



BERKELEY CENTER  
FOR HEALTH TECHNOLOGY

# **Pricing and Patient Access: Strategies and Negotiations between Payers and Pharmaceutical Firms in the US**

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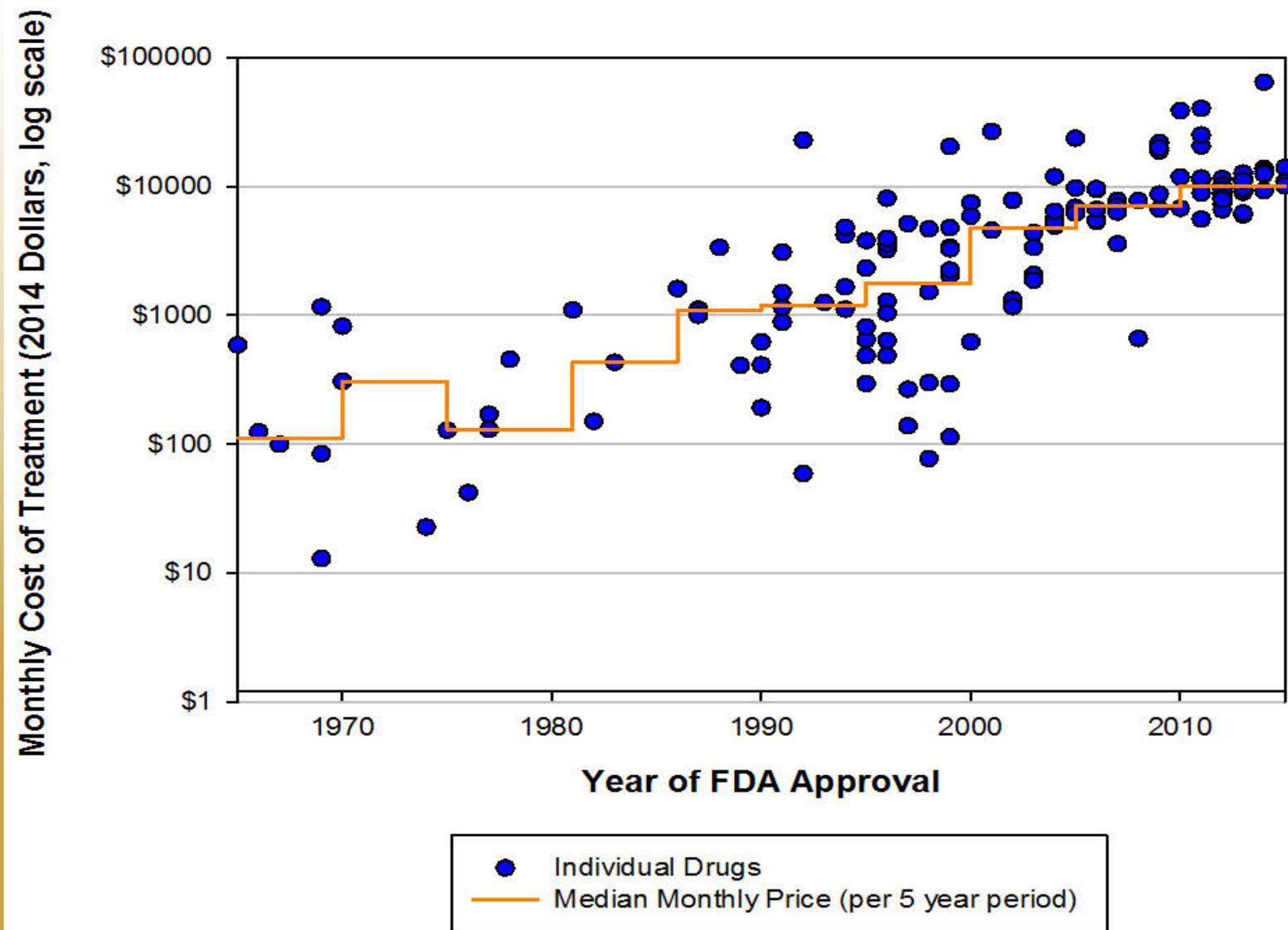
# Overview



- The problem, as viewed by payers
- Payer strategies
- The pharmaceutical arms race
- Negotiations



# Monthly and Median Costs of Cancer Drugs at the Time of FDA Approval 1965-2015



Source: Peter B. Bach, MD, Memorial Sloan-Kettering Cancer Center

## Top selling U.S. drug prices over five years

Prices rose 54 percent to 126 percent.

DRUG (COMPANY)	PRICE*		PRICE GROWTH
	Dec. 31, 2010	Present	
<b>Humira</b> (AbbVie) 40 mg/0.8 ml pre-filled syringes	\$1,676.98	\$3,797.10	126.4%
<b>Enbrel</b> (Amgen) 50 mg/ml subcutaneous sol.	\$427.24	\$932.16	118.2%
<b>Copaxone</b> (Teva) 20 mg/ml subcutaneous sol.	\$3,025.04	\$6,593.00	118.0%
<b>Crestor</b> (AstraZeneca) 10 mg tablets	\$350.17	\$745.41	112.9%
<b>Abilify</b> (Otsuka) 10 mg tablets	\$454.07	\$891.97	96.4%
<b>Lantus Solostar</b> (Sanofi SA) 100 units/ml subcutaneous sol.	\$191.96	\$372.76	94.2%
<b>Advair Diskus</b> (GlaxoSmithKline) 250/50 inhalation discs	\$199.90	\$334.63	67.4%
<b>Remicade</b> (Johnson & Johnson) 100 mg IV powder for solution	\$657.87	\$1,071.48	62.9%
<b>Neulasta</b> (Amgen) 6 mg/0.6 ml subcutaneous sol.	\$3,320.00	\$5,155.65	55.3%
<b>Nexium</b> (AstraZeneca) 10 mg oral packets	\$162.55	\$250.94	54.4%

\* Reflects wholesale acquisition prices before volume-related rebates and other discounts. Prices are based on most commonly prescribed dose.

Source: Truven Health Analytics

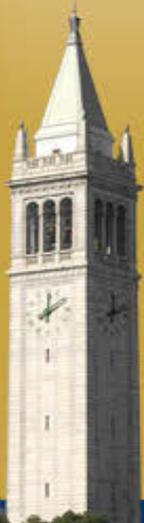
S. Culp, 30/03/2016

 REUTERS

# Payer Responses to Rising Prices

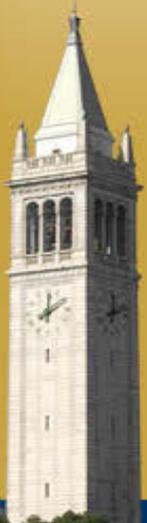


1. Formulary exclusion
2. Mandated discounts
3. More stringent management of use
4. Changed physician payment incentives
5. Increased consumer cost sharing



# 1. Private Payers Deny Coverage for Some Drugs to Obtain Rebates on Others

- High pharmaceutical revenues have stimulated R&D and a full pipeline of innovative new drugs
- Many specialty therapeutic categories have multiple drugs with some interchangeability
  - Hep C, rheumatoid arthritis, multiple sclerosis, melanoma, NSCLC...
- Private insurers and PBMs deny coverage for one or more drugs in a category in order to obtain rebates from the other drugs in the category
  - Gilead reported average 46% rebates for Sovaldi, Harvoni
- Increased divergence of published and paid prices



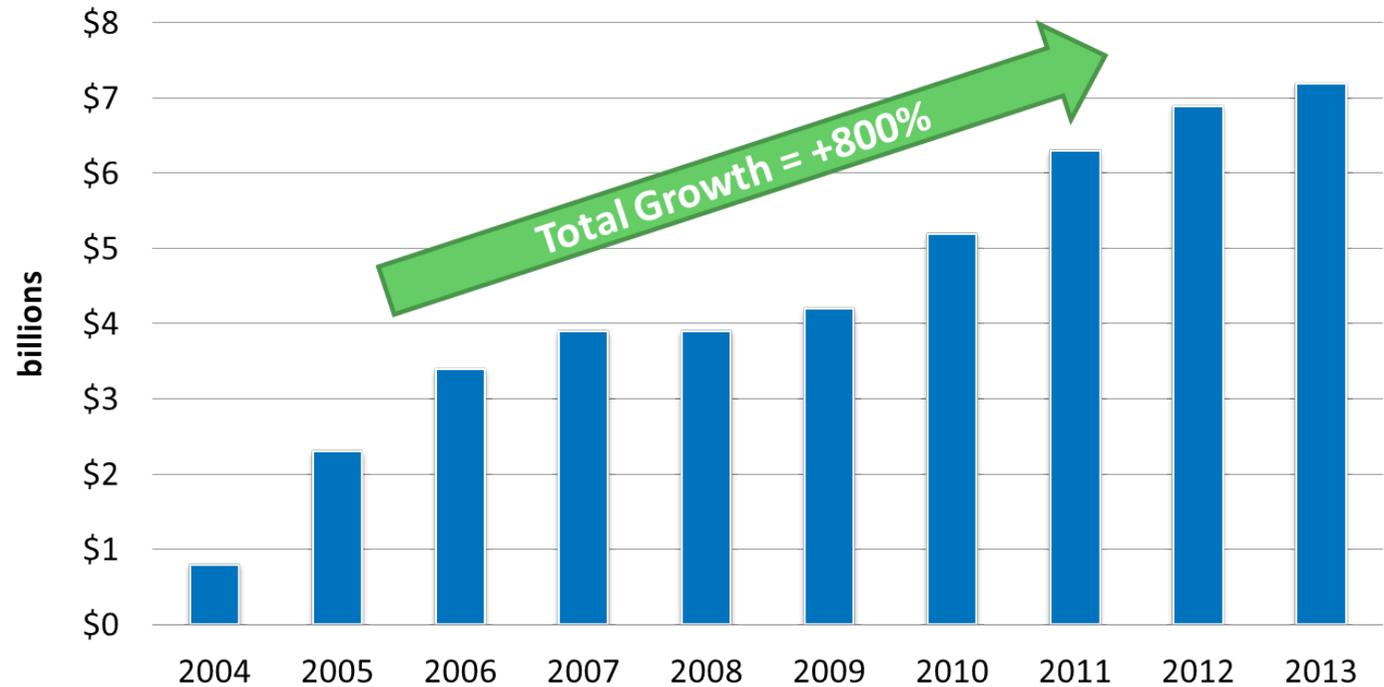
## 2. Public Programs Deepen and Broaden Mandated Price Discounts

- Medicaid 'best price' discount deepened to 23% with further reductions if firms have imposed price increases after launch
- 340B discount (similar to Medicaid) has been extended to 45% of hospitals and numerous clinics
- Proposed extension of Medicaid discount for low-income Medicare beneficiaries
- Proposed reference pricing (Least Cost Alternative) for specialty drugs by Medicare



# 340B Discounts to Reach \$13.4B by 2016

## Discounted Purchases Made Under the 340B Drug Discount Program, 2004-2013



340B purchases are at the 340B contracted price and exclude sales made directly to healthcare institutions by manufacturers.  
Sources: Pembroke Consulting analysis of data from Health Resources and Services Administration, *New York Times*, and Apexus  
Published on Drug Channels ([www.DrugChannels.net](http://www.DrugChannels.net)) on February 25, 2014.

### 3. Private Payers Increase Management of Utilization for Expensive Drugs

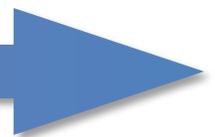
- Private payers impose requirements on physicians seeking to prescribe/administer expensive drugs, even for drugs that are included in the formulary
  - Prior authorization: physician must submit request to payer documenting appropriateness of the patient for the drug
  - Step treatment: physician must first prescribe payer's preferred drug (e.g., cheaper alternative) and only move to more expensive drug if patient does not respond or experiences toxicity
- These utilization management programs are now being applied to a wider range of drugs and are becoming more stringent



# Prior Authorization is More Stringent and Coverage Exclusion More Common. Example: Rheumatoid Arthritis

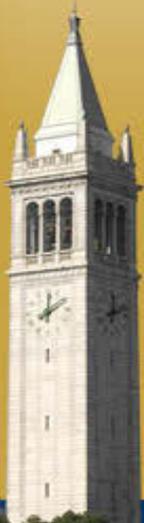
Drug Covered, No PA Required	Less Managed	Moderately Managed <i>Any of the following</i>	Highly Managed <i>Any of the following</i>	Bio Managed 1	Bio Managed 2	Drug Not Covered
	<ul style="list-style-type: none"> <li>Any of the requirements <i>not</i> listed under Moderately, Highly, or Bio Managed</li> </ul>	<ul style="list-style-type: none"> <li>Specialist approval required</li> <li>Requires prior failure or contraindication with 1 DMARD (e.g., MTX)</li> <li>Requires prior failure or contraindication with 2 conventional therapies (e.g., NSAIDs)</li> <li>Initial authorization time limit <math>\geq 3</math> months but <math>\leq 6</math> months</li> </ul>	<ul style="list-style-type: none"> <li>Requires prior failure or contraindication with 2 or more DMARDs</li> <li>Requires prior failure or contraindication with 3 or more conventional therapies</li> <li>Requires prior failure or contraindication with 1 DMARD AND 2 conventional therapies</li> <li>Severe RA only</li> <li>Initial authorization time limit <math>&lt; 3</math> months</li> </ul>	<ul style="list-style-type: none"> <li>Requires prior failure or contraindication with 1 biologic therapy</li> </ul>	<ul style="list-style-type: none"> <li>Requires prior failure or contraindication with 2 or more biologic therapies</li> </ul>	

Degree of management is increasing



## 4. Public and Private Payers Create New Physician Payment Methods in Oncology

- Major payers are offering oncologists a monthly per-patient fee to cover care management services
  - This directly (United, CMS) or indirectly (Aetna, Anthem) discourages use of costly office-administered biologics
- Some payers are offering bonus (shared savings) if oncologists reduce total spending below targets
  - Reward for reduction in infused and patient-administered drugs as well as ED visits, hospitalization
- CMS has announced plans to adjust spending target for new drugs, but only if they are used on-label, at rates not exceeding market, and if the drugs are 'cost-effective'

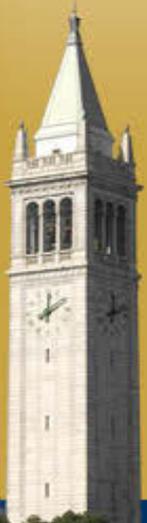


# Population-Based Payment: Pricing Clothes by the Kilo



## 5. Public and Private Payers Increase Patient Cost Sharing

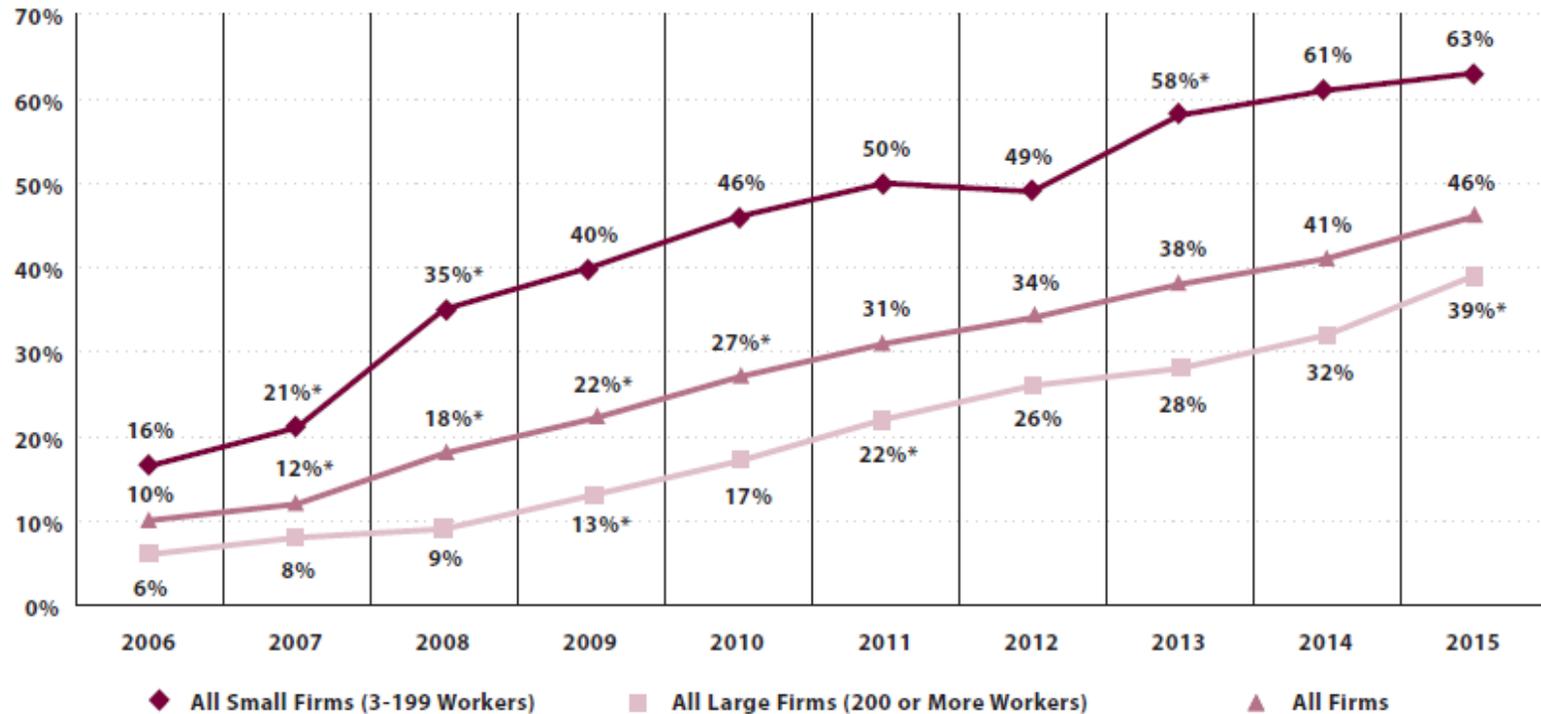
- Employers are increasing annual deductibles for medical services (including office-administered drugs) and coinsurance for ambulatory drugs
- Individuals purchasing coverage through ObamaCare insurance exchanges are favoring products with high cost sharing (and low premiums), with subsidies for low income persons
- Medicare Part B requires 20% coinsurance for office-administered drugs and Part D requires 25-40% coinsurance for ambulatory drugs, with subsidies for low-income seniors



# Employers Move to High-Deductible Health Plans

## EXHIBIT G

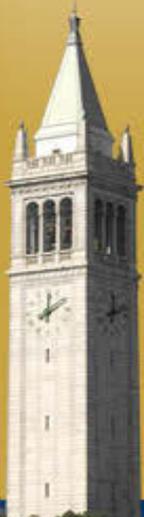
Percentage of Covered Workers Enrolled in a Plan with a General Annual Deductible of \$1,000 or More for Single Coverage, By Firm Size, 2006-2015



\* Estimate is statistically different from estimate for the previous year shown ( $p < .05$ ).

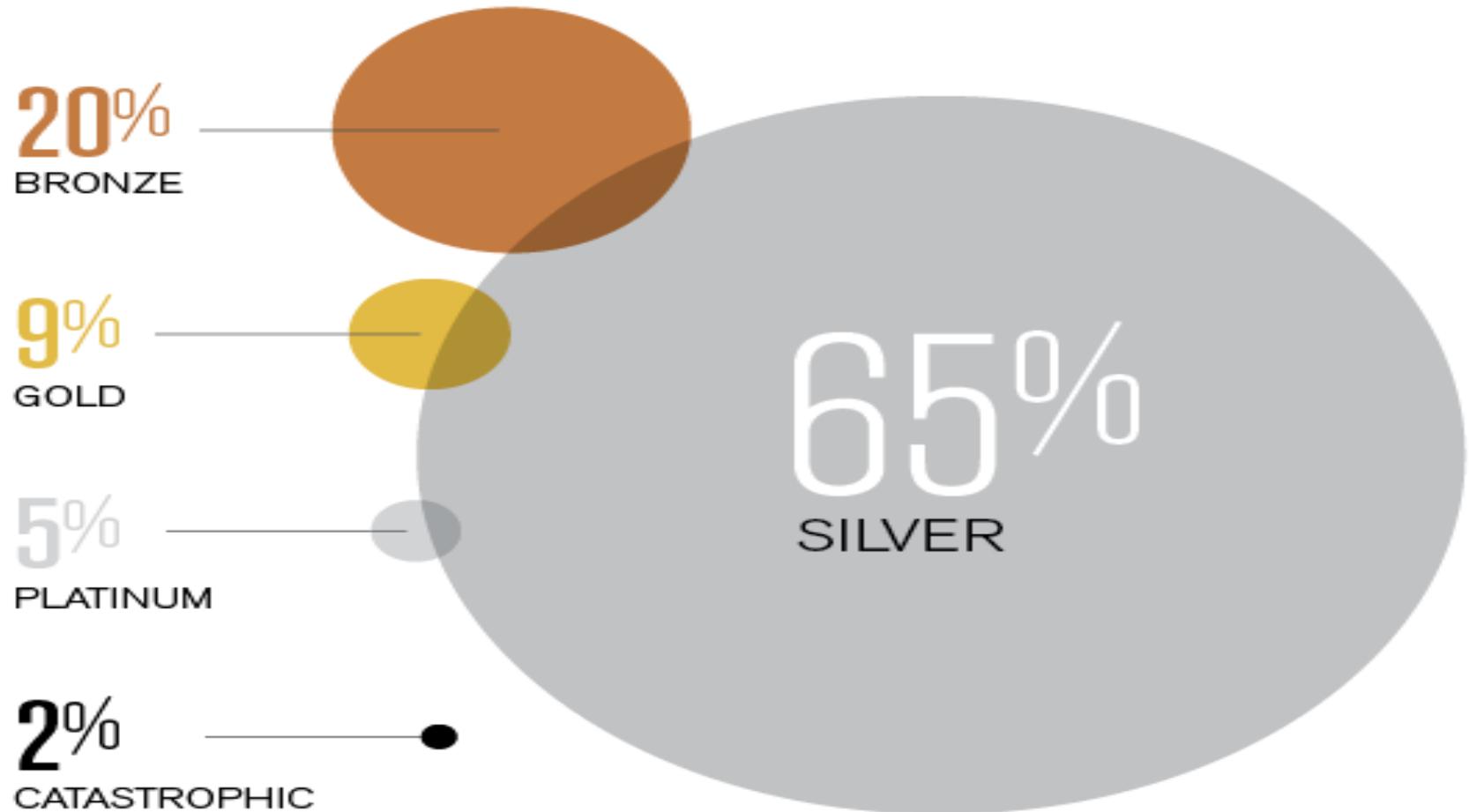
NOTE: These estimates include workers enrolled in HDHP/SO and other plan types. Average general annual health plan deductibles for PPOs, POS plans, and HDHP/SOs are for in-network services.

SOURCE: Kaiser/HRET Survey of Employer-Sponsored Health Benefits, 2006-2015.

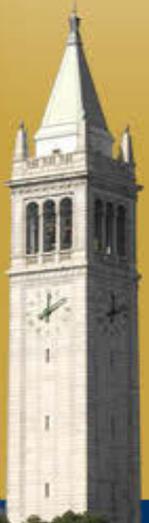


# Individual Consumers Favor High-Deductible Silver and Bronze Plans in ACA Insurance Exchanges

## Plan selection by metal level



Note: Percentages rounded by HHS.



# Pharmaceutical Firms are Responding to the New Payer Initiatives

- Larger clinical studies to support coverage (more endpoints, subpopulations, head-to-head trials, observational studies)
- Mobilize patient advocacy organizations to resist prior authorization
- Physician office support (for prior authorization)
- Consumer copay support programs
- Payers respond by intensifying their initiatives
- This 'arms race' increases administrative costs, demonization, litigation, and regulation



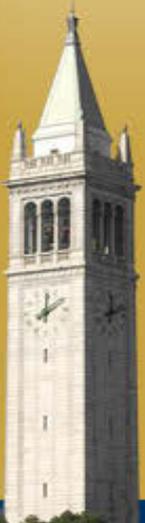
# Is There Hope for Negotiations?

- The era of unchallenged 'free pricing' by drug firms is finished, due to pipeline of therapeutic options
- Payers are negotiating with drug firms for price rebates and conditions of use
- Drug firms are negotiating for reductions in access barriers for patients
- Negotiations between individual payer and drug firms offers interesting possibilities, but imposes high transaction and publicity costs
- Is there a possibility of collective agreements?



# What Does Each Side Really Want?

- What do payers want from manufacturers?
  - Launch price benchmark set at affordable level
  - Launch price for each drug adjusted for clinical and social value
  - Post-launch price increases linked to increases in value
- What do manufacturers want from payers?
  - Faster coverage and limits on prior authorization
  - Fewer mandated discounts
  - Less consumer cost sharing



# What Do Payers Want?

## 1. Launch price benchmark

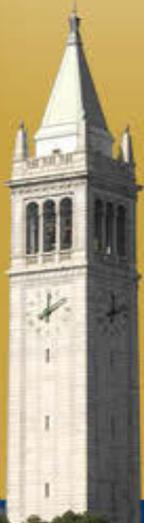
- Despite all the talk about 'value-based pricing', the essence of payer views of value-based launch price is the benchmark against which prices for individual drugs are set
- What is the number?

## 2. Launch prices for individual drugs

- Prices for individual drugs are set relative to the benchmark, based on their comparative value to the patient and to society
- Which are the criteria for comparison?

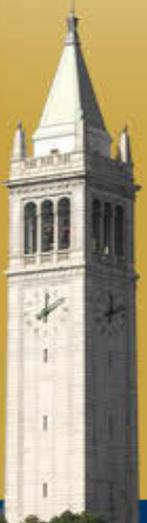
## 3. Post-launch prices increase only if value increases

- How do we define/measure value increases?

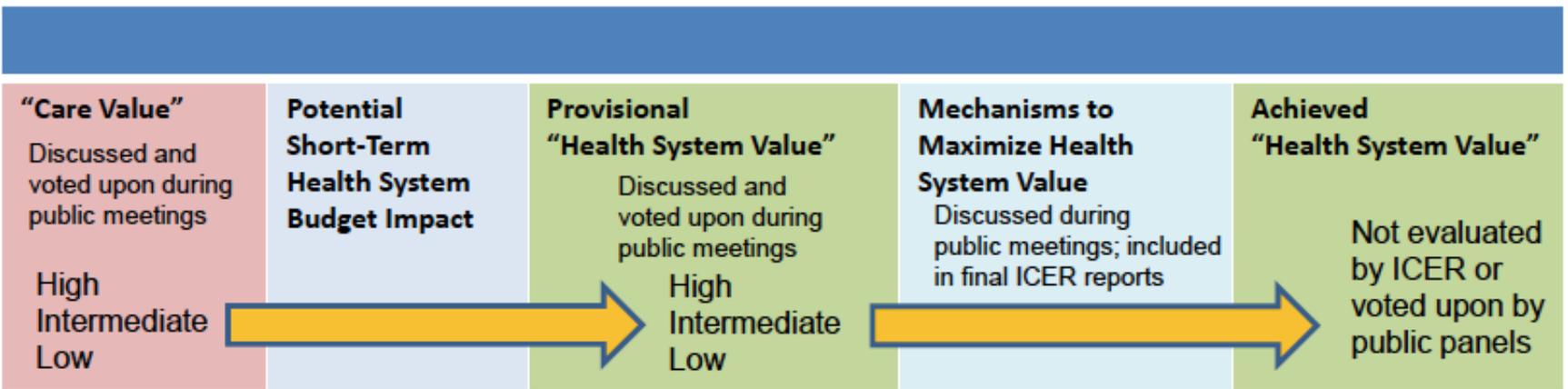
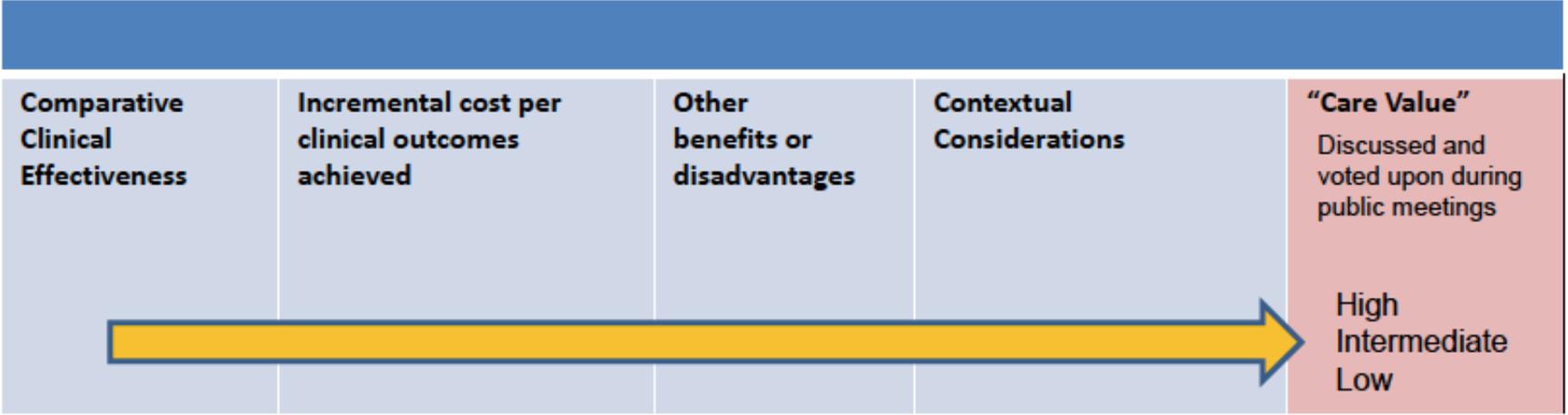


# 1. Benchmark for Value-based Prices

- The acceptable ('value-based') price for any one drug will be determined relative to a benchmark
- Value to the patient (cost-effectiveness threshold)
  - NICE chooses \$50K/QALY
  - ICER & Abacus choose \$125K/QALY
- Affordability to society (budget impact)
  - ICER adds another component to the price benchmark. The price is reduced from the 'value based' price if spending on the new drug (price times volume) would impose incremental costs to payers that would outstrip the rate of growth of the national economy



# Example: ICER



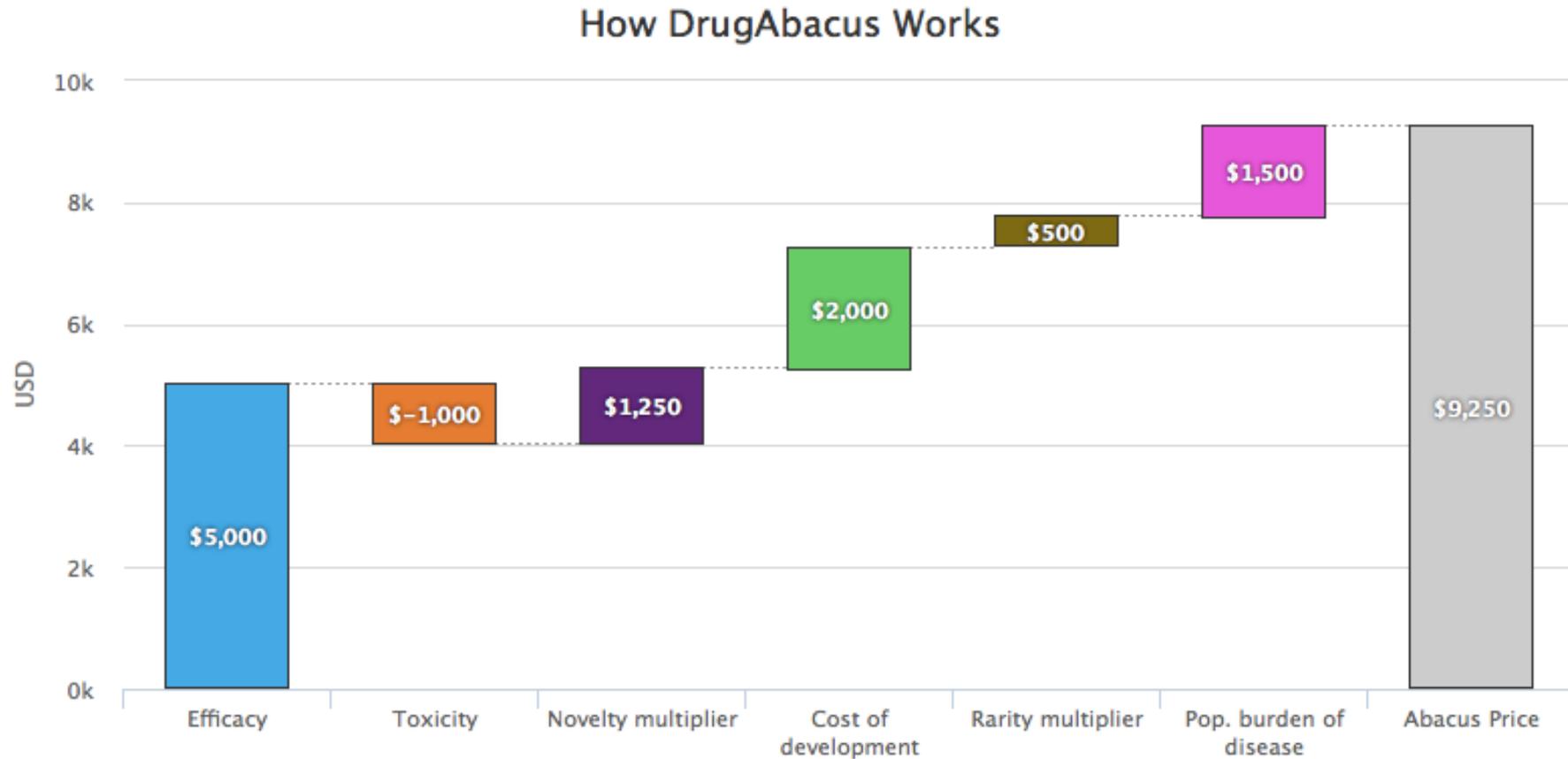
Source: Institute for Clinical and Economic Review, “Evaluating the Value of New Drugs and Devices” (2015)

## 2. Launch Prices for Individual Drugs

- Value to the patient
  - Comparative clinical efficacy
  - Comparative toxicity
  - Mode and ease of administration
- Value to society
  - Novelty (reward for innovation)
  - Well-developed evidence (reward for extensive testing for safety etc.)
  - Targets priority population (e.g., children, disadvantaged)
  - Rarity (drugs targeting orphan conditions need high per-patient price)
  - Public health (reward drugs that reduce disease transmission)



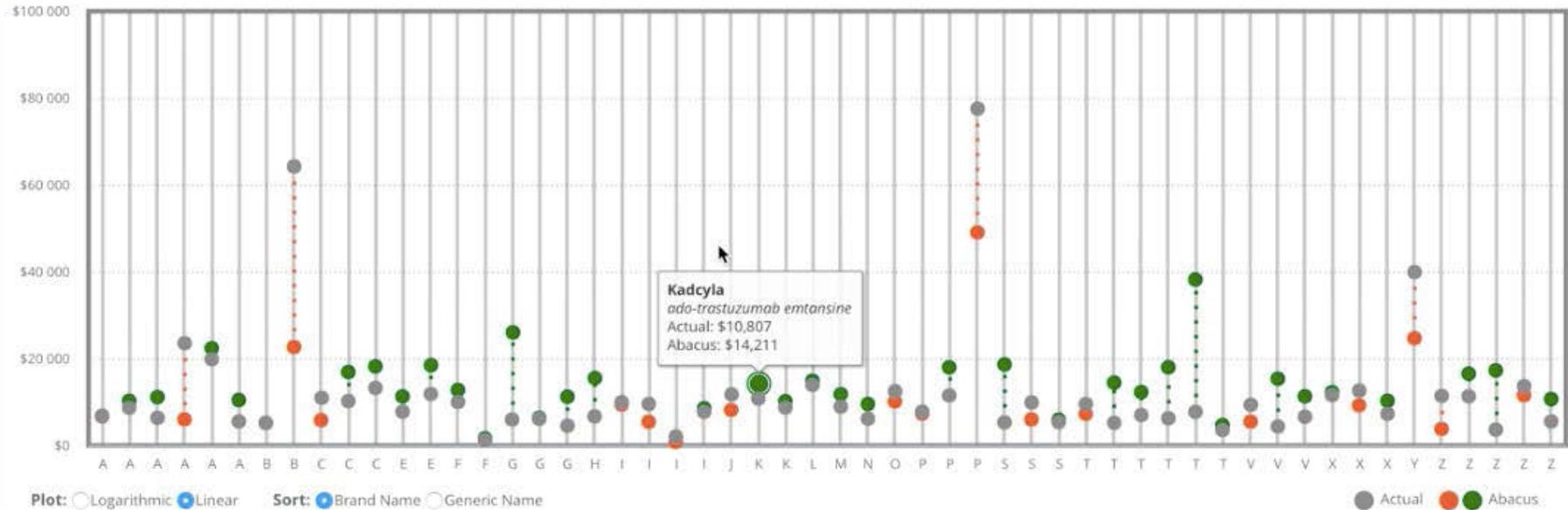
# Example: DrugAbacus



Source: <http://www.drugabacus.org>

# DrugAbacus in Action

US Medicare Monthly Drug Prices at Launch (2014 dollars)



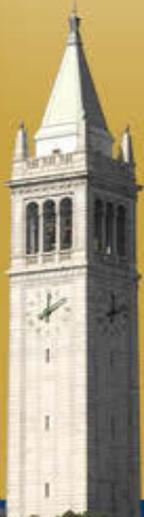
## Modifiable Price Components



## 2015E Spending

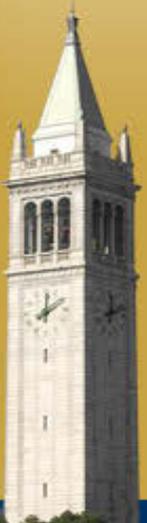


Source: <http://www.drugabacus.org>



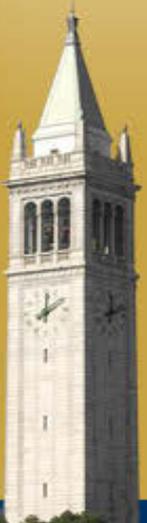
# 3. Price Increases After Launch

- Some EU nations (e.g., France) mandate annual price reductions, regardless of changes in value
- In US, many firms impose annual price increases, regardless of changes in value
- Under value-based pricing, price changes (up or down) reflect new evidence of value
  - Value to the patient: efficacy, toxicity, etc.
  - Value to society: novelty, rarity, etc.
- If there is no change in value, the price of a drug would change at rate of CPI



# What Do Pharmaceutical Firms Want?

1. Faster and more transparent coverage decisions
  - Insurance coverage issued promptly after FDA authorization
  - Coverage decisions based on clear and consistent criteria
2. Fewer physician prescription barriers
  - Prior authorization limited to ensuring appropriate use
  - Transparent and evidence-based physician payment programs
3. Fewer patient access barriers
  - Lower cost sharing



# Negotiations between Payers and Pharmaceutical Firms

- Payers and pharmaceutical firms currently are negotiating new prices based on new formulas:
- Value to the patient and to society
  - Comparative clinical and cost effectiveness
  - Intermediate outcomes for individual patients
- Relief from payer obstacles to patient access
  - Formulary inclusion
  - First line or other favored placement with respect to prior authorization
- In future, these negotiations could extend to:
  - Inclusion in favored pathways for physician reimbursement
  - Reduced consumer cost sharing



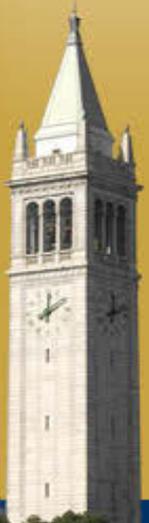
# Limits to Negotiations between Individual Payers and Drug Firms

- Negotiations between individual payers and drug firms can create fruitful agreements and links between price and performance
- But they extend the ‘arms race’
  - Drug firms increase prices at launch and afterwards, so as to offer rebates from a higher base
  - Public payers demand broader and deeper mandated discounts
  - Private payers tighten formulary coverage criteria, prior authorization, physician payment incentives, and consumer cost sharing so as to have something to trade for more rebates
- Administrative costs are high, transparency is zero
- Patients are caught in the middle



# Industry Standards of Conduct?

- There may be a role for collective agreements (standards of conduct) between associations of payers and drug firms over price and access. Individual firms could adhere on voluntary basis
- Standards of pricing
  - Criteria for launch prices
  - Criteria for price increases after launch
- Standards of patient access
  - Criteria (evidence) for formulary inclusion
  - Criteria for prior authorization and step therapy
  - Criteria for physician payment (pathways) development
  - Criteria for consumer cost sharing



# Conclusion

- The era of 'free pricing' in the US is passing
- Payers are tightening criteria for coverage and reimbursement, management of use, physician incentives, and consumer cost sharing
- Drug firms are pushing back
- Major debate over 'value based pricing'
- Increased public and private negotiations

