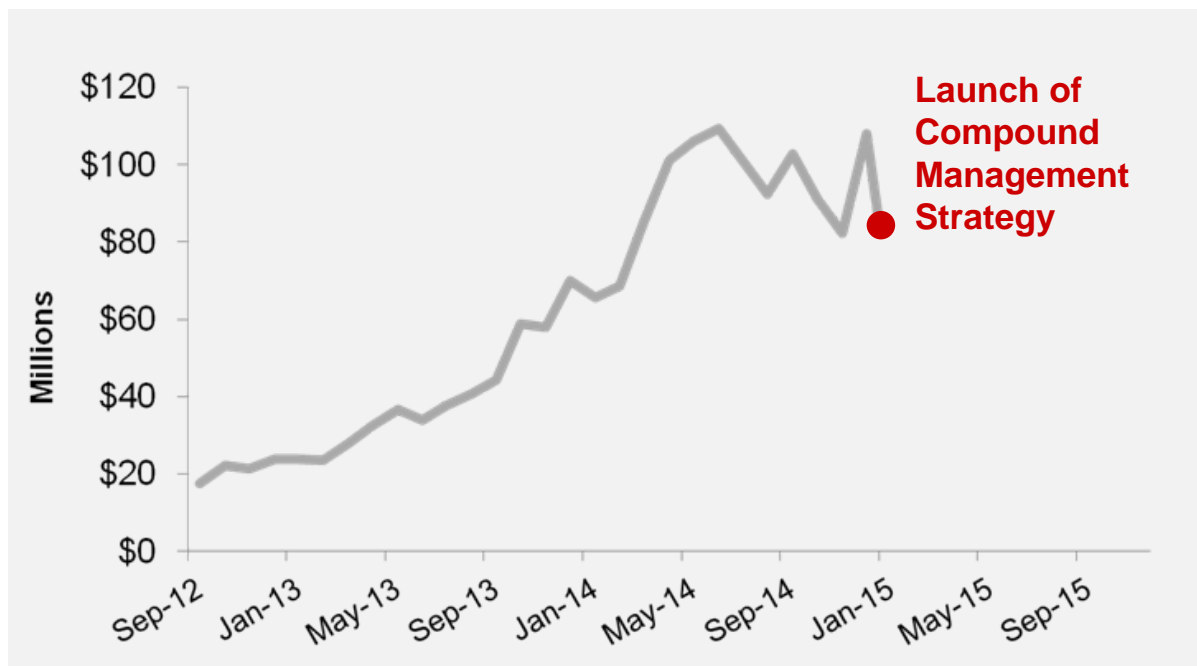
Extraordinarily high prices with new NDCs began to adjudicate on open formularies



Widespread use occurred suddenly

Rapid Response To Manage Rising Compound Costs and Demonstrated Value For Clients

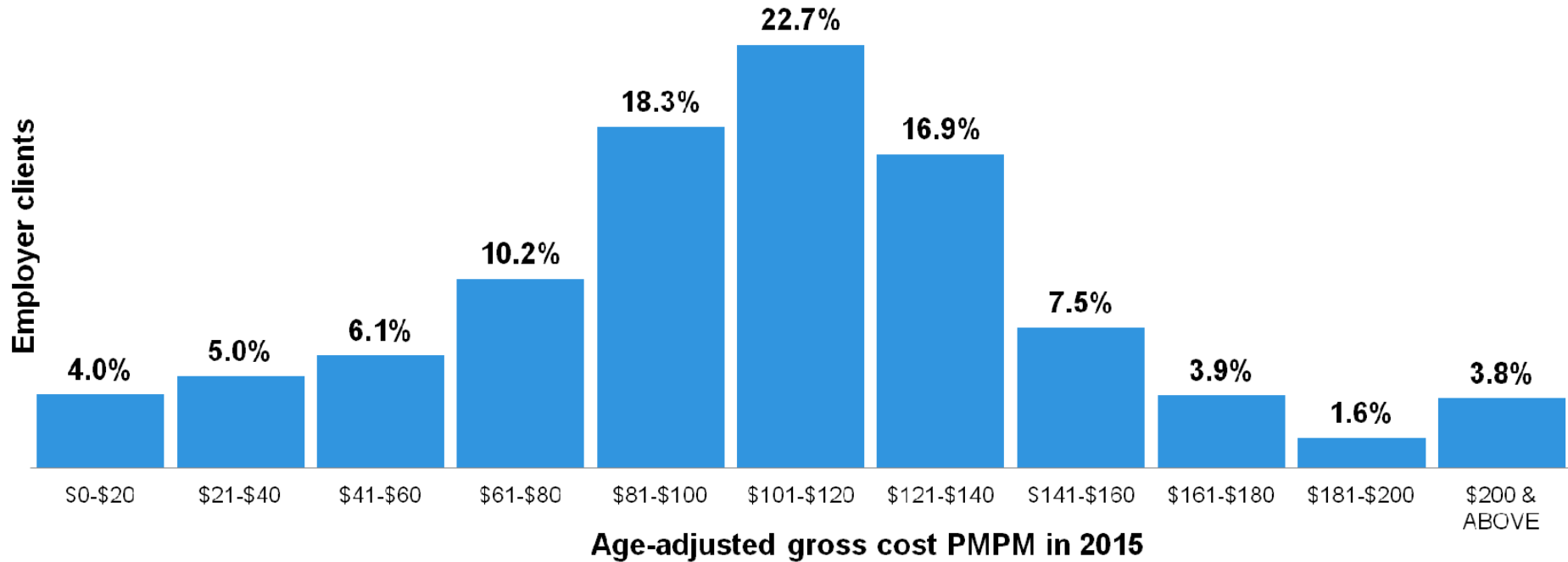
MONTHLY COMPOUND SPEND – EMPLOYERS



CLIENT IMPACT:

\$1 BILLION
in savings across
commercial lives

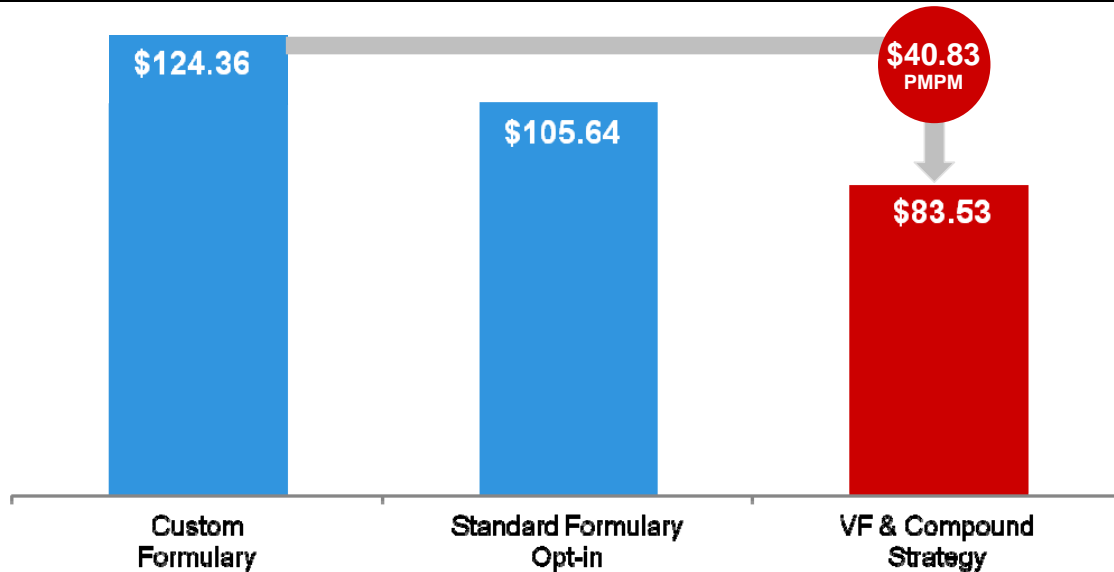
All of Our Clients Are Not Alike: Striking Variation in the Costs of Their Drug Benefit



Analysis based on Enterprise Analytics Book of Business data for Employer clients, 2015.

Savings Achieved by Trendsetter Clients Adopting Our Cost Management Strategies

GROSS COST PMPM



SAVINGS IMPACT

A client with 100K lives could potentially save more than

\$20M

per year.

Adopting formularies that exclude certain products and drive generics is critical to help deliver the lowest net cost