

# Reining in Growth in Prescription Drug Prices: *Markets, Monopolies & Myths*

**Social Insurance: Opportunities & Challenges  
Facing the New Leadership  
& the American People**

**National Academy of Social Insurance  
National Press Club  
Washington DC  
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**Stephen W. Schondelmeyer**

**Professor and Director  
*PRIME Institute*  
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**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.*

# The Market for Drugs Is Unique

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*Supply side factors:*

- ◆ **Monopoly for Pharmaceuticals**

*(Patents & Exclusivity prevent competition)*

- ◆ **High Barriers to Market Entry**

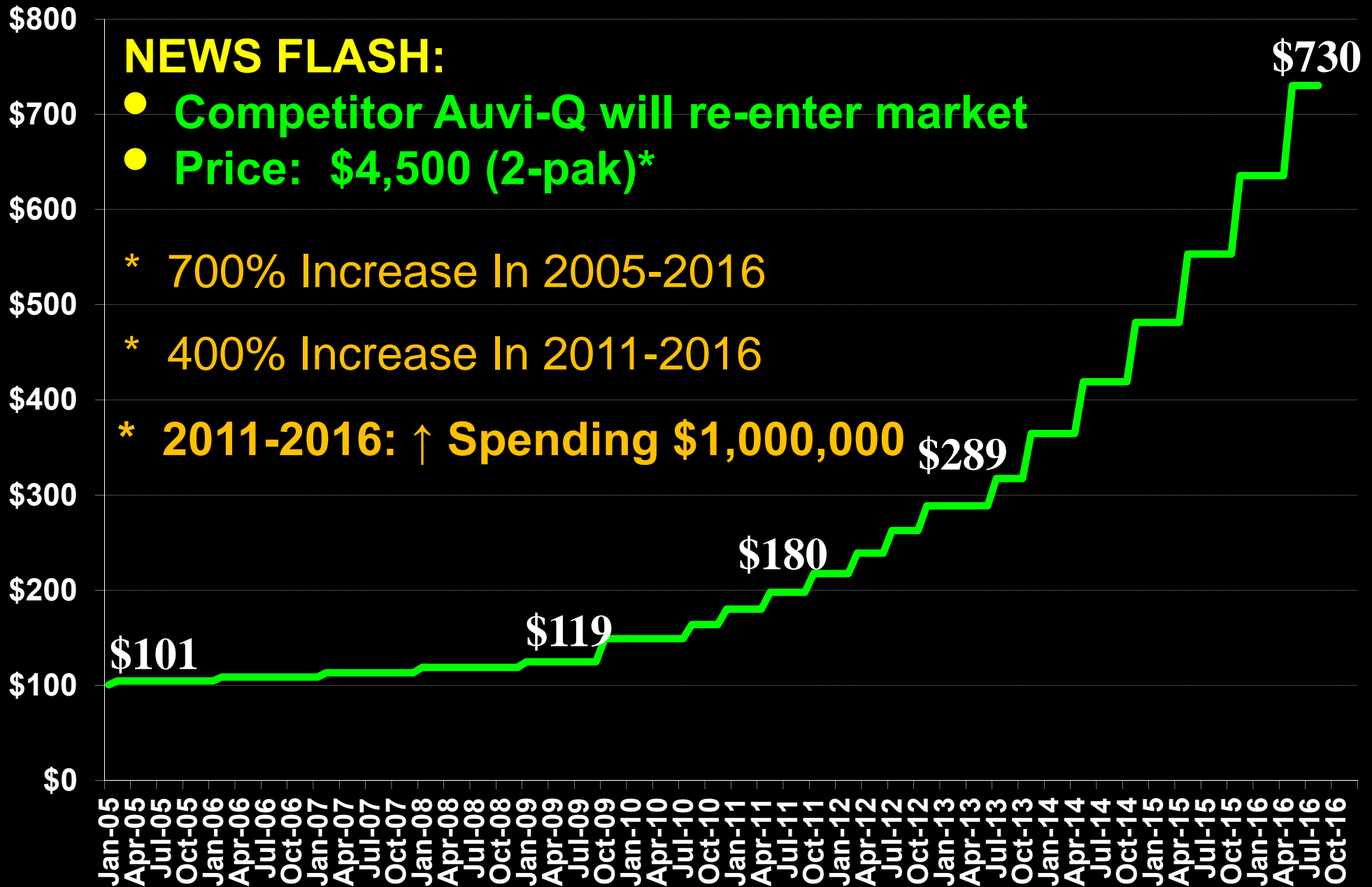
- ◆ **Resources Not Easily Transferable**

- ◆ **Reverse & Perverse Incentives**

- ◆ **Access Requires Permission Slip**

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

\$/ Month



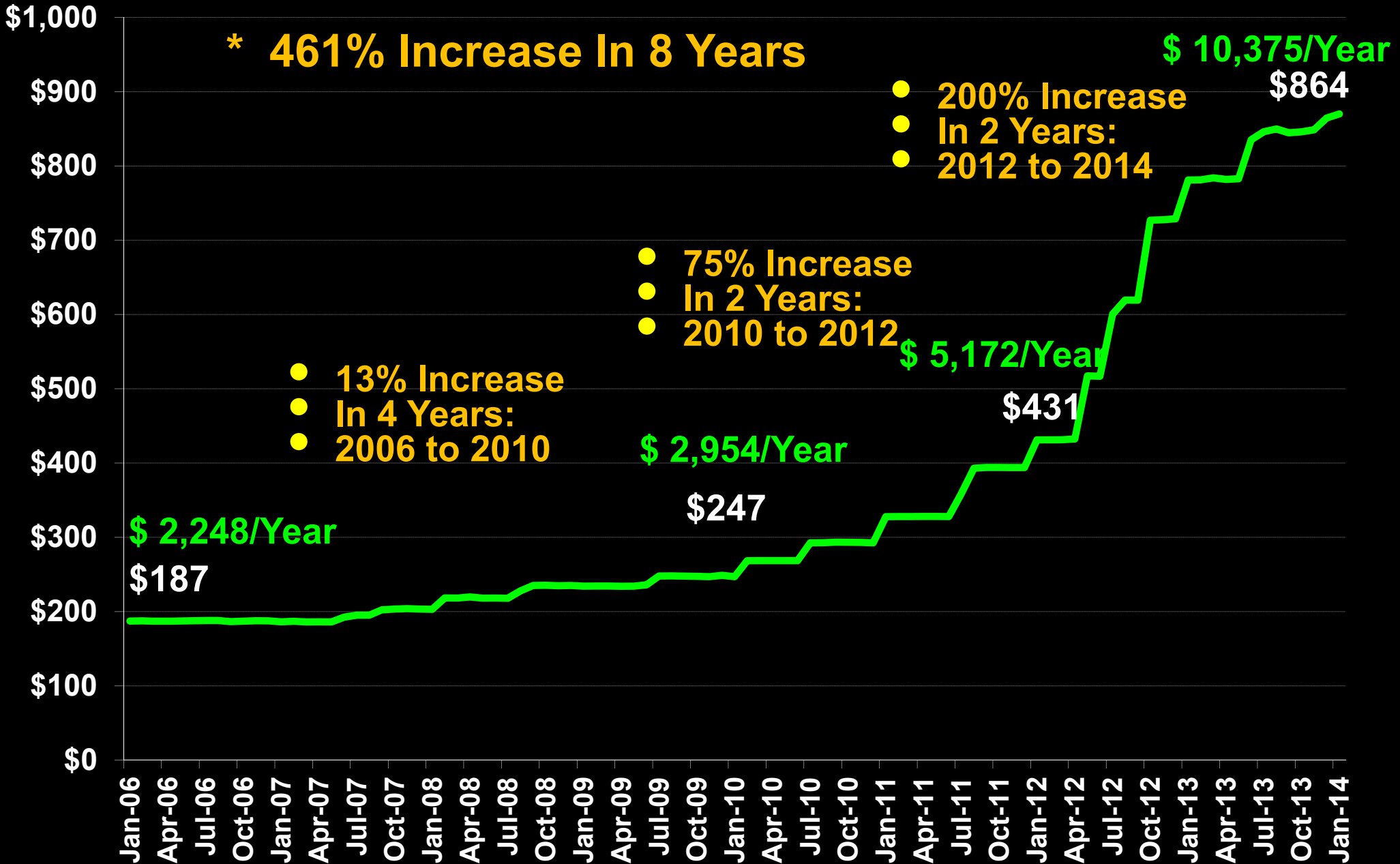
Based on data from self-insured drug benefit 2004 to 2016 & compiled by PRIME Institute, University of Minnesota.

\* 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

\$ / Month



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

**When a drug has a  
200% increase in price  
does the patient's  
diabetes get 200% 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?

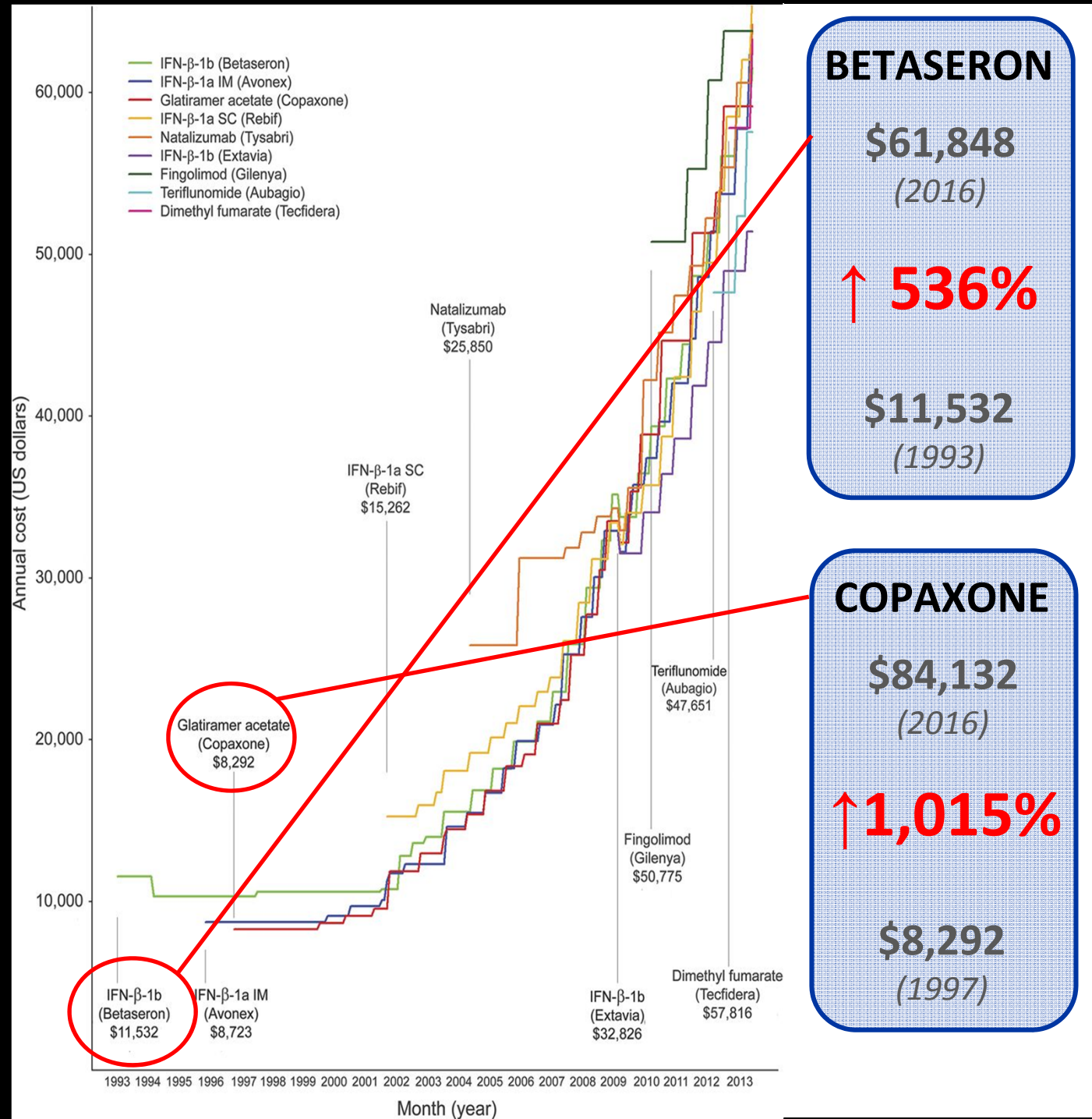
MS Therapy Prices ↑ 500% to 1,000% When 9 Competitors Entered Over 20 Years.

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



# Economics of Prescription Drugs

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

*-- Stephen W. Schondelmeyer*

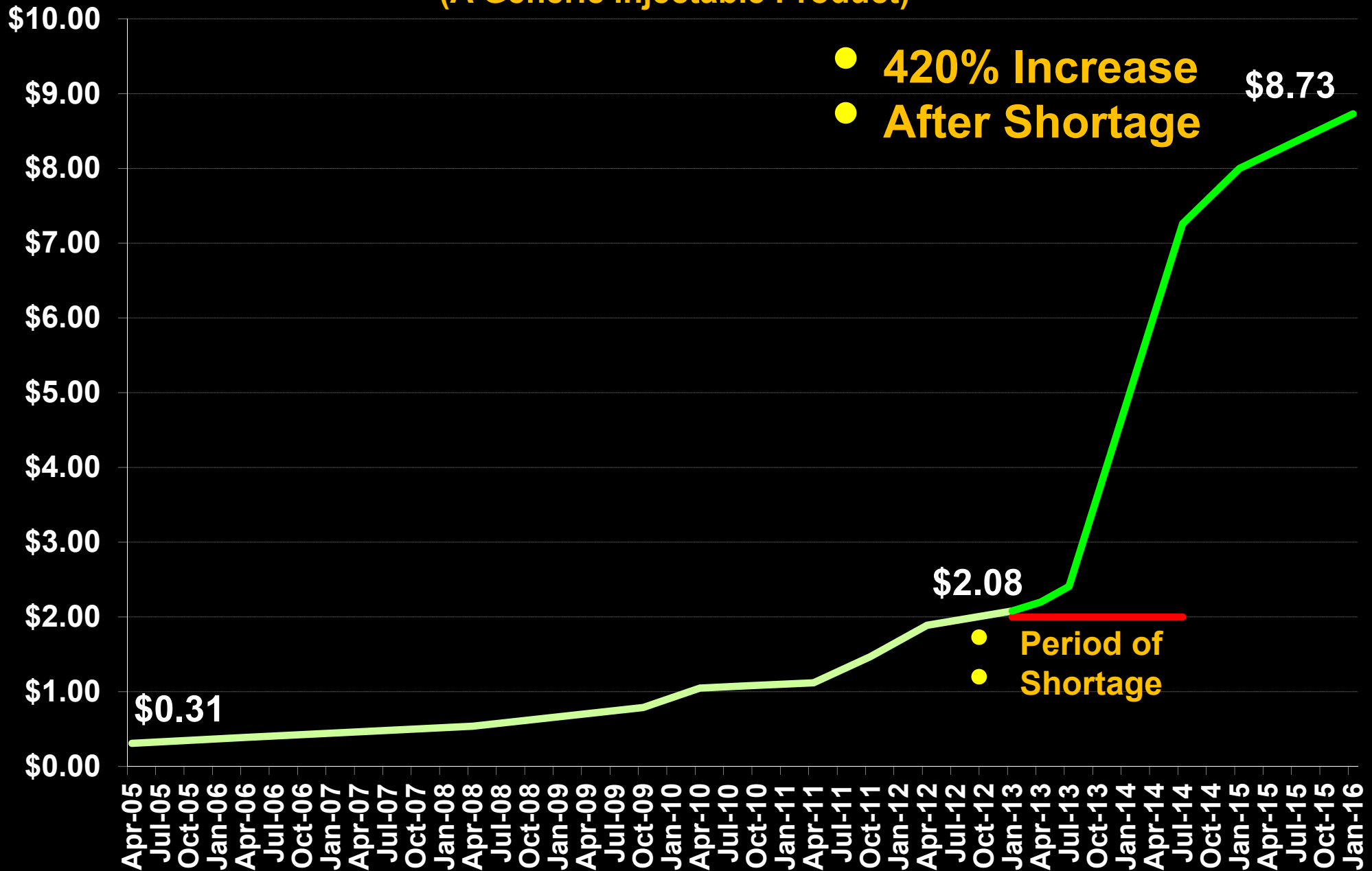


# Verapamil Injection (Hospira)

## Impact of a Drug Shortage: April 2013 to Jan. 2015

• (A Generic Injectable Product)

\$ / Unit

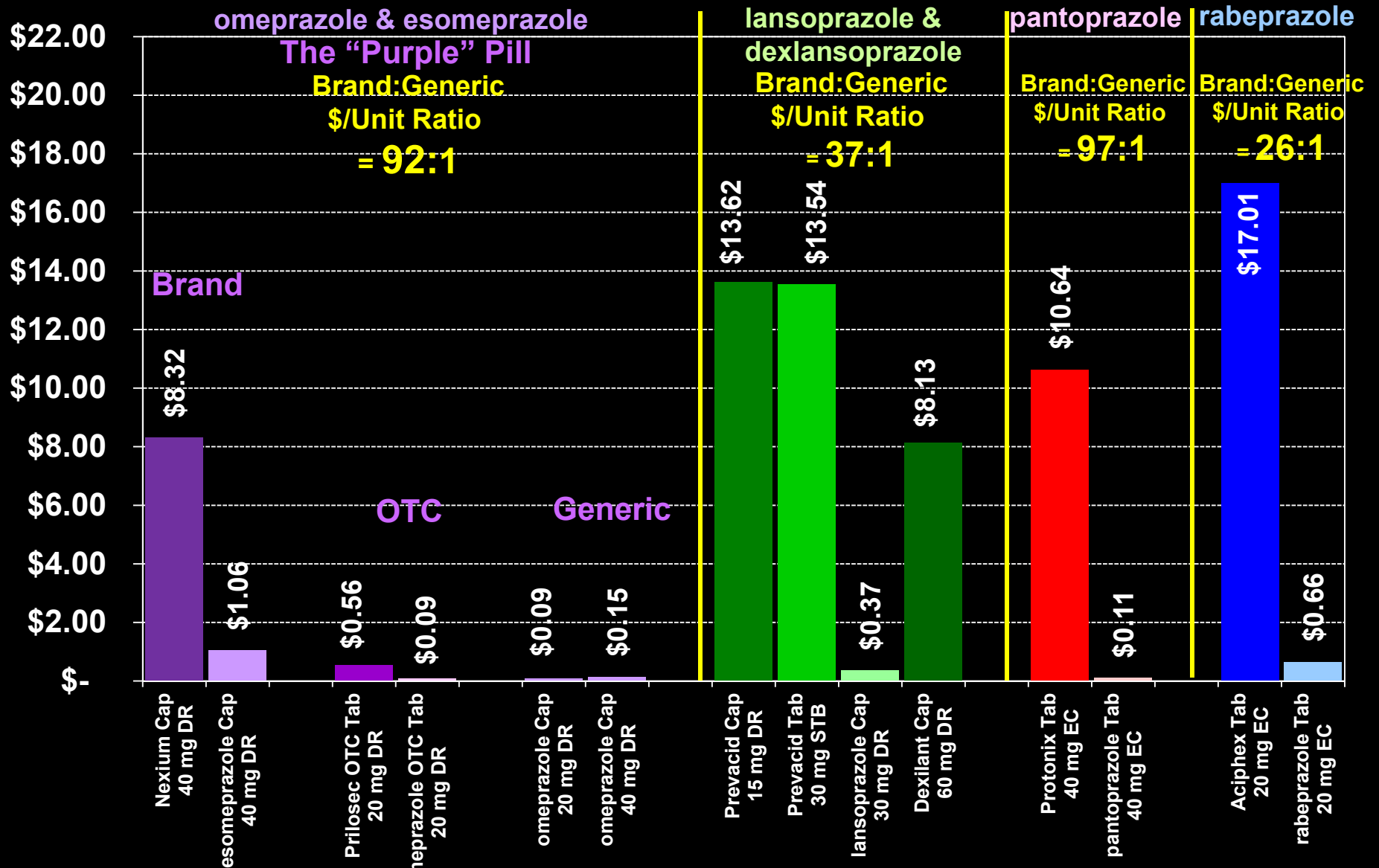


# Proton Pump Inhibitors \$ Cost/Unit for Self-Insured Employer\*: 2016

**New Combination Product:** Zegerid (omeprazole & sodium bicarbonate)

**Price:** \$95 / tab (Price Ratio = 1,000 : 1 vs. Generics)

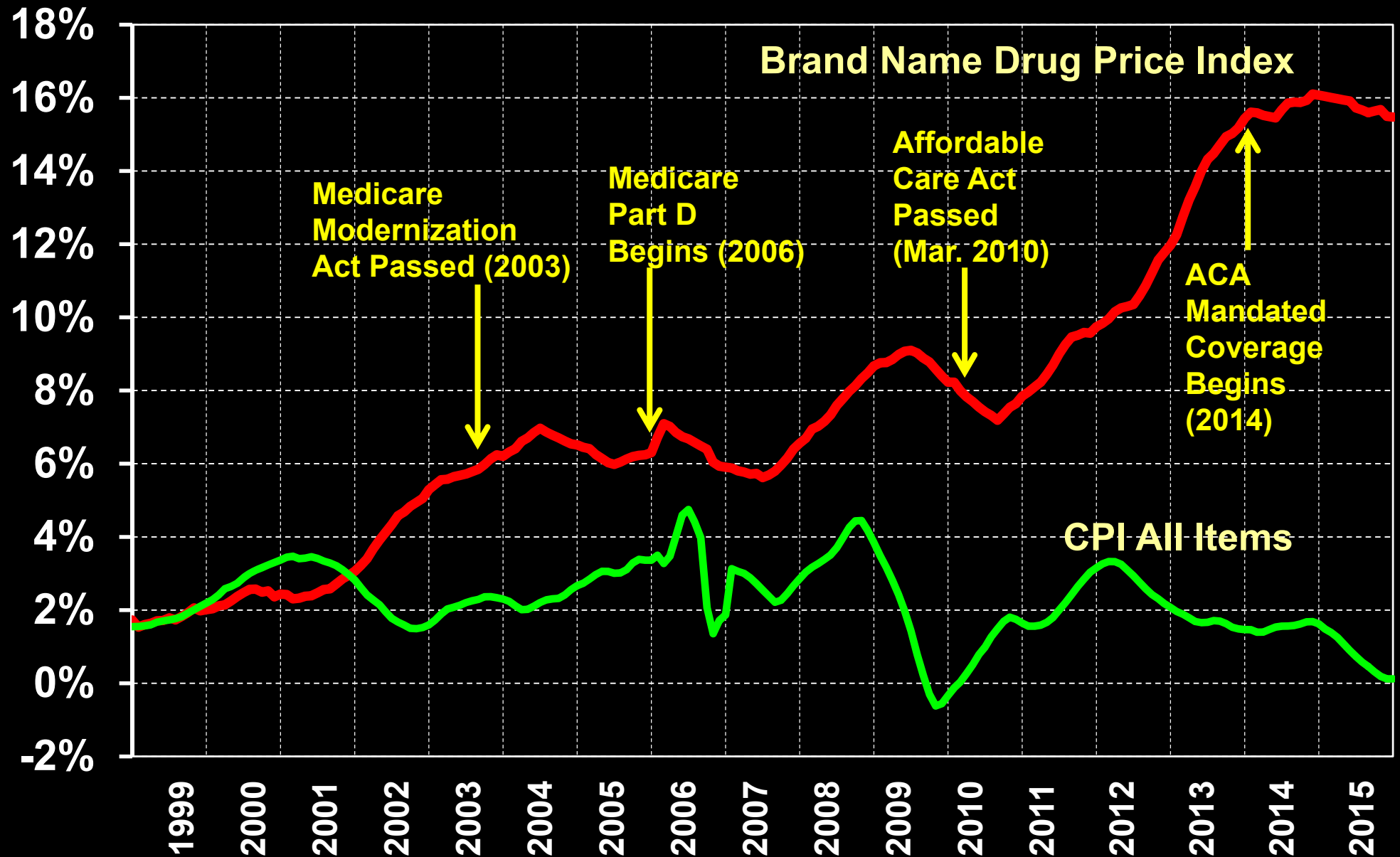
**Zegerid \$17,000 for a 90-day supply vs. \$17 for similar generic**



\* 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.

# Top Brand Name Drugs Most Used by Elderly Drug Price Inflation & CPI-All: 1998 to 2015

Annual %  
Change

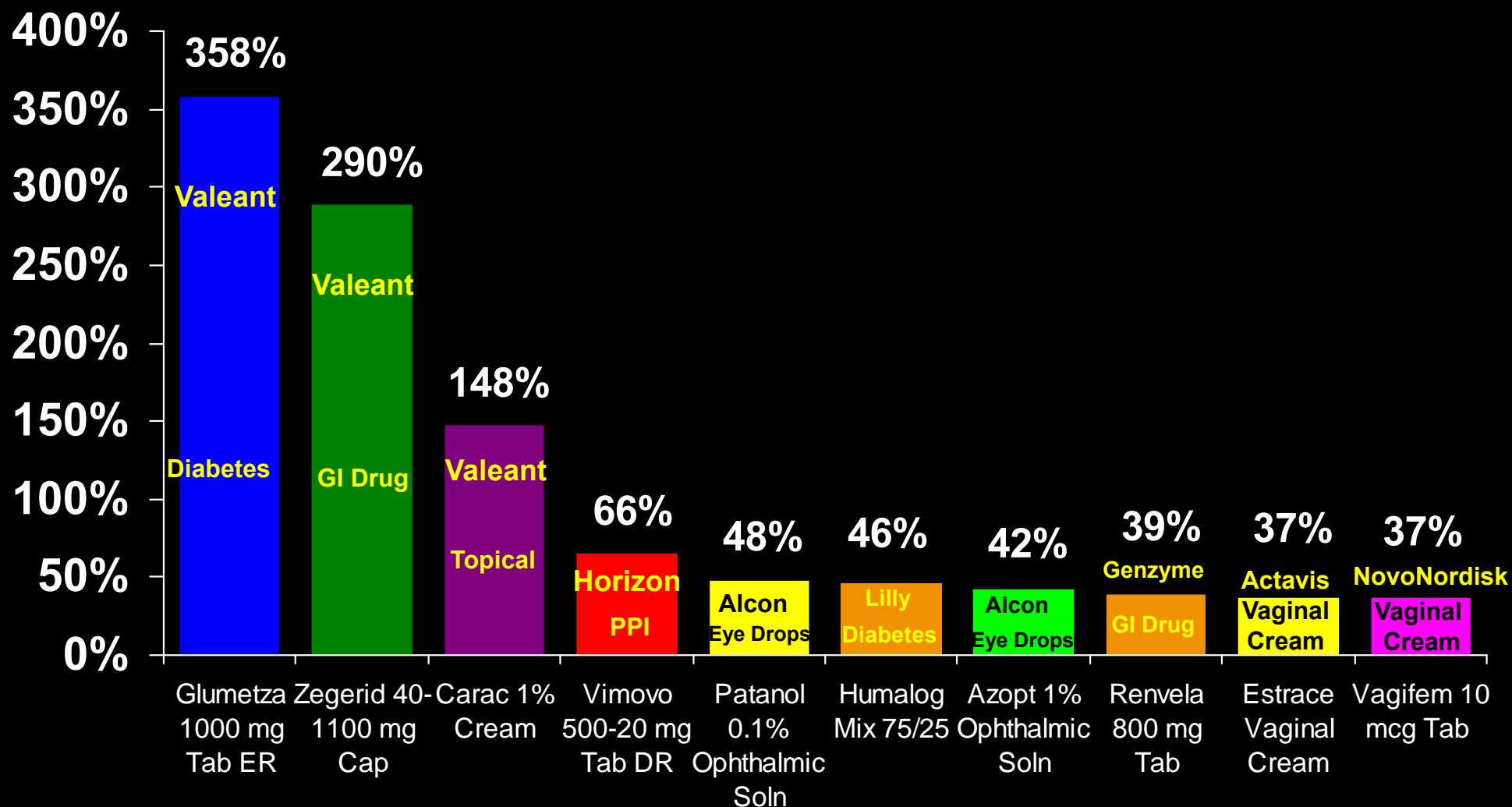


Source: Compiled by the PRIME Institute, Univ. of Minnesota and AARP from data found in MediSpan (Wolters Kluwer Health Inc., May 1, 2010).

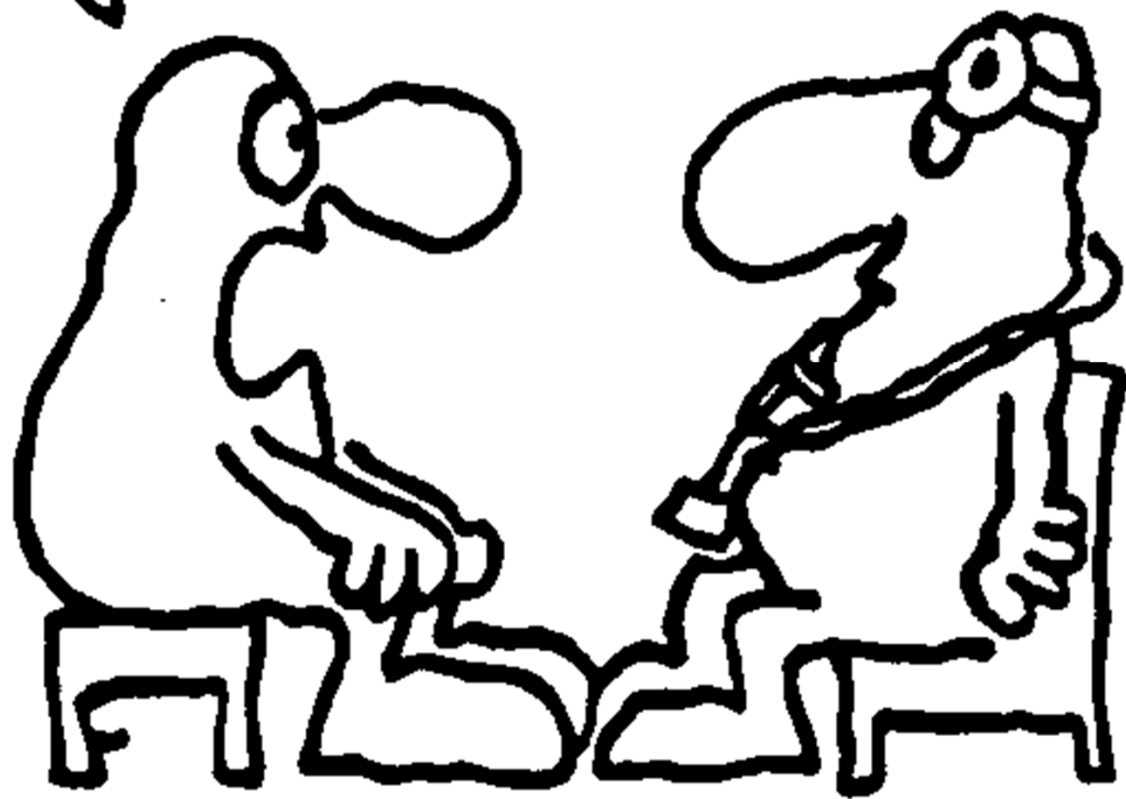
# Brand Drug Price Inflation: Dec. 31, 2014 vs Dec. 31, 2015

(Annual % Change in Price)

% Change in Price



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

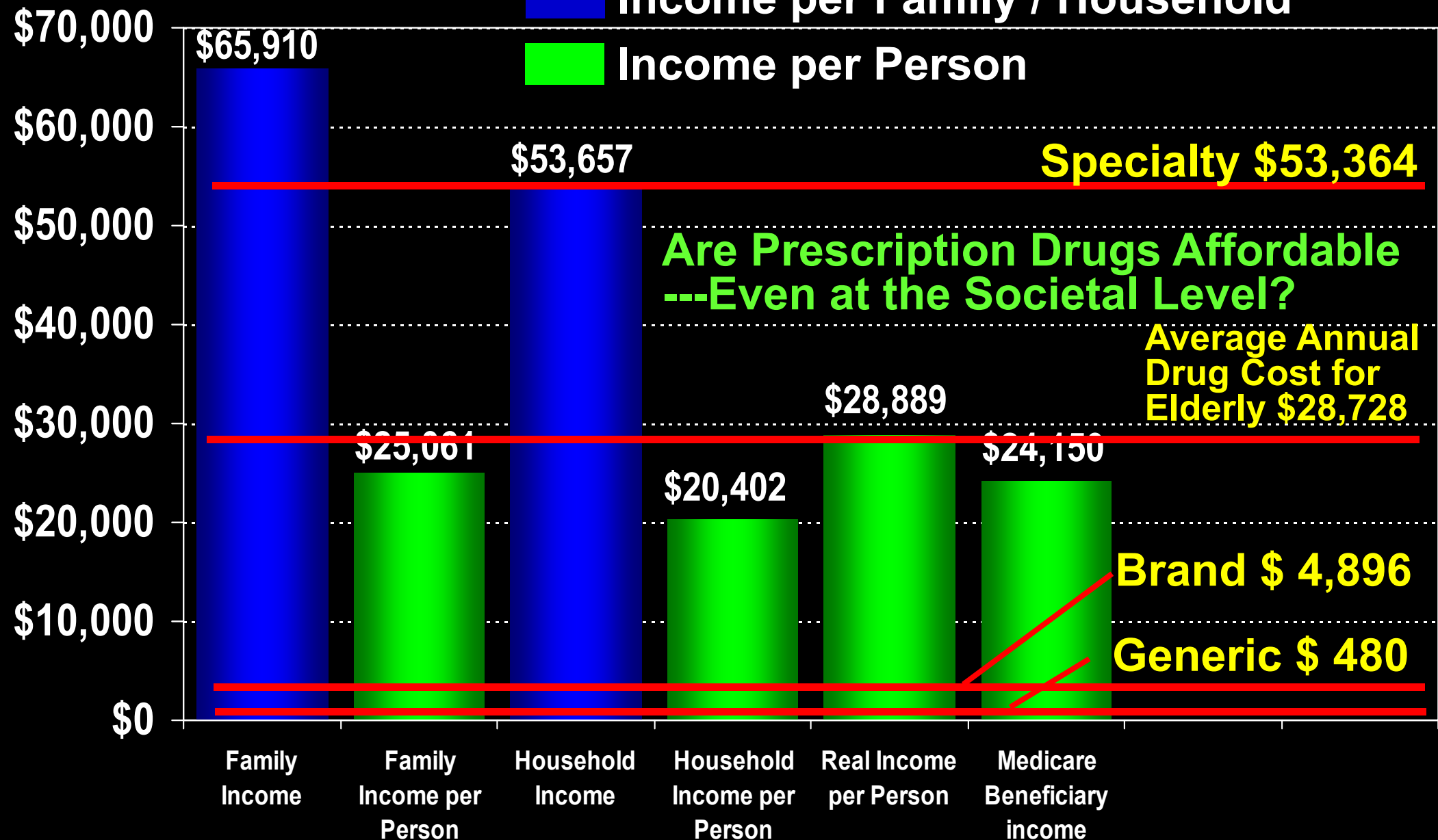


# U.S. Annual Income: 2014

*\$ / Year*

■ Income per Family / Household

■ Income per Person



# Some New Drugs Enter the Market at the Cost of:

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- ◆ **A Week's Vacation** (\$1k to \$5k)  
(copaxone for Multiple Sclerosis)
- ◆ **A New Economy Car** (\$10k to \$25k)  
(Insulin, PCSK9s for cholesterol)
- ◆ **A New Luxury Car** (\$30k to \$100k)  
(Harvoni & Hep C drugs, Gilenya & MS drugs)
- ◆ **A New House** (\$200k to \$500k)  
(Yervoy, Cancer & orphan drugs)



# The Drug Market is Broken !

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- ◆ **FDA Approves Drugs That Are Better Than Placebo**
- ◆ **Medicare & Medicaid Must Cover FDA Approved Drugs**
- ◆ **Drug Firms Set Any Price They Want** (a blank check)
- ◆ **Coverage Has Been Broadened to Include Most People**  
( > 90% of U.S. Residents)
- ◆ **Increased Cost-Sharing for Rx Coverage**
- ◆ **The Cost is on Individuals, Employers, or Govt.**
- ◆ **Cost-Sharing Does Not Increase Resources**
- ◆ **Cost Shifting → Income Re-Distribution**



# **‘Alternative Facts’ About Drugs**

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*Can You Spot Fact vs. ‘Alternative Fact’  
About Drugs & Cost !*

- **Most People Have Coverage, What’s the Problem?**
- **It’s Insured So Don’t Worry About the Cost**
- **Lower Out-of-Pocket Drug Costs Are What Matters**
- **Price Spikes Are Only from a Few Rogue Companies**
- **Drug Coupons Will Save You Money**
- **Patient Assistance Programs Always Help Patients**
- **Patents Focus Reward on ‘True’ Innovation**
- **Spending More on Drugs Is Always a Good Thing**
- **The Market for Prescription Drugs Is Working Well**
- **Drugs Are Not a Public Good**

# Policy Challenges

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## *What are policy challenges in the drug market?*

- **Govt. Grants Drugs a Long-Term Monopoly Position** (i.e., *Patents, Exclusivities, Biologicals, Functional Monopolies, Requires Prescription*)
- **Firms Can Pay Competitors to Delay Market Entry**
- **Prices, Discounts, Rebates & Coupons Hide Actual Price**
- **Decision-Makers Do Not Know Actual Prices**
- **Required Coverage of All FDA-Approved Drug Products** (e.g., *mandated therapeutic categories*)
- **Law Prohibits Negotiation of Prices by Largest Buyer** (i.e., *Medicare and federal government*)
- **Policymakers Rely on the “Market” to Work**

**We Have Been Relying on The Invisible Hand  
To Make the Market Work**

**The Invisible Hand Has Been Handcuffed, Blindfolded,  
& Gagged, Yet We Still Expect It to Work!**

# Policy Options to Meet the Challenges

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## *What are policy options to meet these challenges?*

- **Require Transparency & Disclosure of Prices At All Levels**
- **Require Accountability for Price Decisions** (*Initial Price, Price Changes, Relative Price & Value Over Time; could be done by HHS, FTC, MedPAC, or other entity*)
- **Enable Decision-Makers To Know Prices & to Negotiate** (*Medicare, Medicaid, all govt. programs, commercial plans*)
- **Prohibit Market Distorting Behaviors** (*Rebates, Coupons, Direct-To-Consumer Drug Ads, Patient Assistance Programs, Pay-for-Delay Agreements*)
- **Limit Evergreening of Drug Products** (*new strengths, dosage forms, or combinations, salt forms*)
- **Recognize Economic Impact of FDA Decisions on Drug Cost** (*delayed generic approvals, biosimilar approvals, REMS, limited distr.*)
- **Target Rewards for Innovation to Significant New Drugs** (*Focus patents & exclusivities on significant new therapies, shorten exclusivity periods, limit rewards & market exclusivity for evergreen products [new dosage forms, strengths, combinations], don't reward branded generics that are extracting capital from the market.*)

**We Must Set the Rules for the Drug Market  
To Assure That We Get 'Value' & 'Outcome',  
Not Just Capital Transfer & Extraction.**

# Value is Essential

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*PRICE is not the ONLY issue,  
but price is always  
an important issue in VALUE.*

*-- Stephen W. Schondelmeyer*

## Could High Drug Prices Be Bad Innovation?



GUEST POST WRITTEN BY

**Peter B. Bach**

*Director, Center for Health Policy and Outcomes, Memorial Sloan Kettering Cancer Center*

Policymakers are scrutinizing high prices for specialty drugs like never before. [Gilead's](#) Sovaldi at \$84,000 for a treatment course is in part to blame — or credit — for this, but so are [Vertex's](#) Kalydeco, [Merck's](#) Keytruda, and a series of other six figure drugs.

**Market has seen:**

- > More combinations
- > More new dosage forms
- > More new strengths

**Evergreening Products**

**Not as Many Significant Therapeutic Advances**

**Evergreening is Rewarded The Same as 'True' Innovation**

**Market Does Not Differentiate Among:**

**R&D → Innovation  
vs. Evergreening Products  
vs. Capital Extraction**

# Current Drug Price Policy Issues

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- ◆ Orphan Drugs, Specialty Drugs, Biosimilars
- ◆ Drug Shortages
- ◆ FDA Unapproved Drugs Initiative
- ◆ FDA REMS Drugs
- ◆ Limited Distribution Drugs & Pharmacies
- ◆ Drug Company-Owned Pharmacies
- ◆ Copay Coupons & Patient Assistance Programs
- ◆ 340 B Drug Pricing Program
- ◆ Medicaid Drug Program, Prices & Rebates
- ◆ Medicare Part B Drug Program, Prices & Rebates
- ◆ Medicare Part D Program, Prices & Rebates

# Emerging Issues: Drug Market

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*What are emerging drug market issues?*

- **Shifting Channels of Distribution**
- **Drug Claims under Medical Benefits**
- **FDA, Old Drugs, Drug Firms & REMS**
- **Mandatory Drug Coverage Provisions**
- **Drug Ads, Copay Coupons & Adverse Incentives**
- **PBMs, Fiduciary Role, & Conflicts of Interest**
- **Drug Benefit Coverage & Policies**
- **Direct & Indirect Fees PBMs Charge Pharmacies**
- **Prescribers & Controlled Substances**

*How Much is Your Life Worth?*

**How Much Do You Have  
in the Bank?**

**Can You Afford Yourself ?**

**What Happens When Our  
Expectations Exceed Our Resources**

**Our Expectations & Choices  
May Not Be Sustainable!**



**We Must Make  
Realistic Choices**

**About How to Pay for &  
How to Deliver Needed  
Drugs & Health Care to  
Everyone in Society.**

**If We Don't,  
We Will Pay for It Anyway &  
It Will Cost A Lot More !**

# *PRIME* Institute

*Pharmaceutical  
Research  
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**University of Minnesota**