

The Pharmaceutical Market: *Market Failures, Fixes & the Future*

Health & Human Services Finance Committee
Minnesota Legislature, House

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Overview

Understanding the Pharmaceutical Market:

- u Demand for Prescription Drugs**
- u Drug Markets: Brands & Generics & Specialty**
- u Drug Coverage: Medicare, Medicaid, Commercial, Individual**
- u Extraordinary Prices & Price Changes**
- u Pharmacy Benefit Managers: Role & Issues**
- u Competition & Market Power → Reverse & Perverse Economics**
- u Finding Fixes for the Future**

Legislation, Regulation, Litigation & Indignation

**Is there anyone who has never
been sick a day in their life?**

**Is there anyone who has not needed
(or used) a prescription drug?**

***Virtually everyone needs, has used,
or will use drugs in their lifetime.***

Disruptive Issues

New Things We Aren't Expecting Will Disrupt:

- u Drug Spending** (Hidden Expend., Hidden Prices)
- u Rebates** (Blamed for High Prices, Admin Cost, Wall Street)
- u Copay Coupons & Patient Assistance**
- u Generics** (Authorized Generics, Single Source Generic)
- u PBM Behavior** (PBM Spread, Gag Orders, Mail, Specialty, Preferred Networks)
- u Opioid Use & Adherence → Over-Use**

Features of U.S. Drug Market

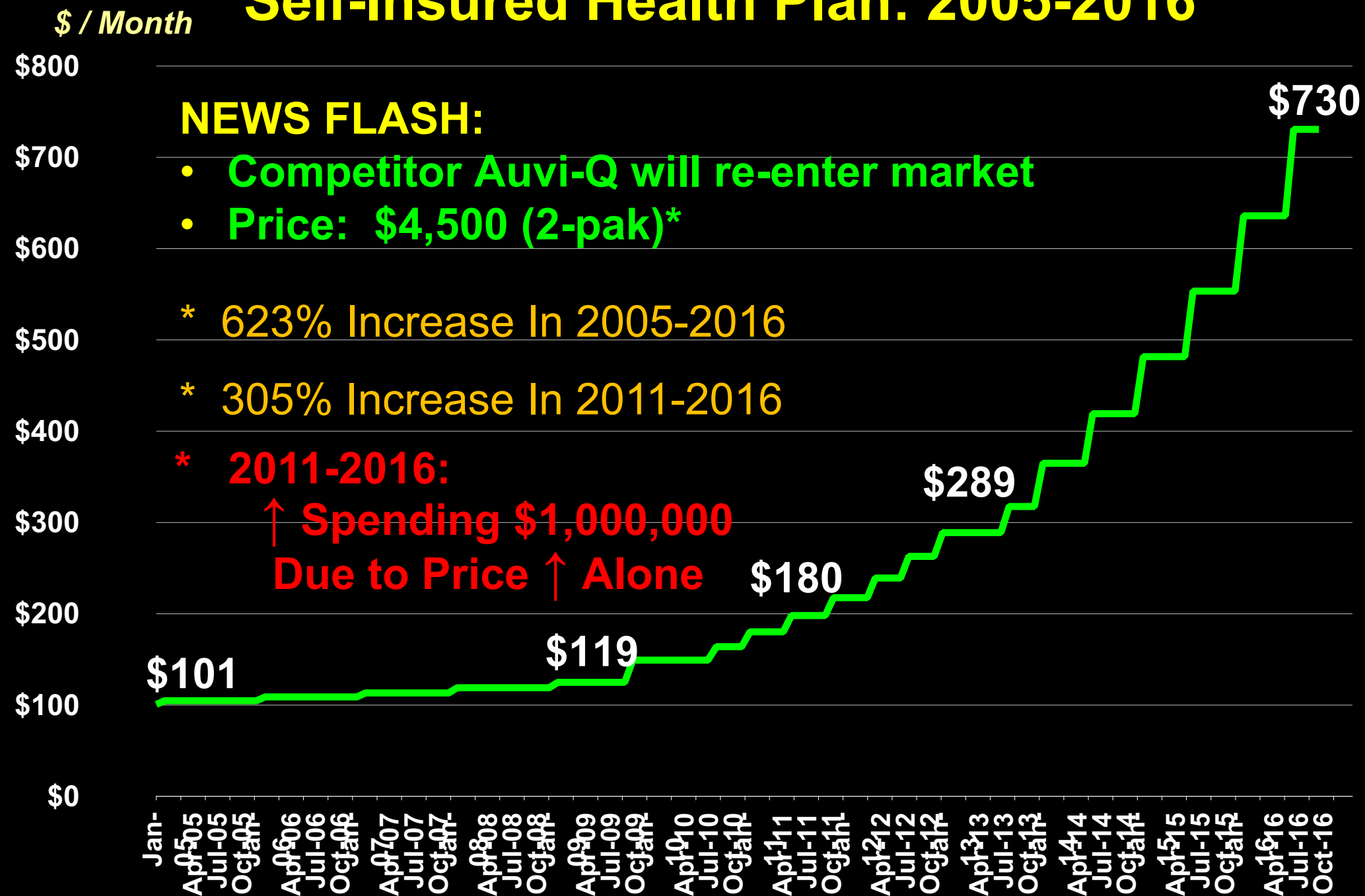
- u FDA Approves Drugs That Are Better Than Placebo**
- u Medicare & Medicaid Must Cover FDA Approved Drugs**
- u Drug Firms Set Any Price They Want (a blank check)**
- u Coverage Has Been Broadened to Include Most
(> 90% of U.S. Residents)**
- u Medicare Can Not Negotiate Drug Prices**
- u Increased Cost-Sharing for Rx Coverage**
- u Drug Cost is Paid by Individuals, Employers, or Govt.**
- u Insurers Process Claims But Don't Pay for Healthcare**
- u Insurance Does Not Increase Resources**
- u Insurance Cost Shifts → Income Re-Distribution**

The Market for Drugs Is Unique

Supply side factors:

- u Monopoly for Pharmaceuticals**
(Patents & Exclusivity prevent competition)
- u High Barriers to Market Entry**
- u Resources Not Easily Transferable**
- u Reverse & Perverse Incentives**
- u Access Requires “Prescription”**
- u Asymmetric Market → Imperfect Information**
Nobel Prize (Patents & Exclusivity prevent competition)

\$/EpiPen (2-pak) for Self-Insured Health Plan: 2005-2016

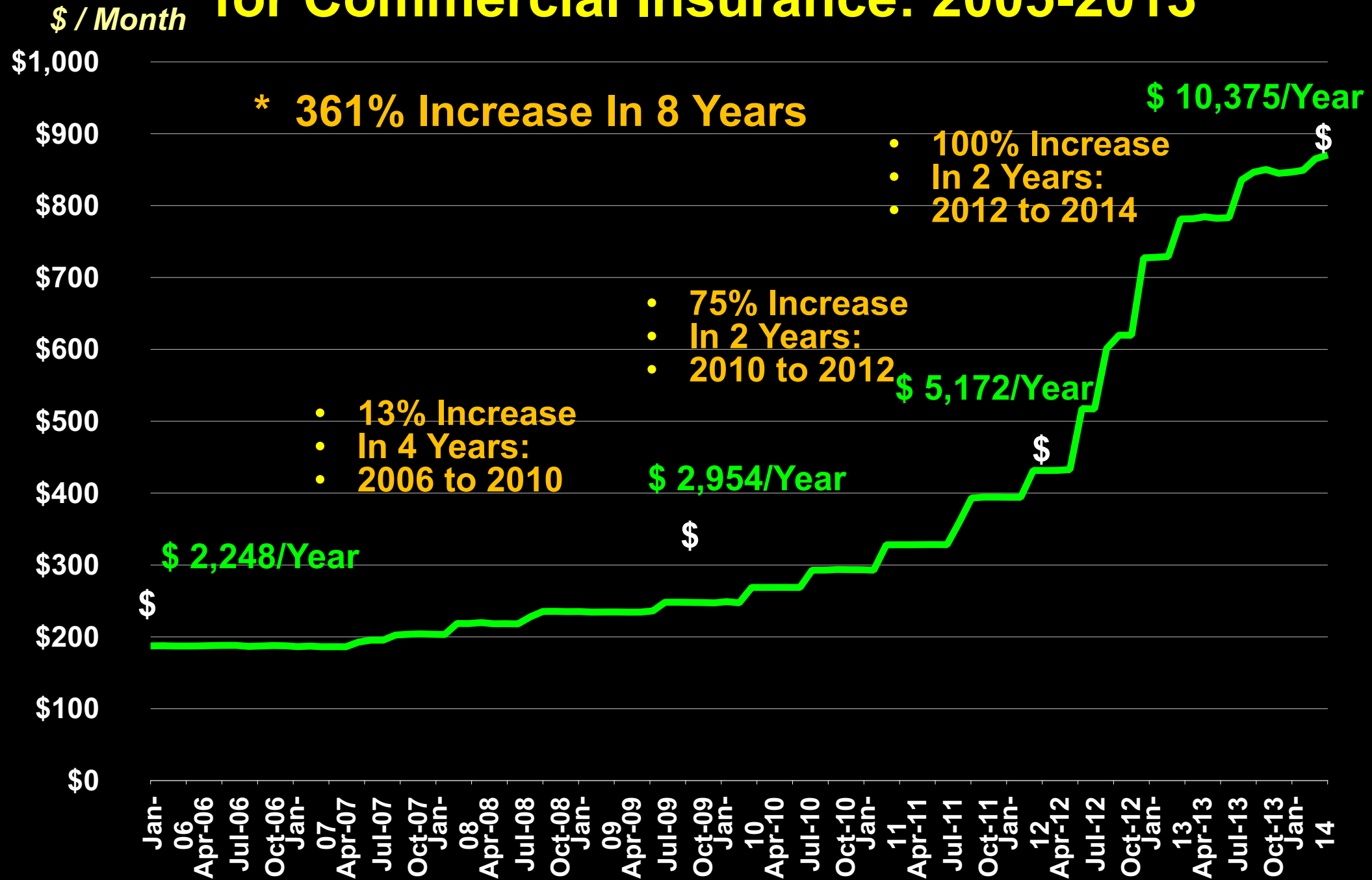


Based on data from self-insured drug benefit 2004 to 2016 & compiled by PRIME Institute, University of Minnesota.

* Reported in Karlin-Smith, Sarah, "EpiPen competitor to cost seven times more", Politico, January 19, 2017 as found at:

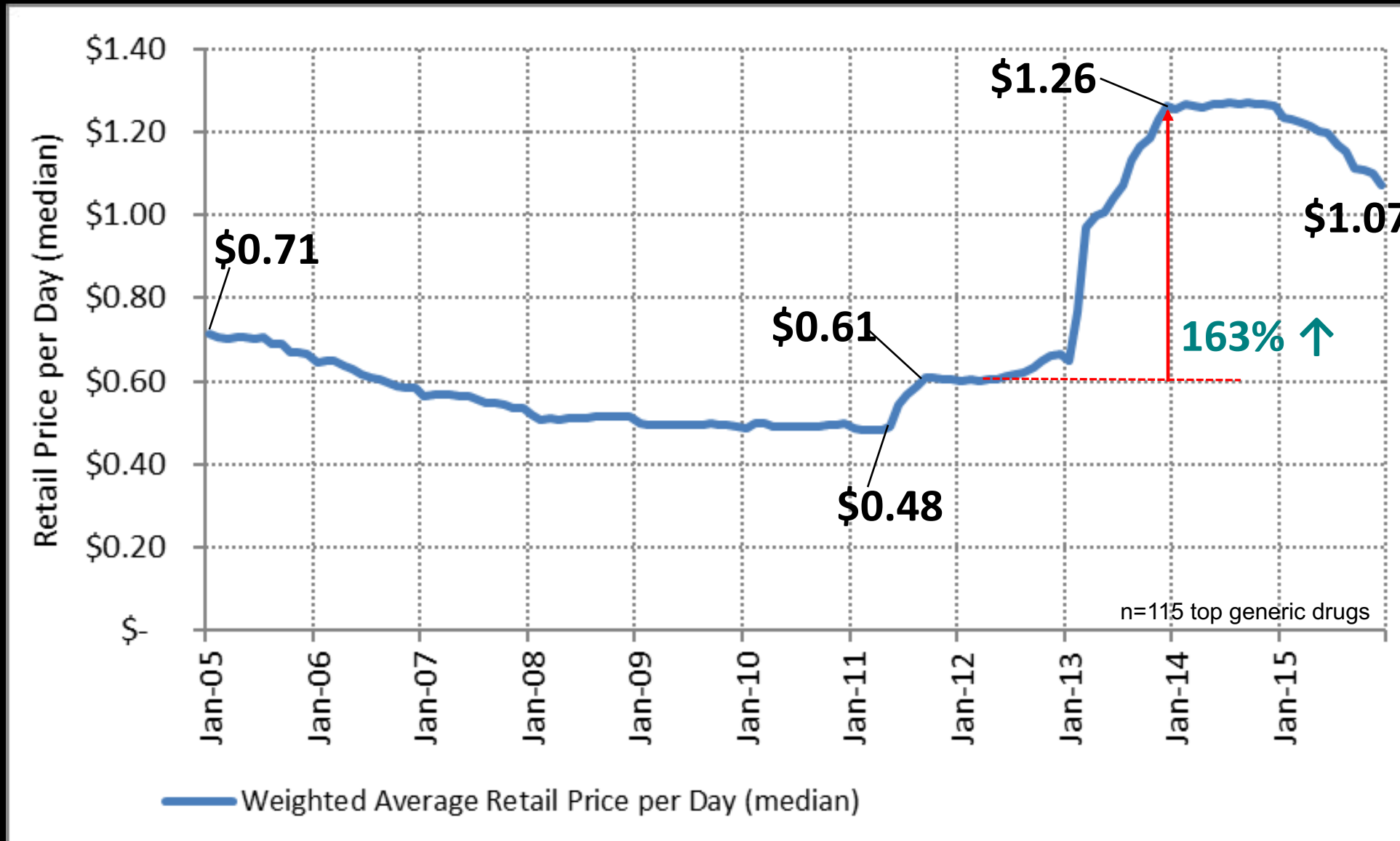
<https://www.politicopro.com/health-care/whiteboard/2017/01/kaleo-to-undercut-epipen-price-with-upcoming-alternative-082511>

Humulin U-500: Average \$/Month for Commercial Insurance: 2005-2013



Based on data from self-insured drug benefit 2004 to 2013 & compiled by PRIME Institute, University of Minnesota.

Weighted Average Retail Price Paid per Day for Older Cohort (1980-2003) of Most Widely Used Generic Prescription Drugs: 2005 to 2015



**When a drug has a
100% increase in price
does the patient's
diabetes get 100% better?**

NO !!!

***Are We Getting Our Money's Worth?
Is the Market Really Working?***

***This Is Not an Efficient Market
Or Value-Based Pricing !***

Annual Cost of Multiple Sclerosis Therapies in the U.S. from 1993 to 2013

We Assume That More Competitors Will Make the Market Work !

What Happened With MS drugs as more competitors entered the market?

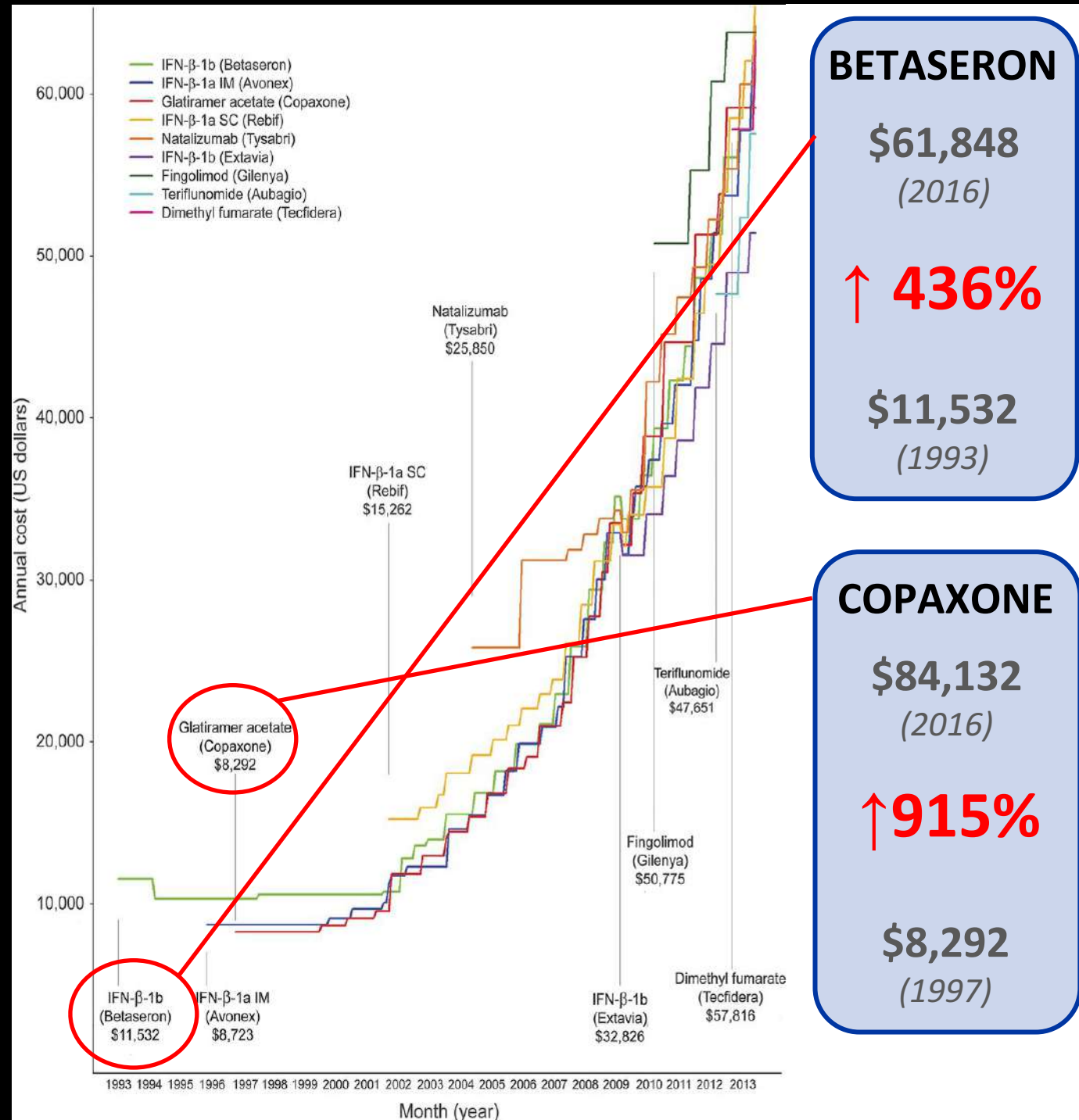
MS Therapy Prices ↑ 500% to 1,000% When 9 Competitors Entered Over 20 Years.

Is This Market Economically Efficient?

Source:

The cost of multiple sclerosis drugs in the US and the pharmaceutical industry: Too big to fail?

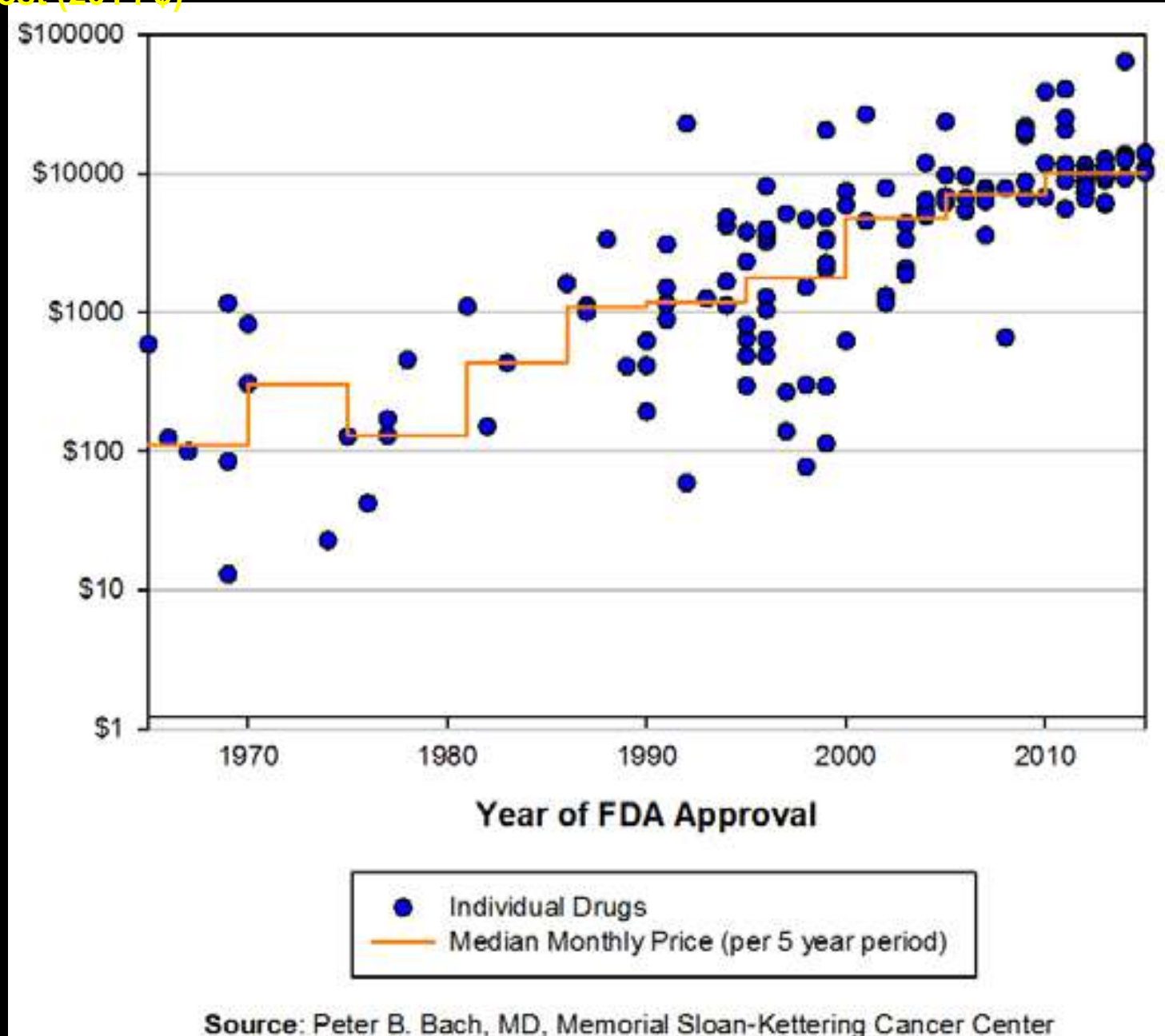
Daniel M. Hartung, PharmD, MPH
 Dennis N. Bourdette, MD
 Sharia M. Ahmed, MPH
 Ruth H. Whitham, MD



Monthly Median Cost of Cancer Drugs at the Time of FDA Approval: 1965-2013

Monthly Cost (2014 \$)

NOTE:
This is a
log scale.



Some New Drugs Enter the Market at the Cost of:

u A Week's Vacation (\$1k to \$5k)

(copaxone (1 month) for Multiple Sclerosis)



u A New Economy Car (\$10k to \$25k)

(Insulin, PCSK9s for cholesterol)



u A New Luxury Car (\$30k to \$100k)

(Harvoni & Hep C drugs, Gilenya & MS drugs)



u A New House (\$200k to \$500k)

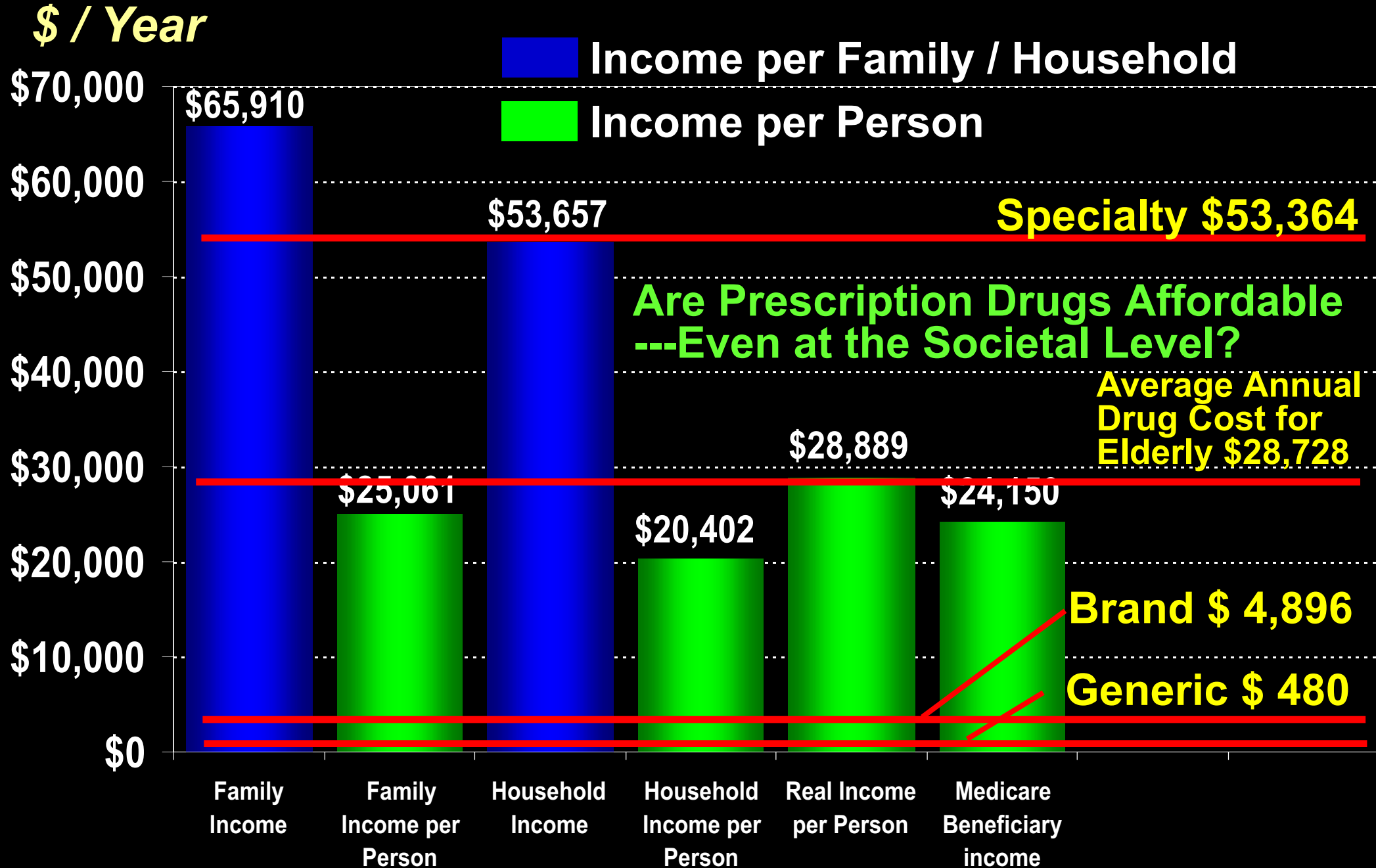
(Yervoy, Cancer & orphan drugs)



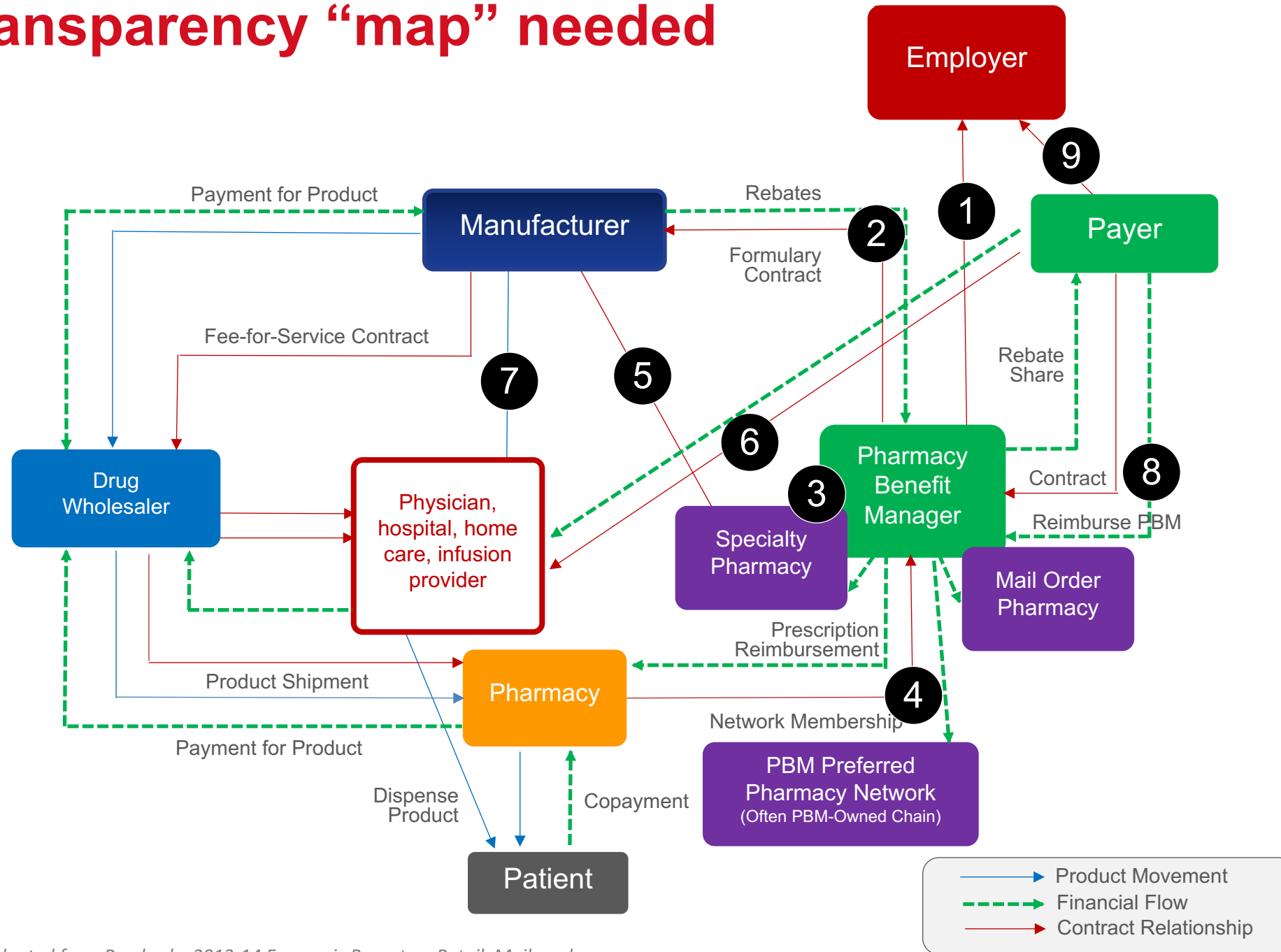
Drug Pricing Issues

- u Fewer Generic Firms & Industry Consolidation**
 - Teva acquired Actavis; Teva acquired Allergan; Teva acquired Anda
- u Most Generic Firms Have Broad Line of Products**
- u Most Brand Name Firms Have Generic Divisions**
 - Pfizer → Greystone & Hospira; Novartis → Sandoz; Teva → Allergan.
- u Authorized Generics Not Really Generics**
 - NDA-authorized, not ANDA; Pre-empt & may dampen “true” generic entry over time
- u Bundling & Tying Arrangements in Contracts**
 - e.g., Must buy firm’s generics to access firm’s discounts & rebates on brands
- u PBMs Sometimes Add “Spread” Onto Generics**
 - Generic spread for mail, specialty, preferred networks, may be higher than retail
 - Some PBMs charge full copay even when actual generic prescription costs less

U.S. Annual Income: 2014



Transparency “map” needed

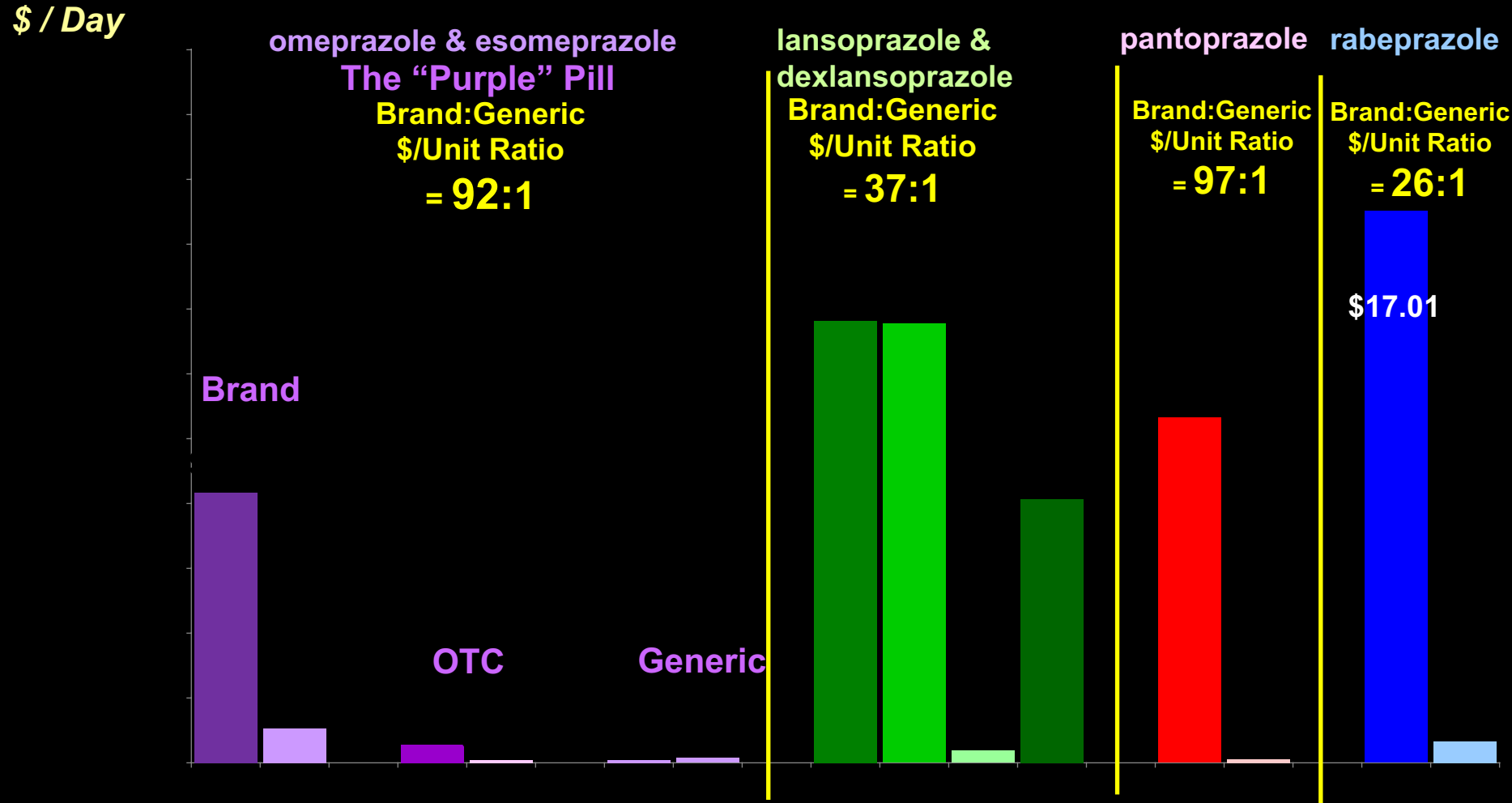


Adapted from Pembroke 2013-14 Economic Report on Retail, Mail, and Specialty Pharmacies; Drug Channels Institute

PBM Practices

- u Gag Rule: Pharmacists Cannot Tell Patient About Lower Cost Alternatives**
- u MAC Pricing Spread on Generics**
- u Rebates & Rebate Admin. Fees & Other Fees**
- u PBM-Owned Pharmacies** (Mail, Specialty, & Limited Distr.)
- u Preferred Network (Chain) & Exclusive Dealing**
- u Utilization Management** (Qty, PA, Step Therapy, Pt. Mgmt.)
- u Payment Parity Across Providers**

Proton Pump Inhibitors \$ Cost/Unit for Self-Insured Employer*: 2016



NEW GENERIC GAMES

- * **New Combination:**
Zegerid (omeprazole & sodium bicarb.)
Price: **\$17,000/Rx** (\$95 / tab)
(Valeant. 90-day supply)
- * **Generic Version of Zegerid**
(Oceanside, 90-day supply)
\$12,000/Rx (30% discount off brand)
- * **Generic Version of Omeprazole & Sod. Bicarb.**
\$17/Rx (90-day supply)
- * **Brand to Generic Ratio**
(1,000 : 1)

BENEFIT DESIGN ISSUES

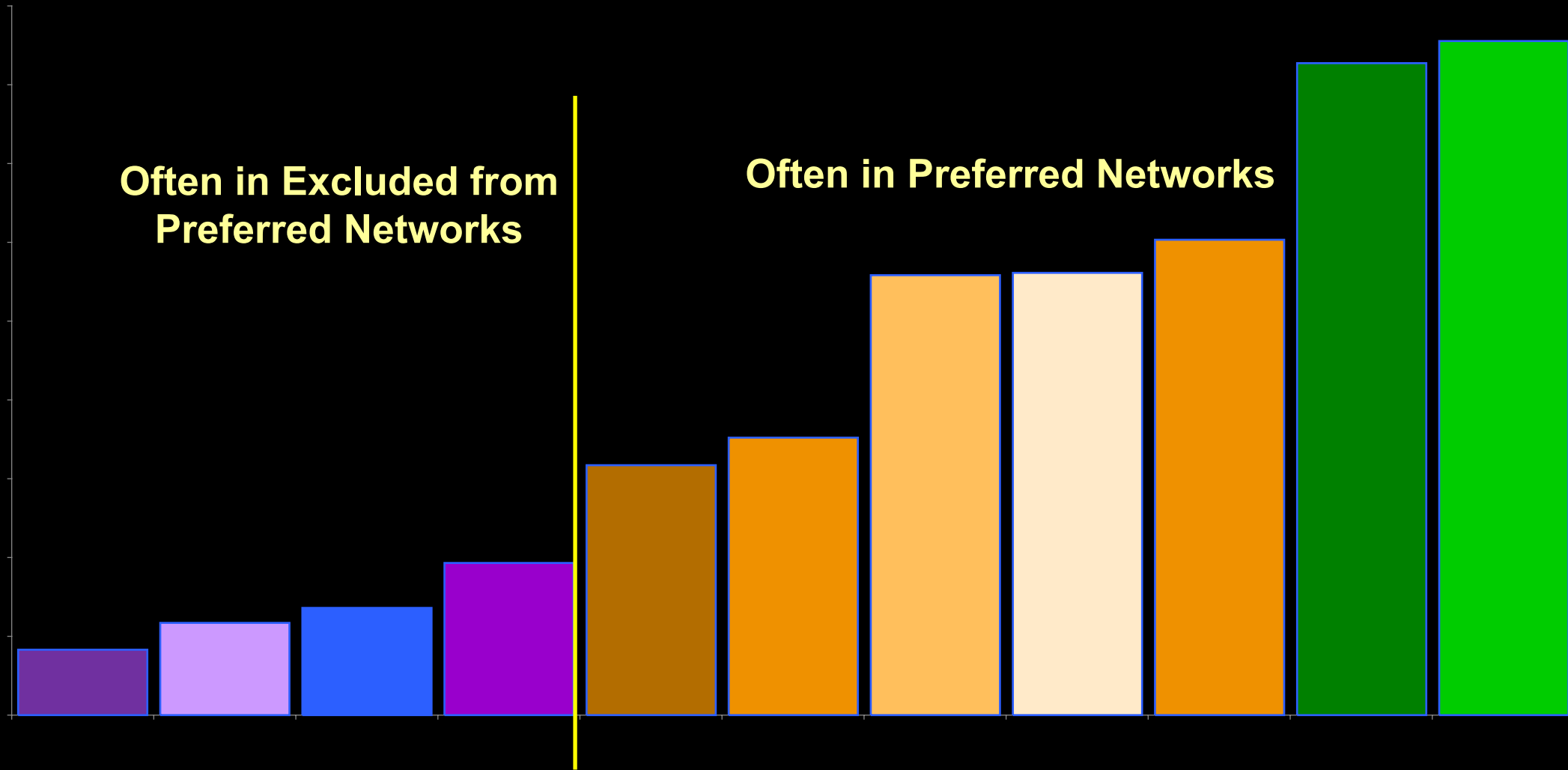
What Should You Do With Drugs Like Zegerid?
 ---Cover Them? or
 ---NDC Block Them?
 ---GPI Block Them?

Should You Cover OTCs?

Should You Cover Brands With Price Ratios > 25:1 ?

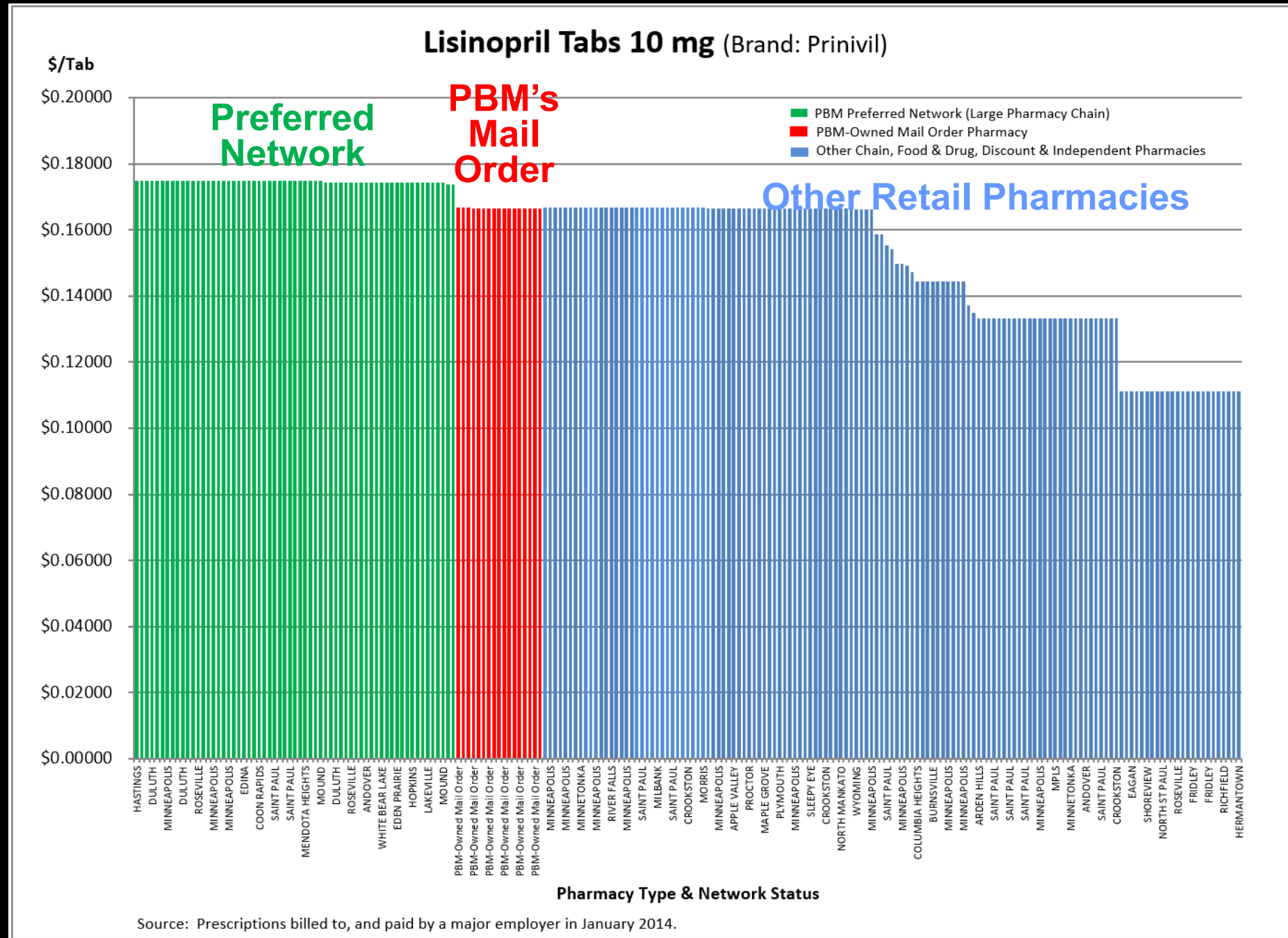
* Compiled by the PRIME Institute, University of Minnesota from actual claims data for total amount paid by a self-insured employer for calendar year 2016.

5 Common Generic Prescriptions at Different Pharmacies: 2016



* Compiled by the PRIME Institute, University of Minnesota from data found in Consumer Reports January 2016.

Amount Paid/Unit for Generic Prescription Drug by Pharmacy Type & Network Status



BENEFIT DESIGN ISSUES

Is the Preferred Network

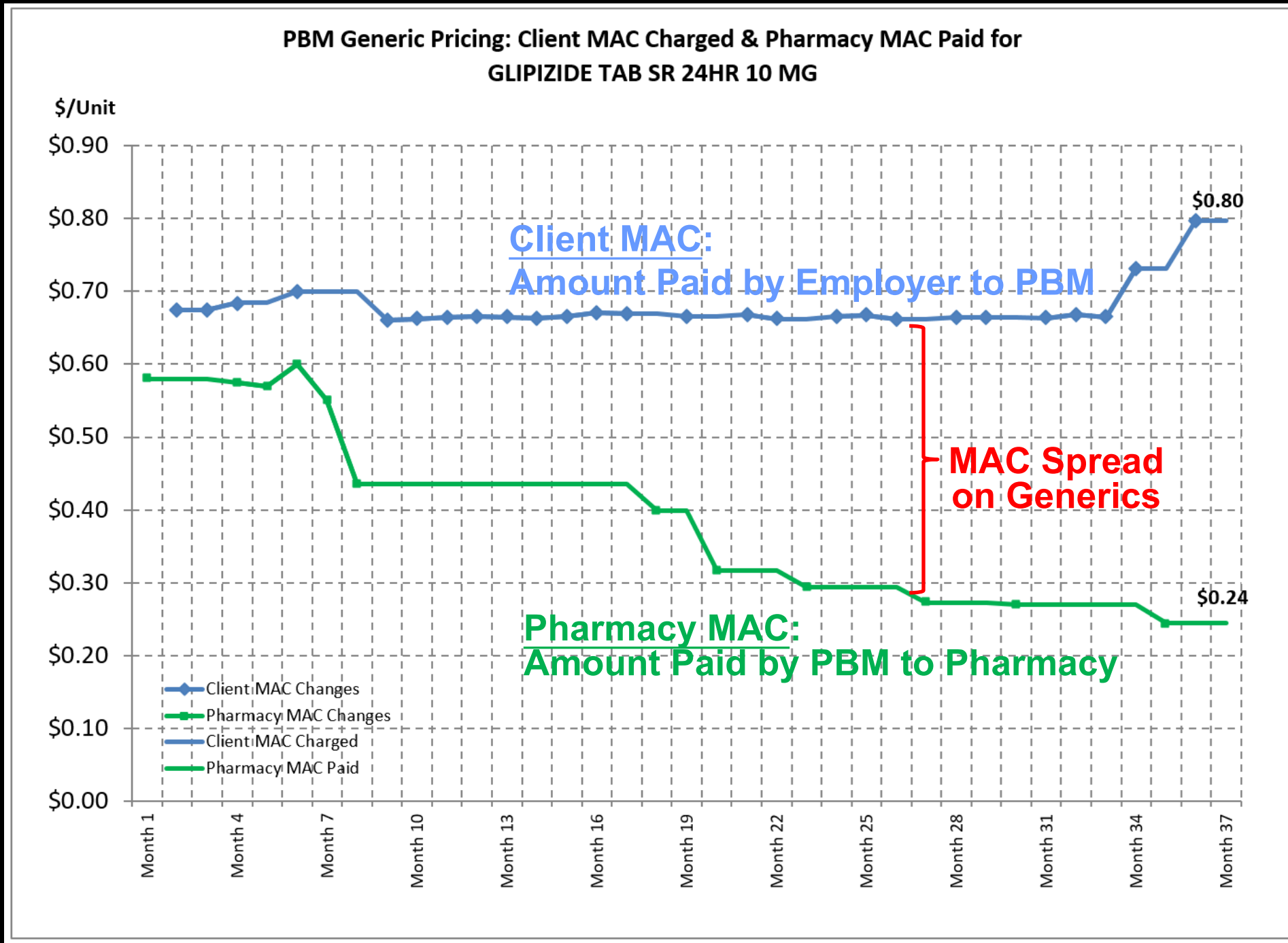
---Less Expensive? or

---More Expensive?

Is Mail Order Saving Money Compared to Retail Pharmacies?

---If Not, Why Should You Allow a Different Copay?

Generic MAC Amount Paid/Unit to PBM to Pharmacy & by Employer to PBM



BENEFIT DESIGN ISSUES

Does Your PBM Use a Pharmacy MAC?

Does Your PBM Use a Client MAC?

How Does the Client MAC Compare to the Pharmacy MAC?

Who Benefits from the MAC Spread on Generics? ---PBM? or Employer?---

Who Benefits When the Pharmacy MAC is Reduced?

Is Mail Order Pharmacy Paid the Same MAC as Retail Pharmacies?

-Or Is Mail Order Paid the Client MAC?

-If Mail Order Is Paid More than Pharmacy MAC Is Mail Order a Good Deal?

Levothyroxine Sodium 75 mg Tablets

Brand & Generic Prices (May 2015)

\$/tablet
(AWP)

\$3.00

\$2.50

\$2.00

\$1.50

\$1.00

\$0.50

\$0.00

Brand Name
(Reference Products)

Generic Equivalents

How Do Brands & Generics Compare?

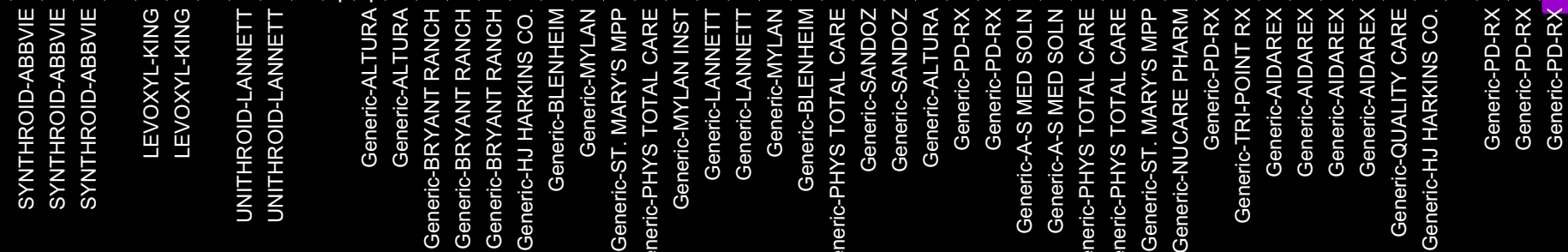
Why are some generics higher than brands?

Does the biggest discount always get the lowest price?

Repackaged or
Re-labeled Brand
or Generic Products

(Set their own AWP & WAC)

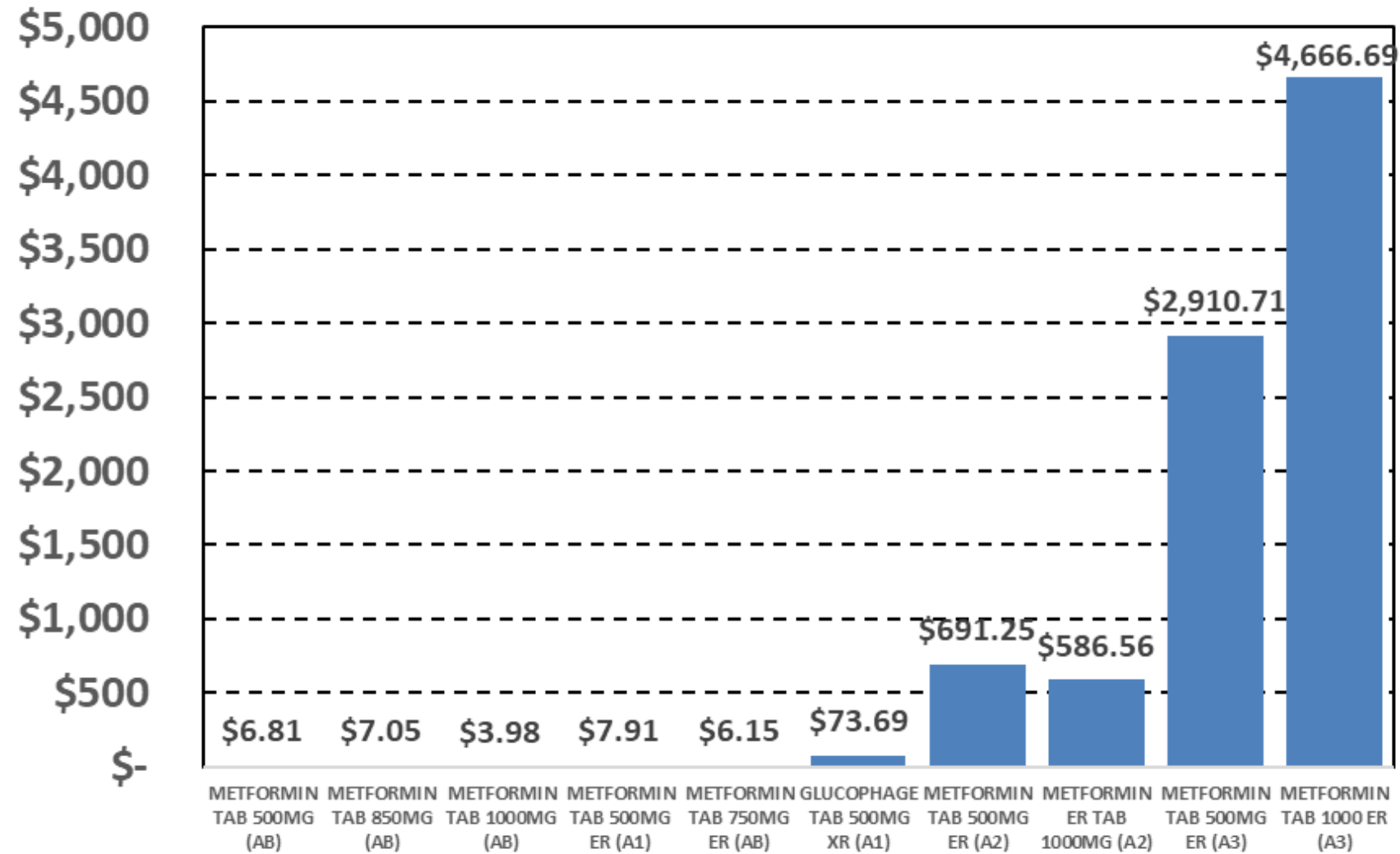
(Often used by:
Mail Order Pharmacies,
Chain Pharmacies,
Specialty Pharmacies &
Physician Dispensers)



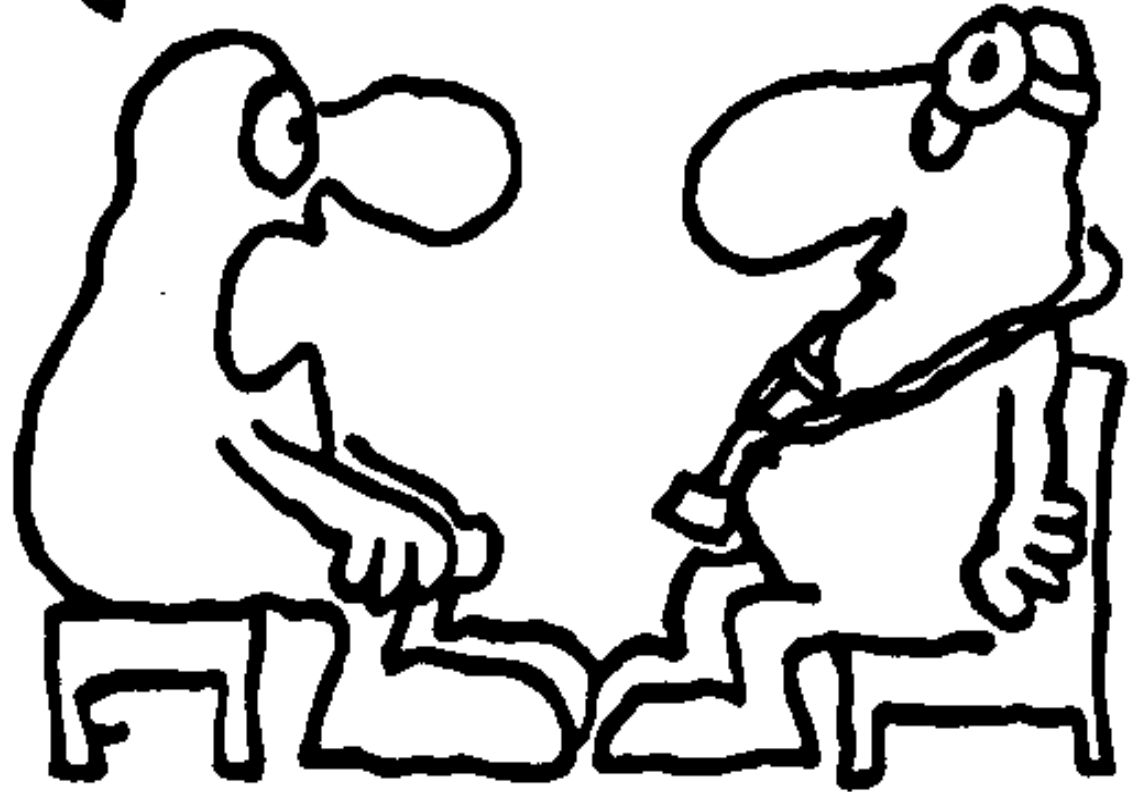
Source: Compiled by the PRIME Institute, University of Minnesota from data found in Micromedex RedBook, May 2015.

Price Disparity Across Therapeutic Alternatives: 2017

Amount Paid (\$)/30-Day Prescription: Metformin
by Product Type



DOCTOR, HOW SICK
AM I - IN DOLLARS
AND CENTS?



The Drug Market is Broken !

- u Lack of Price Transparency**
- u Information Asymmetry**
- u Inelastic Demand**
- u Lack of Negotiation**
- u High Barriers to Entry**
- u Excessive IP Expansion**

President Trump on Drug Prices



U.S. drug prices have been “outrageous.”^{*1}
Pharmaceutical firms are “getting away with murder.”^{*2}

¹ President Donald J. Trump, March 21, 2017, <http://fortune.com/2017/03/21/trump-pharma-stocks-drug-prices/>

² President Donald J. Trump, January 11, 2017, <http://fortune.com/2017/01/11/donald-trump-press-conference-biopharma-stocks/>

Trump on Prescription Drugs

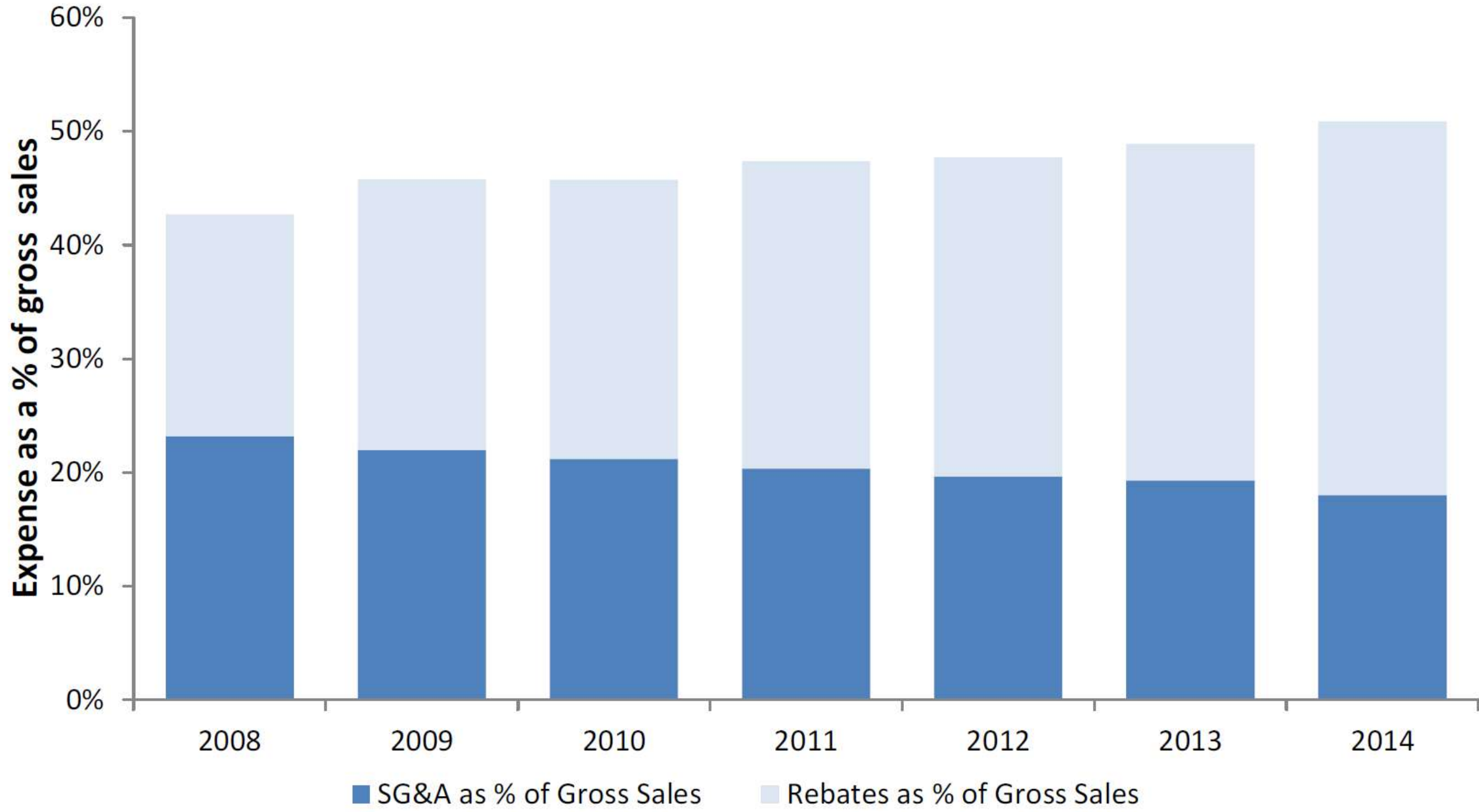
- ***Cutting Prescription Drug Prices is a Top Priority***
 - *Donald J. Trump, Jan. 30, 2018 State of the Union Address*
- ***Asked Congress to Pass “Right to Try” Bill***
 - *Lets terminally ill patients access experimental treatments before FDA approval*
- ***New HHS Secretary is Alex Azar***
 - *Former Eli Lilly (drug company) executive*



Reforming Biopharmaceutical Pricing at Home and Abroad

The Council of Economic Advisers
February 2018

Figure 8: Overall promotional expenses still rising, even if reported SG&A as % is falling



Source: Company data, Credit Suisse estimates

Finding Fixes for the Future

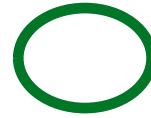
- u Make Drug Prices Transparent & Accountable**
- u Systematically Monitor for Extraordinary Drug Prices**
 - Screen for prices & price changes that are ‘unconscionable’ & ‘unreasonable’
 - Single point price changes >10%, >25%, >50% & >100%
- u Link Transparent Prices, Accountability & Coverage**
 - Quasi-governmental commission reviews & evaluates prices & price changes
 - Price behavior not justified, drug not covered by Medicare, Medicaid, commercial
- u Prohibit Market Distorting Behaviors**
 - Copay Coupons, Undisclosed Rebates, Patents for Product Hopping & Combinations
 - HHS OIG has declared copay coupons as ‘kickbacks’ & prohibited them in govt. plans
- u Recognize Economic Impact of FDA Policy & Actions**
- u Enable Value-Based Decisions → Requires Actual Price**

Medical Benefit Drugs

What Are We Trying to Do:

- u Claims Level Data Reporting at NDC Level**
- u Medical Benefit Drug Formulary** (Drug Value Assessment)
- u Utilization Management** (Qty, PA, Step Therapy, Pt. Mgmt.)
- u Payment Parity from Providers** (Reference pricing)
- u Coordination of Pharmacy & Medical Benefit**
 - Need Vendors to Do This !**

2017/2018 State Rx Legislation by the Numbers



- 2018 Session: 171 Bills (up from 100 bills in 2017)
28 States Enacted 45 New Laws on Drug Costs

Major Categories of Legislation:

- **PBMs** – 92 Bills (31 laws in 20 states)
- **Transparency** – 26 Bills (7 laws: OR, VT, ME, NH, CT, CA*, NV*)
- **Price Gouging** – 13 Bills (1 law: MD*)
- **Wholesale Importation** – 9 Bills (1 law: VT)
- **Bulk Purchasing** – 4 Bills
- **Drug Affordability Review Boards** – 3 Bills: MD, NJ, MN

(* = enacted in 2017)

Disruptive Actions

New Things We Aren't Expecting Will Disrupt:

u New Alignments of Players

PBM (+Mail + Spec) + Pharmacy Chain + Insurer

Caremark

CVS

Aetna

Prime Therapeutics

Walgreens

Blues

u Next Move → PBM-Insurer + Generic Manufacturer

u Non-Profit Generic Manufacturer (InterMountain Health → Project Rx)

u “Waste-Free” Formulary Across Employers/Payers (PBGH)

u Amazon + Berkshire-Hathaway + JP Morgan

→ *Disintermediation + Value to Payer/Patient*

Regulatory & Legal Influences on Generics

- u FDA Review Time for ANDAs Getting Better**
 - Has been a rate-limiting step for ANDA approval & has limited competition
- u Make Sure the 'Total Time' to Market Is Managed**
 - Should not just shift ANDA review time from FDA's clock to firm's clock.
- u Unapproved Drugs Initiative → Competition Worse**
 - Colchicine (Colcrys) reduced competitors and ↑ price from \$.09 to \$4.85
 - Multiple unapproved drugs → 1 high-priced brand instead of more competitors
 - Cost Medicare about \$1.2 billion from 2011-2015 (total national effect ~\$3.7 billion)
- u Pay-for-Delay Invites Gaming & Delayed Competition**
- u Authorized Generics Confuse Consumers**
- u Trade Agreements Expand IP & Limit Generics**
 - TPP would have taken length of biologics exclusivity out of Congress' hands

Economics of Prescription Drugs

**“A drug that
one can not afford is
neither safe nor effective.”**

-- Stephen W. Schondelmeyer