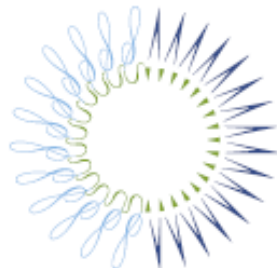


# Specialty Drugs: Managing Costs & Ensuring Access

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# Macro Trends in US Healthcare

- Intensifying need to demonstrate the value of drugs
- Rapid evolution of the healthcare payment & delivery landscape
- Shifting balance of medical decision-making
- Use of Real-World Evidence matures & expands
- ACA being implemented & early impact being assessed

# Rising healthcare costs

Median household income

**\$52,250**

Cost of family's healthcare

**\$22,030**

Employer premium contribution

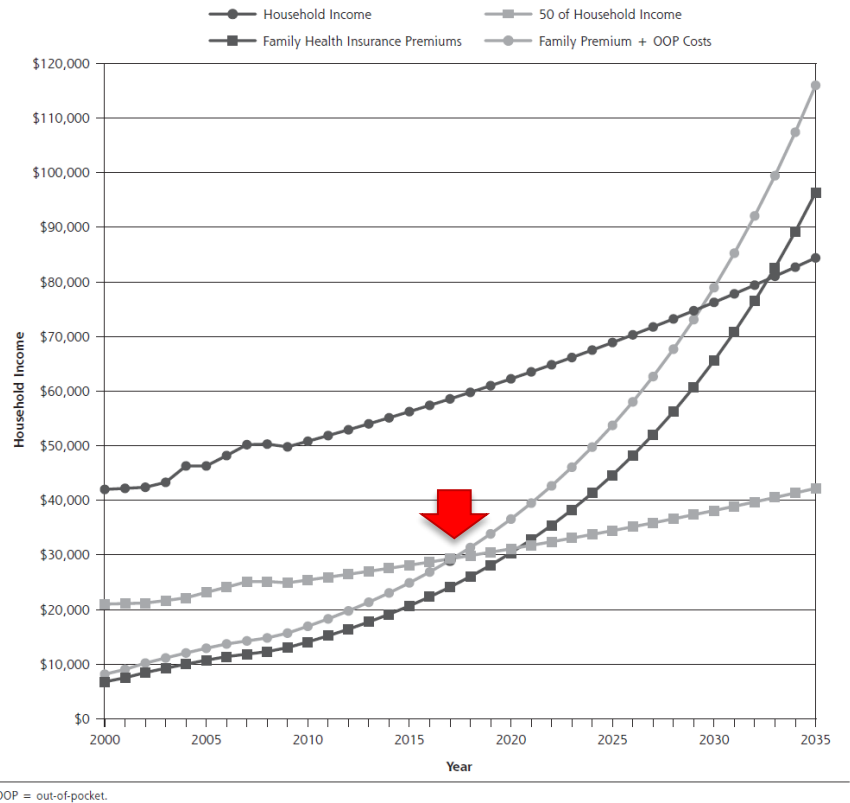
**\$12,866**

Employee premium contribution

**\$5,544**

Employee expenses (e.g. deductible, copays)

**\$3,600**



**In 2 years, premiums and out of pocket health care costs for a family are projected to equal half the median household income**

# Why are pharmaceuticals an issue?

- Drug Spending Increases
  - 13.1% in 2014
- Increasing share of specialty drugs
  - 1% of all prescriptions but 32% of drug spending
  - Est. 50% of prescription drug spending by 2020
- Pipeline drugs heading to market
  - Approximately 700 specialty drugs under development

Sources: IMS (2015), ESI (2011), Milliman (2012)

# Pharmaceutical Costs

- \$374B in pharmaceutical spending in US (2014)
- Public Programs (before rebates):
  - Medicare: \$88B (2016 estimated [CBO])
  - Medicaid: \$36B (2012)

Sources: IMS (2015), OIG (2012)

# Increased Spending on Drugs

## All Drugs

### 2015-2017 TREND FORECAST

	2015	2016	2017
<b>TOTAL OVERALL</b>	<b>6.8%</b>	<b>10.6%</b>	<b>11.2%</b>

## Specialty Drugs

### TREND FORECAST FOR KEY SPECIALTY THERAPY CLASSES

2015 - 2017

THERAPY CLASS	TREND FORECAST*		
	2015	2016	2017
Inflammatory Conditions	21.6%	21.6%	21.1%
Multiple Sclerosis	11.3%	6.5%	3.0%
Oncology	21.6%	20.4%	19.8%
Hepatitis C	66.5%	55.4%	44.3%
HIV	17.3%	16.6%	16.2%
Miscellaneous Specialty Conditions	31.1%	29.7%	28.2%
Growth Deficiency	12.5%	10.4%	10.5%
Hemophilia	3.9%	3.3%	3.4%
Pulmonary Arterial Hypertension	12.5%	12.0%	12.1%
Transplant	-5.8%	-1.3%	0.0%
Hereditary Angioedema	22.5%	24.2%	20.7%
Other Specialty Classes	6.7%	6.7%	6.4%
<b>TOTAL SPECIALTY</b>	<b>22.6%</b>	<b>22.3%</b>	<b>21.3%</b>

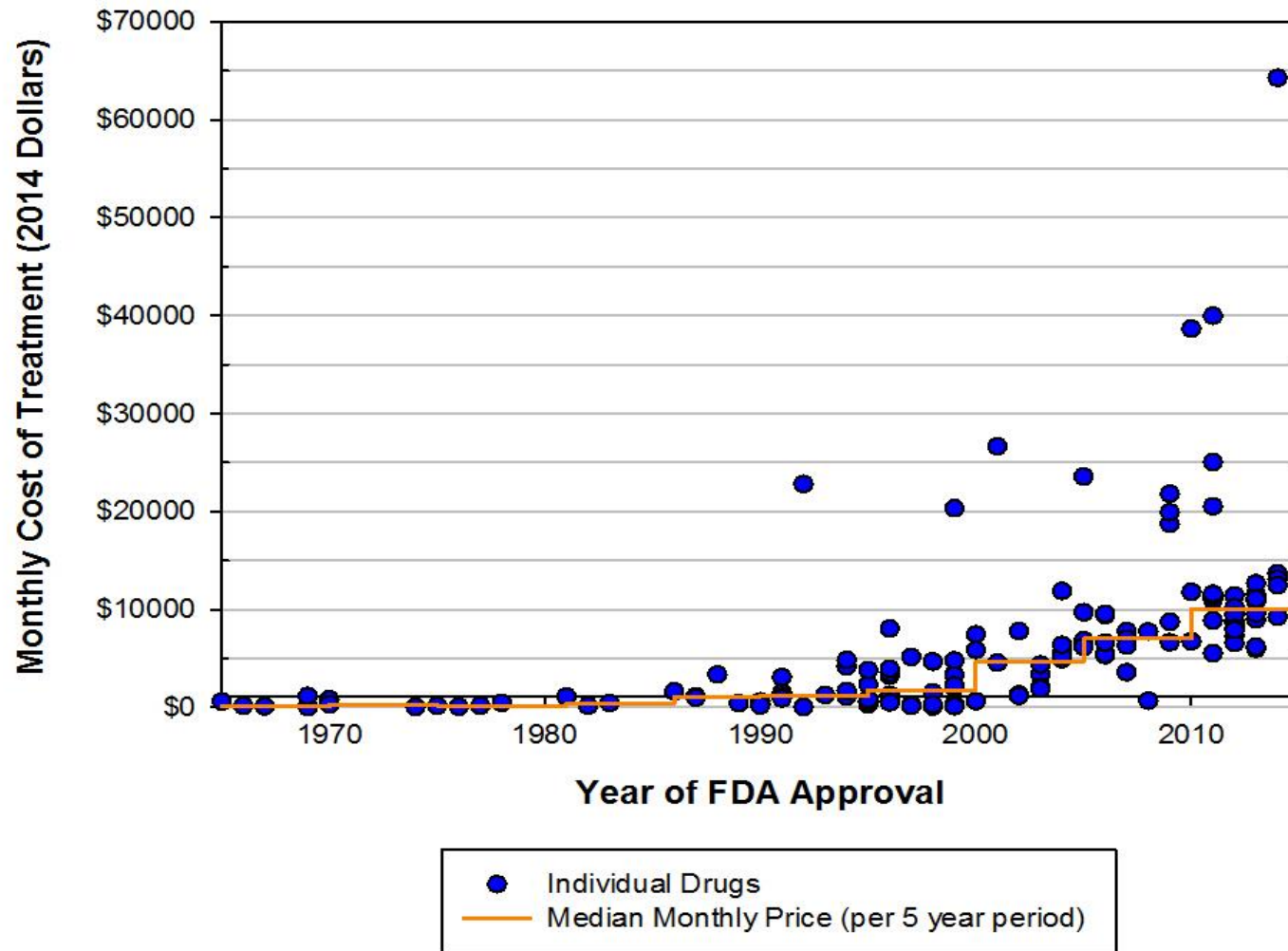
\*Trend is forecast only for specialty medications billed through the pharmacy benefit.

Source: ESI Drug Trend Report(2015)



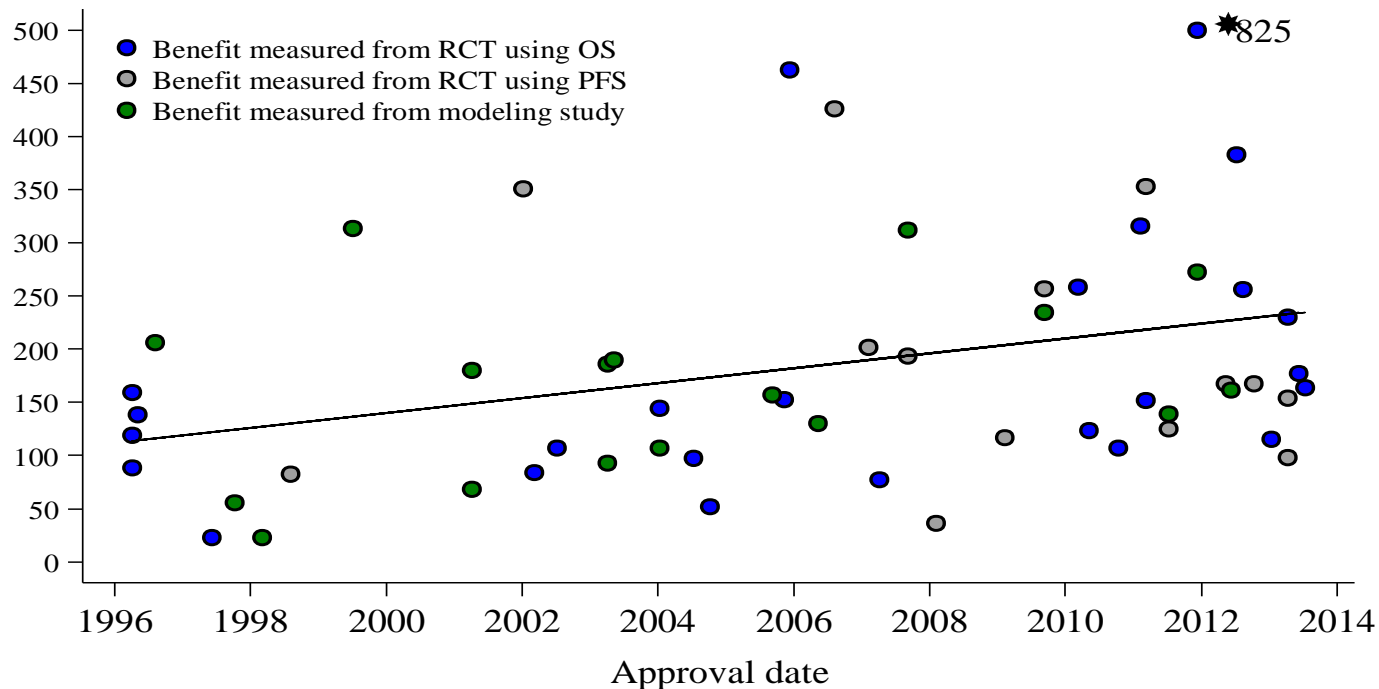
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# Monthly and Median Costs of Cancer Drugs at the Time of FDA Approval 1965-2015



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

Figure 2: Price per year of life gained versus approval date



The best fit line is: Price per year of life gained = \$101,077 + \$7,396 × Approval year.  
 For purposes of display, we re-coded one value from \$825,000 to \$500,000.  
 RCT: randomized controlled trial. OS: Overall survival. PFS: Progression-free survival

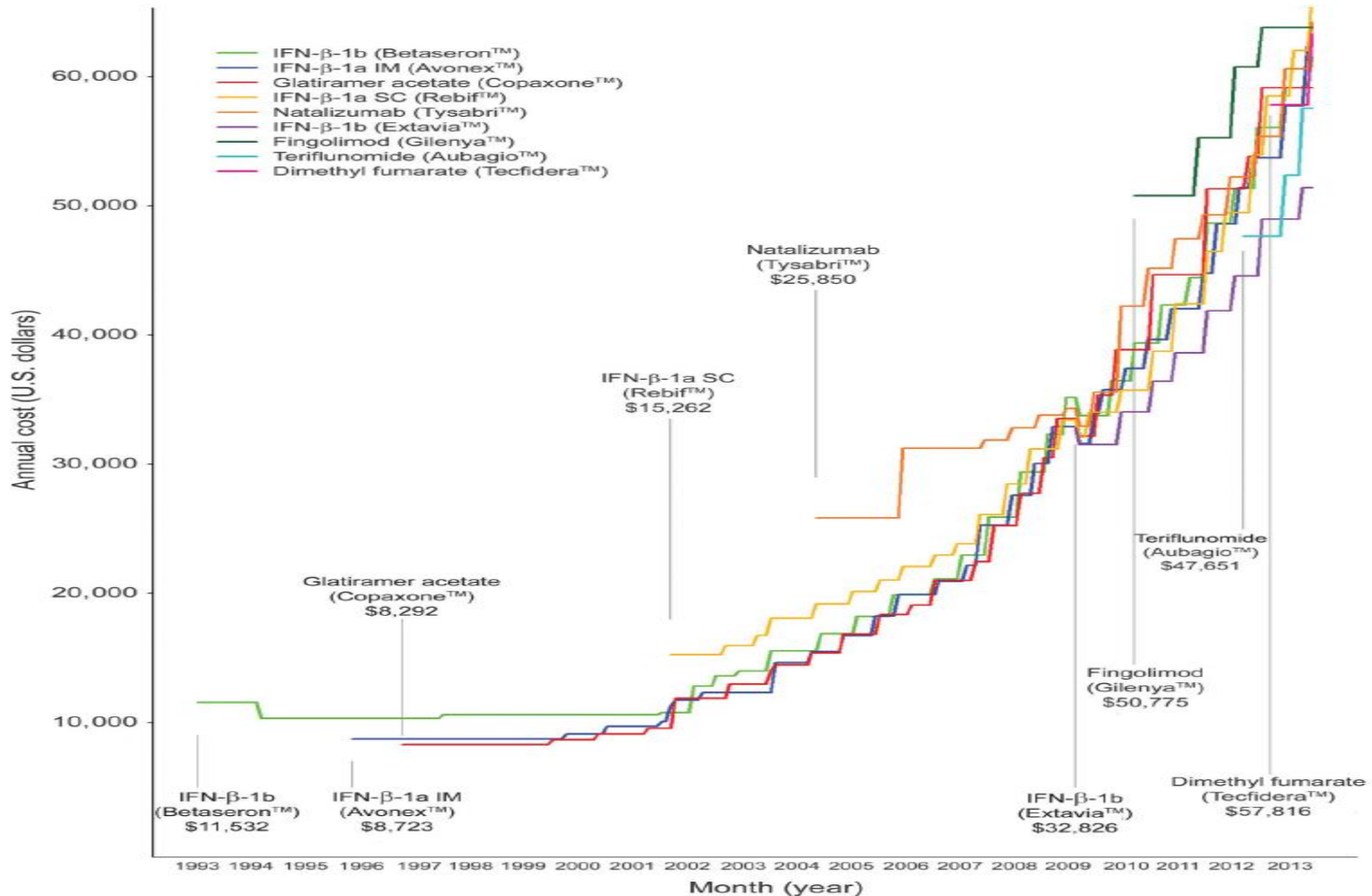
Only 1/5 of increase related to clinical benefits/costs.

In 1995 patients and their insurers paid \$54,100 for a year of life. A decade later, 2005, they paid \$139,100 for the same benefit. By 2013, they paid \$207,000.



# Example: MS Drugs

**Figure 1** Estimated annual costs of multiple sclerosis disease-modifying therapies in the United States from 1993 to 2013

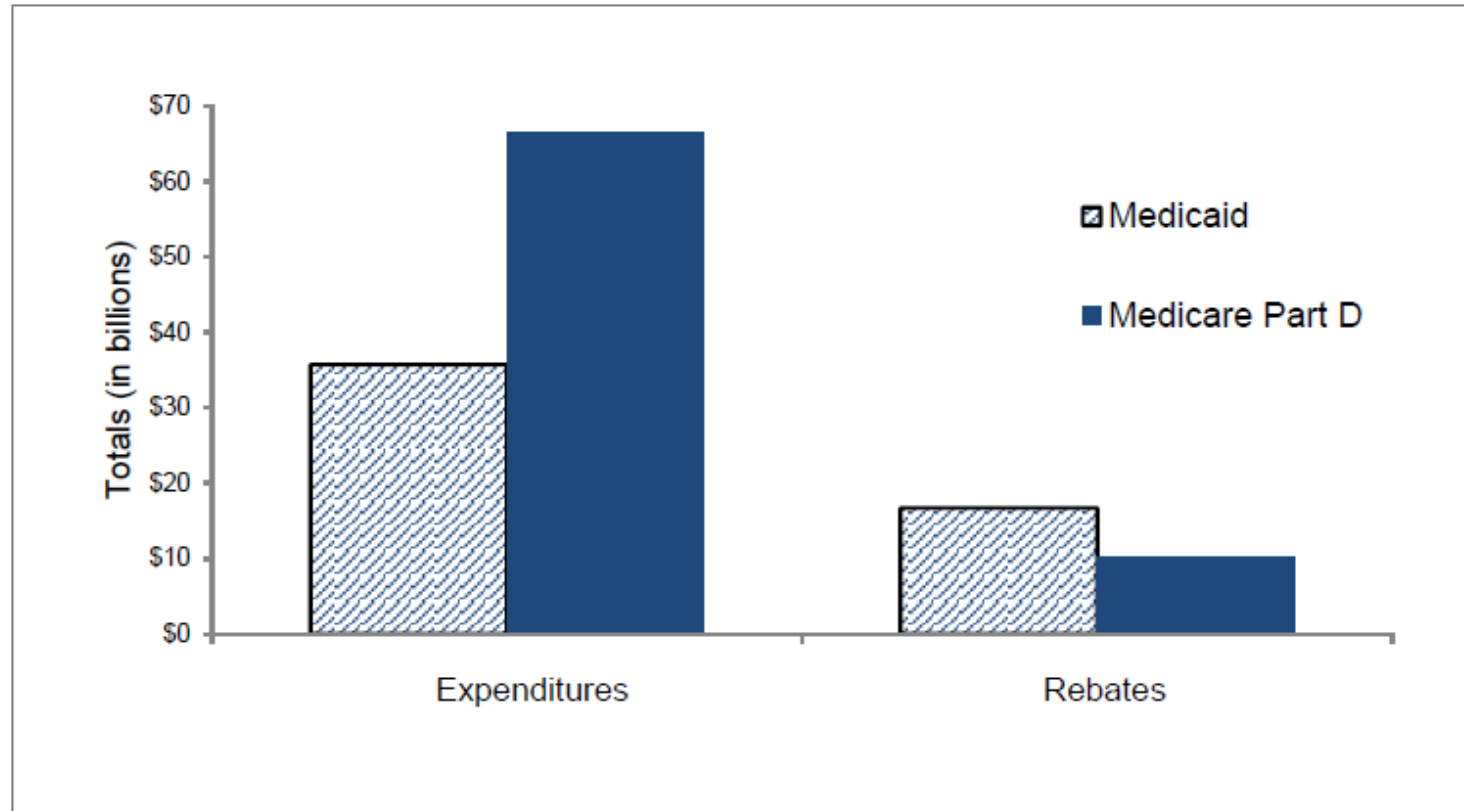


Annual costs estimated from average wholesale prices (AWP), or wholesale acquisition costs if AWP not reported, and discounted 12%. IFN = interferon.

Source: Hartung (2015)

# Rebates for Brand Name Drugs

Figure 1. Medicaid and Medicare Part D Drug Expenditures and Rebates



Sources: OIG analysis of 2012 MBES data, 2012 State Medicaid utilization and rebate data, the *2013 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds*, and 2012 Part D DIR reports

# Potential Health Policy Objectives

- Ensure patient access to the medically appropriate drugs that they need
- Pay for drugs based on the outcomes achieved and their value (informed by evidence)
- Responsibly manage spending in public programs (considering affordability)
- Maintain incentives for innovation

# Approaches being discussed

- Transparency
- Comparative Effectiveness Research
- Utilization Management (& other coverage restrictions)
- New Financing Models
- Others...

# Unanswered Questions

- What is “value” and how do we measure it?
- How do we incorporate considerations of “value” into policy?
- How much are we willing to pay?

# Thank you!

- Questions?
- Comments?
- Insights?

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