What Can be Done to Stem the Rising Cost of Pharmaceuticals?

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Your Money or Your Life

Pyrimethamine

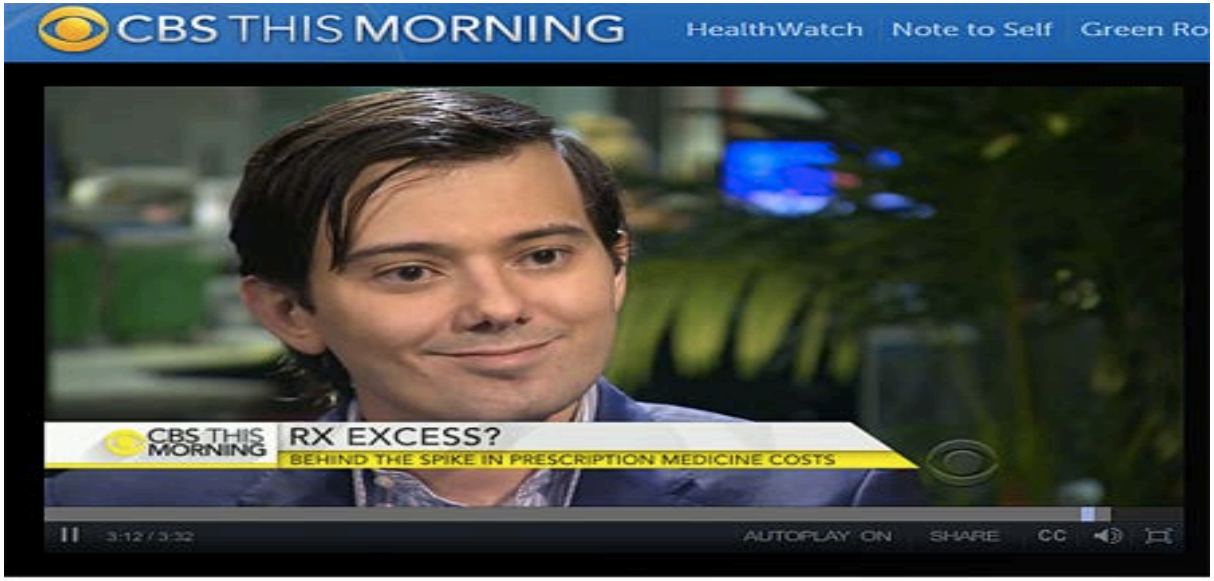
- Available since 1953
- Nobel Prize Medicine – Nucleic acid metabolism -> Discovery
- Worldwide distribution
- On the WHO essential medicines list
- Indications:
  - Prevention and treatment of malaria
  - Toxoplasma Gondii infection (HIV+ patients)
- No patent, single supplier in the US.

Pyrimethamine

- Price:
  - 12+ manufacturers in India ($0.04 to $0.10 per tablet)
  - Brazil - $0.02 per tablet
  - GSK provides the medication in the UK for $20 per 30-day supply ($0.66 per tablet)
  - GSK supplied the drug in the US at a price per tablet of $1.00 in 2002.
  - In 2010, GSK sold rights to market the drug in the US to CorePharma.
  - In 2014, CorePharma supplied the drug at $13.00 per tablet and generated ~$10,000,000 in sales.

Martin Shkreli – CEO, Turing

$13.50 to $750.00 per tablet



CBS NEWS / *September 22, 2015, 7:21 AM*

CEO: 5,000-percent drug price hike "not excessive at all"

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When Turing Pharmaceuticals bought the 62-year-old drug called Daraprim in August, the company immediately raised the price of one pill from $13.50 to $750.

$660 for epinephrine

Mylan's EpiPen price increases are Valeant-like in size, Shkreli-like in approach

Published: Aug 18, 2016 2:27 p.m. ET

EpiPen price rose more than sixfold in the last several years

US Rx Market

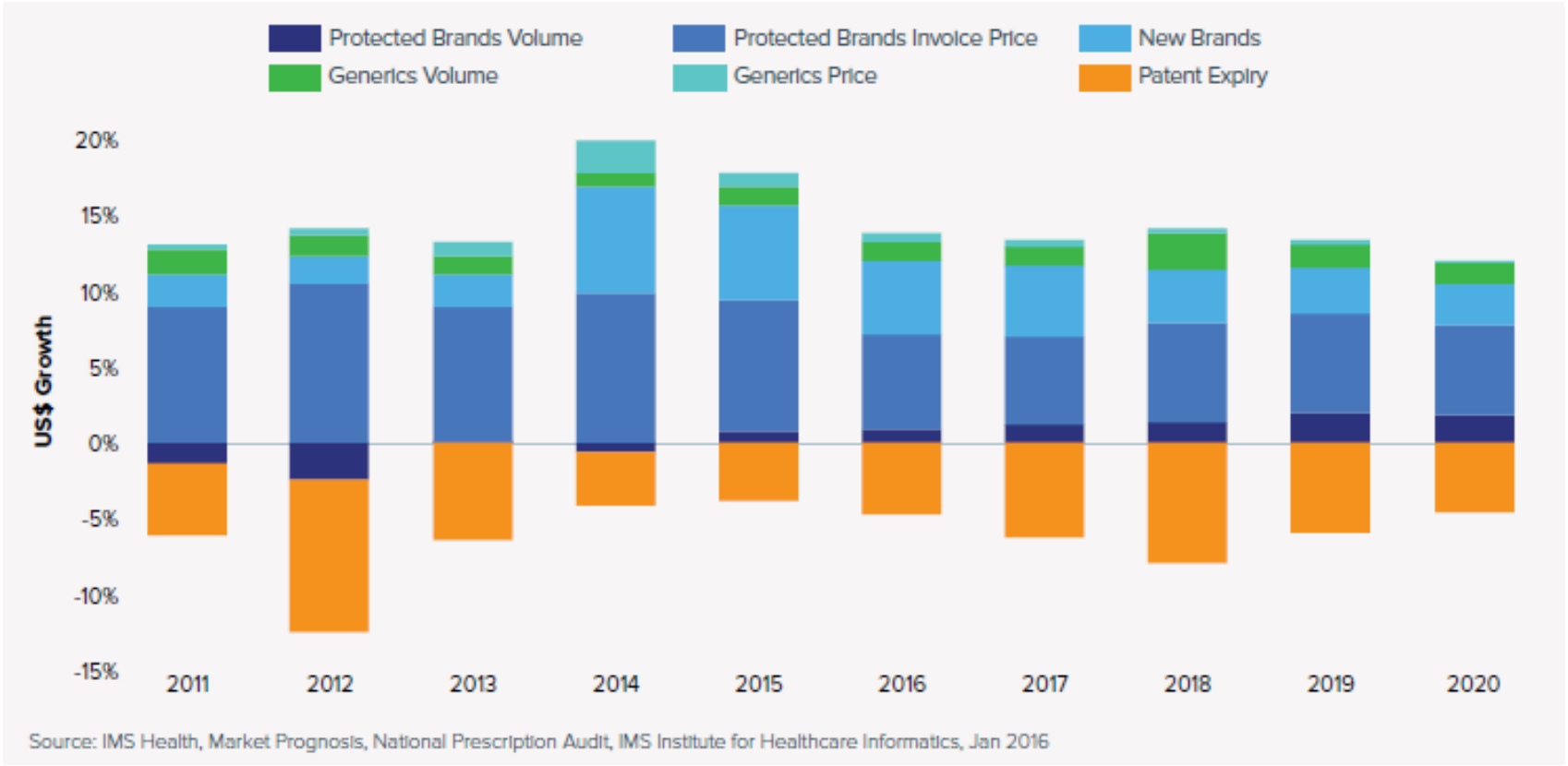
- $424.8 Billion (2015) – On an invoice (list price) basis – 12.5% above 2014
- The US is 50% of the global market by expenditures.
- 1% of prescriptions account for 25% of total sales.
- 80% of dispensed medications are generic – some no longer multi-source.
- Large, multinational firms.

US Rx Market

- An expensive and extensive development and regulatory approval process.
  - High failure rates, even at late stage of development
- An industrial policy/environment that encourages and rewards innovation.
  - 20 year patent granting an effective monopoly position
  - The last free-pricing environment
  - No federal sector price negotiation

US Rx Spending Growth (2010-2020est)

Chart 30: U.S. Spending Growth 2010–2020 US$Bn

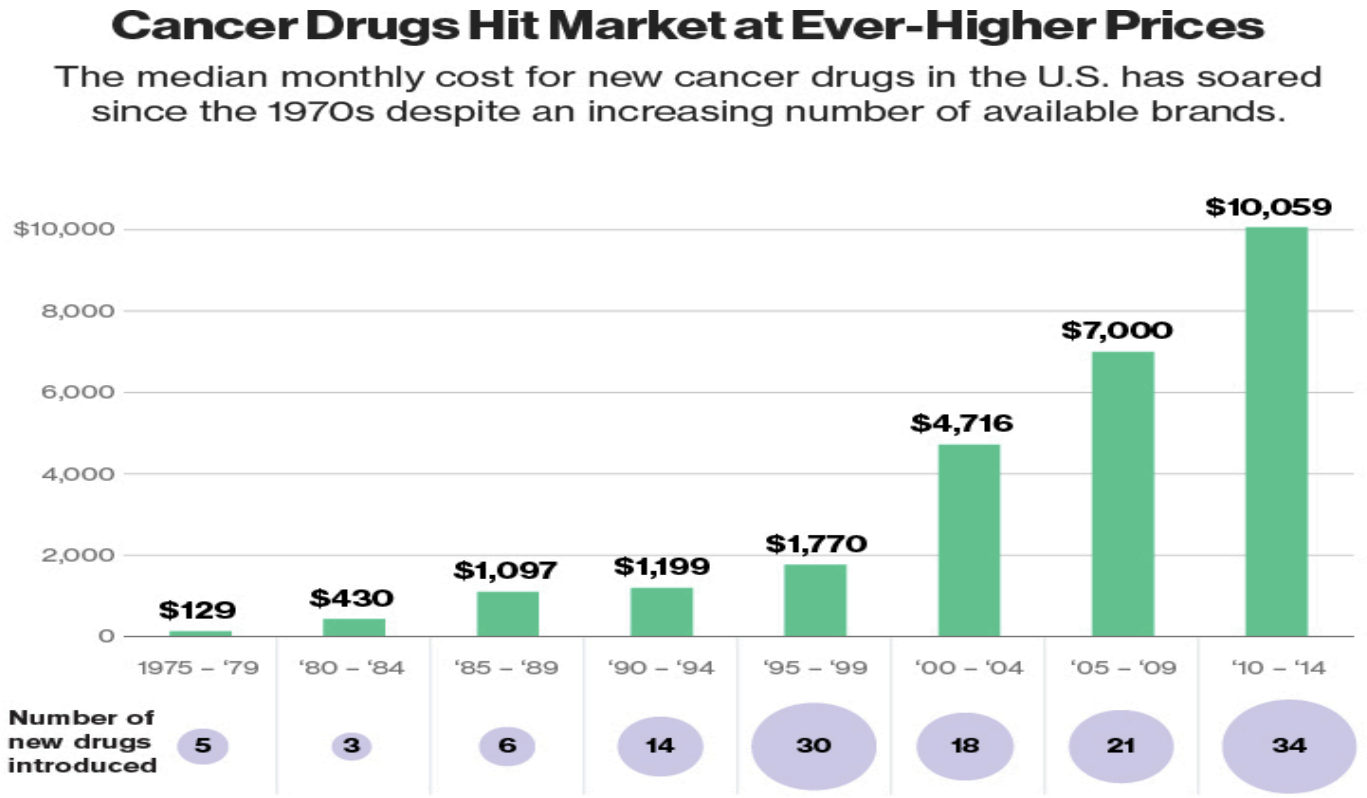


Source: IMS Health, Market Prognosis, National Prescription Audit, IMS Institute for Healthcare Informatics, Jan 2016

Rx Market - Pricing

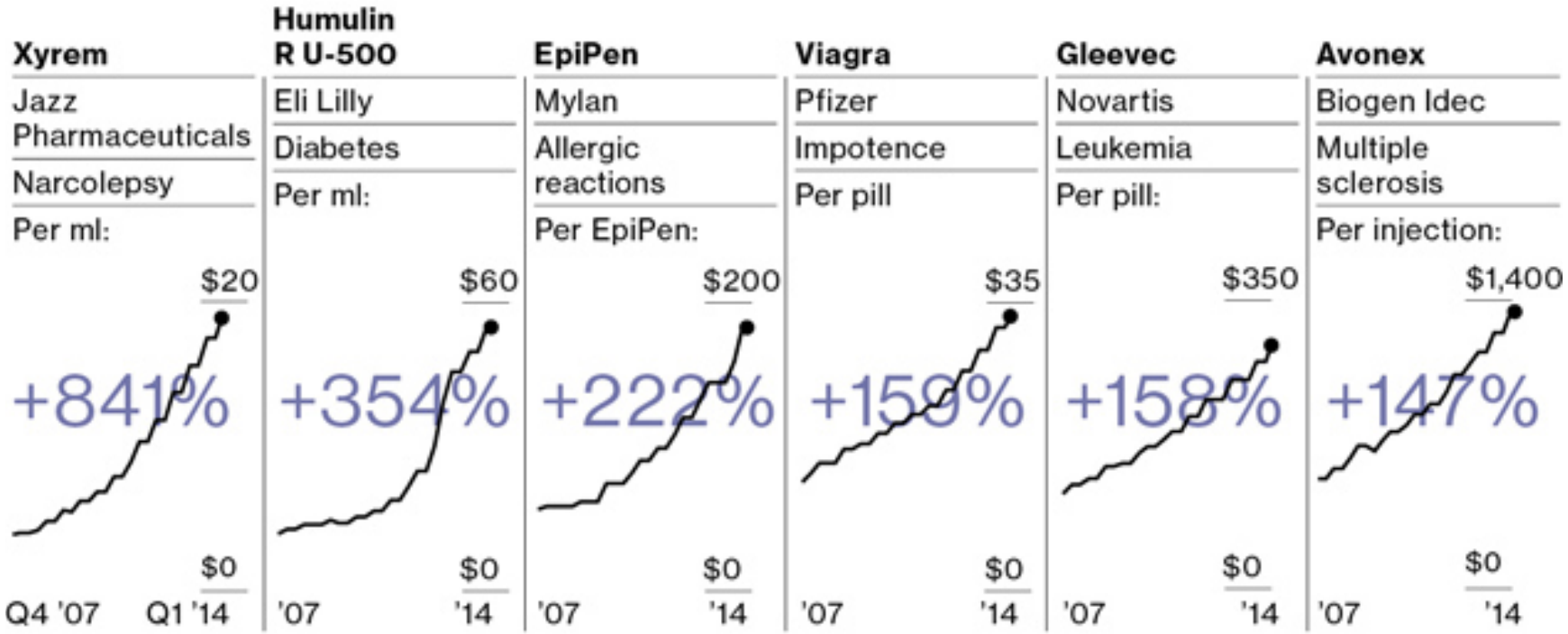
- List prices are set by the manufacturer/marketer/distributor
- Net or acquisition prices are negotiated between the seller and the buyer/payer (hospital, VA, insurer, PBM). In rough terms, rebates are generated as discounts off of the list price.
- In markets with no central price negotiation and little competition (labeled indication or therapeutic alternative), manufacturers offer few discounts.
  - In the US, anticipated discounts are baked into the list price
- Prices do not fall over the life of the patent.

Entry Price


Cancer Drugs Hit Market at Ever-Higher Prices
The median monthly cost for new cancer drugs in the U.S. has soared since the 1970s despite an increasing number of available brands.
$10,000
8,000
6,000
4,000
2,000
0
$129
$430
$1,097
$1,199
$1,770
$4,716
$7,000
$10,059
1975 – '79
'80 – '84
'85 – '89
'90 – '94
'95 – '99
'00 – '04
'05 – '09
'10 – '14
Number of new drugs introduced
5
3
6
14
30
18
21
34
Note: Costs are monthly Medicare prices for each drug the year it was introduced, adjusted for inflation; drugs approved through early December 2014 are included.
Source: Peter Bach and Geoffrey Schnorr at Memorial Sloan Kettering Cancer Center

Taking Price Increases

The price of many top-selling prescription medicines has increased steadily over the past seven years



GRAPHIC BY BLOOMBERG BUSINESSWEEK. SOURCE: DRX, DATA COMPILED BY BLOOMBERG

What Can be Done to Stem the Rising Cost of Pharmaceuticals?

Traditional Options to Manage Rx Costs

- Limit available options for preferred reimbursement/coverage – drug formularies.
- Add co-payments and co-insurance – incr. patient out-of-pocket costs.
- A third party negotiator (PBM industry) to aggregate lives and bargain for better prices.
- Special categories of purchasing (340B or Medicaid best pricing) – only available to the government sector.
- Limit Patient Population - Prior Authorization, Stepped-Therapy, Medical Policy

Emerging Options to Manage Rx Costs

- Limit prescriber access to sales representatives and samples.
- Adding clinical decision support algorithms to e-prescribing tools.
- Restricting ‘buy and bill’ practices of providers who administer expensive, biologic treatments.

Other Policy Considerations

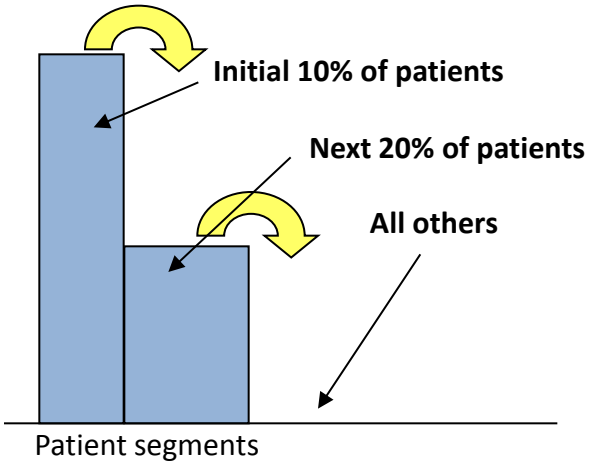
- Value Frameworks –
  - The role of professional societies
  - Large institutions
  - ICER http://icer-review.org/
- Reduce patent exclusivity period to negate monopoly position of the producer
- When there is a public health imperative, buy the patent and distribute at marginal cost (e.g., Sovaldi).
- Dramatically reform the FDA process – reducing time to market.
- *Consider international policies in the US.*

International Policies

- Price referencing (Multiple Countries)
- Price-volume agreements (France)
- Explicit use of cost-effectiveness information (UK, Canada, Aus, Taiwan, Korea)
- Mandatory price reductions (Japan, France)
- **Innovative contracting agreements (Italy, UK, Aus, US)**

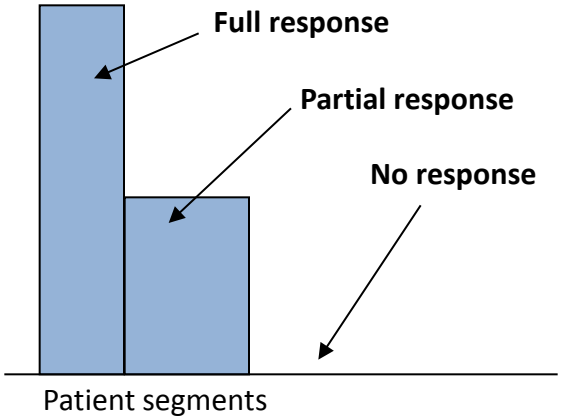
Innovative Contracting Models

Financial Utilization Models



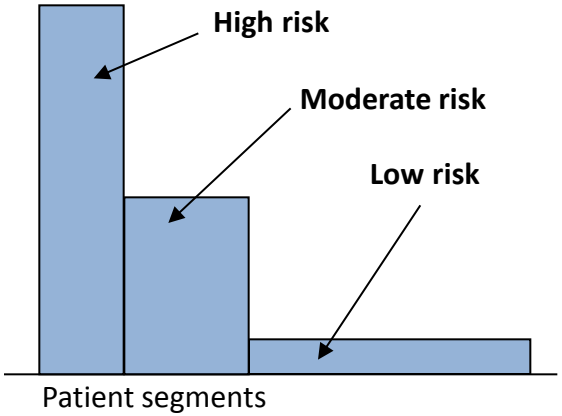
- **Price volume agreement: e.g. if agreed for 10% patient sub population: full reimbursement for first 10% of patients, reduced reimbursement for next 20% of patients, no reimbursement for all others**

Outcomes Based Pricing Models



- **Money back guarantee, e.g. full reimbursement for responders, reduced reimbursement for partial responders, no reimburse ment for non-responders**

Risk Type Based Pricing Models



- **Reimbursement linked to value and level of risk factors (e.g. based on diagnostic test)**

Questions For Panel

- What types of pharmaceutical innovative contracting models (e.g. performance, outcomes or risk-based agreements) could play a role in an ACO arrangement in which an ACO enters into a shared savings or full risk agreement with the state Medicaid program linked to total cost of care, including pharmacy spending?
- Are there examples of successful innovative pharmaceutical contracting models either in the private or government health care sector that you might suggest Washington HCA consider
- What types of pharmaceutical innovative contracting models could support improved performance on any of the HB 2572 quality measures that are being adopted in Washington state?
- What barriers and challenges (logistic, financial, legal) exist from your perspective that would limit the ability to implement innovative contracting models? How can these barriers be overcome?

Questions For Panel

- Risk-based agreements often assume that upfront use of a drug results in down-stream savings. How does your health plan currently view/ calculate (or take account of…) "ROI" on pharmaceuticals? (intent of this question is to understand payer perspective on ROI, and delve into the notion of "cost saving" vs. "cost-effective")

- How does a plan's time horizon affect thinking about/understanding of ROI? (e.g. – if there is an ROI on treating a young patient with hepatitis C who is Metavir 0?)

- What role for PBMs in risk based contracting?