A Brief History of Drug Pricing

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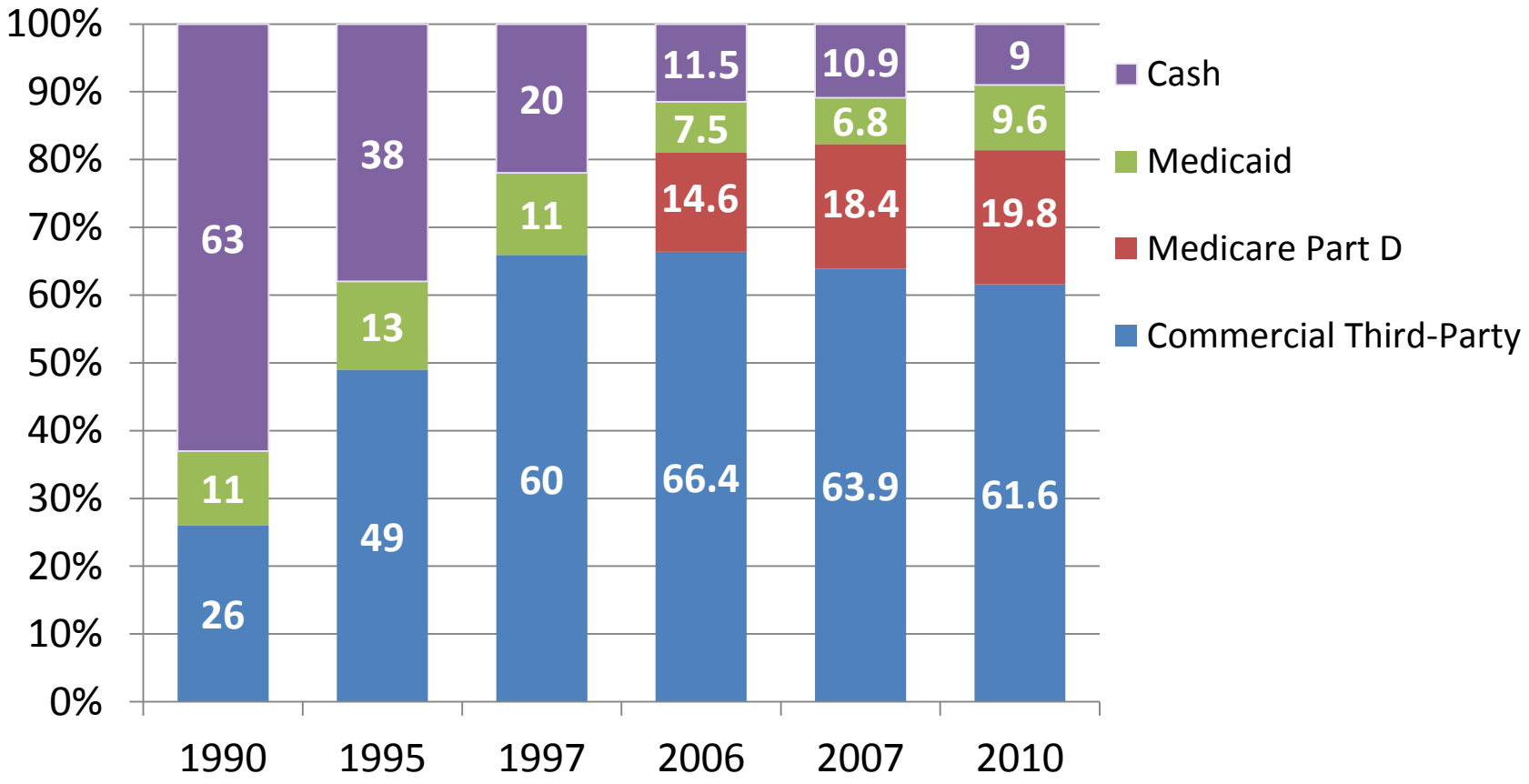
How a Market is Supposed to Work

- Sellers sell for as much as they can, leveraging their market power
  - Measured by optionality vs indispensability, often translated as price elasticity
- Buyers buy for as little as they can, leveraging their market power
  - The measure of this is the ability to walk from the table, by saying “no” and having an alternative
- Hopefully, through a process of competition, prices are determined based on common benefits to the buyer(s) and seller(s)
- The process of competition is protected by law to prevent anticompetitive competitive conduct and to avoid the development of monopolies and monopsonies

Who Pays for Drugs?



Sources: IMS Health Retail Method-of-Payment Report, 1999 as cited in Report to the President, "Prescription Drug Coverage, Spending, Utilization and Prices," Office of the Assistant Secretary for Planning and Evaluation, HHS, April 2000; IMS Health National Prescription Drug Audit 2010; Medicine use and shifting costs of healthcare: A review of the use of medicines in the United States in 2013, IMS Institute for Healthcare Informatics, April 2014, p 48

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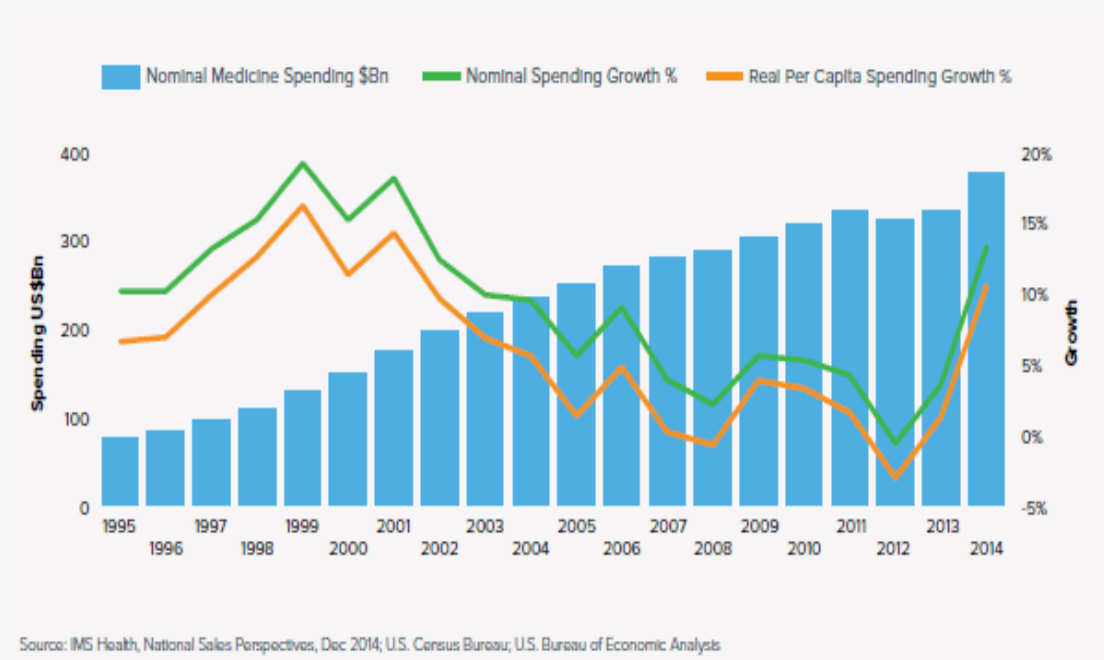
How the Pharmaceutical Market Works

- The law provides monopoly protection for sellers, both in terms of patents and other forms of market exclusivity (for a variety of reasons)
- "Buyers" are divided into ultimate consumers (patients), selecting intermediaries (prescribers), distributors (pharmacies) and payers (public and private coverage)
- Public and private third party payment is now predominant, and the product selectors (physicians) are often anti-price sensitive
- For three decades, buyers (public and private third party payers) have had their bargaining power systematically undermined by policy
- Alternative approaches by organized systems are also undermined by policy

What Led to a Spike in Spending in 2014?

Spending on medicines increased 13.1% in 2014, the highest level since 2001 when spending growth reached 17.0%

Medicine Spending & Growth 1995-2014



Source: Medicines Use and Spending Shifts, Report by the IMS Institute for Healthcare Informatics 2014

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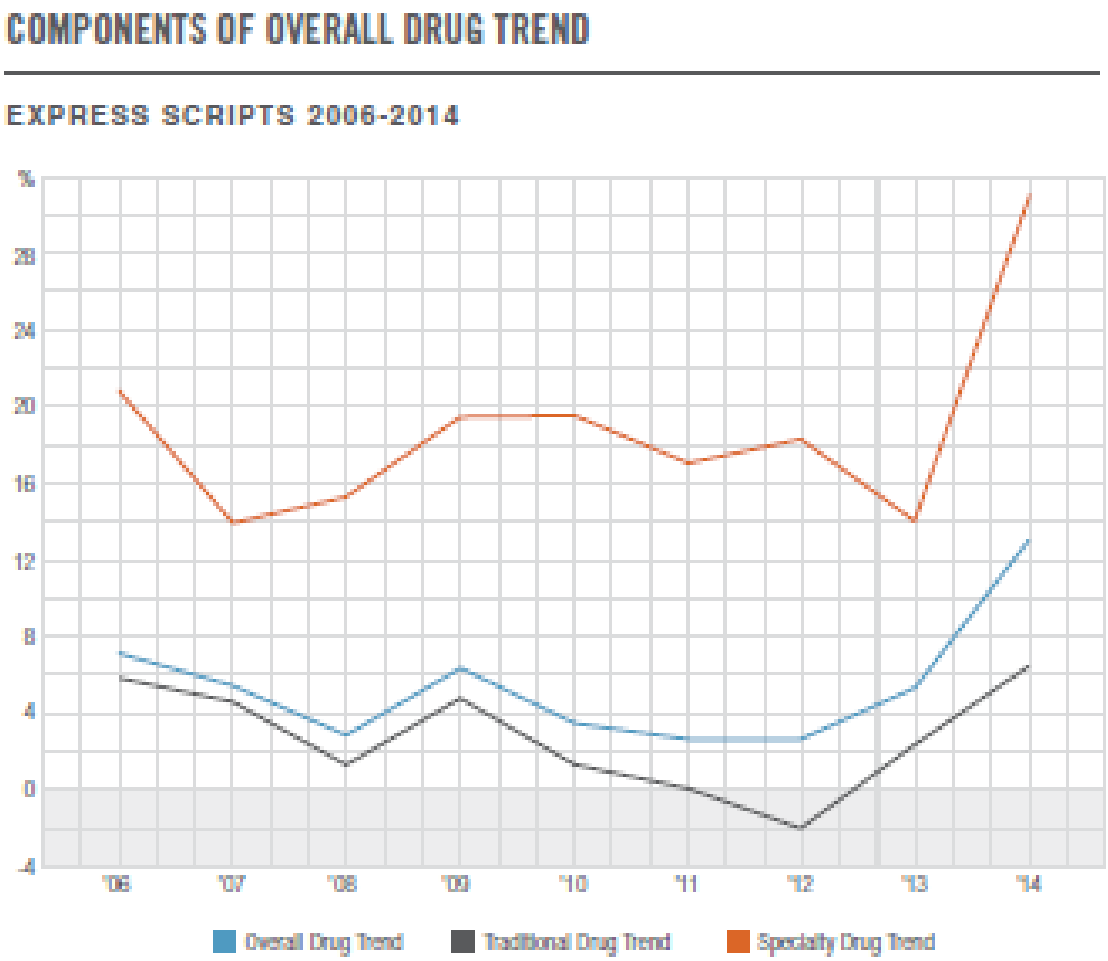
The Trend



Source: Express Scripts 2014 Drug Trend Report Executive Summary, p 2

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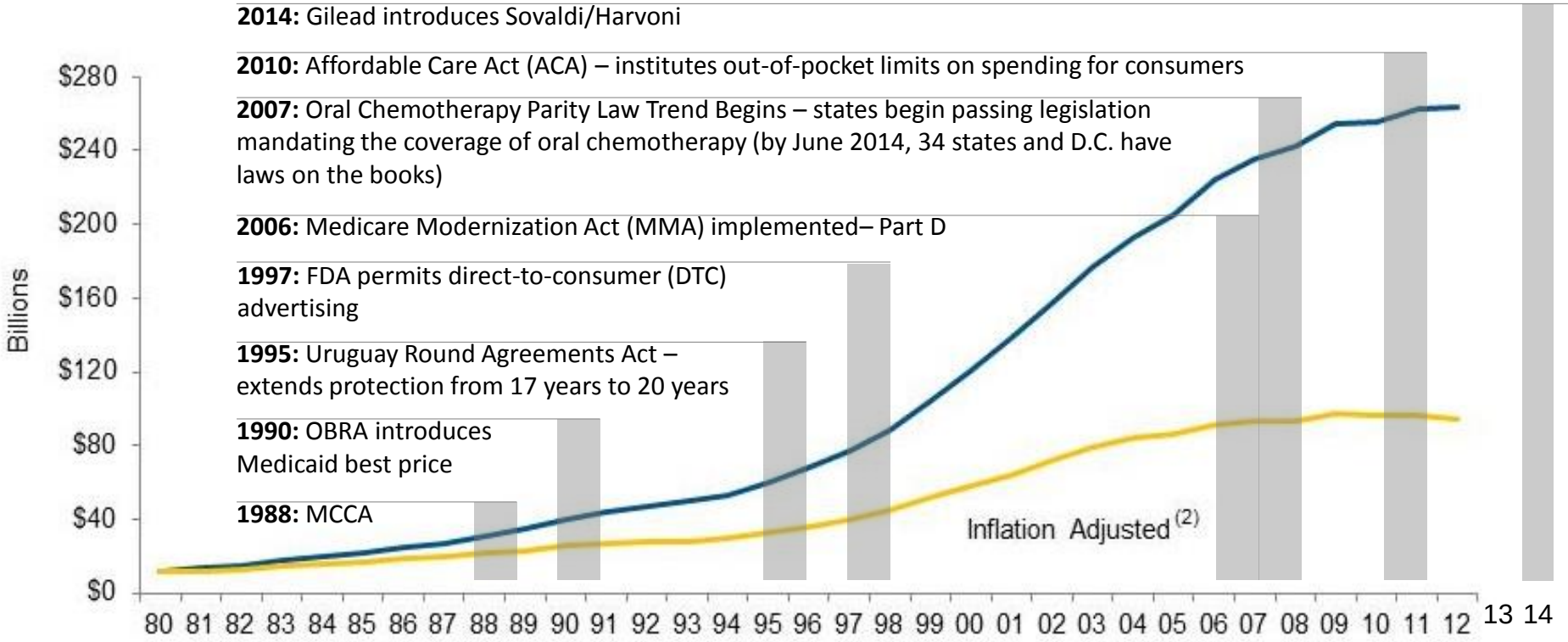
How We Got Here

- 1988: Medicare Catastrophic Coverage Act (MCCA) – drug industry awakens
- 1990: Omnibus Budget Reconciliation Act (OBRA 90) – establishes Medicaid best price, killing off discounting
- 1995: Uruguay Round Agreements Act – extends protection from 17 years to 20 years from date of first filing of patent application
- 1997: FDA permits direct-to-consumer (DTC) advertising
- 2003: Medicare Modernization Act (MMA) – adds Part D to Medicare, non-interference provision, formulary regulation
- 2007: Oral Chemotherapy Parity Law Trend Begins – states begin passing legislation mandating the coverage of oral chemotherapy (by June 2014, 34 states and D.C. have laws on the books)
- 2010: Affordable Care Act (ACA) – institutes out-of-pocket limits on spending for consumers
- 2014: Gilead introduces Sovaldi/Harvoni

Reminder

Chart 1.10: Total Prescription Drug Spending, 1980 – 2012(1)



Source: Centers for Medicare & Medicaid Services, Office of the Actuary. Data released January 7, 2014.

(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.

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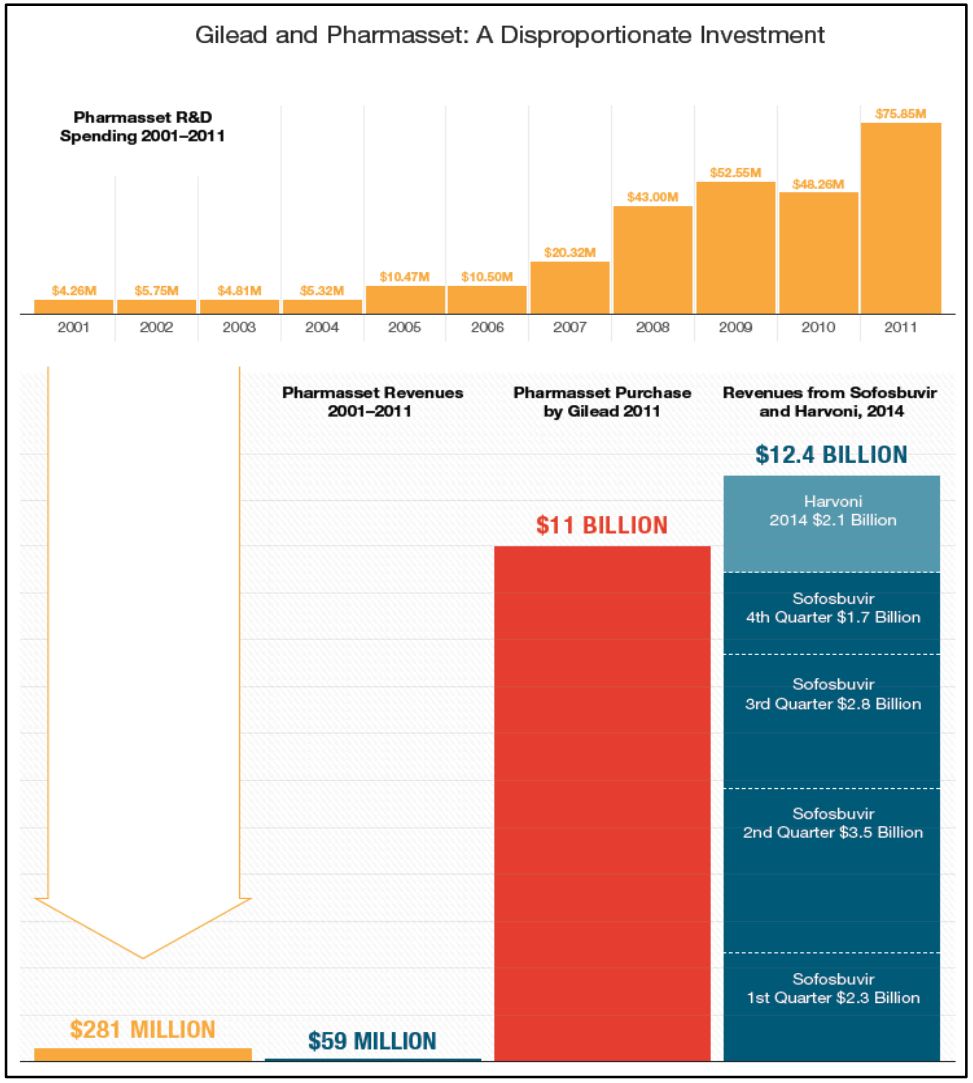
2014 Sales of Sofosbuvir Exceed Gilead's Purchase of Pharmasset



Source: amfAR February 2015 issue brief -- Hepatitis C and Drug Pricing: The Need for a Better Balance

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Realities: Some Math

$94,500 Harvoni List Price

-46% average discount (source: NYTimes)

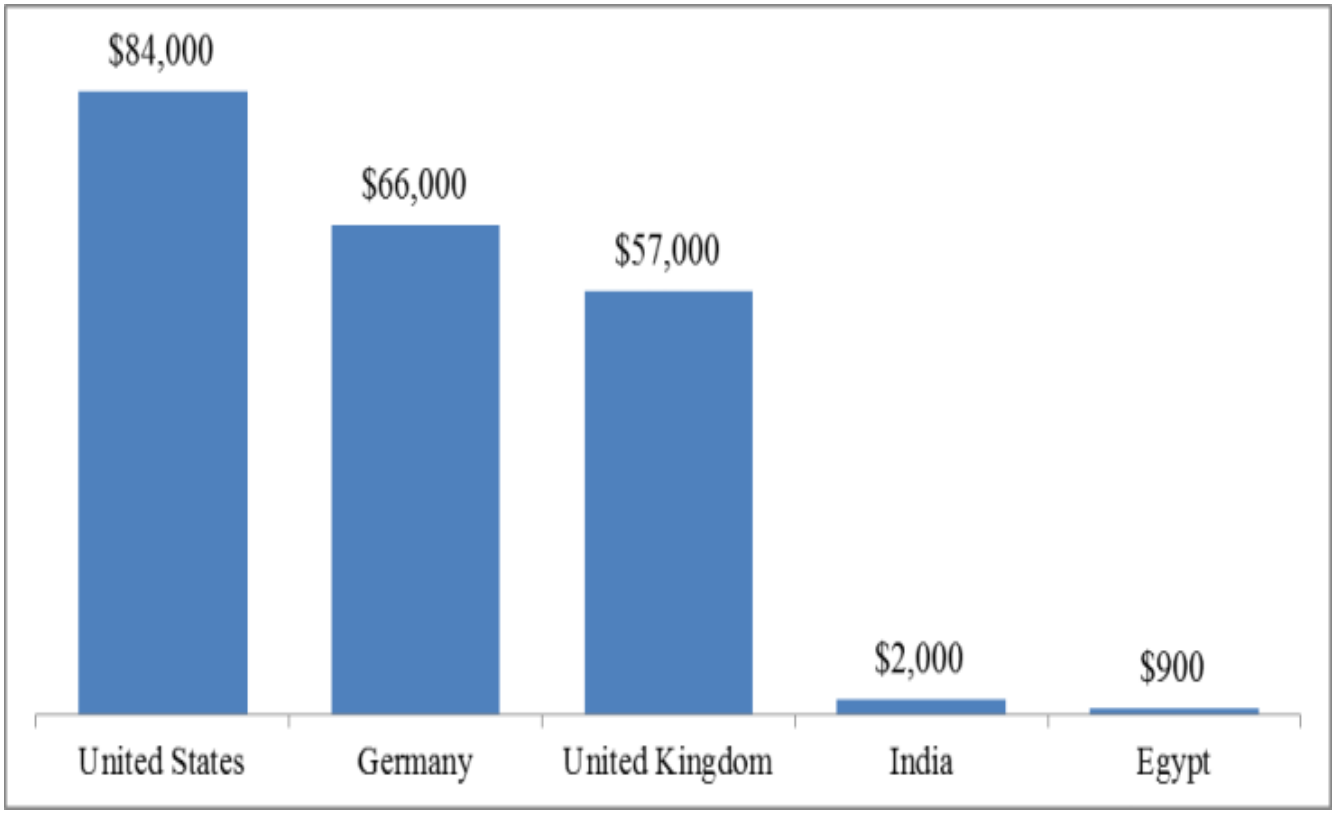
$51,030

X 100,000 KP Members (51K diagnosed)

$5.1 Billion

Total 2014 Pharmacy Spend for KP: $4 Billion

Sovaldi's pricing disparities



Source: AARP.org and B. Berkrot and D. Beasley, "U.S. lawmakers want Gilead to explain Sovaldi's hefty price," Reuters, March 21, 2014.

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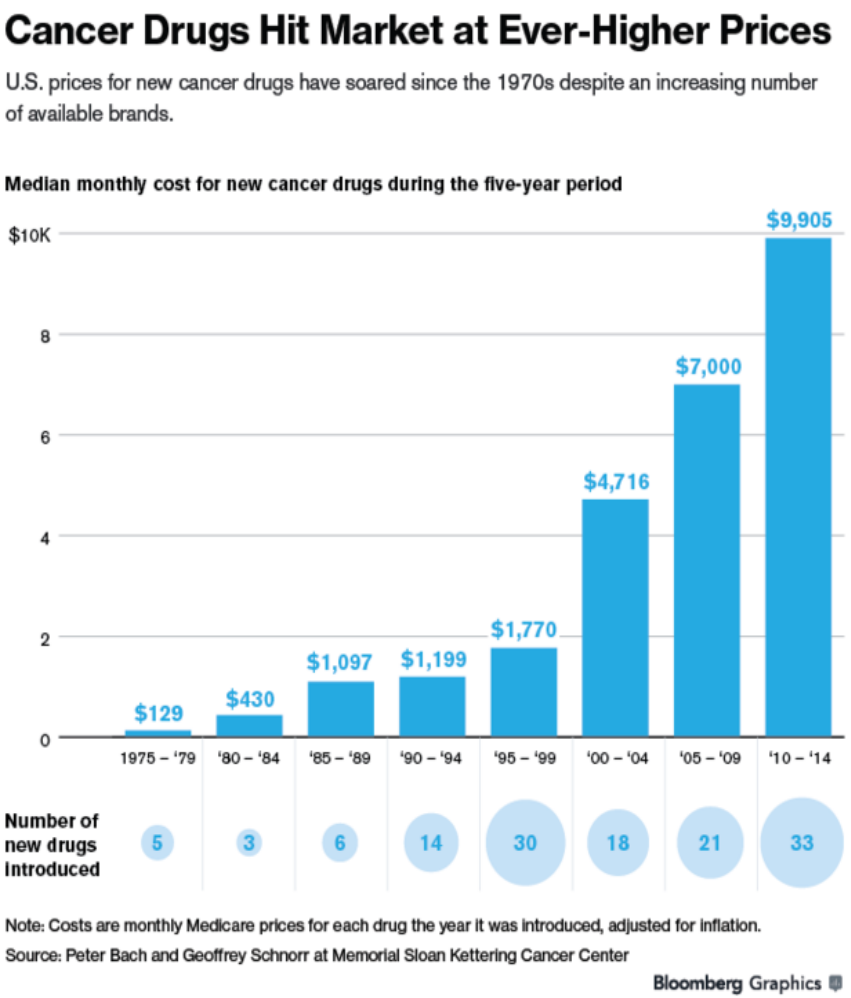
Reminder: It's Not Just Hep C Drugs



- Out 58 cancer drugs approved by the FDA between 1995 and 2013, launch prices increased by 10% a year, or about $8,500.
- The FDA approved 12 cancer drugs in 2012. Eleven of them were priced at $100,000 per year.
- The price of cancer drugs on the market for years are also increasing at dizzying rates.
- Imatinib was $30,000 a year when it was approved in 2001 – it now costs over $92,000 per year.
- Cancer drug prices doubled within the last decade, from an average of $5,000 per month to $10,000 per month.

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Challenge

- Public and private conversations on the issue tend to veer towards "managing" the problem of the cost – by calling for more clinical evidence, creating new regulations around how to manage care for patients, how to help patients with co-insurance costs, etc.

- This problem cannot be solved by:
  - Withholding clinically appropriate treatments
  - More research
  - Eliminating cost sharing

- The pricing stands in the way of achieving the public health benefits that these drugs promise.

Moving Past False Choices

Often, this conversation is about a false choice: without protection of market dominance and resulting high profit levels, innovation dies.

We think that dialogue needs to change.

There's 3 Key Questions We're Asking:

1. Is the problem of drug pricing best discussed as a public health or insurance coverage problem?

2. Who decides the meaning of value? Payers or manufacturers? Society?

3. Is it time for a new social contract when it comes to patent rights and market exclusivity?

Summary

- Drug prices are increasing at an unsustainable rate without any sign of abating.
- Pharmaceutical market competitiveness has been systematically undermined for three decades.
- The most robust debate today is about completing the job of insulating consumers from drug prices – which will further facilitate price gouging.
- Americans are paying the most for drugs, yet facing the most significant obstacles to access.
- Laws that reinforce the status quo must be changed so that a competitive market with affordable pricing can be restored.