



BAY CITY CAPITAL 

Investing in Life Sciences

DRUG PRICING

National Academy of Sciences
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January 23, 2017

PRICING: Factors to Consider

1. RESEARCH AND DEVELOPMENT COSTS
2. COST OF GOODS AND SALES COSTS/MARKETING AND ADVERTISING
3. EFFECT OF REVENUE AND PROFIT INCREASES FROM THE PRODUCT ON THE COMPANY'S OVERALL STATUS
4. CLINICAL ATTRIBUTES/BENEFIT OF THE PRODUCT, BOTH NOW AND POTENTIALLY AFTER A LATER APPROVAL FOR A NEW INDICATION. HOW STRONG IS THE VALUE PROPOSITION
5. SUPPORT FOR THE PRODUCT FROM DOCTORS, PATIENTS AND PAYORS
6. LIKELY COMPETITIVE LANDSCAPE: (A) SHORT TERM; AND (B) ANY LIKELY FUTURE COMPETITORS – PURCHASING POWER OF BUYERS AND LOCUS OF WHO WILL BE MAKING DECISIONS AND IN WHAT LOCATION
7. INTELLECTUAL PROPERTY SITUATION
8. LIKELY MARKET EXPECTATIONS: (A) WALL STREET/INVESTORS; AND (B) PROVIDERS AND INSURERS

PRICING: Factors to Consider

- A. COST OF GOODS AND GENERAL AND ADMINISTRATIVE COSTS (INCLUDING ADVERTISING AND DTC). MARGINAL COSTS FOR TOP TIER MARKETS.
- B. COST OF DEVELOPMENT (BOTH OUT OF POCKET, TIMING OF SPEND, AND OVERALL COSTS INCLUDING THE ROUGHLY 50% ATTRIBUTABLE TO THE TIME VALUE OF MONEY) FOR INDIVIDUAL DRUGS LIKE REPATHA AND OVERALL FOR A PUBLICLY TRADED COMPANY'S PORTFOLIO. NOTING THE NEAR TERM SPENDING NEEDS FOR ADDITIONAL R& D SPENDING.
- C. THE ROLE OF SHAREOWNERS (AND SEPARATELY ANALYSTS AND WALL STREET VIA STOCK PRICE).
- D. THE NATURE AND EXTENT OF THE CLINICAL BENEFIT. DIFFERENCES, IF ANY, IN MARKET SIZE BETWEEN COUNTRIES BY ADDRESSABLE MARKET.
- E. STRENGTH OF THE "VALUE" PROPOSITION. NOTING THE ROLE OF BOTH GOVERNMENTAL AND PRIVATE SECTOR GATEKEEPERS IN THE FORM OF HEALTH TECHNOLOGY AUTHORITIES.
- F. NATURE OF MARKET POSITION RELATIVE TO COMPETITION (INCLUDING LABELING DIFFERENCE, TIMING OF COMPETITOR APPROVALS), AND THE ROLE OF IP (WHETHER PATENT(S) OR DATA/ MARKET EXCLUSIVITY).
- G. THE PURCHASING POWER OF THE BUYERS OF THE MEDICINE (E.G. GOVERNMENT RUN SINGLE PAIR OUTSIDE THE US), PBM AND INSURERS/EMPLOYEES IN THE US.
- H. LOCUS OF THE PRESCRIBING DECISION-MAKING (DOCTOR, IN HOSPITAL, IN A DOCTOR'S OFFICE AND THE ROLE OF INSURERS PRIOR AUTHORIZATION, TIERING, HIGH DEDUCTIBLE, COUPONS/DISCOUNT CARDS, AND WHEN/WHETHER SUBSTITUTION IS POSSIBLE, INCLUDING AT THE PHARMACY LEVEL).
- I. PROJECTED ROLE -- OVER TIME -- OF LAUNCH PRICE TIMING BY MARKET, GEOGRAPHIC PRICING DIFFERENCES BASED ON WHAT RULES, AND PRICE INCREASES.

Price Setting Process

1. WHEN TO BEGIN CONDUCTING RESEARCH/WITH WHOM AND ABOUT WHAT
2. MARKET AND FINANCIAL ANALYSIS USING HYPOTHETICAL OR SAMPLE FDA LABELS
3. OPTIONS TO CONSIDER
4. DISCOUNTING

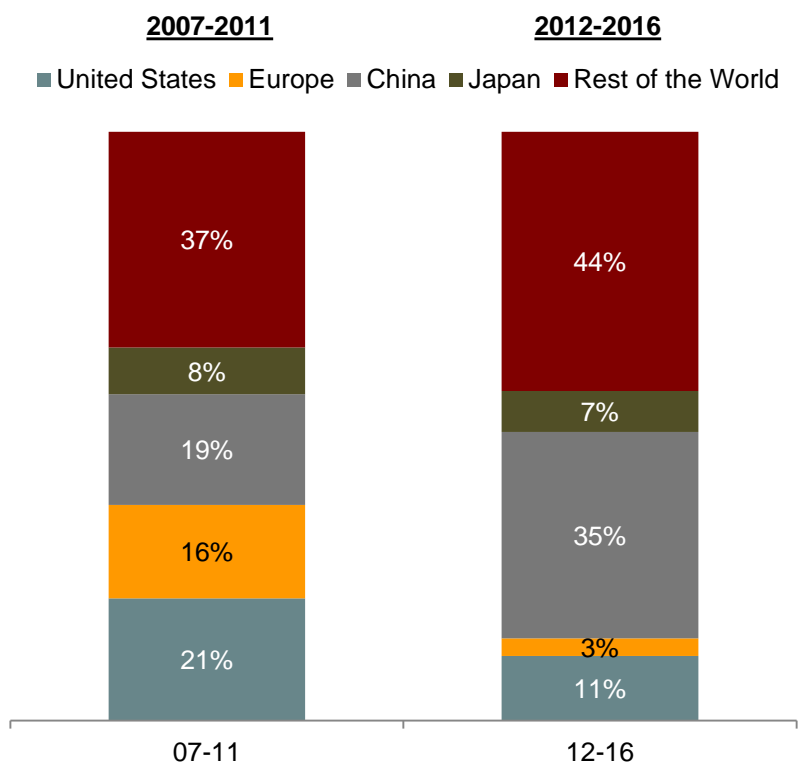
New Factors in Drug Process

1. OUTCOMES RESEARCH FROM REAL WORLD DATA/AND CHART ANALYSIS
2. PAY FOR PERFORMANCE AND OUTCOMES GUARANTEE CONTRACTS
3. DISCOUNTING STRATEGY: (A) ROLE OF MEDICAID BEST PRICE; AND (B) PRECEDENT SETTING BETWEEN PROVIDERS/INSURERS
4. RESPONSES TO COMPETITORS
5. MEDIA AND PUBLIC REACTION TO SCRUTINY

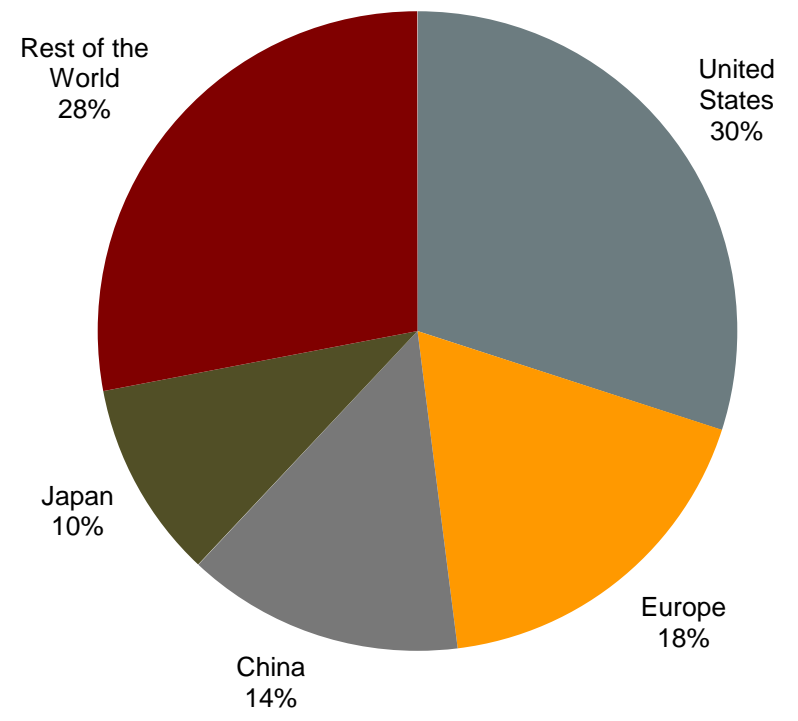
APPENDIX

Context of the Expenditures on Pharmaceuticals

Contribution to Global Growth (Constant USD)



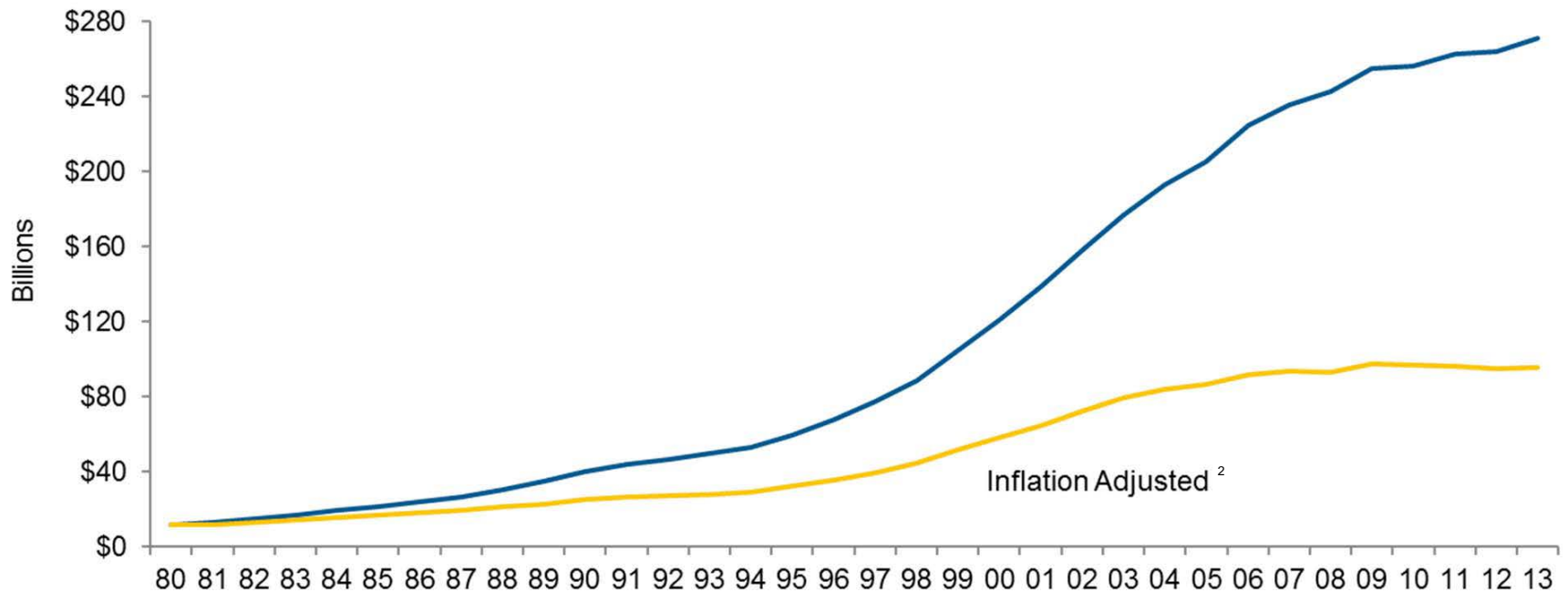
2016 Market Share (USD)



Source: [https://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/vwimages/appendixb.jpg/\\$file/apendixb.jpg](https://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/vwimages/appendixb.jpg/$file/apendixb.jpg)

Prescription Drug Spending Trends

Total Prescription Drug Spending, 1980 – 2013 ¹



Source: Source: Centers for Medicare & Medicaid Services, Office of the Actuary. Data released December 3, 2014 (<http://www.aha.org/research/reports/tw/chartbook/2015/chart1-10.pdf>)

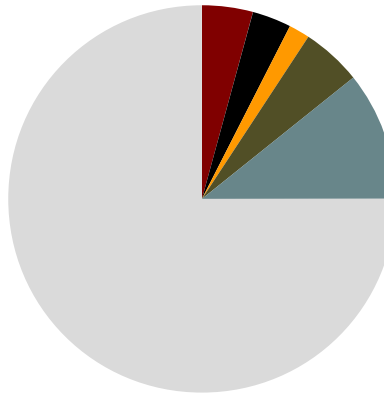
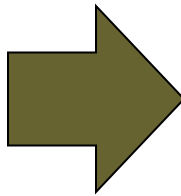
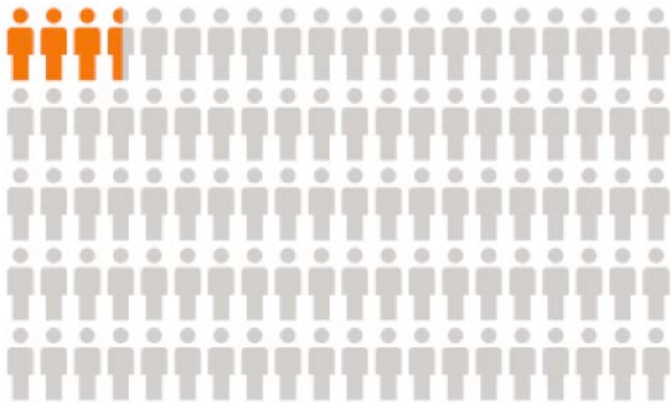
¹ CMS completed a benchmark revision in 2009, introducing changes in methods, definitions and source data that are applied to the entire time series (back to 1960). For more information on this revision, see <http://www.cms.gov/nationalhealthexpenddata/downloads/benchmark2009.pdf>.

² Expressed in 1980 dollars; adjusted using the overall Consumer Price Index for All Urban Consumers.

Traditional Drugs vs. Specialty Drugs and Rising Annual Drug Costs

- The 3.5% of members who use specialty medications account for 25% of healthcare

Specialty Drug Costs as % Total Healthcare Costs



- 17% Specialty Drug Costs Under Pharmacy Benefit
- 13% Specialty Drug Costs Under Medical Benefit
- 7% Non-specialty Medication Under the Pharmacy Benefit
- 20% Medical Costs Related to Specialty Condition
- 43% All other Medical Costs

Percent of Patient with Annual Drug Costs Above \$50,000

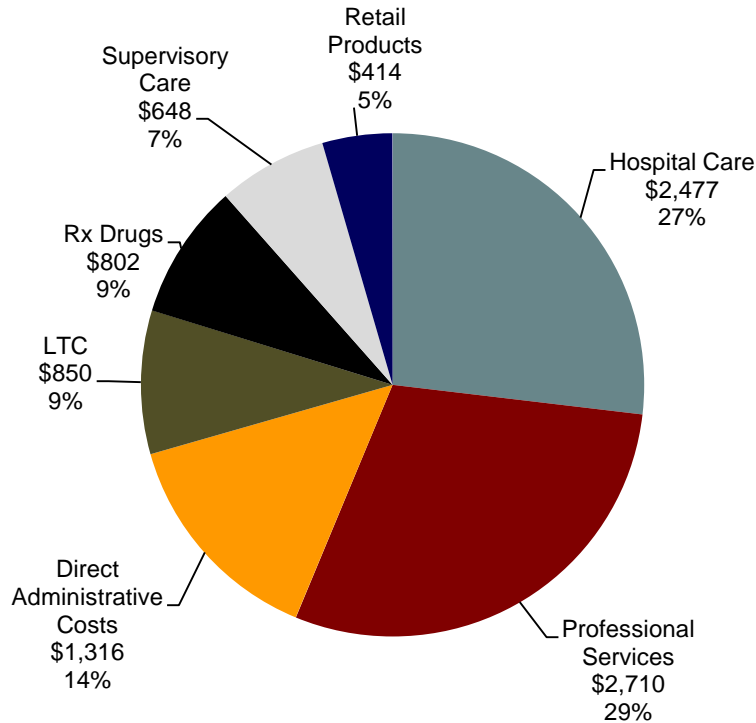
Plan Type	2013		2014	
	% Patients	% Total Costs	% Patients	% Total Costs
Medicaid	0.05%	7.3%	0.10%	14.0%
Medicare	0.30%	9.1%	0.50%	14.9%
Commercial	0.11%	9.7%	0.18%	16.1%
Overall	0.14%	9.5%	0.22%	15.7%

Source: <https://patientadvocate.files.wordpress.com/2013/11/specialty-cvs-costs.png>

Nature of the U.S. Market and Hospital M&A Trends

Per Capita Health Care Costs in U.S. by Services

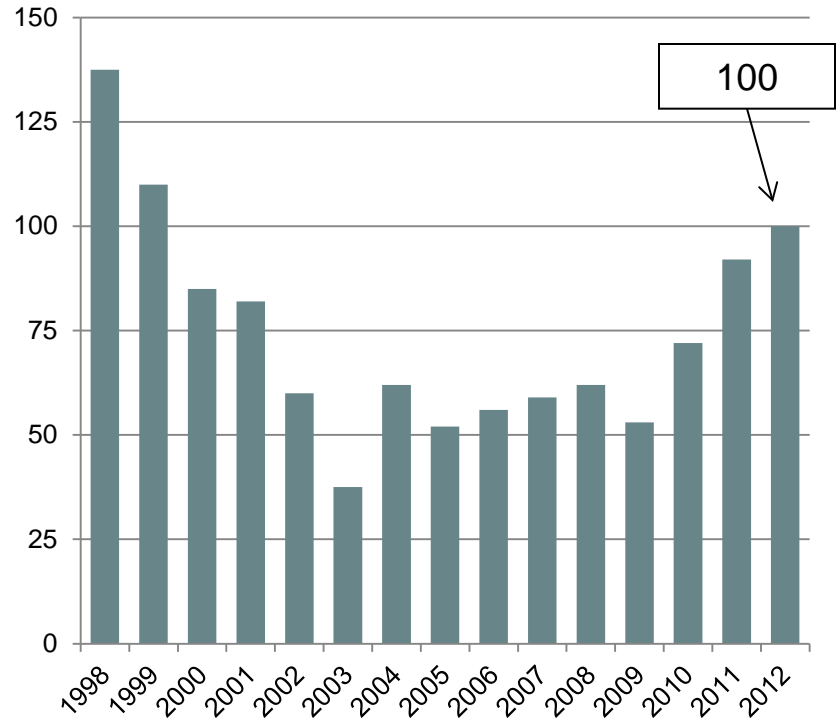
- Per capita health care costs in the U.S. are concentrated in doctor and hospitals
- But consumers spend a lot on non-traditional health goods and services



Source: NHEA, Centers for Medicare and Medicaid Services, and Deloitte analysis, March 2011

Number of Hospital Deals

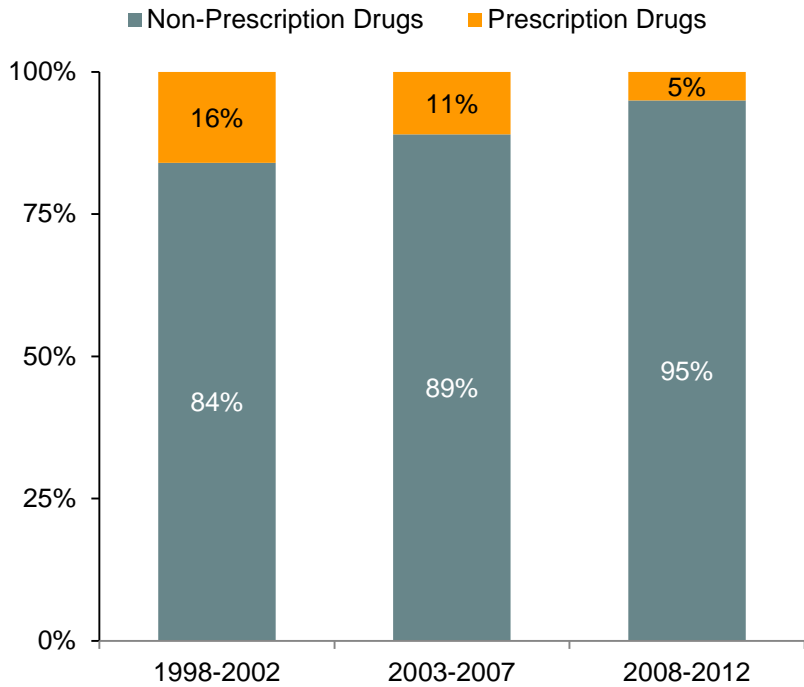
- In 2012, there were 100 hospital mergers and acquisitions
- Since 1998, there have been 1,113 such deals, averaging about 74 per year



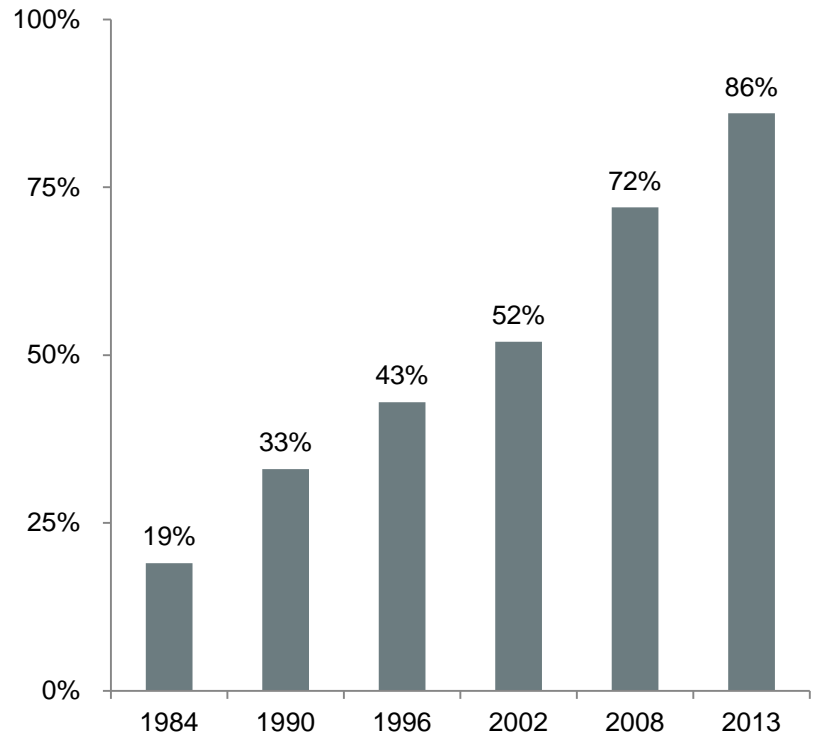
Source: American Hospital Association, "Trends Affecting Hospitals and Health Systems," *Trendwatch Chartbook 2012*, <http://www.aha.org/research/reports/tw/chartbook/index.shtml> (accessed June 18, 2014)

Competition from other Products Post-Patent / IP Expiration

Growth in Healthcare Expenditures Attributable to Prescription Drugs, 1998-2012









Generic Share* of Prescriptions Filled 1983-2013



Source: Zirkelbach, Robert, "The Reality of Prescription Medicine Costs in Three Charts," <http://www.phrma.org/catalyst/the-reality-of-prescription-medicine-costs-in-three-charts>

Pricing in Selected Countries

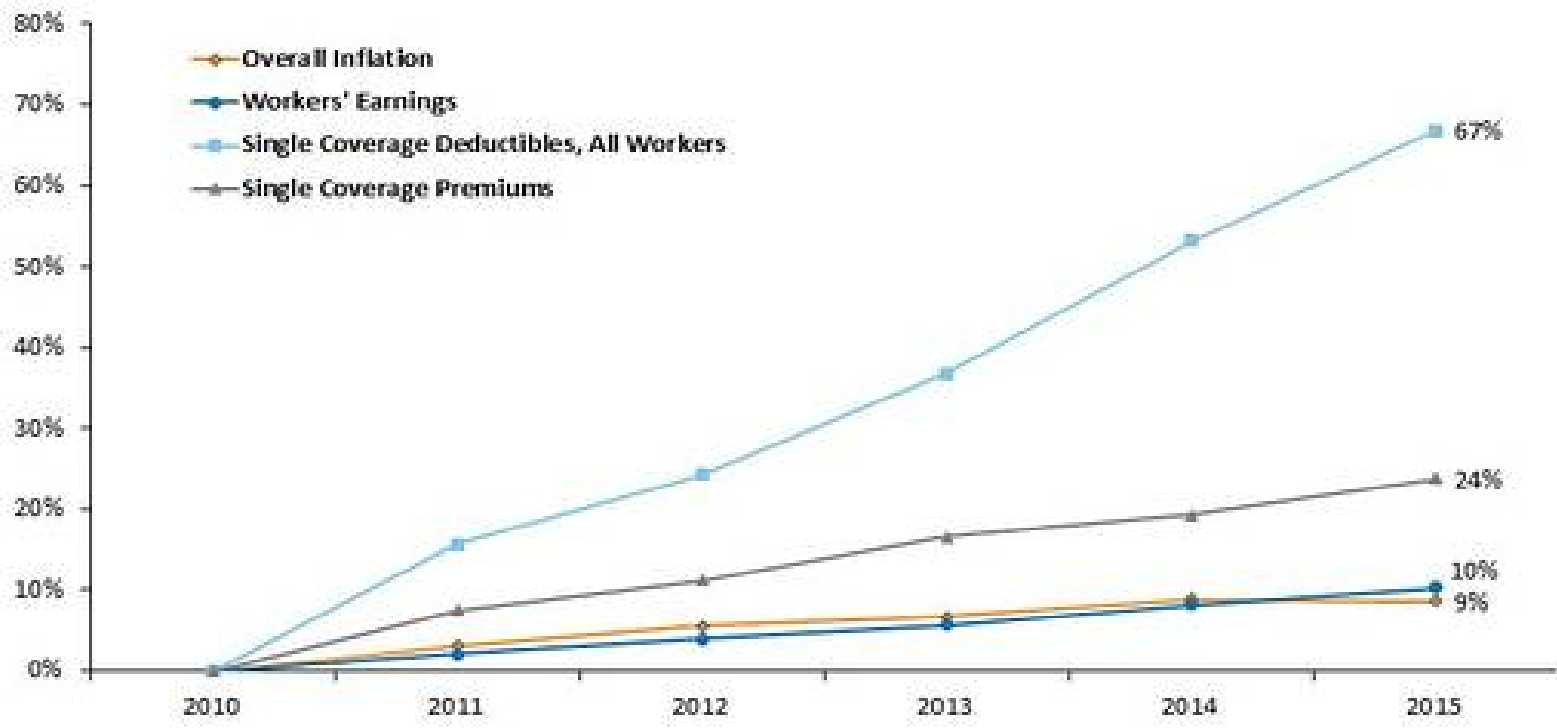
Country		Price Controls	Reference Pricing	Profit Controls	HTAs	Physician Budgets	Limits on Price Increases	Goals
United States		Medicaid* Rebates					Medicaid*	★★★★
United Kingdom		✓		✓	1	✓		★★★★
France		✓	✓	Negotiations	2		✓	★★★★
Germany		✓	✓		2	✓	✓	★★★★
Spain		✓	✓		2		✓	★★★★
Japan		✓			2		✓	★★★★

* = Price control measures are also found in: (1) Section 340 B hospital sales; (2) sales to the VA; (3) mandatory discounts on certain products in Part D of Medicare when a beneficiaries expenditure is in the so-called doughnut hole; and (4) the BIOPHARMACEUTICAL industry also pays a fee to the federal government based on the firm's total sales to federally financed health programs

- ★★★★ = Affordable and Equitable Access to Effective Medicines
- ★★★★ = Cost Growth Sustainable
- ★★★★ = Focus on Innovation
- 1 = Formal Pharmaco Economic Assessment Plus Explicit Qual Limit
- 2 = Assessment of the Added Therapeutic Value of New Product Over Comparatives

Costs are Shifting to Patients

Deductibles Rising Much Faster Than Premiums, Wages and Inflation

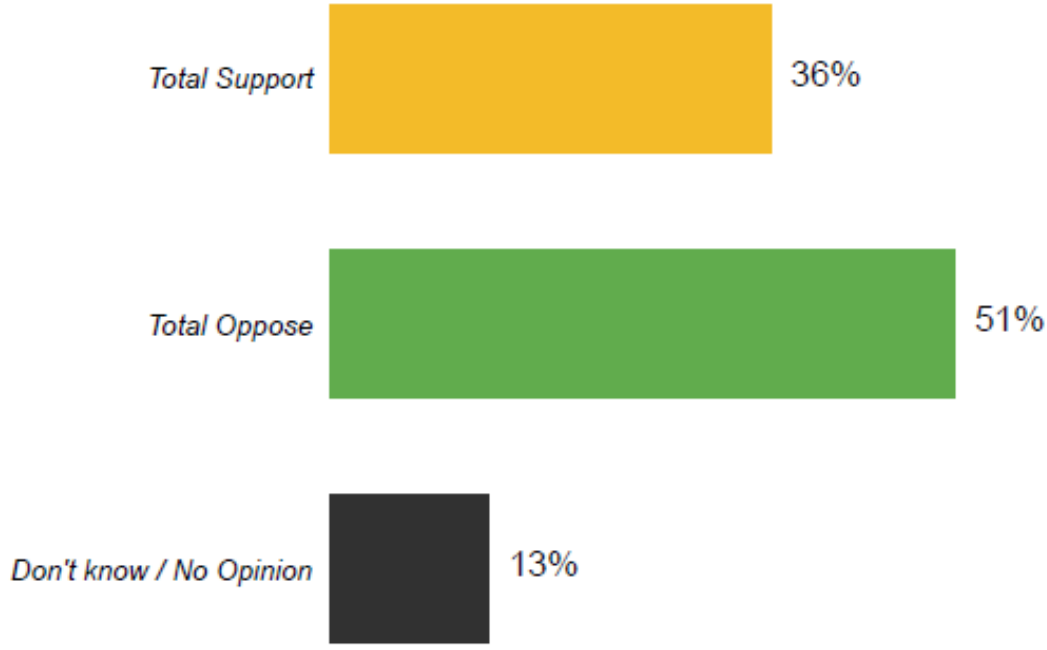


NOTE: Average general annual deductible is among all covered workers. Workers in plans without a general annual deductible for in-network services are assigned a value of zero.
SOURCE: Kaiser Family Foundation/HRET Survey of Employer-Sponsored Health Benefits, 2010-2015; Bureau of Labor Statistics, Consumer Price Index, U.S. City Average of Annual Inflation (April to April), 2010-2015; Bureau of Labor Statistics, seasonally adjusted data from the Current Employment Statistics Survey, 2010-2015 (April to April).



More than half (51%) oppose the government setting prices of prescription medicines

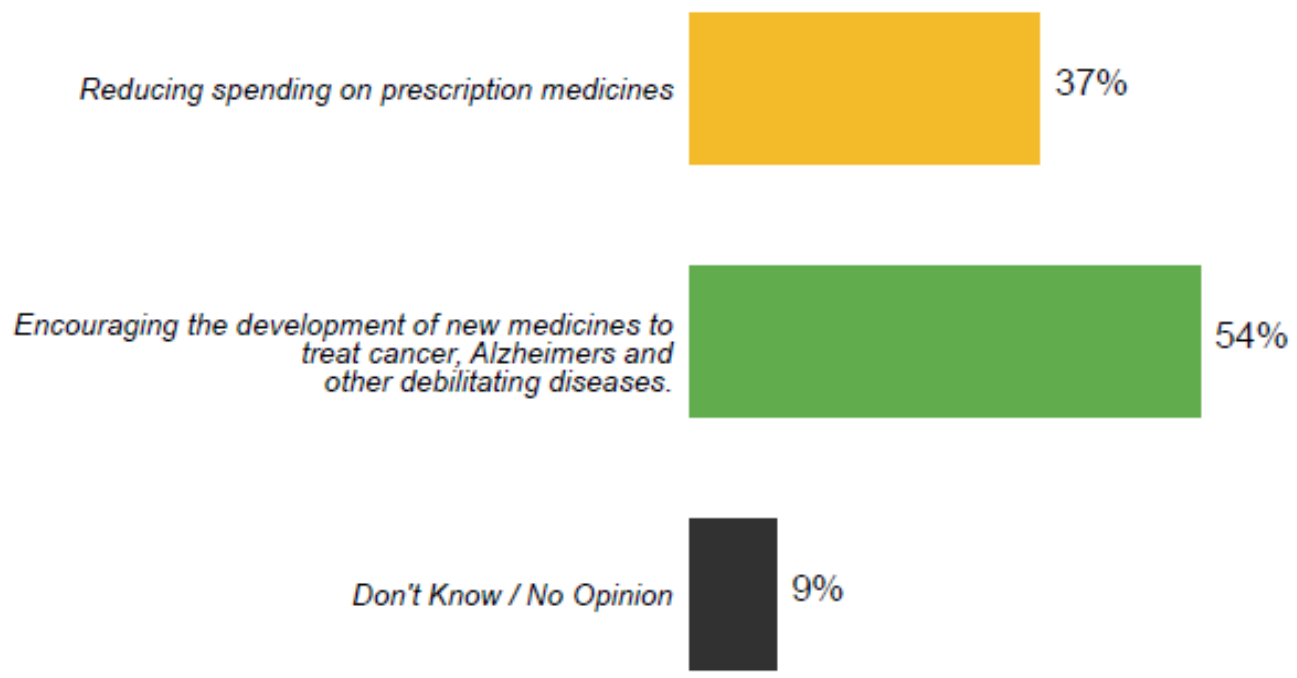
Do you support or oppose allowing the federal government to set the price of prescription medicines?



By Party		
DEM	IND	GOP
51%	34%	23%
36%	52%	65%
13%	14%	12%

Source: Gollaher, David, "Initiatives to Redefine Gilead's HCV and HIV Narratives," Gilead

Which of the following should be more of a priority for the next president and Congress?

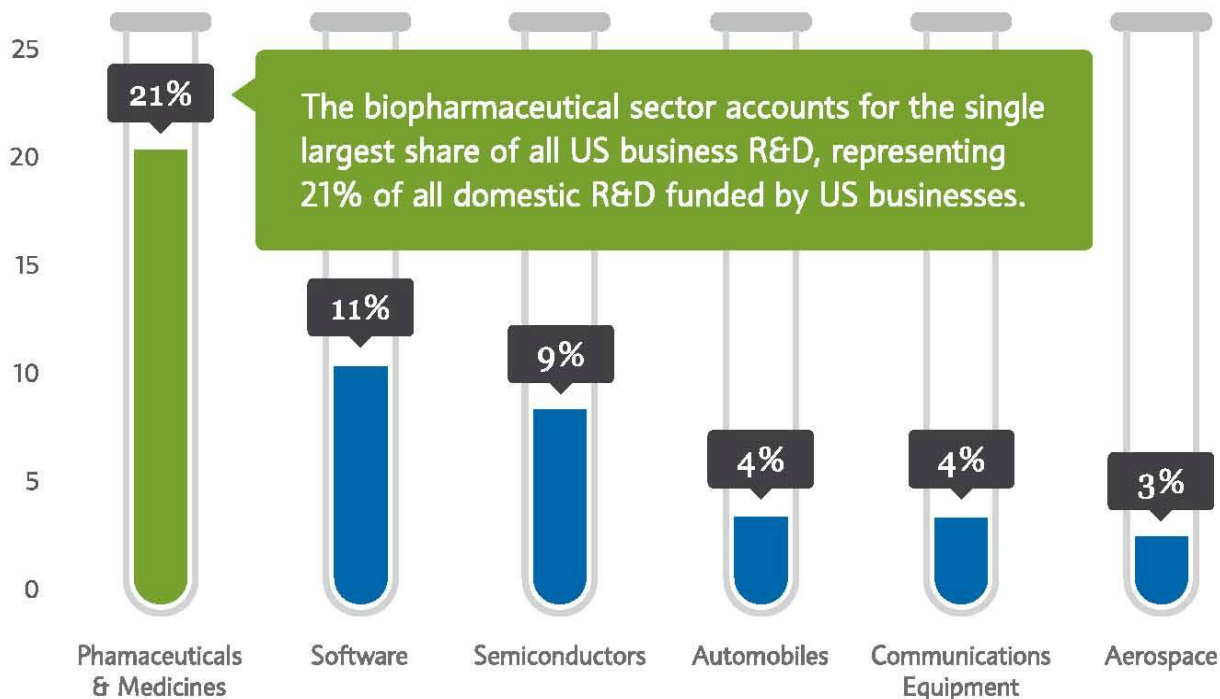


By Party		
DEM	IND	GOP
42%	33%	37%
52%	55%	54%
6%	12%	9%

Source: Gollaher, David, "Initiatives to Redefine Gilead's HCV and HIV Narratives," Gilead

The Biopharmaceutical Sector Is the SINGLE LARGEST FUNDER OF BUSINESS R&D IN THE UNITED STATES

Share of Total US Business R&D by Industry, 2011*



The remaining 48% share of business R&D spending is conducted by other industries including subsectors of the machinery sector, the electrical equipment sector, and the professional, scientific, and technical services sector among others.