U.S. Pharmaceutical Pricing and Politics: 50 Shades of Gray

By Susan Dentzer
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Presentation to the Pharmaceutical Summit on
Business and Compliance Issues in Managed Markets
June 8, 2016

This Presentation at a Glance

- **The “problem” of rapidly rising pharmaceutical prices isn’t one problem, but many – including a political one**
- **Among manifestations of the problem: steep new prices for old drugs, and steep new prices for new innovative drugs**
- **A fundamental issue is balancing need for, and cost of, biomedical innovation with affordability for the nation**
- **No consensus in US policy or among politicians in how to approach this issue – so what’s ahead?**

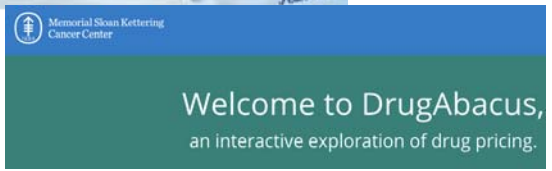
This Presentation at a Glance

- **A crash course in pharmaceutical pricing 101 – and trends in pharmaceutical spending**
- **The varying shades of the pricing “problem”**
- **Potential solutions and assessing value**

Recent Faces of the Issue

Hillary Clinton
@HillaryClinton
Follow

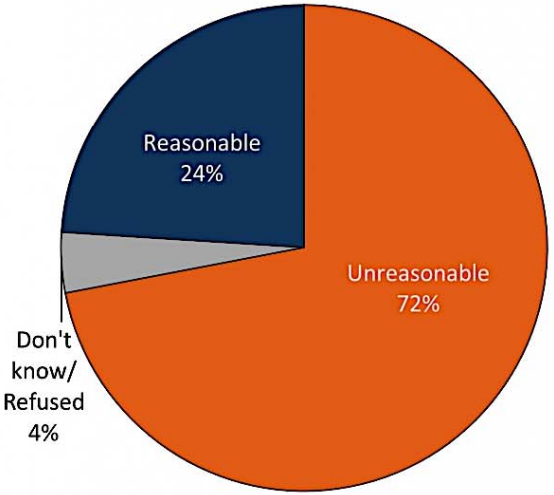
Price gouging like this in the specialty drug market is outrageous. Tomorrow I'll lay out a plan to take it on. -H



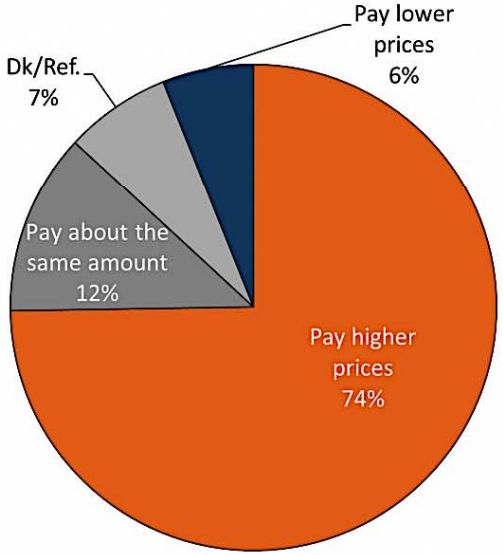
The Politics

Most Say Costs Are Unreasonable And Prices Higher Than In Other Countries

In general, do you think the cost of prescription drugs is reasonable or unreasonable?



In general, do you think people in this country pay higher or lower prices than people in Canada, Mexico, and Western Europe pay for the same prescription drug, or do you think they pay about the same amount?



SOURCE: Kaiser Family Foundation Health Tracking Poll (conducted August 6-11, 2015)

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Presidential Candidates Proposals

- **Hillary Clinton**
- **Deny write-offs for direct-to-consumer advertising; require companies to invest target shares of revenues on R&D or pay rebates to support basic research**
- **Allow Medicare to negotiate Rx drug prices and require bigger rebates**
- **Require health insurance plans to place a monthly limit of $250 per covered individual on out-of-pocket prescription drug costs encourage competition to get more generics on the market**
- **Create “federal backstop” when excessively high-priced drugs face no competition.**

Presidential Candidates' Proposals

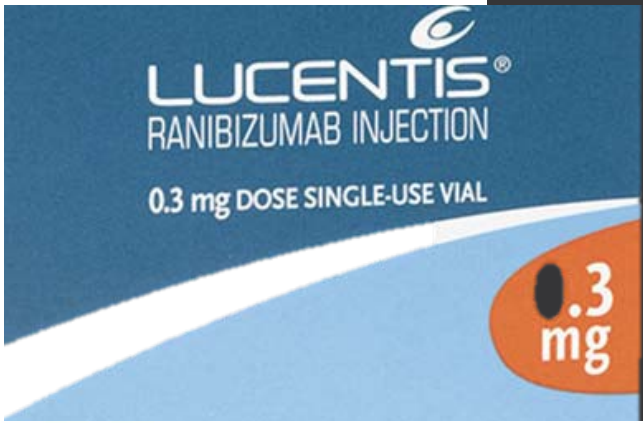
- **Donald Trump**
- **Previously said Medicare did not "bid out" drugs and could save $300 billion annually if it did (although proposal not mentioned now)**
- **"Remove barriers to entry in free markets for drug providers that offer safe, reliable, and cheaper products" -- reimportation?**
-

State Proposals

- **Legislation proposed or introduced in at least 6 states – CA, MA, NC, OR, PA, VT**
- **Transparency focus**
- **Would require drug manufacturers to report costs related to development, production, distribution, and administration for prescription drugs offered to patients in the state**
- **Other legislation would direct states to study the issue in the interim**

Proposal to test changes in Medicare Part B drugs

- For drugs covered under Part B (largely injectables and infusables)
- Providers order and purchase drug; prescribe/administer to patient, then submit claims for drug and professional services (“buy and bill”).
- Medicare Part B generally pays physicians and hospital outpatient departments the average sales price (ASP) of a drug, plus a 6 percent add-on
- Percentage add-on: perverse incentive to use more costly drugs?
- Drug reimbursements/mark-ups = 70% of revenues of typical oncology practice



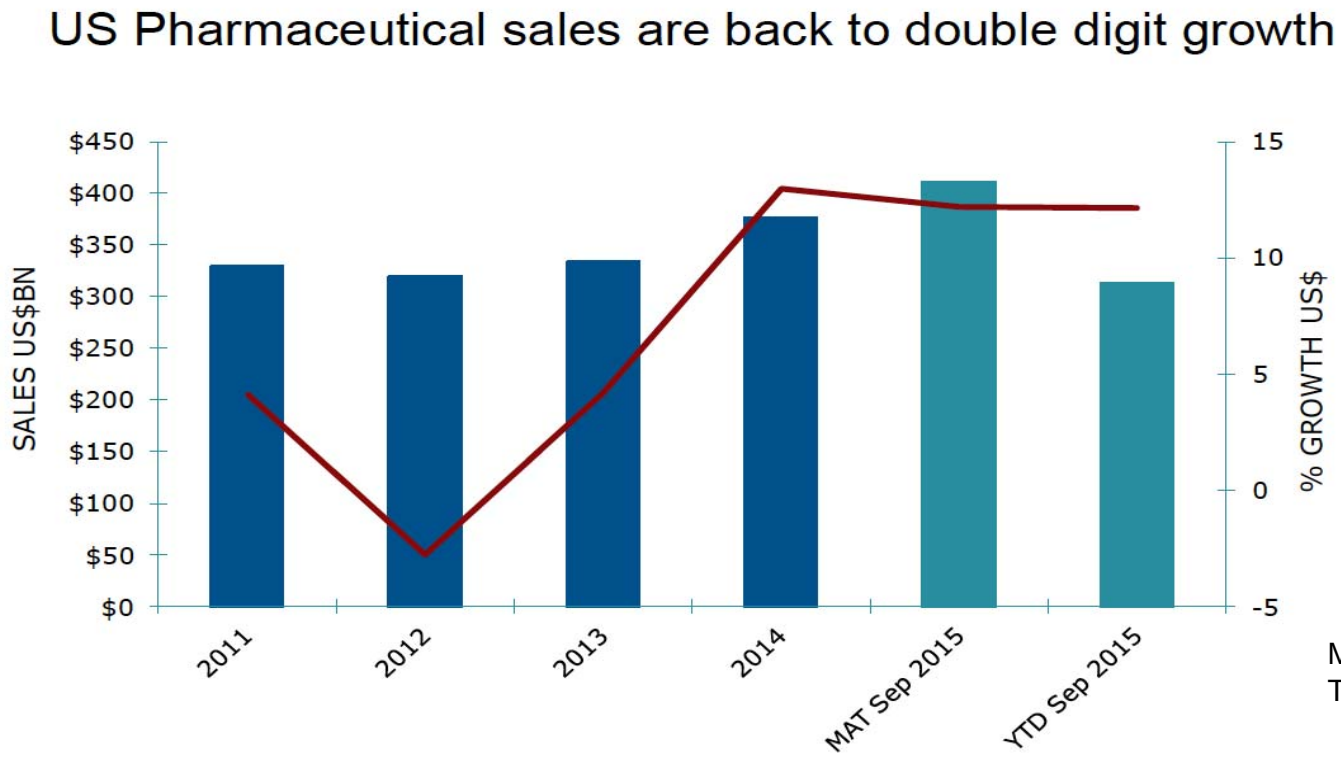
Proposal to test changes in Medicare Part B drugs

- **Proposed model would test changing add-on payment to 2.5 percent plus a flat fee payment of $16.80 per drug per day changes prescribing incentives**
- **CMS would update flat fee each year by the percentage increase in the consumer price index for medical care for the most recent 12-month period.**
- **For test, providers to be assigned to Primary Care Service Areas; ½ will get existing payment (ASP + 6%), ½ will get new fee structure**
- **Differences in quality/value to be examined**
- **Test to would begin in late 2016 (no earlier than 60 days after the rule is finalized).**

Part B Proposal Pushback

- **Community Oncology Alliance: “We are actively pursuing every legal, legislative and related option to stop the CMS Medicare Part B Drug Payment Model, which is nothing more than a perverse experiment on cancer care provided to seniors.”**
- **Concerns: test not double-blind trial; behavioral effects of practices and patients; effects on multi-location practices**
- **Senate Finance Committee chairman Orrin Hatch (right); House Ways and Means Committee Chairman Kevin Brady; House Energy and Commerce Committee Chairman Fred Upton – all Republicans**
- **“….Another troubling example of unelected bureaucrats making decisions behind closed doors that impact the American people and their healthcare.”**

Recent Trends



MAT = Moving Annual Total = Trend over 12 months

Source: IMS Health, National Sales Perspectives, Sep 2015

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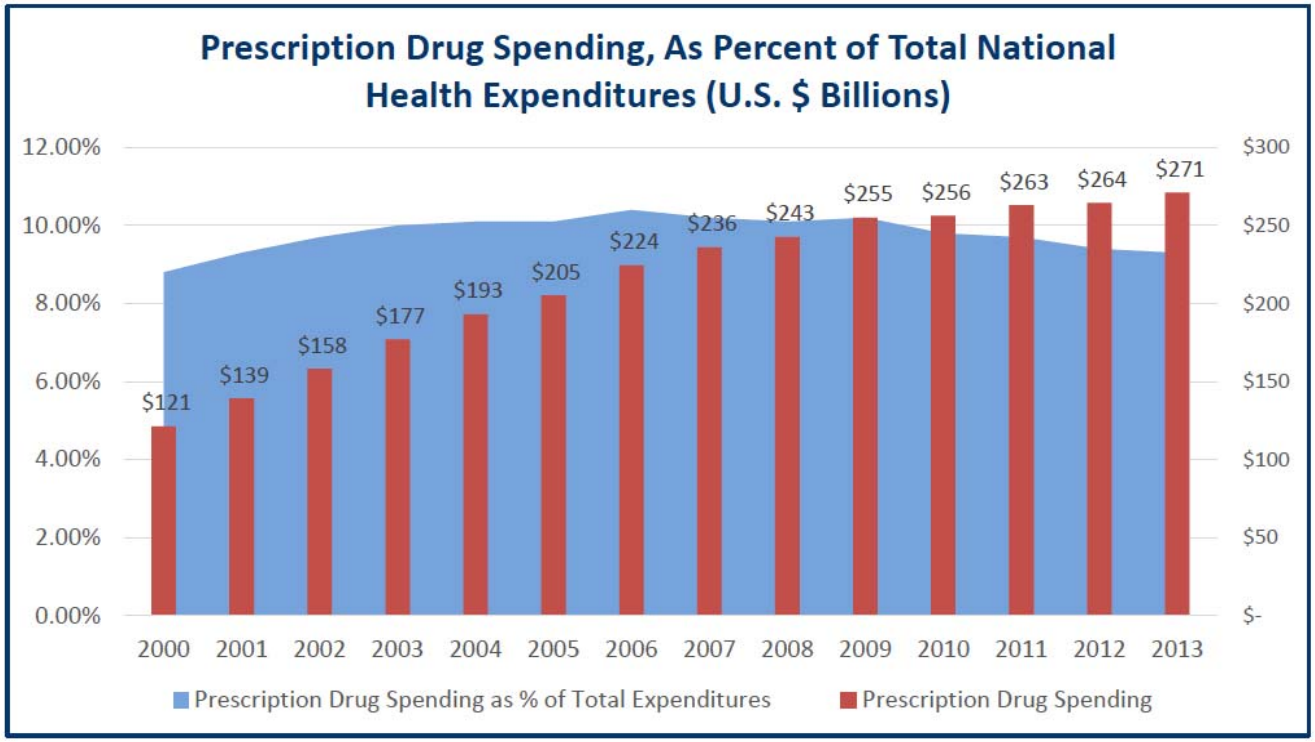
Prescription Drugs as Share of Overall Health Care Spending



Source: Peterson-Kaiser Health System Tracker using National Health Expenditure (NHE) data from CMS. Note that non-retail prescription use (e.g., hospital or clinic administered) is not included in national heath accounts

Value of Pharmaceuticals: Price Is Only Part of It

- **Longer, better lives**
- **Disease outcomes transformed: diabetes, HIV, coronary artery disease, cystic fibrosis, cancers, multiple sclerosis (among others)**
- **Prospect of looming breakthroughs in Alzheimers, mental illnesses, degenerative joint disease (among others)**
- **Avoided health care costs**
- **Avoided non-medical costs – e.g., disability**
- **Increased employment and work productivity**
- **Economic growth with high-quality jobs**

Pharmaceutical pricing: A Zen *Koan*

- **Koans, or ancient riddles, from Zen Buddhism**
- **The classic one: What is the sound of one hand clapping?**
- **A contemporary one: What is one thing that is said to exist that actually doesn't exist?**
- **Answer: A specific list price for a pharmaceutical drug that people or entities actually pay**

The crazy quilt of pharmaceutical pricing

“A system that is nearly impossible for the average person to navigate”

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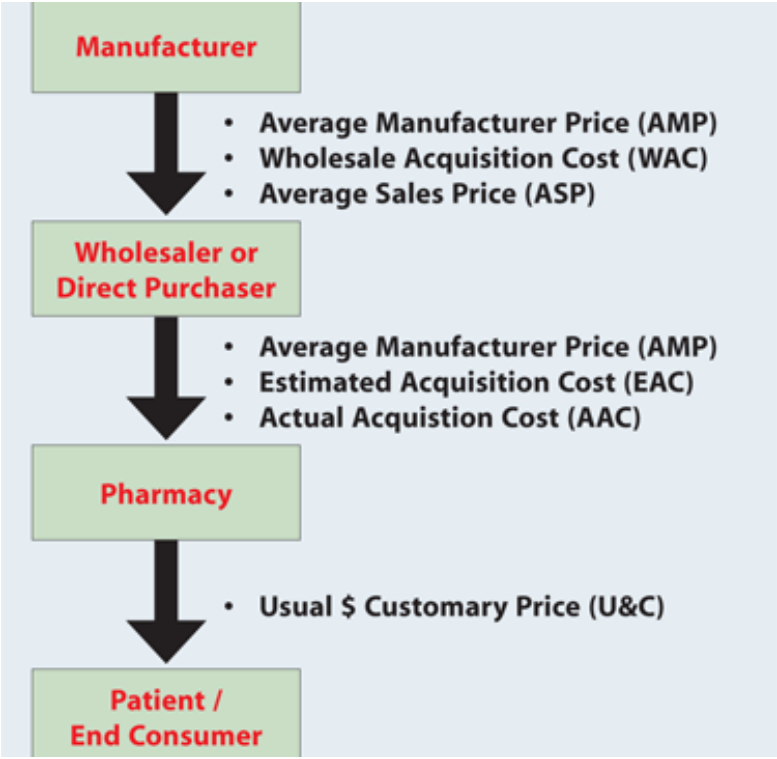
How pharmaceutical prices are arrayed – part 1

- **As with most of health care, conventional supply/demand forces aren't determinative of price**
- **Information is asymmetric and provider prescribing preferences typically matter more than consumer preferences**
- **Prices are relatively inelastic to demand**
- **Supply chain – from manufacturer to wholesaler to provider/pharmacy to ultimate consumer – produces different prices along the chain**



The Lexicon of Drug Pricing

Term	Definition
Federal upper limit (FUL)	A price ceiling used by the Centers for Medicare and Medicaid Services (CMS) to control prices for certain medications paid to pharmacies
Maximum allowable cost (MAC)	A price ceiling, similar to the FUL, established at the state level
Usual and customary price (U&C)	The average cash price paid at a retail pharmacy
Average wholesale price (AWP)	An estimate of the price retail pharmacies pay for drugs from their wholesale distributor. This price is calculated and published by companies such as Medi-Span and First Databank
Wholesale acquisition cost (WAC)	An estimate of the manufacturer's list price for a drug to wholesalers or other direct purchasers, not including discounts or rebates. This price is defined by federal law
Average manufacturer price (AMP)	The price a manufacturer charges wholesalers or pharmacies that purchase directly from the manufacturer after discounts. This price is defined by federal law
Average sales price (ASP)	A calculation of the weighted average of manufacturer's sales price for a drug for all purchasers, net of price adjustments. This price is defined by federal law
Estimated acquisition cost (EAC)	An estimate of the price generally paid by providers for a drug. Formula specific for each state as defined by the state Medicaid agency
Average Actual cost (AAC)	An estimate of retail pharmacy acquisition costs for drugs through a review of actual pharmacy invoices

Source: US Pharm. 2012;37(6)(Generic Drug Review suppl):40-45.

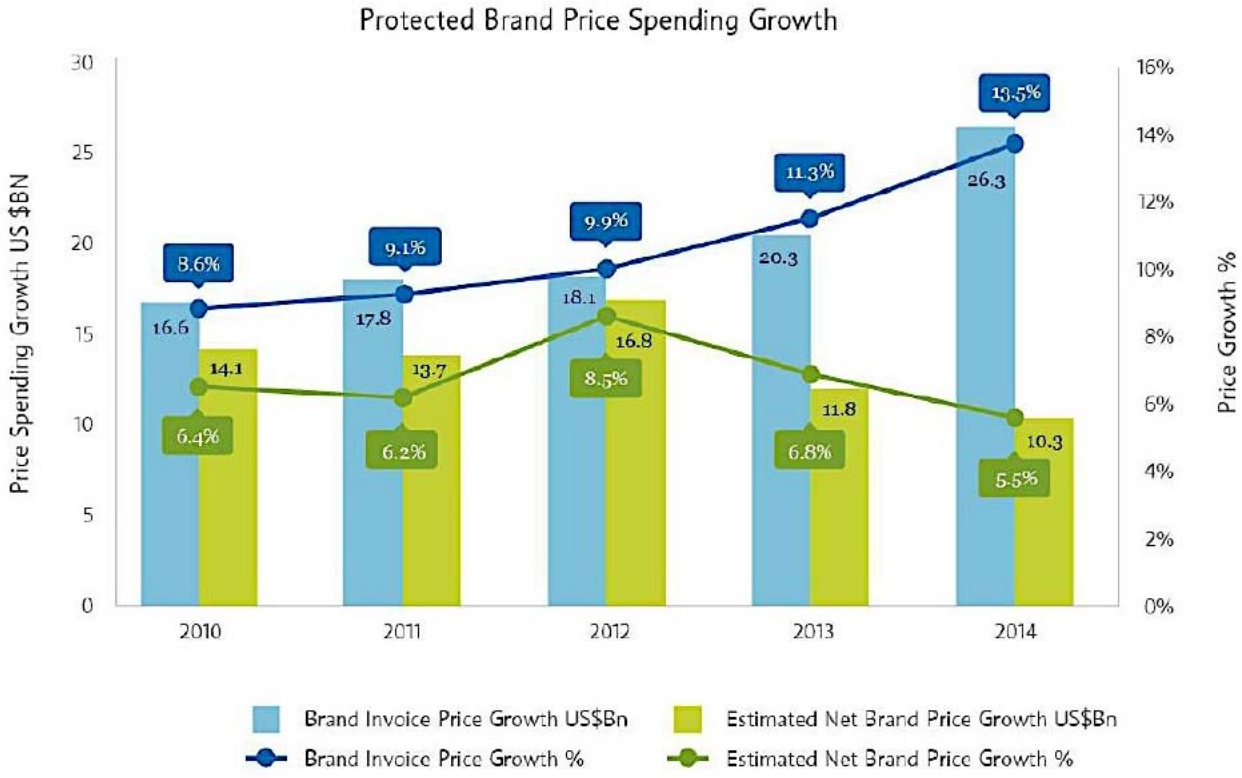
Prices vary across payers and programs

- **In Medicaid, a complex system of mandatory rebates off the Average Manufacturer Price based on type of drug**
- **In Medicare, drugs covered under Part B (physician-or hospital-administered drugs): amounts reimbursed are calculated by CMS off the Average Sales Price**
- **In Medicare, drugs covered under Part D (outpatient drugs) are purchased by private plans, typically through pharmacy benefit managers (PBMs) that negotiate rebates with manufacturers; rebates must be disclosed to CMS but by law CMS cannot make these public**
- **The Veterans Health System (VA) has a formulary that covers about 60 percent of the top 200 most popular drugs; it negotiates prices with manufacturers and pays about 40 percent less than Medicare**

Prices vary across payers and programs

- **The so-called 340B program (authorized in that section of the Public Health Service Act) allows certain hospitals and other providers that historically treated underserved populations to obtain sizeable drug discounts from manufacturers**
- **The Health Resources and Services Administration calculates a ceiling price for each outpatient drug and providers receive at minimum an estimated 22.5 percent discount off the Average Sales Price***
- **In private insurance, prices paid by plans also typically determined via proprietary non-public contracts between PBMs and manufacturers; what consumers must pay in copayments or cost sharing is typically determined by formularies and "tiering"**
- ***Source: MedPAC report to Congress onf 340B Program, http://www.medpac.gov/documents/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf?sfvrsn=0**

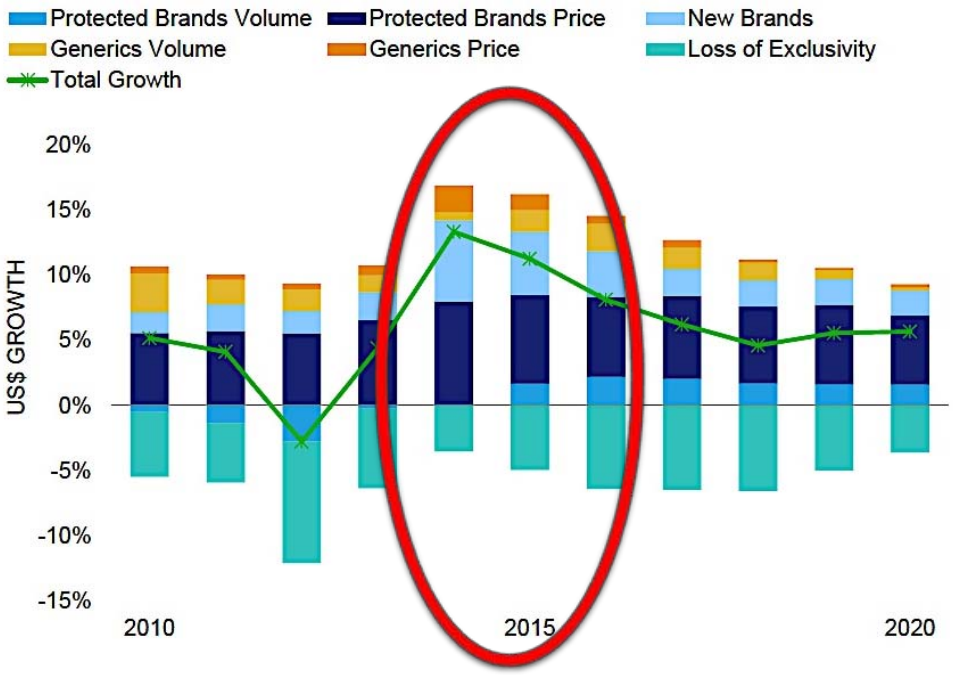
Impact of Rebates on Pricing



Source: Prescription Medicines: Costs in Context. PhRMA, 2015.

How much are price increases contributing to overall prescription drug spending?

U.S. Spending Growth, 2010-2020



United States

- 2020 Spending: $560-590Bn
- 2016-20 Growth: +146Bn
- CAGR 2016-20: 5-8%
- Increase over 2015: +34%
- 2020 Brand Share of spending: 67%; unchanged since 2015
- 2020 Specialty Share of spending: 34% + 0.4pts; 34% of increase since 2015

Source: IMS Health Market Prognosis, IMS Institute for Healthcare Informatics, October 2015

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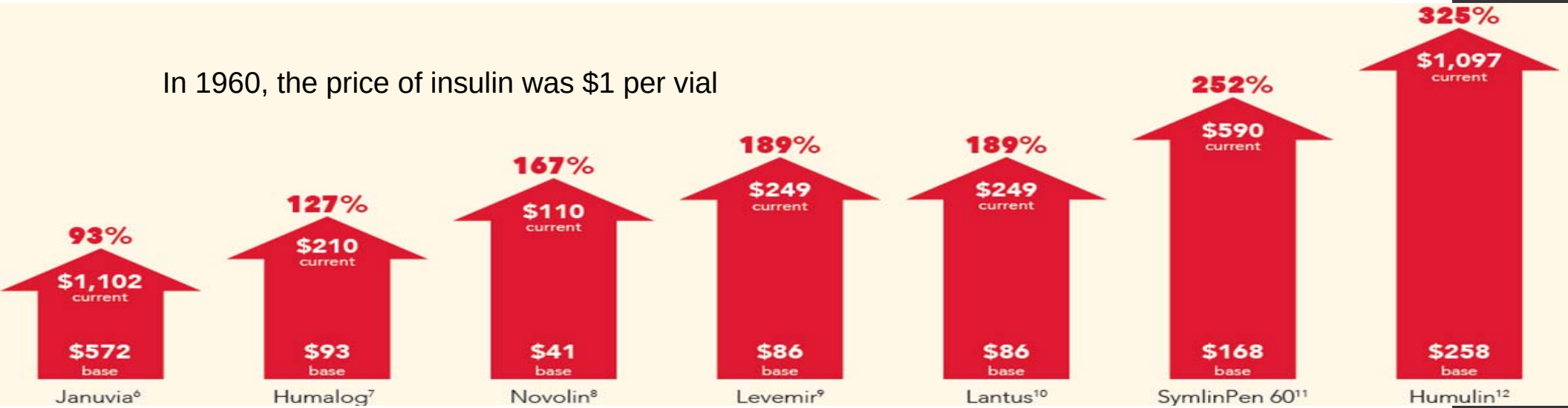
CAGR =
compound annual growth rate

Old Drugs with Steep New Prices

Old Drugs With Steep New Prices: Diabetes Medications

Diabetes Drugs with Significant Percent Price Changes Over Five Years
(3/1/2010 – 2/28/2015)

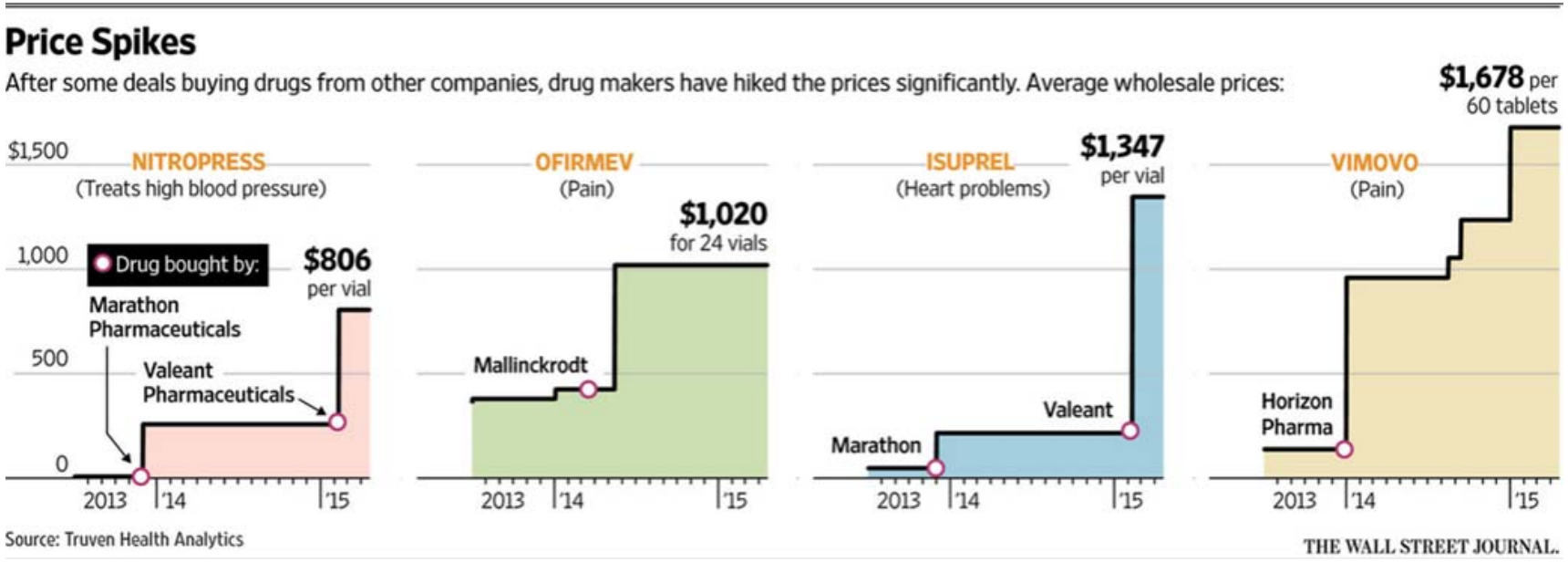
In 1960, the price of insulin was $1 per vial



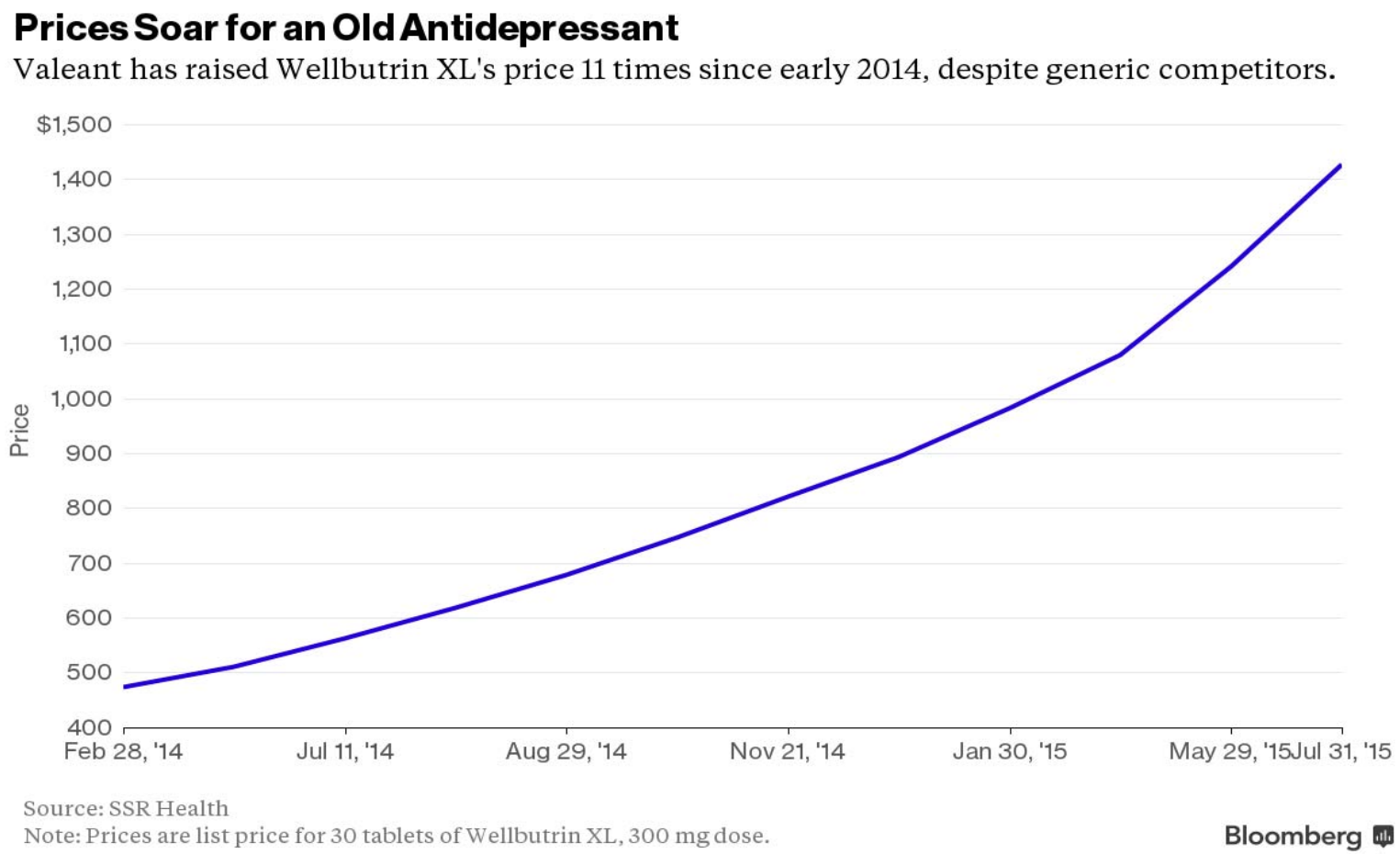
NB: Most of these forms of insulin are off patent but face no generic (biosimilar) competition

Source: *Medi-Span® Price Rx®.* Figures reflect wholesale acquisition cost.
Note: Price modifications will alter the values reflected above.

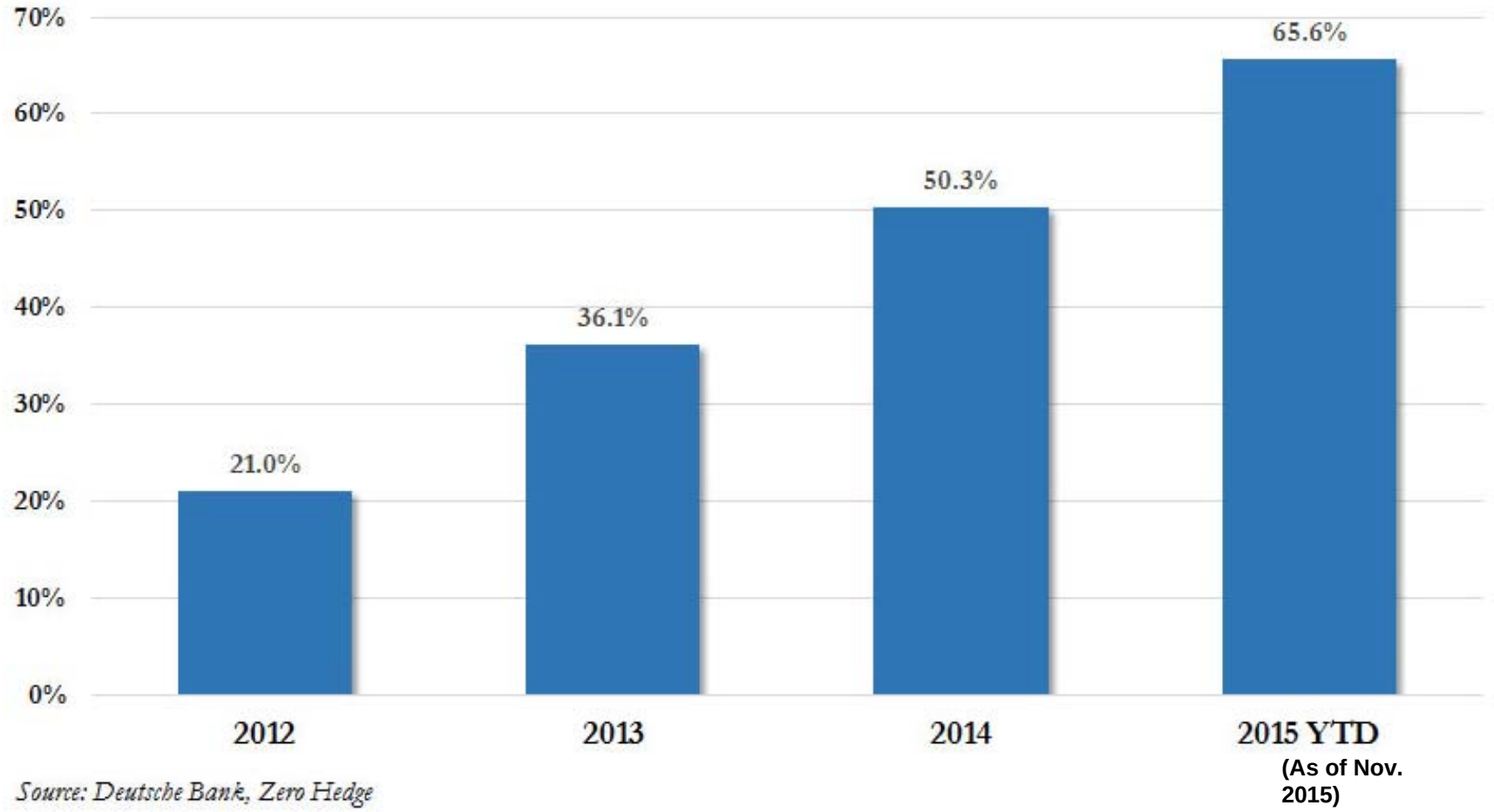
New Model: Buy Drug, Hike Price



New Model Pharmaceutical Company: No R&D, Just Sales



Valeant's Average Annual Price Increases, All Drugs



Source: Deutsche Bank, Zero Hedge

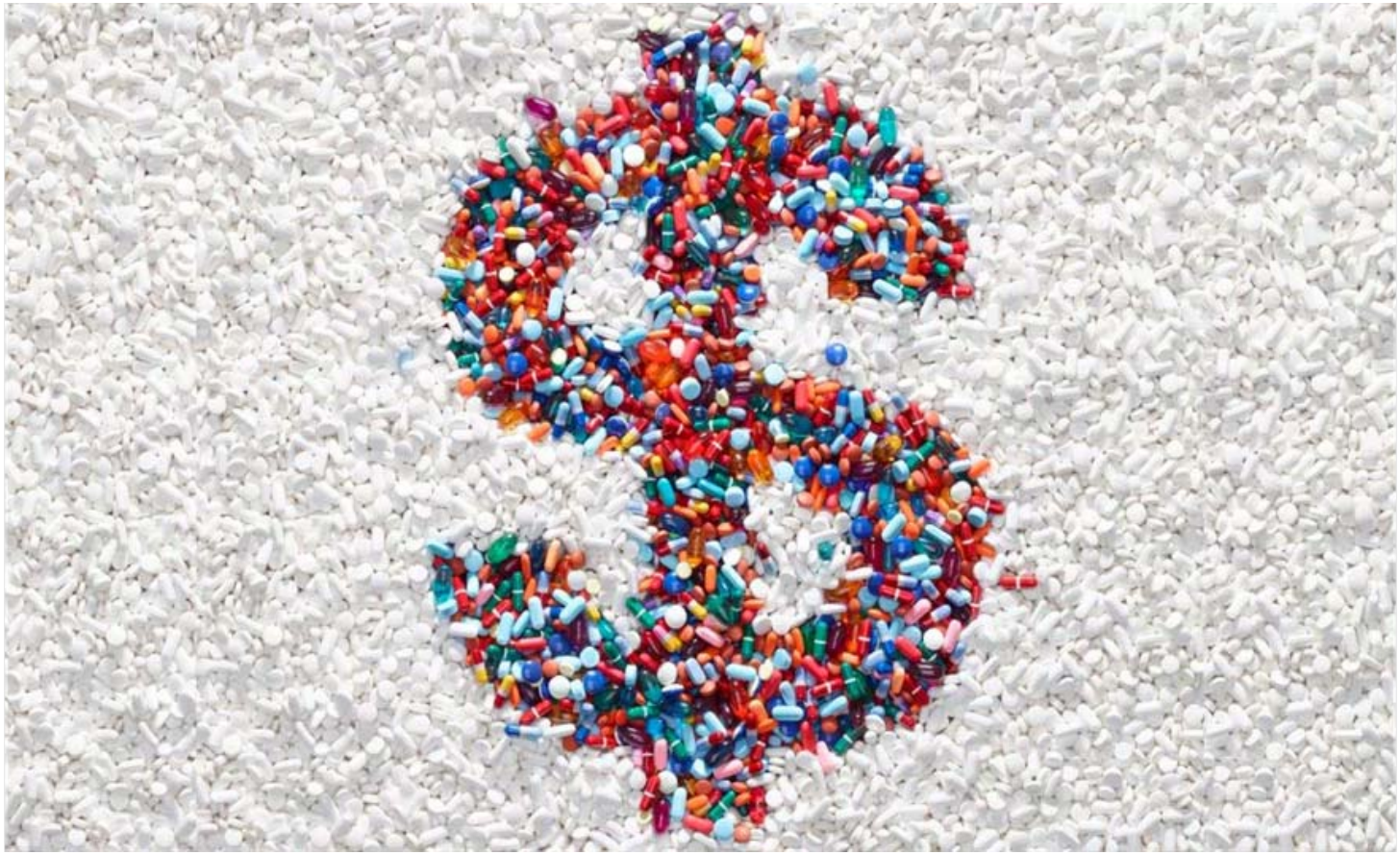
(As of Nov. 2015)

Valeant's Relationships with Specialty Pharmacies

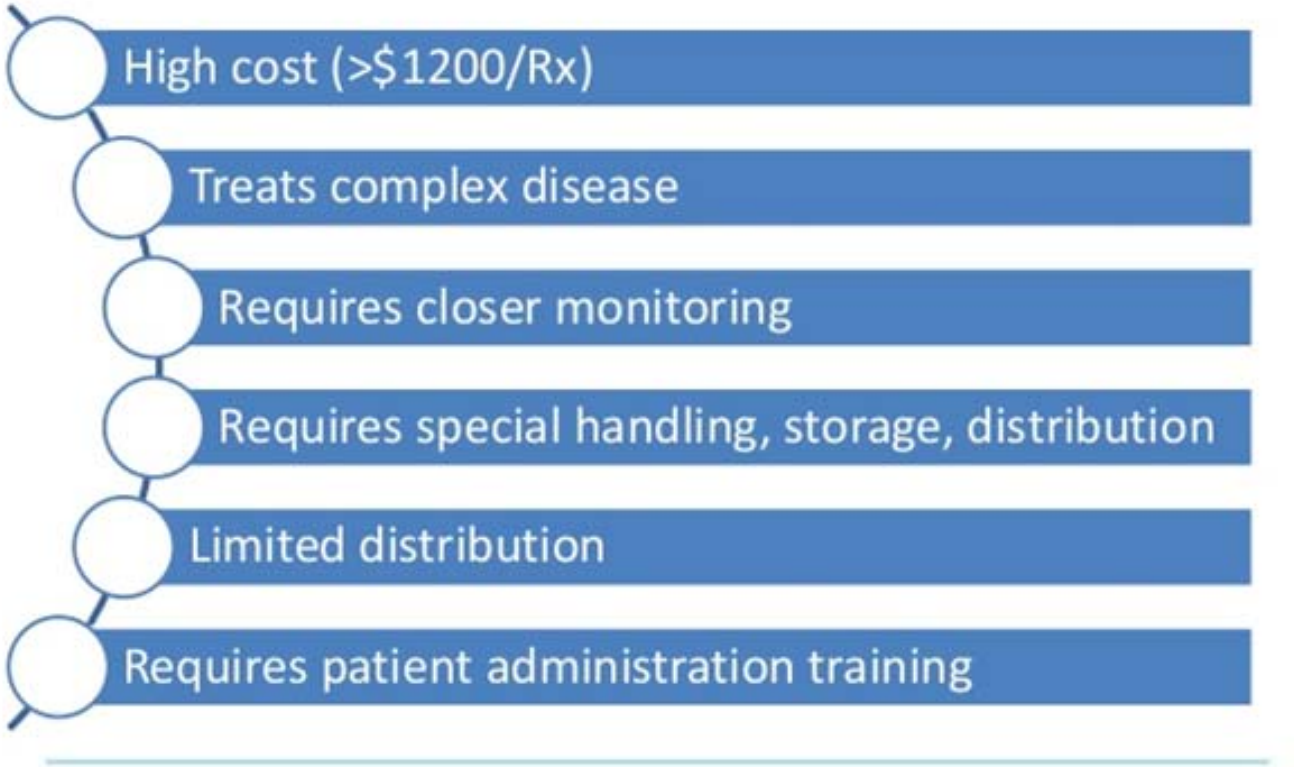
- **Philidor Rx Services LLC – questionable relationship with Valeant now under investigation**
- **Direct Success – manages Wellbutrin XL Guarantee Program, which offers prescriptions for low co-pays, or for free, to consumers; receives drug at discounted price and fees per each prescription filled**
- **Enrollment page for doctors enables them to approve Rx without generic substitute and promises "No hassles and no need for call-backs"**
- **"Valeant's marketing relationship with Direct Success 'raises the question of whether Philidor was just the tip of the iceberg,' said Mark Merritt, president and CEO of the Pharmaceutical Care Management Association.**
- **"Such relationships tend 'to get patients a much more expensive product they don't need.'"**

Source: Bloomberg Business, 1/8/16, http://www.bloomberg.com/news/articles/2016-01-08/how-valeant-tripled-prices-doubled-sales-of-flatlining-old-drug

New Drugs With Steep New Prices



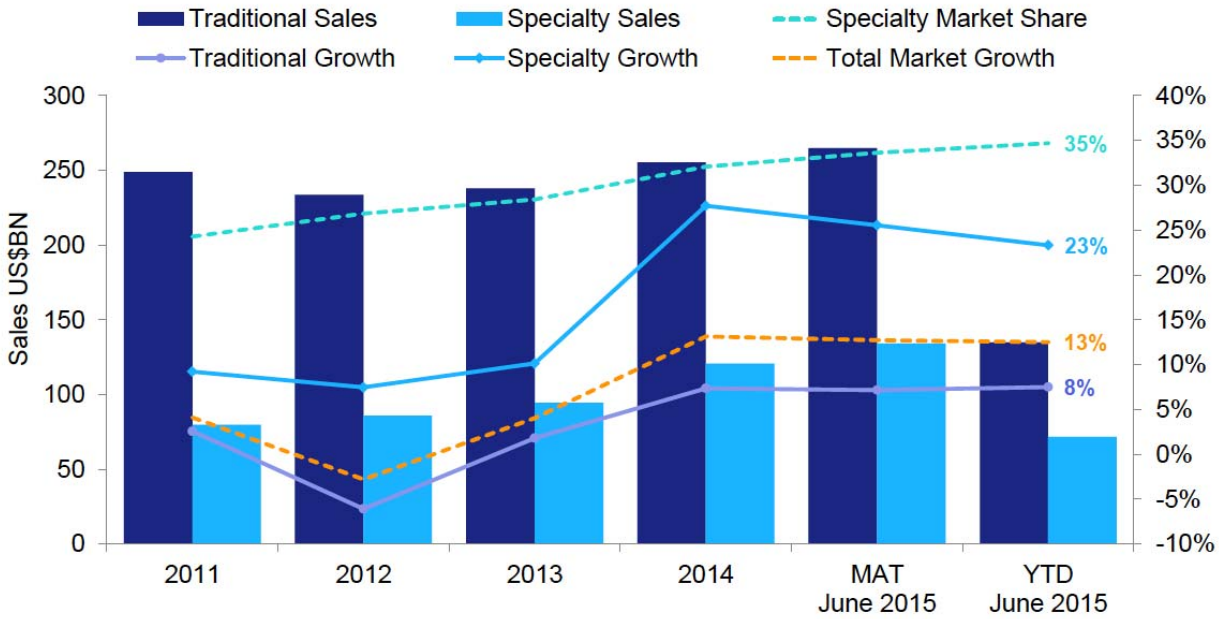
Many New Drugs Are “Specialty” Drugs: Definitions



Specialty Pharmaceuticals: Sales Growth

Specialty medicines now account for 35% of US sales

Specialty growth surpasses 24% while traditional growth hovers at 8%



Source: IMS Health, National Sales Perspectives, June 2015

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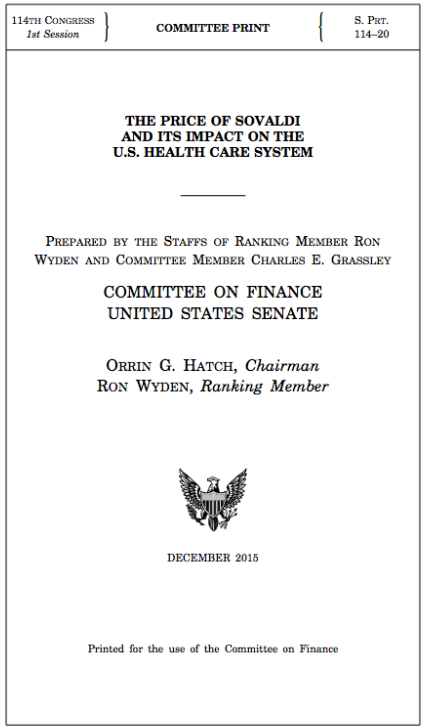
The “Poster” Drug: Sovaldi for Hepatitis C – The $1,000 per pill cure

Competition and the Hepatitis C Drugs

- **Sovaldi: initial US list price in early 2014 $84,000 for 12 weeks of treatment; total treatment price (with 2 companion drugs, interferon and ribavirin) neared $150,000**
- **State governments faced up to $55 billion in spending on patients on Medicaid or in prisons**
- **Gilead, Sovaldi's manufacturer, then introduced Harvoni ($94,000 for 12 weeks of treatment)**
- **In December 2014, AbbVie's Hep C drug, Viekira Pak, approved by FDA; initial list price $83,390**
- **AbbVie and PBM's such as ExpressScripts negotiated significant discounts for exclusive formulary listing (Genotype 1, approximately 70 percent of all patients)**
- **Gilead agrees to 46% discounts and rebates**
- **Estimated price in US now in range of $60,000 (vs. $46,000 in Europe)**

Senate Finance Committee Investigation

- **Bipartisan inquiry led by Sens. Ron Wyden (D-OR) and Chuck Grassley (R-IA)**
- **Original developer of drug, Pharmasset, expected price of $36,000; Gilead purchases Pharmasset in 2011**
- **"Gilead pursued a calculated scheme…based on one primary goal, maximizing revenue, regardless of the human consequences."**
- **"No concrete evidence…that basic financial matters such as R&D costs" were a factor in price**
- **In 18 months post approval, Medicare spent nearly $8.2 billion before rebates on Sovaldi and Harvoni; monthly spending on Hepatitis C treatments grew more than six-fold**
- **Because of state access restrictions, fewer than 2.4 percent of 700,000 Medicaid enrollees with Hep C were treated with Sovaldi**
- **Gilead's US sales of Sovaldi and Harvoni totaled $20.6 billion after rebates over 21 months**



114TH CONGRESS *1st Session* | COMMITTEE PRINT | S. PRT. 114–20

THE PRICE OF SOVALDI AND ITS IMPACT ON THE U.S. HEALTH CARE SYSTEM

PREPARED BY THE STAFFS OF RANKING MEMBER RON WYDEN AND COMMITTEE MEMBER CHARLES E. GRASSLEY

COMMITTEE ON FINANCE
UNITED STATES SENATE

ORRIN G. HATCH, *Chairman*
RON WYDEN, *Ranking Member*

DECEMBER 2015

Printed for the use of the Committee on Finance

Full report at www.finance.senate.gov/download/the-price-of-sovaldi-and-its-impact-on-the-us-health-care-system-print-114-20

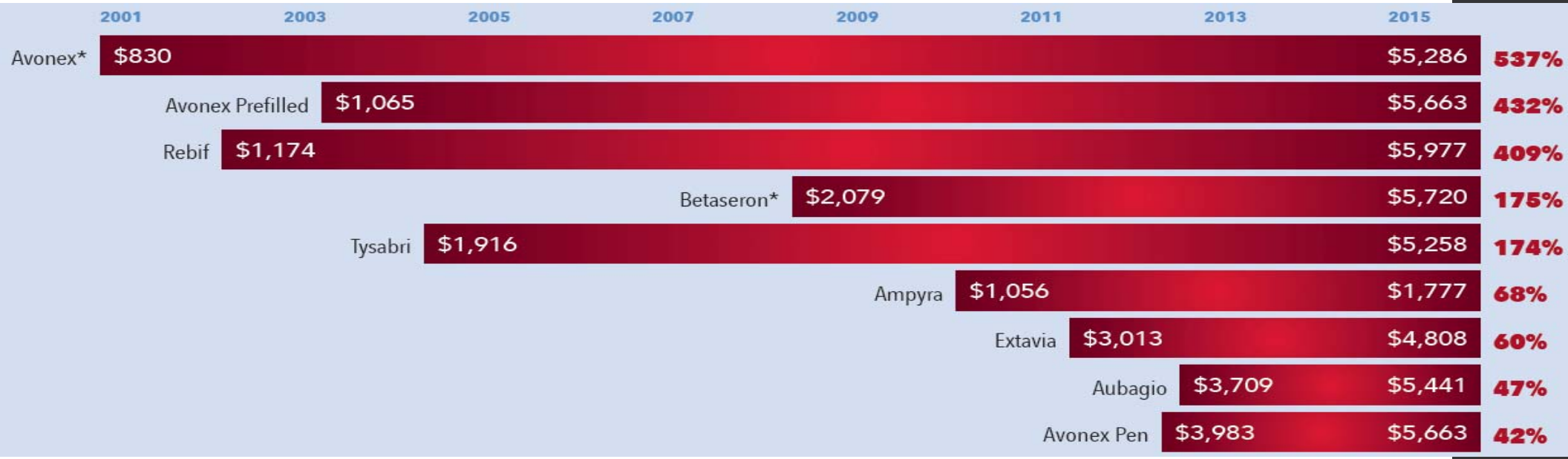
Harvoni cost around the world

Source: http://esofosbuvir.com/

Multiple Sclerosis Drugs

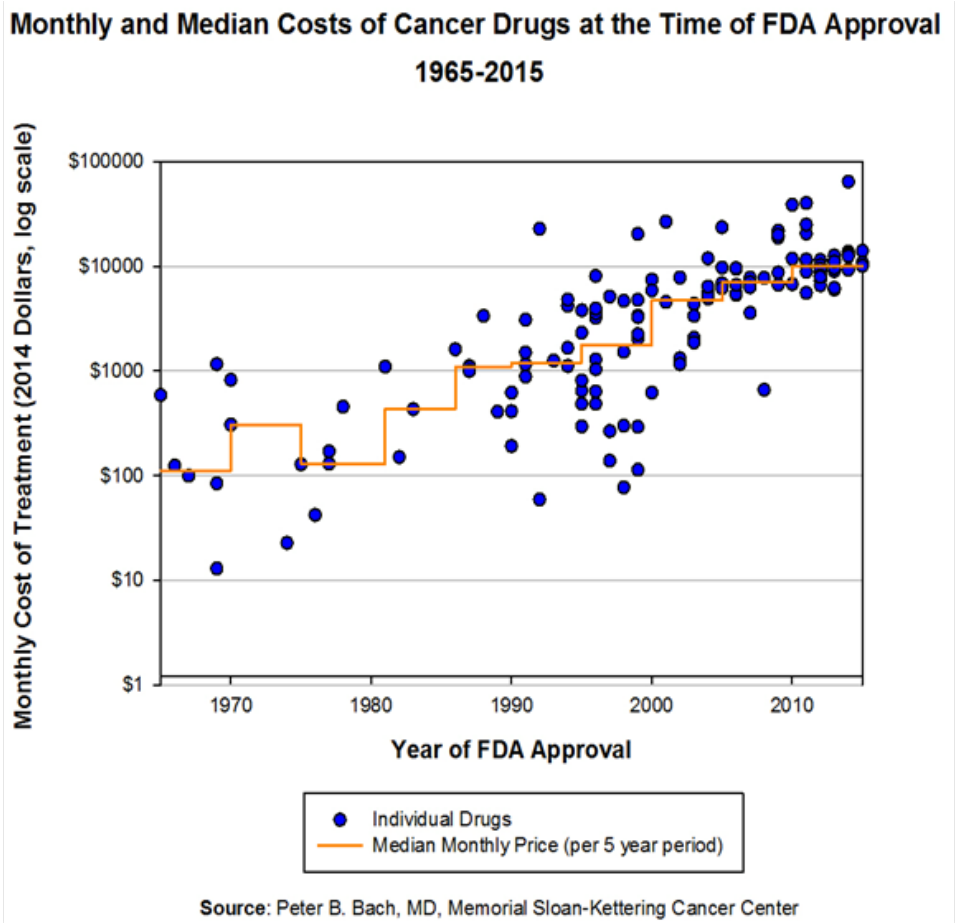
First-generation MS drugs,
originally costing $8,000 - $11,000,
can now exceed $60,000 a year

MS Drugs with the Highest % Price Changes Since Launch for a 30-Day Supply



*Date listed is the first instance of available pricing data in Medi-Span® Price Rx®. The true launch date is earlier than that listed.
Source: Medi-Span® Price Rx® and www.rxlist.com. Figures reflect wholesale acquisition cost.
Note: Price modifications will alter the values reflected above.

Cancer Drugs: Long-Term Cost Trend



Drawing the line on cancer drug prices

The Opinion Pages | OP-ED CONTRIBUTOR

In Cancer Care, Cost Matters

By PETER B. BACH, LEONARD B. SALTZ and ROBERT E. WITTES OCT. 14, 2012

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AT Memorial Sloan-Kettering Cancer Center, we recently made a decision that should have been a no-brainer: we are not going to give a phenomenally expensive new cancer drug to our patients.

The reasons are simple: The drug, Zaltrap, has proved to be no better than a similar medicine we already have for advanced colorectal cancer, while its price — at $11,063 on average for a month of treatment — is more than twice as high.

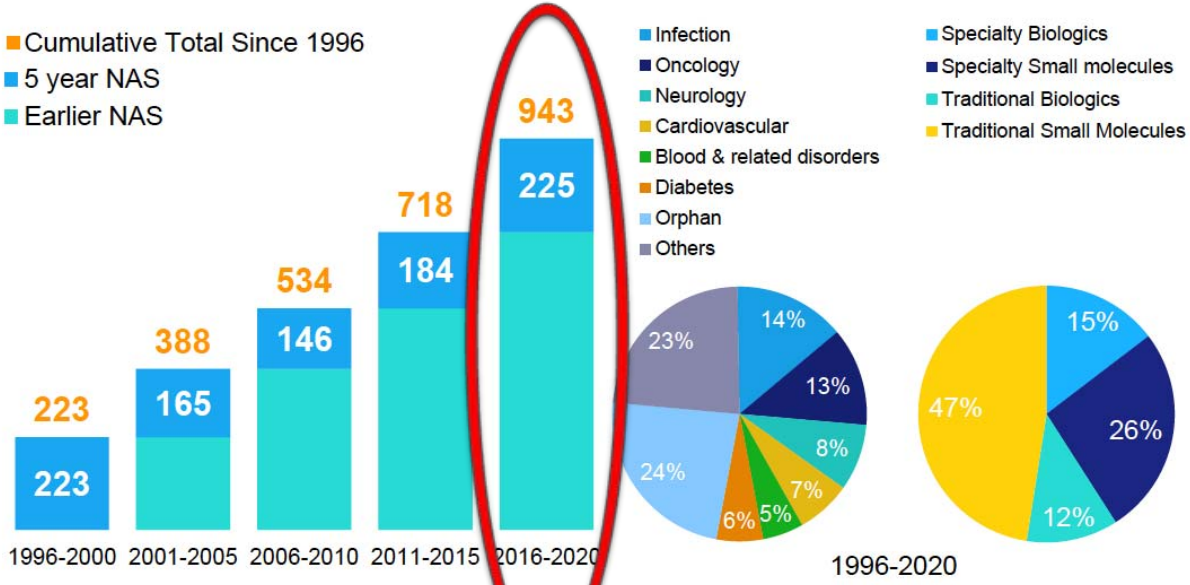
- **Zaltrap (Sanofi) for metastatic colorectal cancer, introduced in 2012**
- **Price: $11,063 on average per month**
- **Compared to standard chemotherapy, additional median survival = 1.4 mos.**
- **MSK chose to use Avastin at less than half Zaltrap's price**
- **Noted that 1 in 10 cancer patients reported spending more than $18,000 out of pocket on care**
- **Sanofi offered discounts of 50 percent**

Innovative Cancer Therapies

- **Example: Keytruda (pembrolizumab) – Merck’s immune therapy melanoma drug introduced in 2014**
- **Engineered monoclonal antibody**
- **Former President Jimmy Carter diagnosed in August 2015 with metastatic melanoma (including brain metastases)**
- **In December, brain scan showed no cancer; Carter deemed cancer-free**
- **Keytruda’s US cost: $150,000/year**

Burgeoning Pipeline of New Drugs

Global New Active Substances (NAS) Available Since 1996



Source: IMS Health, IMS Institute for Healthcare Informatics, October 2015

Note: Disease categories based on therapy areas and expected launches 2016-20. Orphan drugs are those to treat small populations with rare diseases, and are defined separately by U.S. FDA and the European Medicines Agency (EMA). Any medicine with an orphan designation for an approved use within the first year after global launch are categorized as Orphan. Half of designated orphan indications are granted more than a year after original approval.

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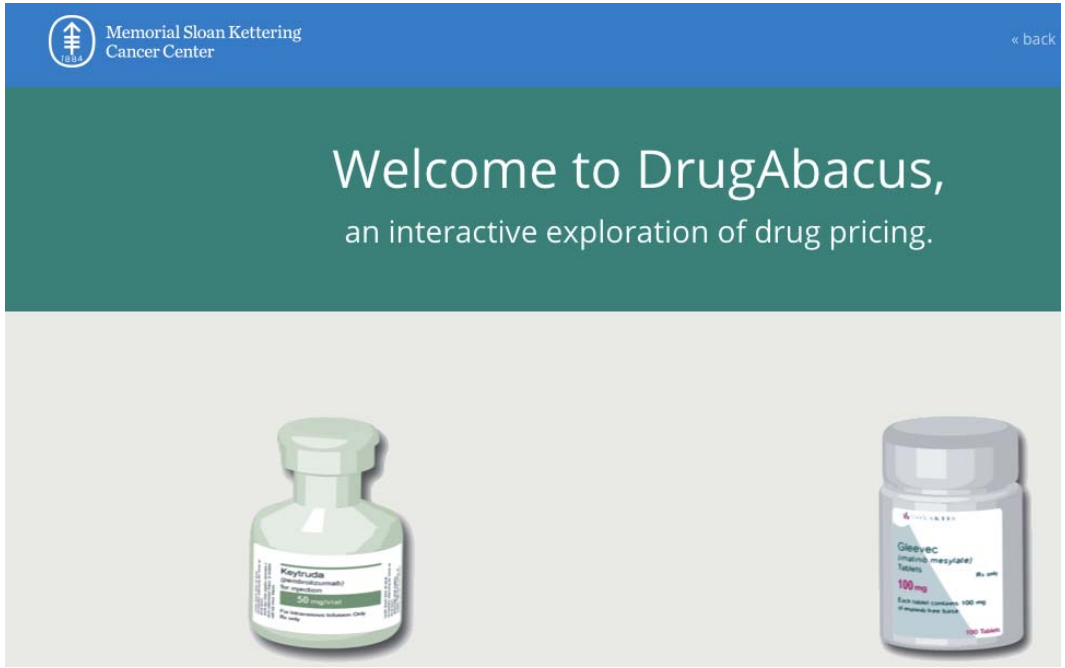
Defining Drugs' Value

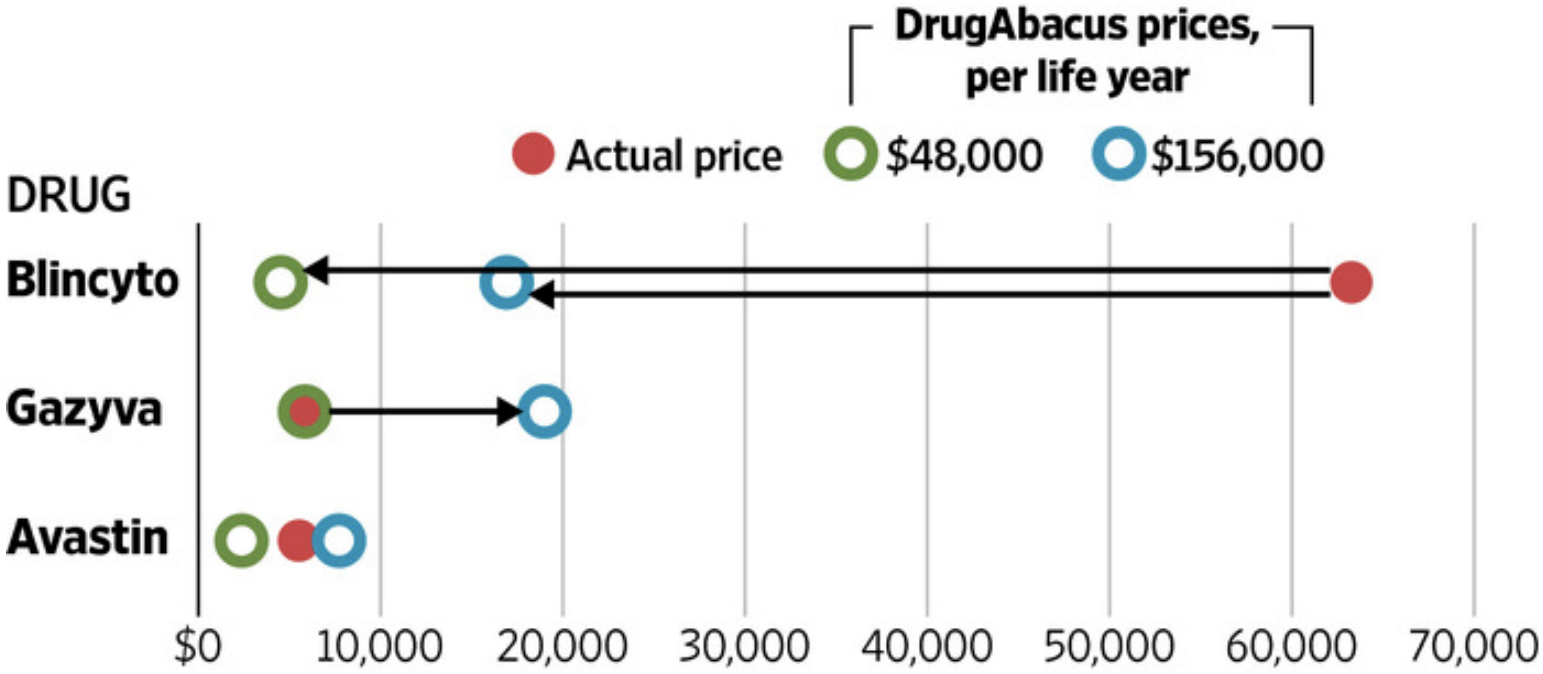
- **PCSK9 Inhibitors: anti-cholesterol drugs aimed at patients with genetic condition, familial hypercholesterolemia; patients unable to tolerate statins, or those on statins with inadequate reduction in LDL**
- **Repatha (Amgen), list price $14,100 a year**
- **Praluent (Sanofi), list price $14,600 a year**
- **Institute for Clinical and Economic review analyzed drugs' cost-effectiveness according to typical "willingness to pay" thresholds (e.g., $50,000-$150,000 per quality-adjusted life year, or QALY)**
- **Found drugs' current prices translated to $500,000 per QALY**
- **Determined drugs should cost $3,615 to $4,811/year to be cost-effective at $50,000 to $150,000 per QALY**
- **To avoid sharp constraints on use/coverage by health plans, drugs should cost $2177 a year, or 85 percent below wholesale acquisition costs**
- **Source: ICER report at http://cepac.icer-review.org/wp-content/uploads/2015/04/Final-Report-for-Posting-11-24-15.pdf**

Similar approaches in cancer drugs



Drug Value

Actual price versus the DrugAbacus price for a month's worth of selected drugs. DrugAbacus prices are adjusted by dollars per life year, or the monetary value assigned to an additional year of life.



(B-cell ALL)

(CLL)

(Multiple Indications)

Source: Memorial Sloan Kettering Cancer Center

THE WALL STREET JOURNAL.

Other Potential Value-Based Approaches

Table. Potential Policy Options for Incorporating Value-Based Pricing for Drugs Into Regulation and Payment

Actor	For Drugs With Value-Driven Prices	For Drugs Priced Above Value-Driven Prices
Private payers	Guarantee formulary inclusion in first tier	Allow exclusion, placement in higher tier, or "step" therapy
	Attach zero or nominal copayment	Attach coinsurance or apply reference pricing
Medicare formulary	Require inclusion in all Part D formularies in first tier	Allow exclusion or high-tier placement in Part D formularies
	Set Part B coinsurance at low level, such as 5% or flat fee	Keep Part B coinsurance at 20% or reference pricing above value-based price
Medicare add-ons	Include entire price in new technology and pass-through payments	Include only portion of cost of new drugs up to value-based price in new technology and pass-through payments
	Include entire price in projection of costs for bundle and gain share calculations	Include only portion of cost up to value-based price in calculating the cost of bundles and other performance payments
HRSA	Exclude drug from 340B drug discount program	Include in 340B program mandatory discounts
FDA	Increase exclusivity period	Decrease exclusivity period. Grant priority review to speed competitors to market

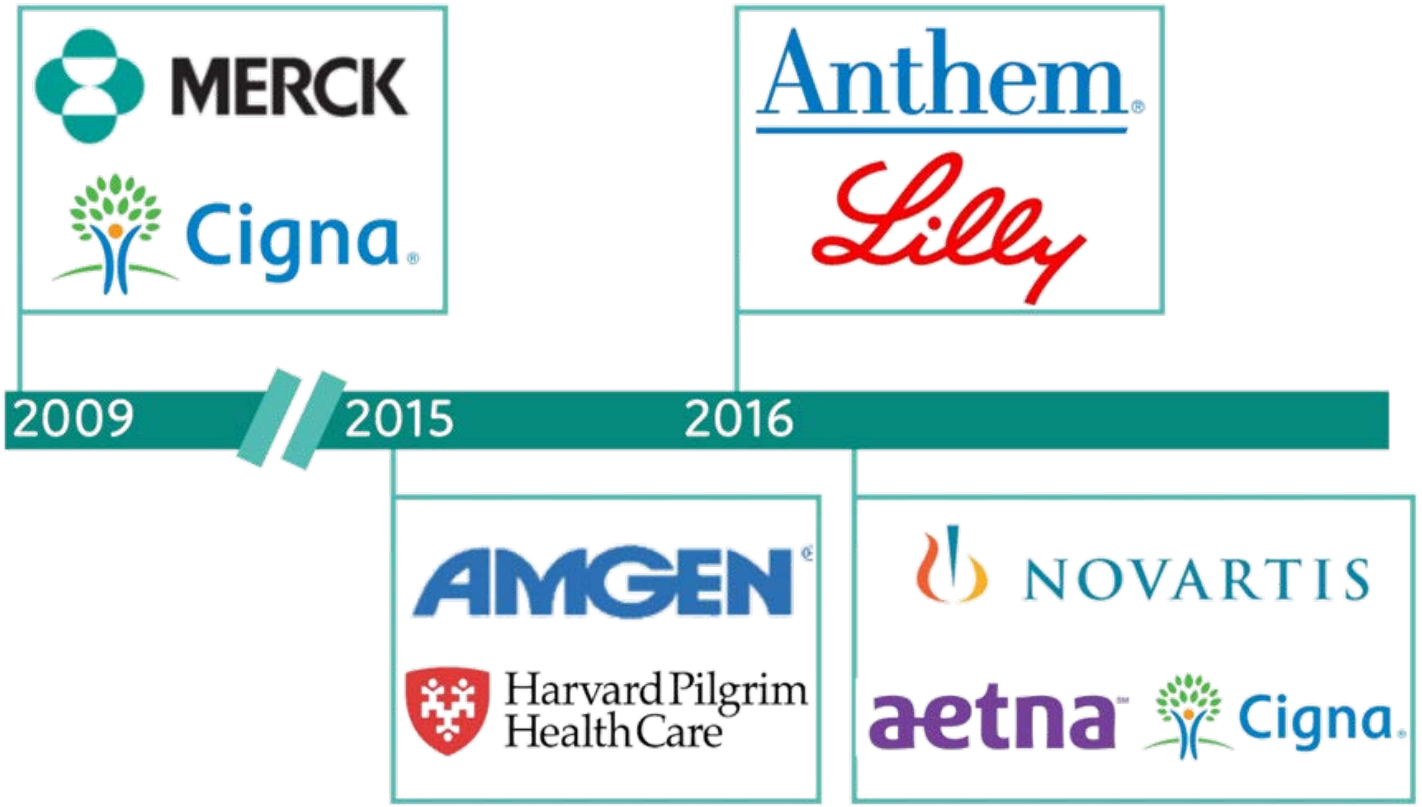
Abbreviations: FDA, Food and Drug Administration; HRSA, Health Resources and Services Administration.

Source: Bach PB, Pearson SD. "Payer and Policy Maker Steps to Support Value-Based Pricing for Drugs." JAMA. 2015;314(23):2503-2504.

Additional Policy Options

- **Greater transparency around pricing and variations; pharmaceutical company R&D**
  - **CMS Medicare Part D "data dump" of 12/15 a start**
- **Medicare Part D prices**
  - **Negotiation – but unless government could limit formulary, little power to affect prices**
  - **Alternatives: binding arbitration**
- **Faster approval of new competitor drugs and generics**
  - **FDA making progress**

Value-Based Contracting Examples



Additional Policy Options

- **Other value-based contracting arrangements**
  - **With total of 943 new active substances soon to be on market, how realistic?**
  - **Need to address regulatory issues such as Medicaid best price, anti-kickback/fraud and abuse laws and regulations**
- **Payment based on prior evidence – indication specific pricing**
- **Coverage with evidence development**
- **Payment based on patient results; outcome determines rebate (e.g. Merck/Cigna arrangement around diabetes drugs)**
  - **Need better measures of outcomes, especially for specialty conditions**
- **Value-based insurance design**

The End