



Division of
Pharmacoepidemiology & Pharmacoeconomics



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Prescription Drug Prices and “Value”

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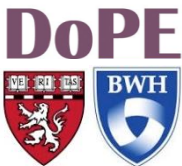
Program On Regulation, Therapeutics, And Law

What is PORTAL?

- PORTAL has core faculty with expertise in medicine, business, law, epidemiology, ethics; post-docs and numerous students
 - Research on interactions among the regulatory, legal, economic, and clinical components of the pharmaceutical marketplace
 - No one in our Division has personal financial relationships with any pharmaceutical company
 - Largest, independent research centers in the country focused on these topics
 - www.PORTALresearch.org; Twitter: @PORTAL_research; @akesselheim
- Current research funding from Laura and John Arnold Foundation, Harvard Program in Therapeutic Science
 - Past research funding from FDA CDRH/OGD, Harvard Clinical and Translational Science Center, AHRQ, Robert Wood Johnson Foundation, CVS Caremark, Commonwealth Fund, Greenwall Foundation

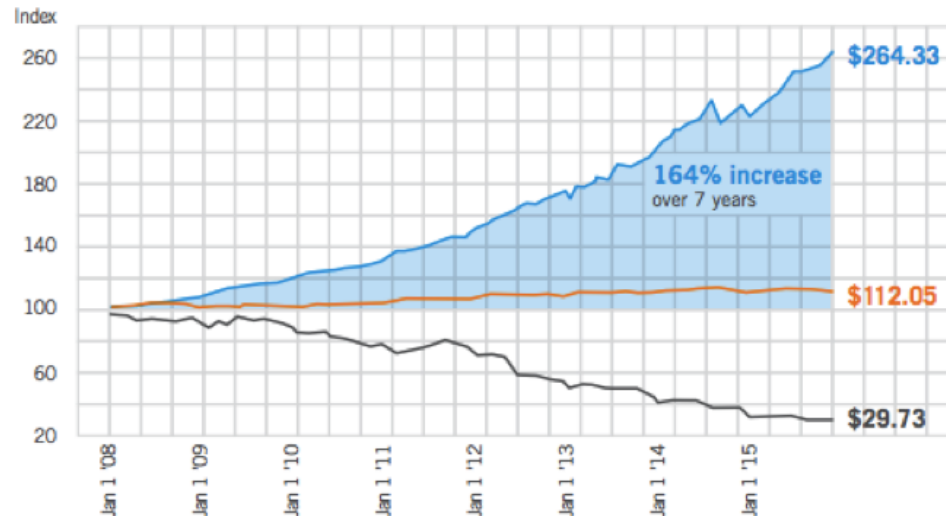


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Prescription Drug Spending in the US

- Rose 12% in 2015, 6% in 2016 to \$450 billion
 - 22% of health care spending (IMS)
 - 19% of Medicare spending (MEDPAC)
 - 19% of employer-based insurance benefits (Kaiser)
- International per capita comparisons
 - US: **\$858**; avg 19 industrialized countries: **\$400**
- Due to brand-name drug prices



AVERAGE ANNUAL BRAND NAME DRUG PRICES CONTINUE TO GROW SUBSTANTIALLY FASTER THAN GENERAL INFLATION IN 2015

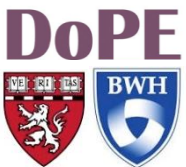


Note: Calculations of the average annual brand name drug price change include the 268 drug products most widely used by older Americans (see Appendix A).

Prepared by the AARP Public Policy Institute and the PRIME Institute, University of Minnesota, based on data from Truven Health MarketScan® Research Databases and MediSpan Price Rx Pro®.

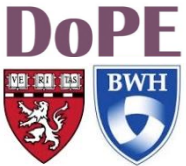


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Clinical consequences

- 25% of patients in 2015 reported that they or another family member did not fill a prescription in the last year due to cost
- Patients prescribed a costly branded product rather than a more affordable generic alternative adhere less well, and have worse health outcomes

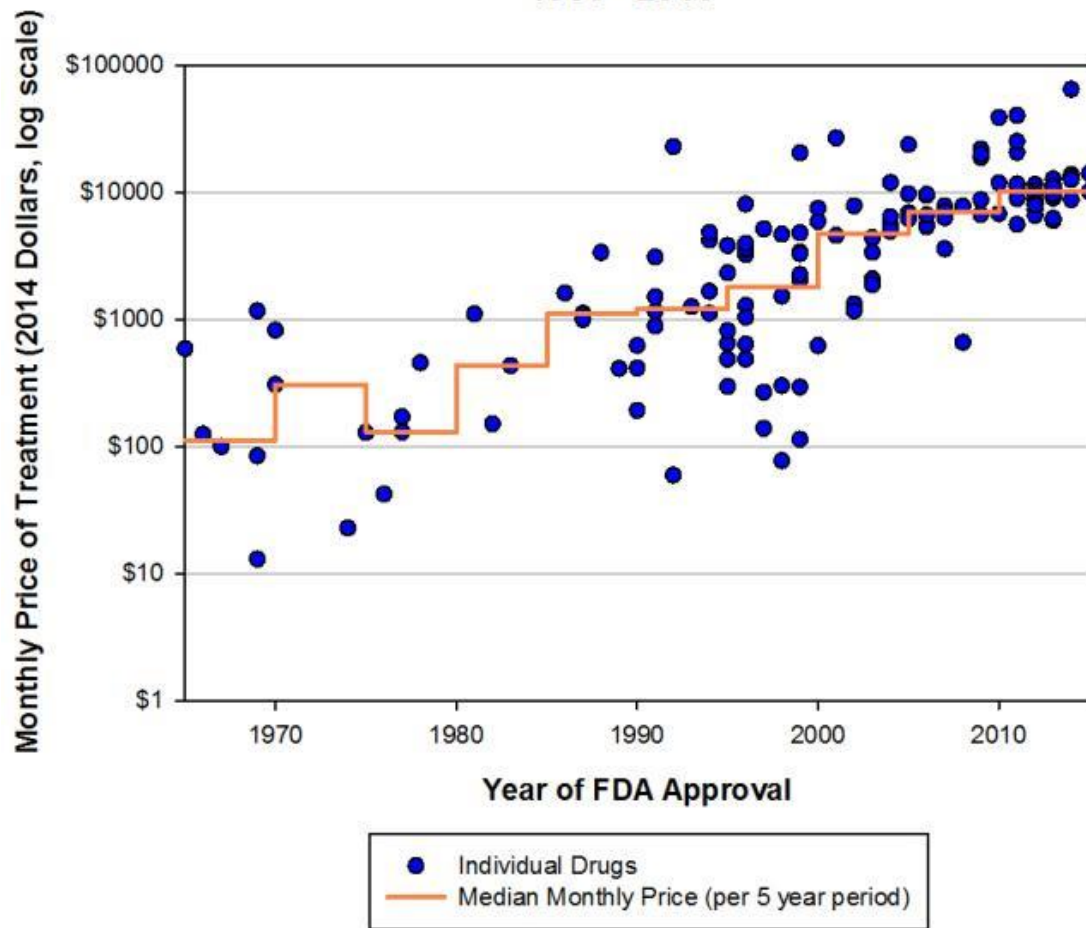


Do prescription drug prices reflect “value”? No

- Drugs are priced by manufacturer based on what the market will bear
 - Gilead internal company documents indicate drug priced based on a plan to maximize revenue from it and its expected successor, a combination of the drug with ledipasvir (Harvoni), which it also owned



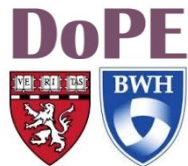
Monthly and Median Costs of Cancer Drugs at the Time of FDA Approval 1965 - 2015



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



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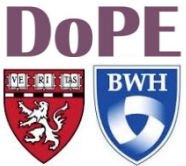


Why don't drug prices reflect value?

- 1. The FDA doesn't measure value



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Meeting FDA's ever-more-tolerant approval standard

- “Substantial evidence of efficacy”
- But among drugs approved in the last decade:
 - 1/2 approved based on testing against a placebo
 - 2/3 approved based on studies lasting 6 mos or shorter
 - 1/2 approved based on surrogate measures (vs actual clinical endpoints)
 - 1/2 of drugs have any comparative effectiveness information at the time of approval



Why don't drug prices reflect value?

- 1. The FDA doesn't measure value
- 2. Drugs don't need to reflect value to get covered by payors



Limits on public and private payors' abilities to exclude low-value drugs

- Medicare Part D cannot use a national formulary or negotiate drug prices
 - 6 protected drug classes
- Medicaid cannot exclude most FDA approved drugs from coverage
- State laws requiring coverage of certain protected drugs
 - NCSL 2009: 36/50 states require coverage of off-label use of cancer drugs



Why don't drug prices reflect value?

- 1. The FDA doesn't measure value
- 2. Drugs don't need to reflect value to get covered by payors
- 3. Drugs don't need to reflect value to get prescribed by physicians

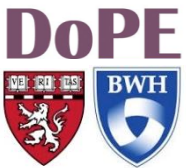


Potential solutions?

- 1. “Value-based contracts”



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Very limited application

Advantages

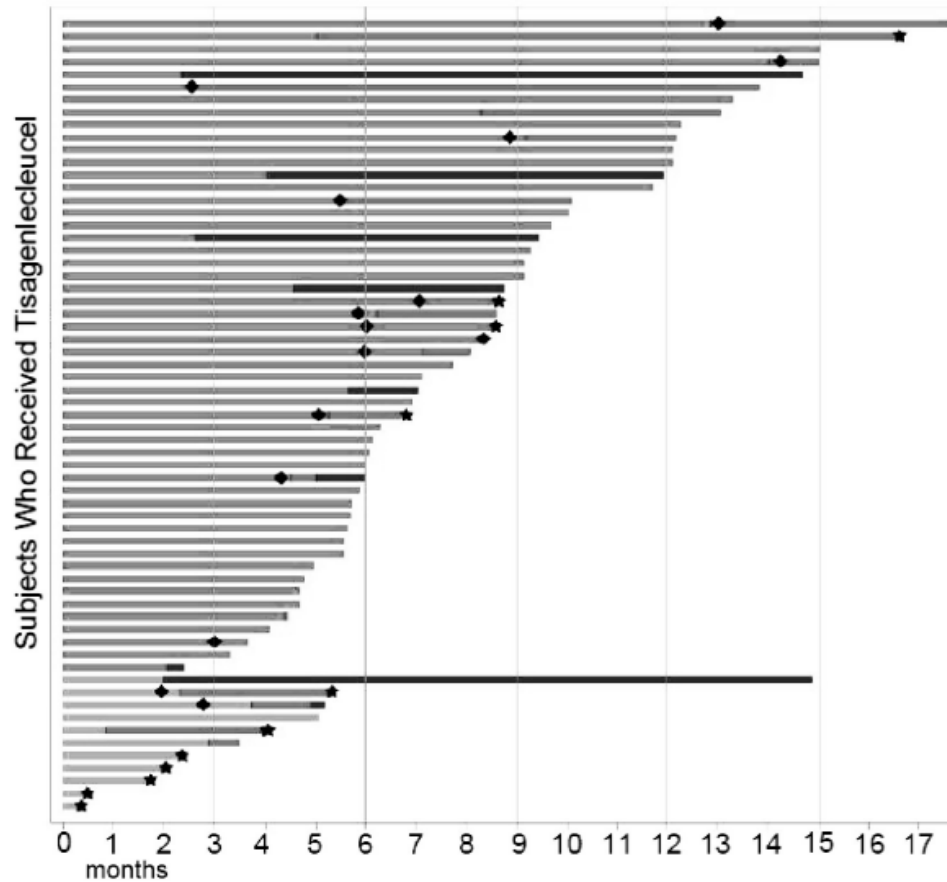
- Opportunity to pay for drugs only in patients in which “appear to work”

Limitations

- Outcomes measurement limitations (short-term, observable in claims data, surrogates)
- Can account for in price-setting
- Costly to implement
- Unclear application to patient out-of-pocket costs

CAR-T Value-Based Contracting: Cost (\$475,000) paid if patients respond by end of first month (83%)

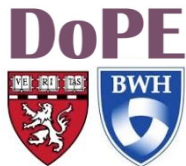
Outcomes of 63 Subjects* in Phase 2 Study of Tisagenlecleucel



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(since date of tisagenlecleucel infusion)

- responders
- non-responders/unknown
- HSCT
- new cancer therapy other than HSCT
- ◆ relapse
- ★ death



Potential solutions?

- 1. “Value-based contracts”
- 2. Systematically assess value of drugs



ICER Value-Based Pricing

Drug	Listed Price	ICER Value-based Price	Difference (%)
Sacubitril/valsartan (Entresto)	\$4,560/yr	\$4,168	9%
PCSK9 Inhibitors	alirocumab: \$14,600/yr evolocumab: \$14,100/yr	\$2,177	85%
Carfilzomib (Kyprolis)	\$1,862/unit	\$673	64%
Ixazomib (Ninlaro)	\$2,190/unit	\$181	94%



Potential solutions?

- 1. “Value-based contracts”
- 2. Systematically assess value of drugs
- 3. Effective policy changes to promote value-based prescribing
 - Academic detailing
 - Therapeutic substitution, when clinically appropriate
 - Promote timely competition from generic drugs and biosimilars

