Berkeley School of Public Health

BCHT
BERKELEY CENTER FOR HEALTH TECHNOLOGY

Evolution of Pharmaceutical Price Negotiations in the United States

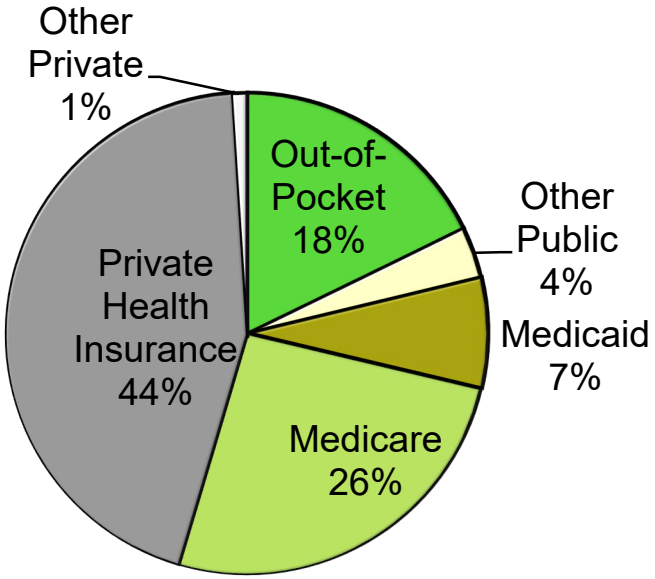
James C. Robinson
Leonard D. Schaeffer Professor of Health Economics
University of California

Overview: the US Market and Policy Context

- Free drug pricing in principle, but not in practice
- Price negotiations by private insurers
- Price administration by public Medicare program
- Possible futures: private negotiations
- Possible futures: public policy

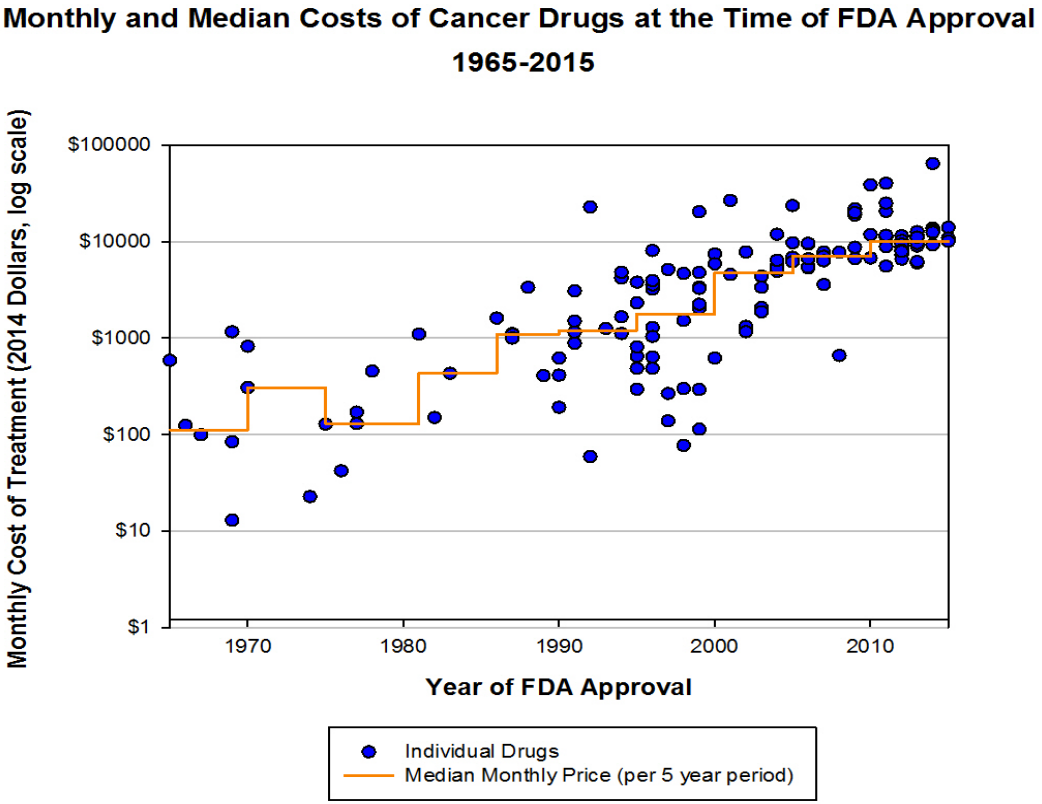
The Payer and Pharmaceutical Context

- The US has a mix of public and private insurance with no centralized negotiation or regulation of drug prices
- Manufacturers are able freely to set list prices at launch
- They are able freely to raise list prices yearly thereafter
- These high list prices now are coming under increased negotiations



Source: California Healthcare Foundation

Manufacturers Set Ever-Higher Launch Prices



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

Manufacturers Raise List Prices After Launch

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

Responses by private insurer and public programs

- Private insurers take the lead, with public payers benefitting from average or lowest net prices negotiated by private payers
- The strategy pursued by private insurers is to limit physician prescription and patient access to specialty drugs, with the offer to partially relax restrictions in exchange for price rebates
- These access barriers, including prior authorization and consumer cost sharing, are rapidly becoming more intense, sparking a backlash from physicians and patients
- Both insurers and manufacturers face strong adverse publicity
- The strategies have been effective in reducing the growth, and in some cases the level, of net prices

Private Insurers Create Positive Lists (Formularies) and Manage Access

- More drugs excluded from insurer formularies: narrower ‘positive lists’
- Physicians face more stringent prior authorization requirements for prescription
- Patients face rapidly rising cost sharing
- These strategies have been effective in reducing volumes (prescription/adherence) and net prices in competitive indications

Medicare: Reliance on Private Insurers to Negotiate Prices for Self-administered Drugs

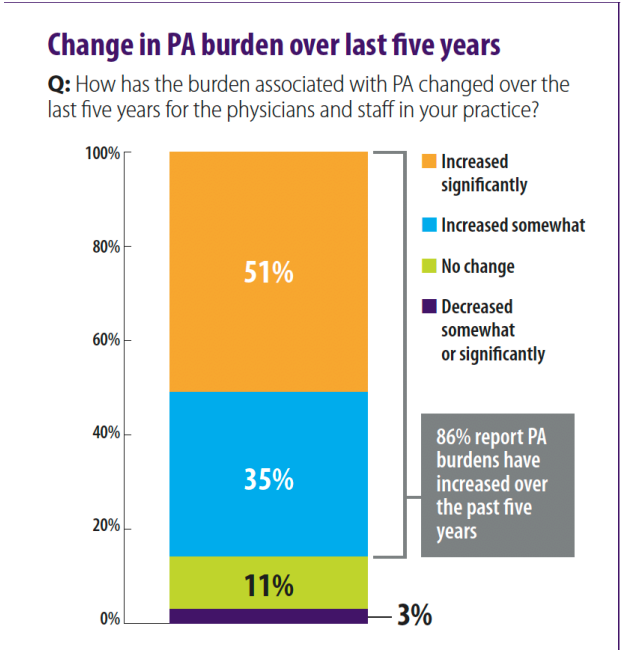
- Medicare delegates management of self-administered (Part D) drugs to private payers, who negotiate individually with manufacturers
- They use similar tactics as other private payers (prior authorization, consumer cost sharing)
- Their negotiating leverage is limited in oncology and other ‘protected classes’ where they cannot restrict coverage or impose stringent controls on prescription for Medicare patients

Medicare: Adoption of Net Prices from Private Insurers for Physician-Administered Drugs

- Medicare must cover all physician-administered (Part B) drugs and pays the average net prices paid by private insurers
  - Manufacturers are required to report all discounts and rebates so Medicare can compute the average sales price (ASP)
- These drugs mostly are administered in hospital outpatient clinics and physician offices
- Physicians and hospitals are reimbursed at average net price plus % markup, which creates incentives for providers to use the most expensive option

Increased Payer Resistance to Prescription of Expensive Treatments

- Tighter and more stringent criteria for prior authorization
- Criteria increasingly linked to disease severity, going 'inside the FDA label'
- Requirement for documentation, not merely MD attestation
- More stringent step therapy, with more patients required to 'try and fail' drugs

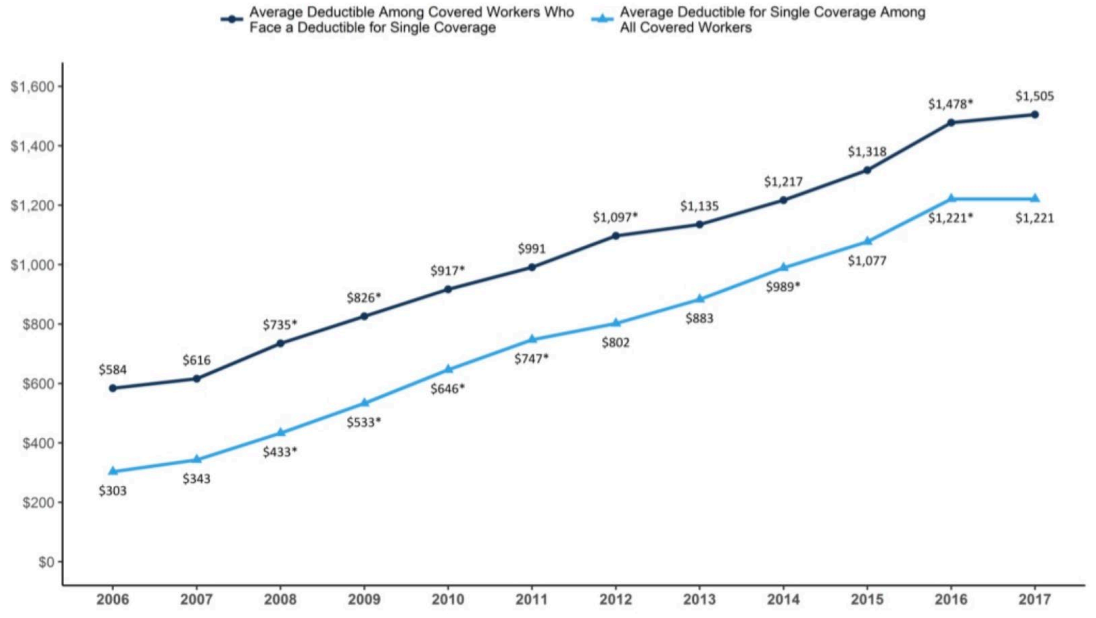


Source: 2017 AMA Prior Authorization Physician Survey

Patients Face Ever-Higher Cost Sharing

Figure 15

Average General Annual Health Plan Deductibles for Single Coverage, 2006-2017



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

NOTE: Average general annual deductible is among all covered workers. Workers in plans without a general annual deductible for in-network services are assigned a value of zero.

SOURCE: Kaiser/HRET Survey of Employer-Sponsored Health Benefits, 2006-2017

Systematic Literature Survey: Utilization Management Reduces Drug Use, with Adverse Outcomes

SYSTEMATIC REVIEW

The Effect of Formulary Restrictions on Patient and Payer Outcomes: A Systematic Literature Review

Yujin Park, PharmD; Syed Raza, MS; Aneesh George, MS; Rumjhum Agrawal, MPharm; and John Ko, PharmD, MS

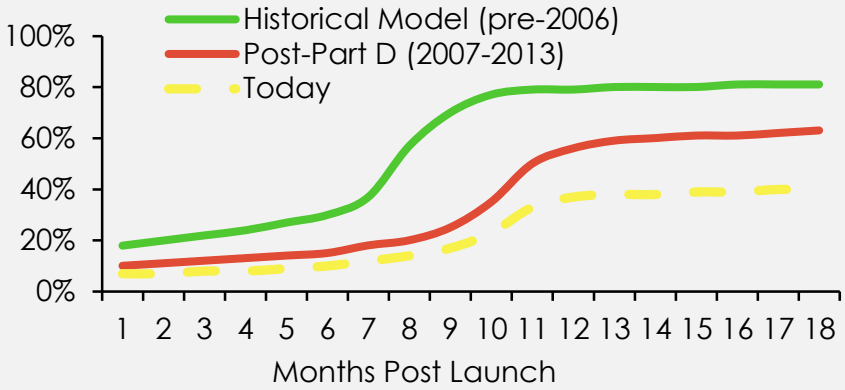
Systematic review of peer-reviewed articles (n=59) published 2005-18 on drug utilization management by US payers:

- 90% of studies find formulary exclusions, prior authorization, and step therapy to reduce drug use and spending
- Some reductions in drug spending were offset by increases elsewhere
- 10/12 studies using clinical endpoints report adverse outcomes

Journal of Managed Care & Specialty Pharmacy 2017 Vol. 23, No. 8

Prior Authorization and Cost Sharing Are Slowing Drug Adoption and Sales

Percent of Potential Post-Launch Adoption Actually Achieved, With Changing Intensity of Payer Management

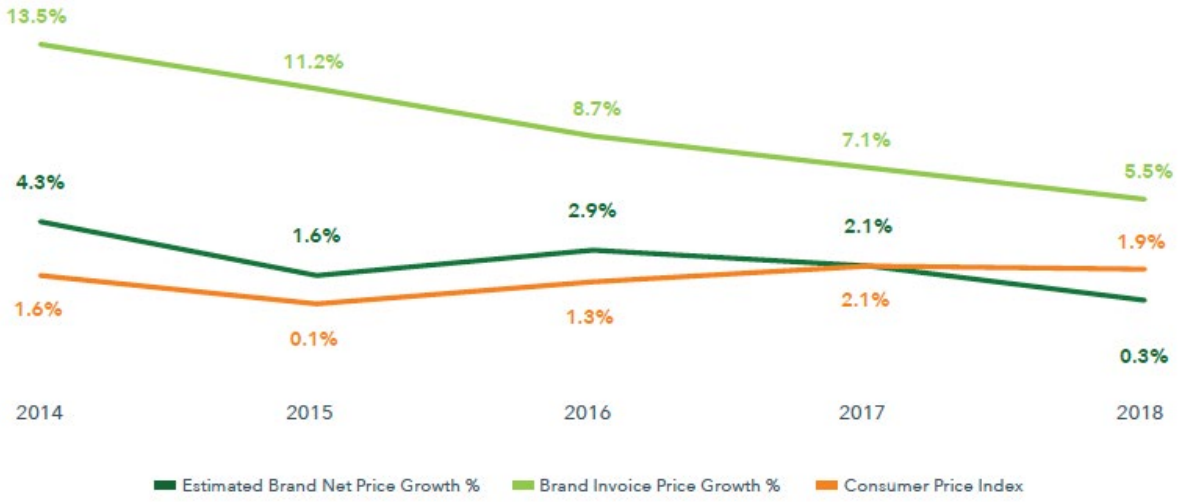


‡ *Source: QuintilesIMS,* Payer and Managed Care Insights

Price Negotiations Are Reducing Growth in Net Prices, in Some Case to Negative

Protected brand net price increases moderated to 0.3% on average in 2018 as invoice price growth continued to fall

Exhibit 18: Protected Brand Invoice and Net Price Growth %



Source: IQVIA National Sales Perspectives, Jan 2019; IQVIA Institute, Apr 2019

Possible Futures: Reform of Drug Price Negotiations

- Some manufacturers are responding to the increased effectiveness of insurer restrictions on price and access by softening their historical resistance to health technology assessment and price benchmarks, as conducted by the private nonprofit Institute for Clinical and Economic Review (ICER)
- In exchange for setting net prices near ICER benchmarks, they seek enhanced patient access and product sales (‘value based access’)
- This is especially evident in highly competitive indications where insurers have been most effective
- Insurer initiatives are not effective for orphan and gene therapies

Example: Manufacturer Reduces Price to ICER ‘Value-based’ Benchmark in Exchange for Lighter Prior Authorization

BUSINESS | HEALTH CARE

Regeneron and Sanofi Plan to Cut Cholesterol Drug Price in Exchange for Wider Coverage

They seek to offer rebates and discounts for Praluent and want insurers to ease restrictions on some patients

A cost-effectiveness analysis by an independent group incorporated new clinical trial data showing that Praluent reduced the risk of death. PHOTO: SANOFI AND REGENERON PHARMACEUTICALS/ASSOCIATED PRESS

By Joseph Walker

March 10, 2018 9:00 a.m. ET

ey

School of Public Health

Example: Manufacturer Reduces Price to ICER 'Value-based' Benchmark in Exchange for Reduced Consumer Cost Sharing

- Amgen Makes Repatha® (Evolocumab) Available In The US At A 60 Percent Reduced List Price
- **New Option Will Lower Out-of-Pocket Costs for America's Seniors at Risk for Heart Attacks and Strokes**THOUSAND OAKS, Calif., Oct. 24, 2018 /PRNewswire/ -- Amgen (NASDAQ: AMGN) today announced that it is making Repatha® (evolocumab), an innovative biologic medicine for people with high cholesterol who are at risk for heart attacks and strokes, available at a reduced list price of $5,850 per year. This 60 percent reduction from the medicine's original list price will improve affordability by lowering patient copays, especially for Medicare patients.

VIEWPOINT

Value-Based Pricing and Patient Access for Specialty Drugs

James C. Robinson, PhD, MPH
University of California, Berkeley.

Scott Howell, MD, MBA
Novartis Pharmaceuticals Corp, East Hanover, New Jersey.

Steven D. Pearson, MD, MSc
Institute for Clinical and Economic Review, Boston, Massachusetts.

Insurers, employers, and pharmacy benefit managers (PBMs) bemoan high prices for specialty drugs and respond by closely managing patient access to drugs through prior authorization, step therapy, and consumer cost sharing. Pharmaceutical firms are concerned when the use and sale of specific drugs fall short of projections. High prices and access barriers compound each other. Pharmaceutical firms help physicians to navigate utilization management and patients to cover their financial obligations, but then must consider the costs of these programs in subsequent prices. Payers respond to price increases by intensifying access management. Physicians and patients are caught between payers and manufacturers, facing ever-higher administrative and financial obstacles.

The list prices charged for specialty drugs have been rising rapidly in the past decade, both at the time of initial market launch and through post-launch increases.[1] Between 2005 and 2013, for example, the launch price of new oncology drugs increased 12% per year without commensurate increases in efficacy, implying that the price per life-year gained increased from $139 000 to $207 000.[2] Even after accounting for negotiated discounts and rebates, prices for major specialty drugs in

been interrupted. When poorly designed and implemented, step therapy programs may also make it difficult for physicians and patients to avoid having to start again with therapies that patients have already "tried and failed" before (eg, when enrolled in a different health plan). Some health insurance plans feature annual deductibles and percentage co-insurance instead of dollar co-payments. These have created meaningful financial barriers to specialty drug access. In 2016, 23% of individuals with employment-based insurance had an annual deductible of $2000 or more[5] and 48% of Medicare Part D enrollees were subject to percentage co-insurance for specialty drugs.[6]

The concerns of insurers, manufacturers, physicians, and patients highlight the failure of the current model of drug pricing and access in the United States. Innovative purchasers and manufacturers are potentially interested in closer and longer-term relationships that support the need of the purchasers for affordability and the need of the manufacturers for patient access and net revenue. This requires a new framework for linking price negotiations with improved patient access.

Value-Based Prices

Robinson JC, Howell S, Pearson SD. JAMA 2018; 319(21):2169-70.

Possible Futures: Increased public regulation of prices

- Congressional Democrats and President Trump are promoting very aggressive legislation to support price negotiations and regulation
- Congressional Republicans traditionally have opposed regulation, but face strong public pressure to cooperate
- All need to ‘do something’ but neither the Democrats nor the Trump administration want to give the other a perceived policy victory
- Chances for cooperation and successful legislation are limited
- Legislation will depend on the outcome of 2020 elections, which cover the presidency, all Congressional seats, and 1/3 of Senate seats
- A victory by Democrats would almost certainly result in stringent new drug price negotiations and regulations

Pharmaceuticals: the Least Loved Industry

Americans' Views of U.S. Business Industry Sectors, 2019

For each of the following business sectors in the United States, please say whether your overall view of it is very positive, somewhat positive, neutral, somewhat negative or very negative.

	Total positive	Neutral	Total Negative	Net positive
	%	%	%	
Restaurant industry	66	25	8	+58
Computer industry	61	28	11	+50
Grocery industry	58	27	15	+43
Farming and agriculture	58	24	17	+41
Travel industry	52	35	13	+39
Accounting	45	45	9	+36
Automobile industry	53	29	18	+35
Retail industry	50	28	19	+31
Real estate industry	49	31	19	+30
Banking	50	25	25	+25
Electric and gas utilities	47	28	24	+23
Sports industry	45	29	25	+20
Airline industry	42	32	23	+19
Telephone industry	42	32	26	+16
Publishing industry	39	36	24	+15
Internet industry	43	26	30	+13
Movie industry	41	31	28	+13
Education	45	18	35	+10
Television and radio industry	40	27	32	+8
The legal field	35	34	30	+5
Oil and gas industry	39	25	36	+3
Advertising and public relations industry	33	32	34	-1
Healthcare industry	38	14	48	-10
The federal government	25	23	52	-27
Pharmaceutical industry	27	15	58	-31

GALLUP, AUG. 1-14, 2019

Congressional Democrats Focus on Launch Price "Negotiations" with Heavy Regulation

- Government would negotiate prices for Medicare, which would apply to private payers
- Upper limit on prices would be 120% of prices for other wealthy nations (reference pricing)
- If manufacturers refuse to price below benchmarks, they face 75% tax on sales

STAT+[2]

Pelosi's drug pricing plan is more aggressive than expected

By Nicholas Florko[3] @NicholasFlorko[4] *and* Lev Facher[5] @levfacher[6]

September 9, 2019

Bipartisan Senate Committee and Trump Emphasize Limits on Price Increases

- Manufacturers must rebate to Medicare any price increases faster than inflation
- Limits on consumer cost sharing, requiring private insurers to pay greater share of total costs
- No controls on launch prices, which will continue to be negotiated by private insurers

HEALTH AFFAIRS BLOG

RELATED TOPICS:
MEDICARE PART B | MEDICARE PART D | MEDICAID | DRUG PRICING | PRESCRIPTION DRUGS

Understanding The Senate Finance Committee's Drug Pricing Package

Rachel Sachs

JULY 26, 2019 DOI: 10.1377/hblog20190726.817822

Beyond politics: implementation limitations of policy proposals

- The political debate ignores the challenges facing any centralized process for assessing value and negotiating/regulating prices
- How to assess value? Private ICER is favored by Democrats, opposed by Republicans. No public HTA entity exists
- Which process for Medicare negotiations? The stringent limits on outcomes (limited by global reference prices, US price inflation, compulsory licensing, and/or mandatory arbitration) make this more a process of regulation than negotiation
- How would Medicare prices affect private insurers? Will private insurers be allowed to limit payments to Medicare levels, or will manufacturers be able to increase prices to private payers to offset reduced prices to public payers?

A New Openness to New Approaches

- Traditionally the US did not look to Europe for models of value assessment and price determination
- It now is more open-minded, due to rising discontent with the status quo
- Comparative research and educational initiatives increasingly are valued

Negotiating drug prices without restricting patient access: lessons from Germany

By James C. Robinson, Dimitra Panteli, *and* Patricia Ex

June 27, 2019

STAT, June 27, 2019

Conclusion

- The US has free drug pricing in principle, but negotiated and increasingly regulated prices in practice
- The current negotiations process is very inefficient, imposing severe burdens on patients and physicians and high transactions costs
- Pharmaceutical pricing has become the most important domestic policy and political topic, with intense attention
- Payers, the public, and politicians are aroused against the industry but lack a coherent and feasible set of reforms

BCHT

BERKELEY CENTER
FOR HEALTH TECHNOLOGY

The Berkeley Center for Health Technology (BCHT) promotes the efficiency and effectiveness of health care through research and education on the development, insurance coverage, payment, and appropriate use of medical technologies.

BCHT.Berkeley.Edu