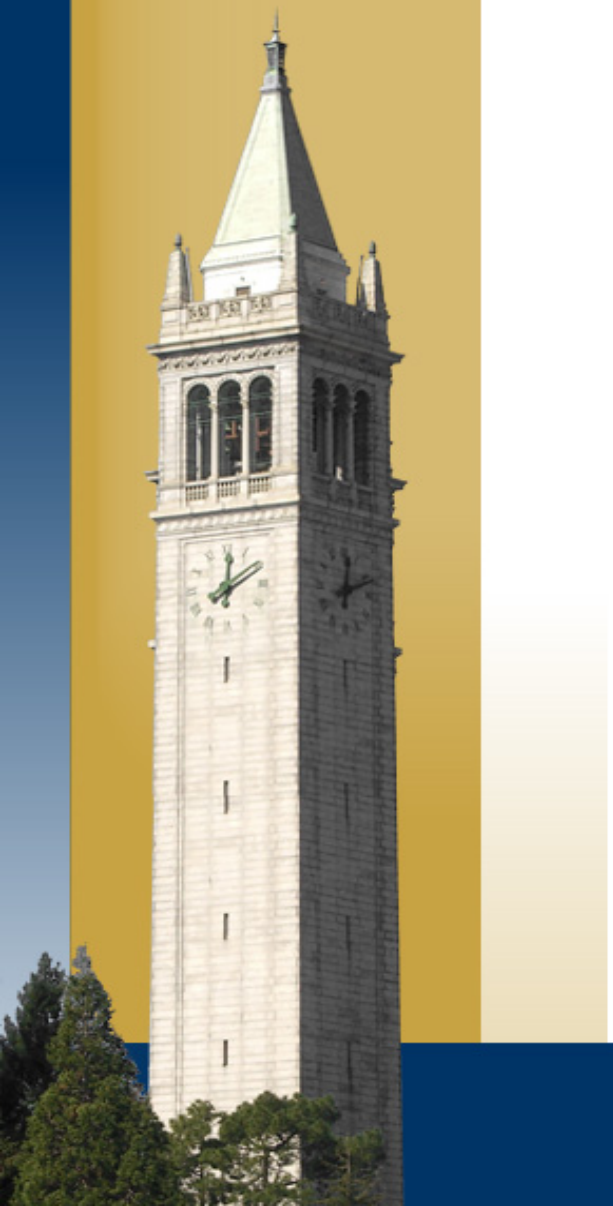

BERKELEY CENTER
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Pharmaceutical Industry Challenges in the US: Pricing and Patient Access

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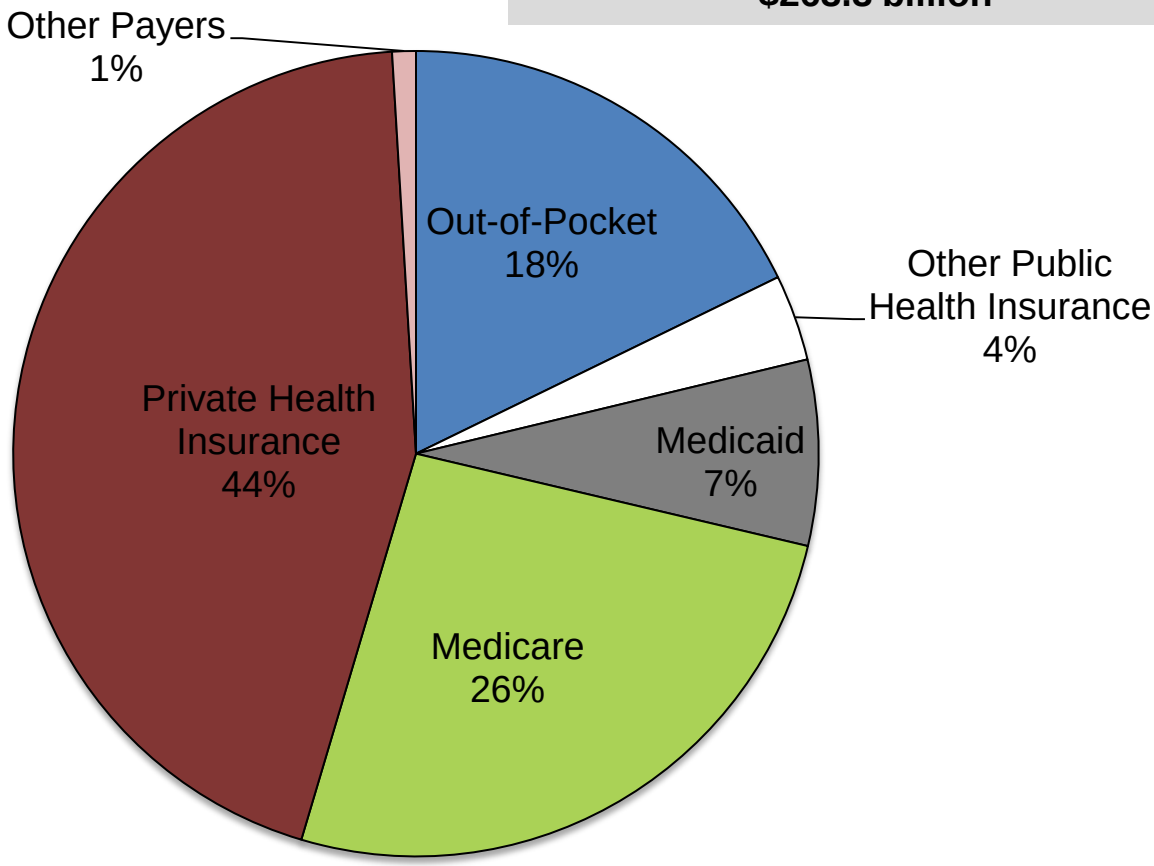
Overview

- A history of free drug pricing
- Emerging payer strategies
- Pharmaceutical industry strategies
- A better way?

U.S. Prescription Drug Expenditures, by Type of Payer

Total Prescription Drug Spending: $263.3 billion

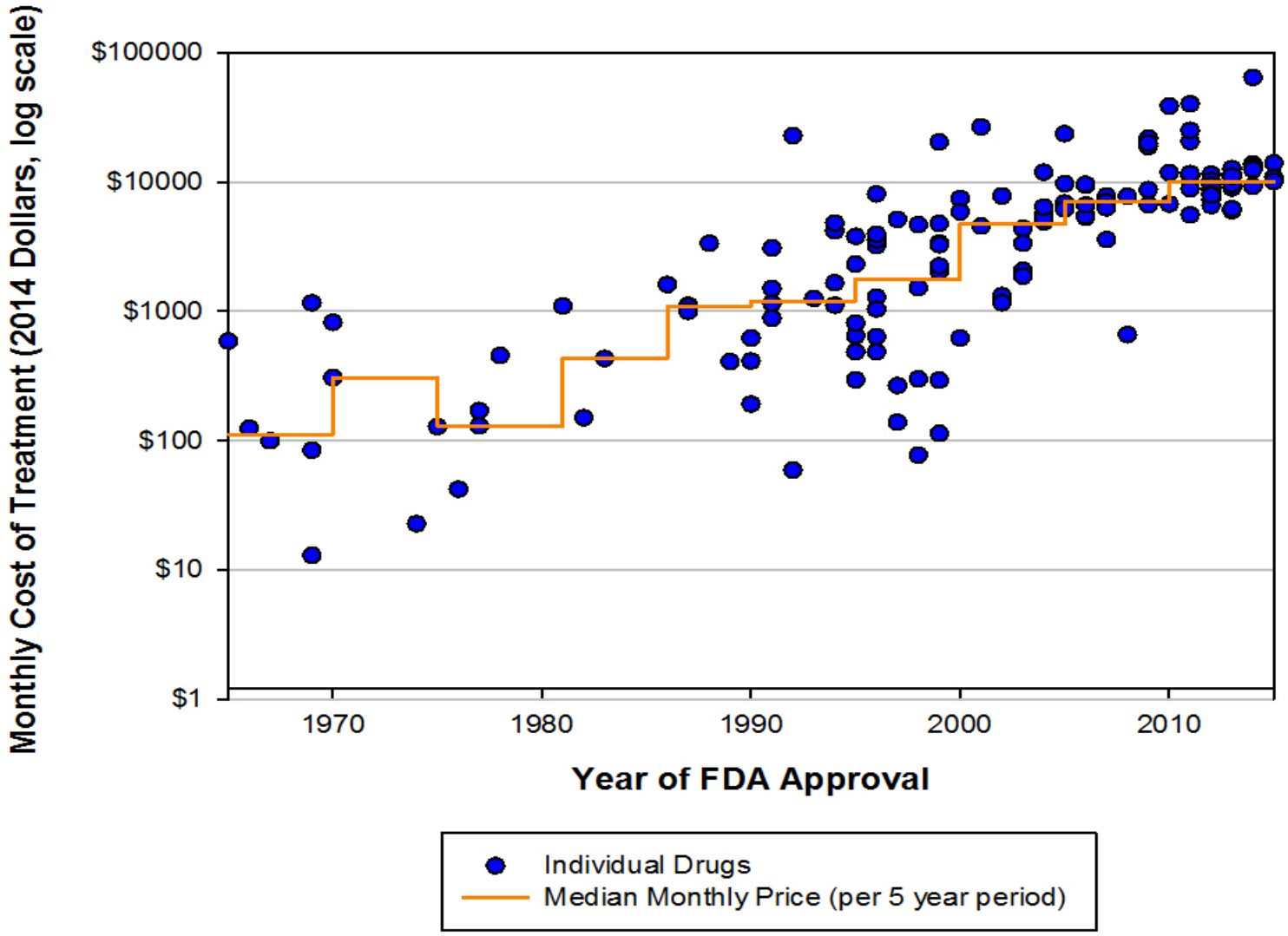


Source: California Healthcare Foundation, Health Care Costs 101, 2014 Edition

A History of ‘Free Pricing” for Drugs

- Pharmaceutical firms historically were able to set prices for private payers based on physician and patient perceptions of clinical value, with little interference (neither regulation nor competition)
- This permitted high launch prices and significant post-launch price increases
- Margins were capable of supporting extensive investments in research and a pipeline of innovation

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

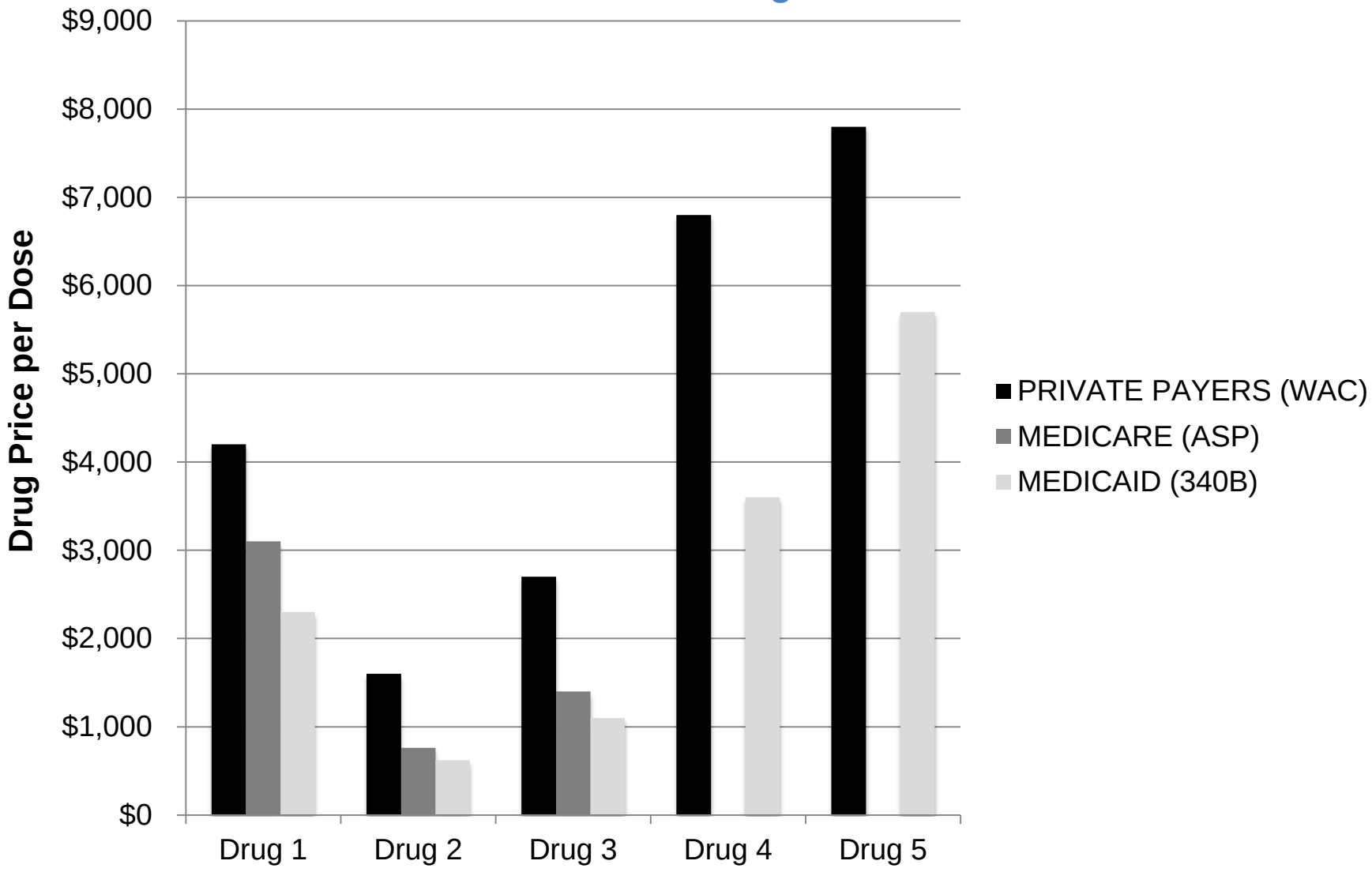
S. Culp, 30/03/2016

REUTERS

Public Payers Obtain Mandatory Discounts, Linked to Private Payer Discounts

- Medicaid (74 million members)
  - 23% rebate, plus penalties on price increases after launch
- Medicare (44 million members)
  - For infused drugs, pays average of private payer prices, taking into account all discounts and rebates obtained from pharma firms
  - For oral drugs, negotiate prices similar to private payers
- 340B program, covering 1/3 of hospitals, all cancer hospitals, and many safety net clinics
  - 23-75% discount on infused drugs, expanding to ambulatory drugs
- Federal programs (Veterans, Defense, etc.)
  - Minimum 26% discount, plus penalties for price increases after launch, plus further negotiated discounts

Private Payer, Public Program, and Medicare Prices for Selected Cancer Drugs



Innovation Leads to Competition

- In recent years, continued innovation and product launches have introduced many new drugs into specialty indications (e.g., cancer, RA, MS, HCV)
- Private payers have consolidated and developed several increasingly successful strategies to limit prices and volumes of specialty drugs

Payer Strategies

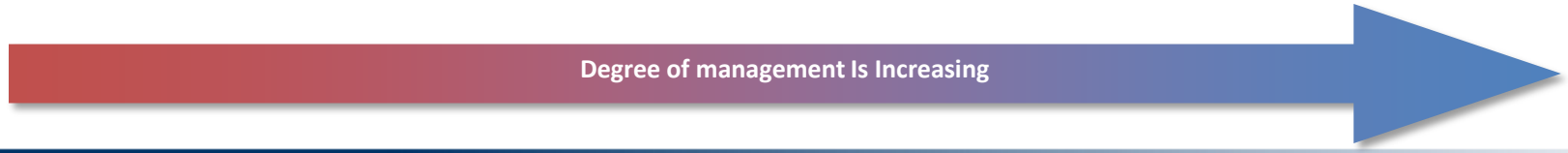
1. Utilization management
2. Consumer cost sharing
3. Physician payment incentives
4. Negotiated price discounts

1. Utilization Management

- Private payers impose requirements on physicians seeking to prescribe/administer expensive drugs
  - Prior authorization: physician must submit request to payer documenting appropriateness of the drug for the patient
  - Step therapy: 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 toxic side effects
- These utilization management programs are becoming more stringent, now often deny use even for patients with FDA approved indications

Example: Rheumatoid Arthritis

Moerately Managed	Highly Managed	Bio Managed 1	Bio Managed 2	Drug Not Covered
Any of the following	***Any of the following***			
• Specialist approval required • Requires prior failure or contraindication with 1 DMARD (e.g., MTX) • Requires prior failure or contraindication with 2 conventional therapies (e.g., NSAIDs) • Initial authorization time limit ≥3 months but ≤6 months	• Requires prior failure or contraindication with 2 or more DMARDs • Requires prior failure or contraindication with 3 or more conventional therapies • Requires prior failure or contraindication with 1 DMARD AND 2 conventional therapies • Severe RA only • Initial authorization time limit <3 months	• Requires prior failure or contraindication with 1 biologic therapy	• Requires prior failure or contraindication with 2 or more biologic therapies	



Source: Zitter Health Insights

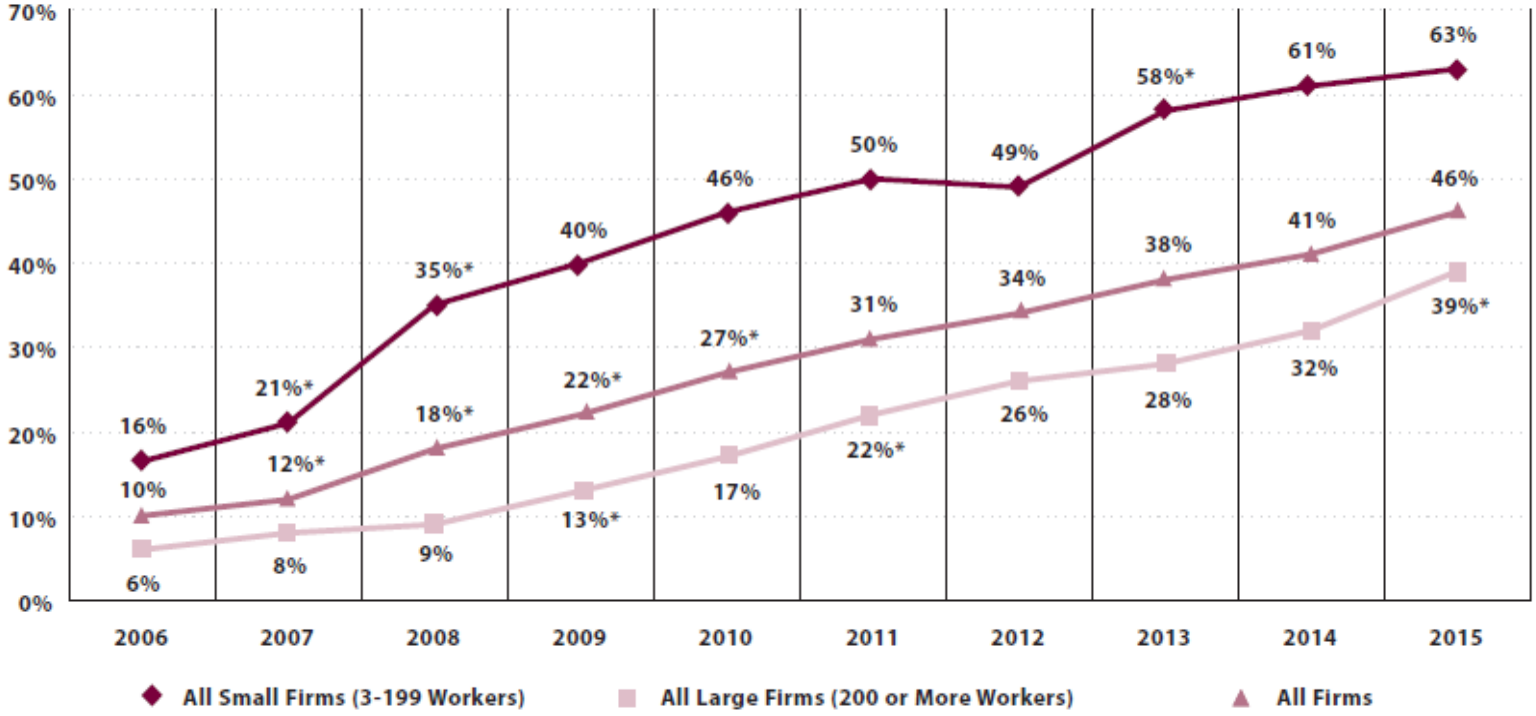
2. Consumer Cost Sharing

- Consumers and patients are being required to pay an ever-larger share of medical and drug costs at the time of receiving care
  - Infused drugs are managed through high-deductible plan designs
  - Oral drugs are managed through copayments and coinsurance
- Therapeutic reference pricing
  - An emerging strategy protects consumer from cost sharing if he/she uses the low priced drug within the therapeutic class
  - The employer or insurer establishes a maximum contribution it will make towards payment for all drugs within each therapeutic class.
  - Patients selecting a drug costing above this reference level must pay the full difference themselves, unless they obtain an exemption on clinical grounds (e.g., physician submits exemption form for them)

Example: High-Deductible 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

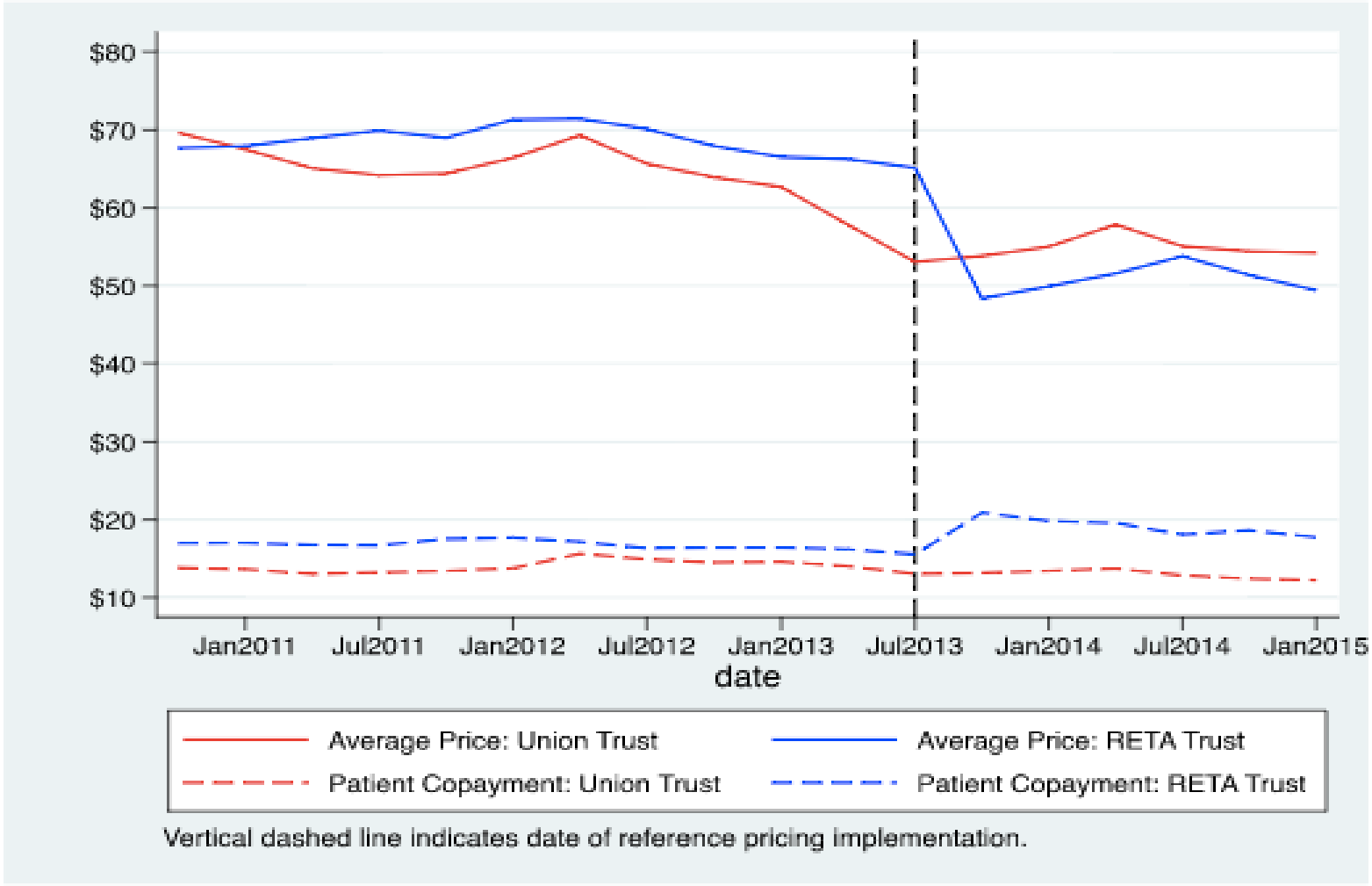


* Estimate is statistically different from estimate for the previous year shown (p<.05).

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.

Example: Reference Pricing



Vertical dashed line indicates date of reference pricing implementation.

3. Physician Payment

- Physician payment methods are being changed to create incentives to prescribe cheaper drugs
- Some payers are offering oncologists a monthly per-patient fee, as supplement to office visit FFS
  - Care planning and shared decision making, drug management, patient education and monitoring, coordination with other providers
  - Oncologists adhere to approved (lower-cost) drug pathways
- Some payers are offering bonus (shared savings) if oncologists reduce total spending below target
  - Reward for reduced spending on drugs, ED visits, hospitalization
  - Practices must perform well on quality metrics to obtain bonus

Example: Oncology Physician Payment

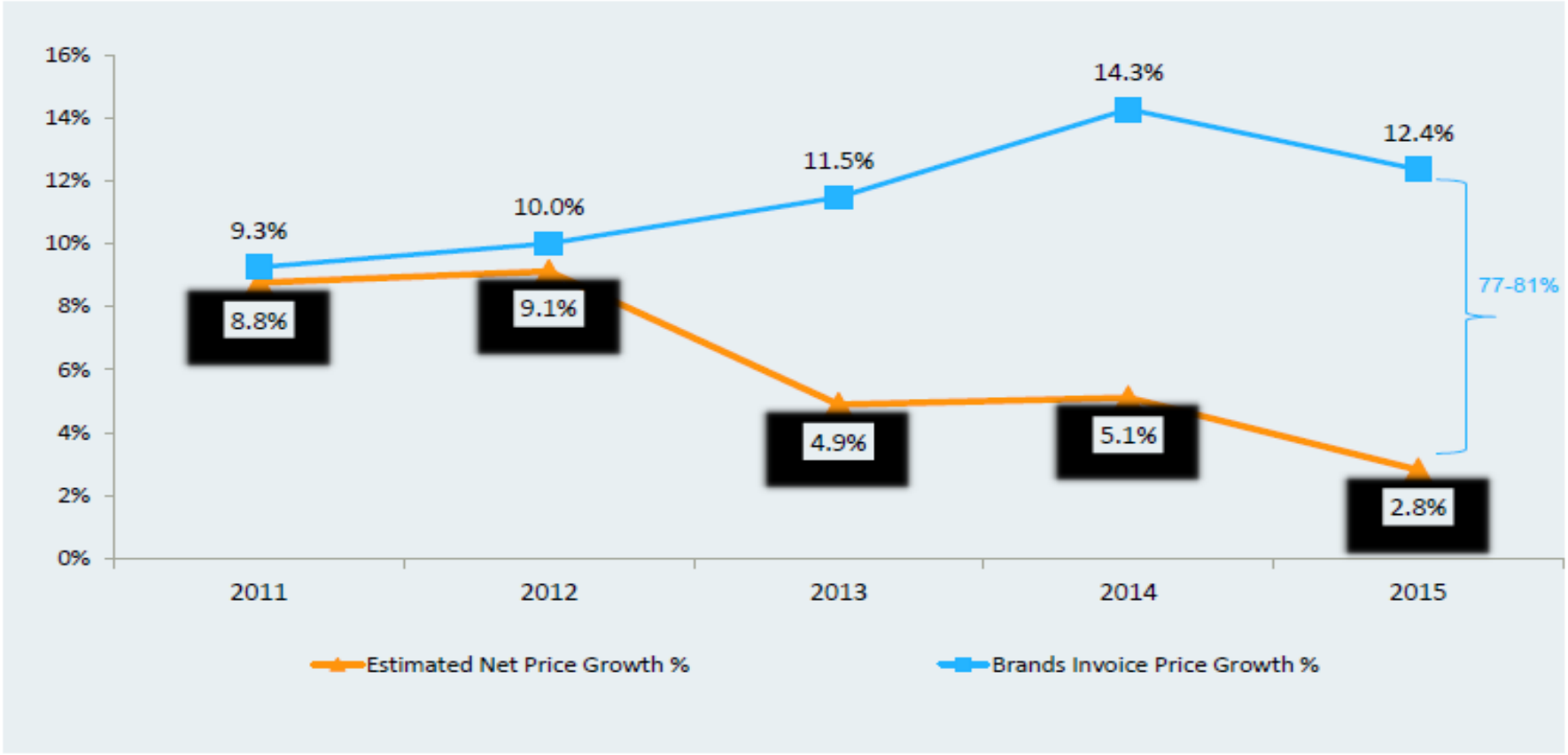
- Medicare model combines monthly care management fee with shared savings bonus
  - Oncologist bills $160/month for 6 months for patients in active treatment, in addition to FFS for office visits
  - Must comply with IT ‘meaningful use’, clinician accessible 24/7, patient ‘navigation’ services, care plan for every patient consistent with IOM
  - Must perform well on measures of care quality
- Shared savings will be based on the difference between future and past expenditures on services to cancer patients (e.g., office visits, drugs, lab, radiology, surgery, hospitalization, post-acute care)

4. Discounts in Competitive Indications

- As innovation leads to more crowded indications, payers negotiate aggressively on drug prices
- This generates very large differences between announced and paid prices
- Some after-discount prices in the US have fallen to levels found in Japan and Europe, though most still remain higher

Although invoice price growth for protected brands was 12.4%, net price growth is estimated at 2.8%

Protected Brand Invoice and Net Price Growth



IMS INSTITUTE FOR HEALTHCARE INFORMATICS

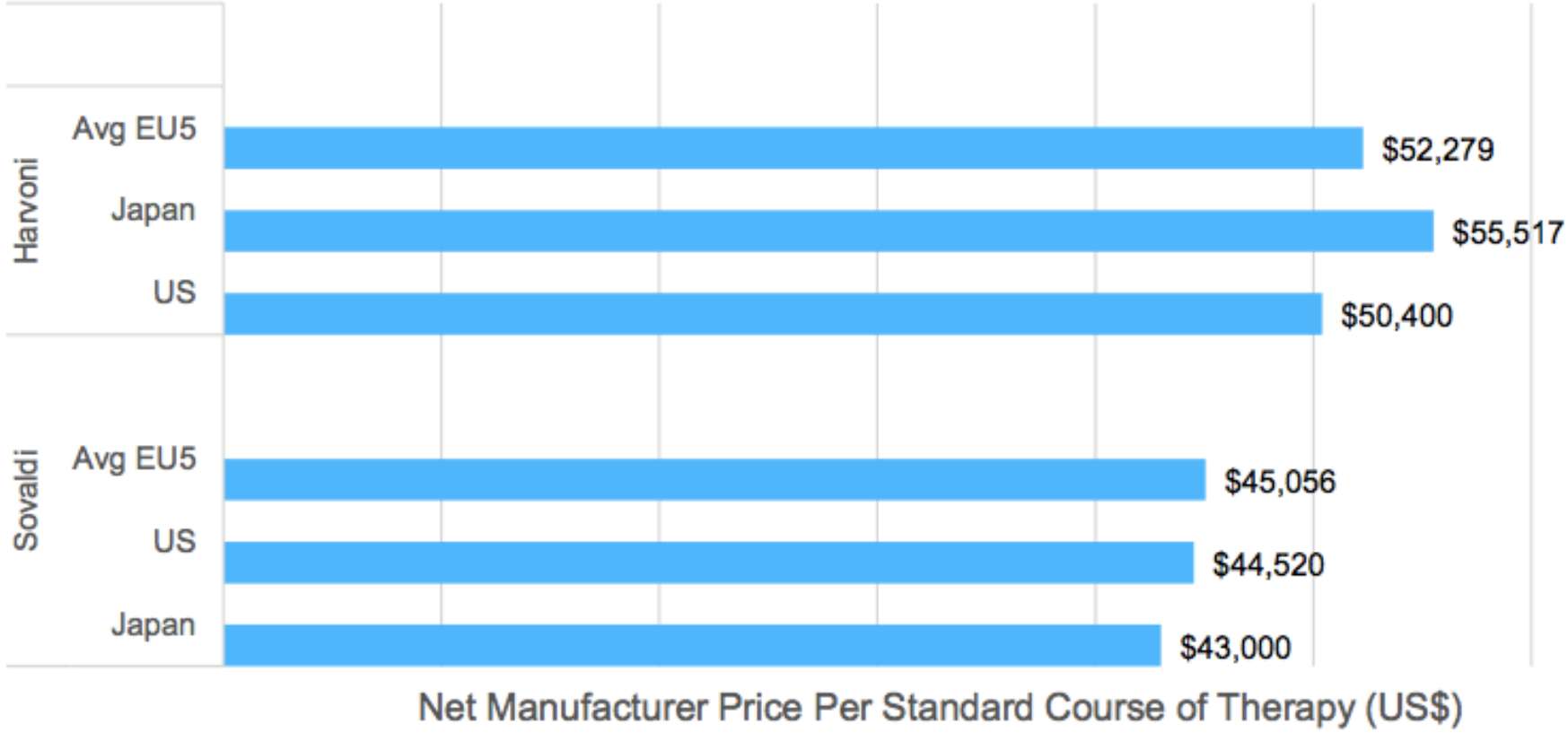
But Even After Negotiated Discounts, Most Drug Prices Are Higher in US than in Other Nations

Examples of Country-Specific Average Drug Prices for Top-Selling Drugs in 2015

Drug	Monthly Price, US $				
	United States				
	Nondiscounted Price	Estimated Discounted Price	Canada	France	Germany
Adalimumab (Humira), 40 mg biweekly	3430.82	2504.50	1164.32	981.79	1749.26
Fluticasone/salmeterol (Advair), 250 µg, 50 µg daily	309.60	154.80	74.12	34.52	37.71
Insulin glargine (Lantus), 50 insulin units daily	372.75	186.38	67.00	46.60	60.90
Rosuvastatin (Crestor), 10 mg daily	216.00	86.40	32.10	19.80	40.50
Sitagliptin (Januvia), 100 mg daily	330.60	168.61	68.10	35.40	39.00
Sofosbuvir (Sovaldi), 400 mg daily	30 000.00	17 700.00	14 943.30	16 088.40	17 093.70
Trastuzumab (Herceptin), 450 mg every 3 wk	5593.47	4754.45		2527.97	3185.87

AS Kesselheim et al. The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform. JAMA 2016;316(8):858-871.

Some US Discounts Exceed Those in EU and Japan: HCV Drugs (2015)



Pharmaceutical Industry Strategies

Pharmaceutical firms have developed effective but expensive responses to payer strategies

Pharmaceutical Counter-Strategies

1. Pharmaceutical firms maintain large staffs of physicians, nurses, and pharmacists to support physicians facing prior authorization and step therapy for expensive drugs
2. They maintain large programs, both internal and independent, that offer to pay most of the patient's cost sharing (for their drug)
3. They maintain large programs that work with physician practices, seeking to improve efficiency and thereby minimize pressures to cut drug prescription under 'value-based payment'

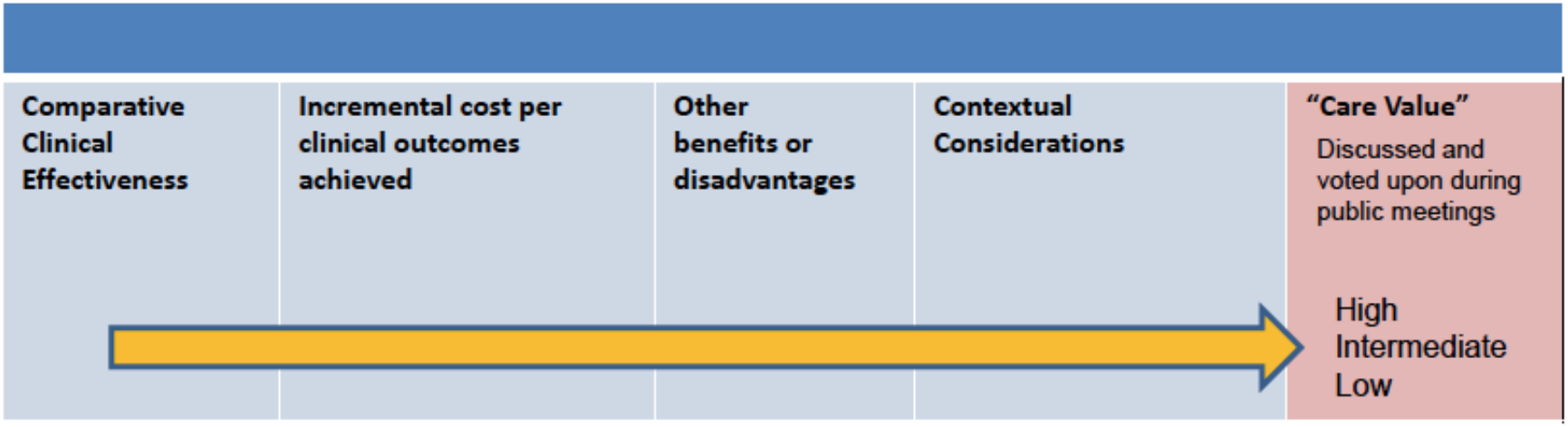
The Drug Pricing "Arms Race"

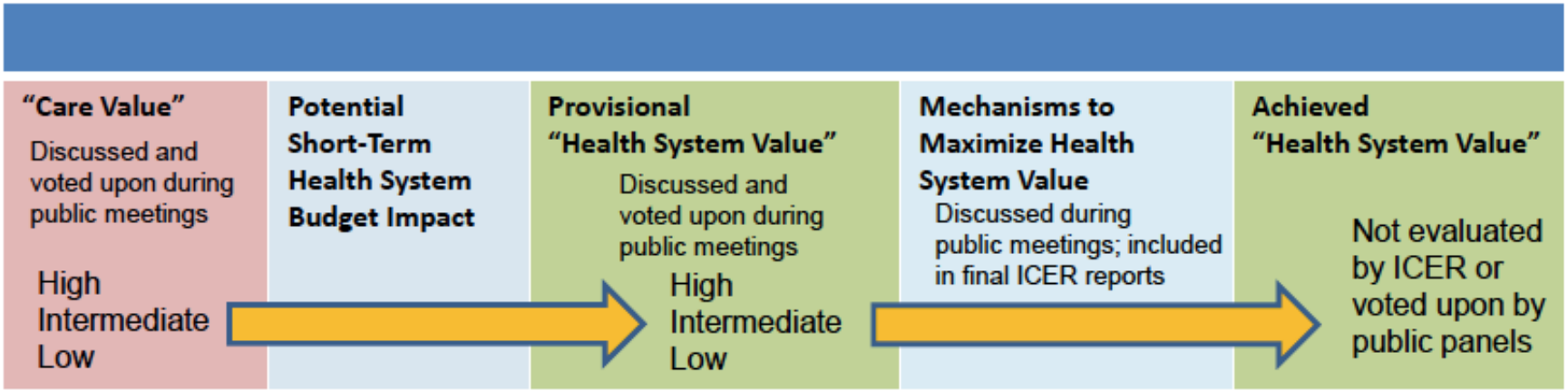
- Payers use utilization management, consumer cost sharing, and physician incentives to limit use and convince drug firms to offer discounts
- Drug firms then develop physician and consumer support programs to counteract these strategies
- Payers then intensify their initiatives
- Drug firms then intensify their counter-initiatives
- This is very expensive
- Patients and doctors are caught in the middle

From Free Pricing to Value-based Pricing

- Some drug firms are voluntarily limiting prices and price increases (to single digits) in response to public hostility to high prices
- Even some drugs launched without competitors in their indication (e.g., gene therapy) are being priced below analyst expectations
- Some are considering accepting ICER price benchmarks in exchange for reductions in payer obstacles to patient access (high volumes)
- US is groping towards definition of ‘value-based access’ in exchange for ’value-based prices’

Value-based Pricing





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

Value-Based Patient Access

My proposal (joint with others): If drug firms accept ‘value-based’ prices for particular drugs, payers should adhere to ‘value-based’ patient access

1. Prior authorization would be limited to documentation that the patient has the FDA authorized indication, with no further limits
2. No step therapy (all drugs charging value-based priced would be treated the same)
3. No onerous coinsurance & deductibles on drugs charging value-based prices
4. Drugs charging value-based prices exempted from new physician payment incentives

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