A Payor and Provider's Perspective on Drug Pricing

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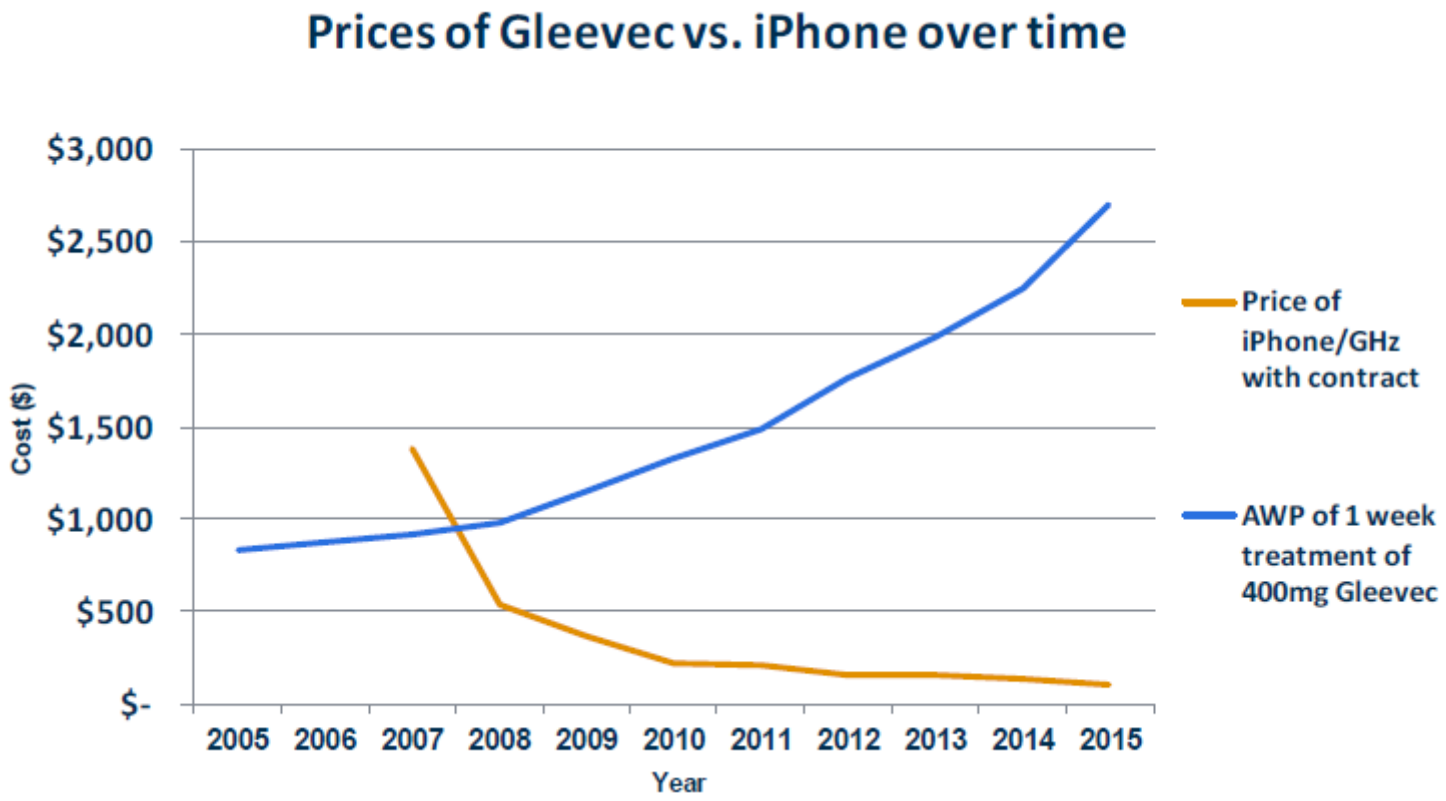
On Innovation



Source: Peter Bach, Memorial Sloan Kettering Cancer Center

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About Kaiser Permanente

- Kaiser Permanente: recognized as one of America's leading health care organizations
- Integrated delivery system and financing scheme: 8 self-governed, self-managed Permanente Medical Groups; not-for-profit community hospitals; and not-for-profit Health Plan, founded 1945
- Our mission: to provide high-quality, affordable health care services and to improve the health of our members and the communities we serve
- Almost 11 million Health Plan members, 8 million in California
- Located in California, Colorado, Georgia, Hawaii, Maryland, Oregon, Virginia and Washington and the District of Columbia

Kaiser Permanente Pharmacy

Kaiser Permanente Pharmacy

Our pharmacists and staff are often the last interaction and serve as a primary point of contact for members throughout the care delivery process

Outpatient	Inpatient	Clinic Administered Medications
72.8 Million[1] Prescriptions Filled [$5.4B]	**38 Million**[2] Doses Administered [$0.5B]	**10.6 Million**[2] Doses Administered [$1.6B]

$5.8 billion in annual drug expense[3]

$1.7 billion in annual dispensing cost[3]

Our Member Reach

510 KP Pharmacy Patient Sites[4]

- **378** Outpatient and **38** Inpatient Pharmacies
- \+
- **72** Clinic Administered Sites
  Oncology, Outpatient Infusion, & Specialty
- \+
- **22** Call Center and Central Fill Operations

Employing **13,234** KP Pharmacy Staff Members[5]

~138,000 + Daily Member Interactions[6]

One of the highest volume and most frequent member touch points across our Kaiser Permanente network

Source: (1) KP Pharmacy Outpatient Prescription Volume, 2013; (2) National Pharmacy Acute & Transitional Care Services Leadership & Regional Operations Teams; (3) Total KP Pharmacy Drug Expense and Dispensing Costs 2014 (National Pharmacy Finance); (4) KP Pharmacy Facilities Count; (5) KP Pharmacy Employee Count – People Soft, February 2015; (6) Total KP Pharmacy Estimated Daily Member Interaction, 2014 Note: See "02_Reference Materials_KP Pharmacy Strategic Plan" additional information and source content

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KP: How It Works

- **Physicians prescribe, pharmacists dispense, and insurer pays for drugs - within an integrated care delivery system**
- **Patients "relatively" insulated from cost (based on benefit design), stimulated (by DTC) to seek high margin, heavily advertised drugs**
- **Physicians insulated from industry: self-imposed restricted access to industry reps; instead close links with pharmacists**
- **Incentives aligned**
  - Physicians practice together, with a common formulary: **created by clinician experts, supported by PhD pharmacists**
  - Clinical decisions drive contracting, not the reverse
- **Availability of comparative data**
  - Significant resources invested in Drug Information Services, academic detailing and pharmacoeconomic research
  - Results available at point of prescribing in EHR

Negotiating on Price: when we can

- **Effecting market share, not "volume discounts"**
  - Ability to say "no", walk away is essential
- **Limited impact with sole–source drugs, without close competitors**
  - Opportunity with 3 or more competitor drugs
  - Prescriber alignment, clinical discipline
  - Commitment, not compliance

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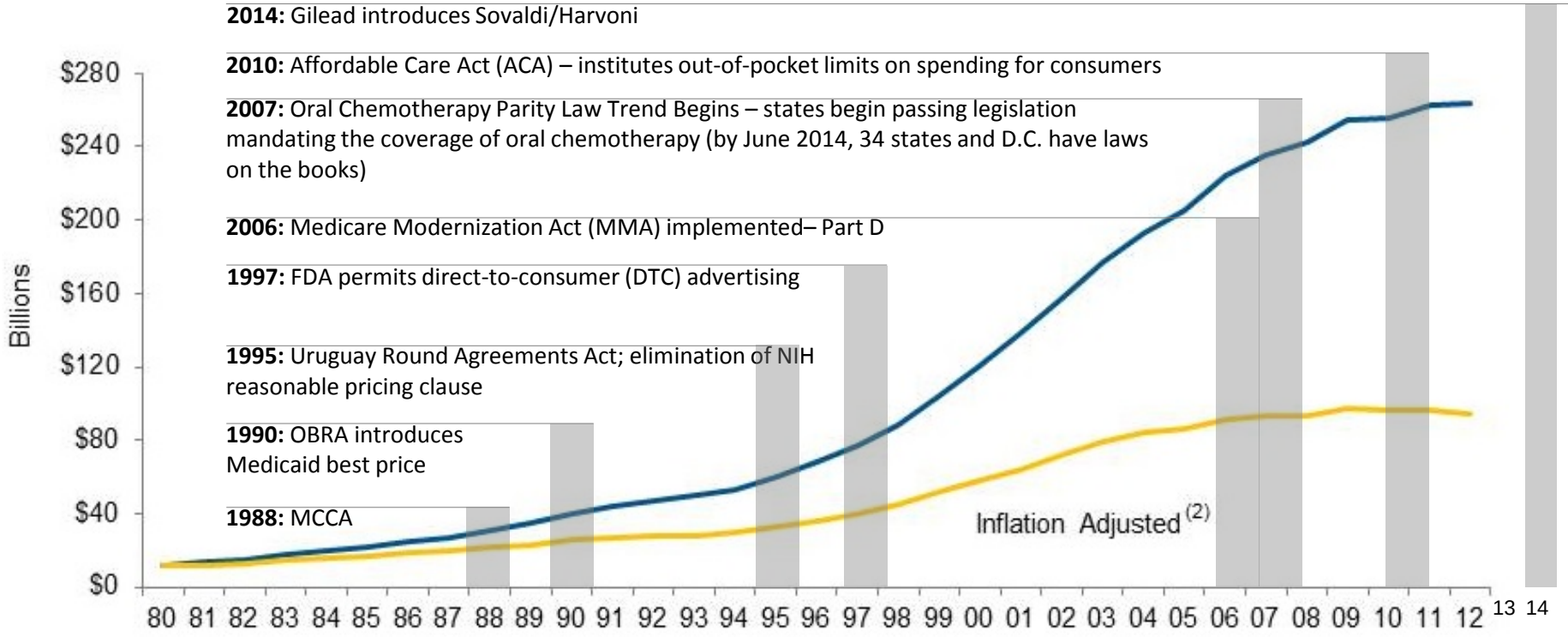
A Tale of 3 Drugs, 3 Facets of the Problem

- Gleevec (imatinib)
  - Novartis novel oral cancer drug, introduced 2001: year over year price inflation on existing therapy
- Colcrys (colchicine)
  - Treatment for gout used for >200 years; available as multi-source generic until 2010: NDA filed, competitor generics forced to leave the market, 100X price inflation overnight
- Sovaldi, Harvoni (ledipasvir), VieraPak
  - Gilead Sciences' and AbbVie Hepatitis C treatments, novel therapies, highly effective : launch price "because we can"..

Law: How We Got Here

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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Detail

- 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; elimination of NIH reasonable pricing clause
- 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

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

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), distributing intermediaries (PBMs), distributors (pharmacies) and payers (public and private coverage)
- Public and private third party payment is now predominant, and the product selectors (physicians) are often not 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

Policy Challenges

- Public and private conversations until recently **accept the price as a given**, focus on "managing" the cost – e.g. more clinical evidence; guidance for "staging treatment" based on severity of illness for Hepatitis C patients; help for patients with cost sharing; long term financing of short term expense (think, "mortgage" for your Hep C Tx)
- Little consideration of public health implications: Hep C a potentially eradicable communicable disease; distortion of state public health priorities
- Avoid the "third rail" of policy: administered pricing/price regulation

But

- There is no “free market” for prescription drugs.
  - Legal and regulatory framework creates market that disadvantages all payers – public and private, individual and group
  - Drugs insulated from market forces: “insurance effect”; government-granted monopolies, exclusivity, trade agreements
  - Shadow pricing of competitor products
- Unsustainable –growing demand for health system affordability, accountability.
  - Drug prices put vital therapies out of reach for patients, strain family, public and private budgets.

And

- All parties, including manufacturers, must be accountable for their role in driving costs up for consumers.
  - Calls for manufacturer transparency in their pricing models
  - Balance among public health, health of individuals and a fair return on investment that doesn't bankrupt society
  - Need for multi-stakeholder agreement on definition of "**value**".

What Hasn't Worked/Won't Work

- Shaming
- Self-regulation
- Congressional hearings
- Creating new expansions of "most favored nation" pricing – e.g. Medicare **and** Medicaid "best price"
- Capping consumer cost sharing – expense shifts to premiums
- Reimportation: US consumes 48% of global Rx drug supply
- Blaming the insurance industry
  - "if insurers were as innovative as we are, their Plans would protect consumers from (our) outrageous drug prices"

What's Needed

- Public awareness -
- Transparency
  - Legislation in the states
  - Obama 2017 budget proposal: "Establishing Transparency and Reporting Requirements in Pharmaceutical Drug Pricing"
- ? A different revenue model
- ? Role for Medicare in changing the way it pays for drugs
- ? Value- or outcomes-based payment models; requires multi-stakeholder definition of "value", and disciplined enforcement of post-market surveillance requirements

What's Needed?

- Re-examine FDA Charter, funding sources: "untie the FDA's hands"
- View trade agreements re impact on US consumer access to Rx drugs/devices
- Re-examine current patent law/exclusivity grants, starting with grants of additional exclusivity for "orphan drugs"
- Congressional action, not just hearings
- Campaign finance reform

In summary

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- **As a provider of care we appreciate and increasingly depend upon the clinical value delivered by prescription drugs; yet we experience every day the impact that drug prices have on our patients and members and the threat they pose to affordability and accessibility.**
- **As a payor, we see drug pricing as an aberration in a health care system which is otherwise committed to transforming itself to ensure affordability, and undergoing changes to pay for results and outcomes.**
- **The U.S. market is the most extreme, but we see the effects of the pricing globally.**